



**School of Public Health**

**The Practice and Regulatory Requirements of  
Naturopathy and Western Herbal Medicine**

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**November, 2005**

**Funded by the Department of Human Services, Victoria**

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[www.health.vic.gov.au/pracreg/naturopathy.htm](http://www.health.vic.gov.au/pracreg/naturopathy.htm)

**ISBN-13: 978-0-9775864-0-0**

**ISBN-10: 0-9775864-0-5**

**Published by**

School of Public Health, La Trobe University

Bundoora

Victoria, 3086

Australia

# THE PRACTICE AND REGULATORY REQUIREMENTS OF NATUROPATHY AND WESTERN HERBAL MEDICINE

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# The Practice and Regulatory Requirements of Naturopathy and Western Herbal Medicine Summary Report

## 1. Introduction

Demand for complementary and alternative healthcare in Australia has increased considerably in the last two decades. This has been accompanied by growth in the professions of naturopathy and Western herbal medicine (WHM), the complementary and alternative medicine (CAM) education sector, the natural medicines manufacturing industry, and in the size of the naturopathy and WHM workforce. Consumers are using naturopathy and WHM as primary healthcare services, but these professions lie outside the public health sector. Naturopathy and WHM are an unregulated workforce and represent an untapped resource to the public health sector, but their potential inclusion raises questions about the risks and benefits of their practices.

In June 2003, the Victorian Department of Human Services (DHS) contracted with the School of Public Health, La Trobe University, to coordinate research on the benefits, risks, and regulatory requirements for the professions of naturopathy and Western herbal medicine (WHM). The aim of the project was to investigate and understand the practice of naturopathy and WHM in Australia, and to make recommendations on the need, if any, for measures to protect the public.

## 2. Methodology

The methodology adopted in various components of the study included: (i) literature reviews (including systematic reviews); (ii) reviews of documents and reports; (iii) reviews of administrative data; and (iv) primary data collections through surveys and focus groups. The specific approaches adopted for each component of the study are listed in Table 1.

**Table 1 Components and methodology of the project**

Component	Methodology
1. Risks	Literature review; media reports; coroners' data; Health Services Commissioner data; data from professional associations; reporting in workforce surveys; ADRAAC data
2. Benefits	Review of systematic reviews
3. Workforce (a) Naturopathy and WHM (b) Western medicine	(a) national survey of practitioners (b) national survey of GPs
4. Education and training	National survey of educational institutions
5. Professional associations and institutional recognition	National survey of professional associations; enquiries of health funds; Workcover authorities; Australian Taxation Office; professional indemnity organisations; survey of hospital practices in Victoria
6. Consumers (a) Opinions (b) Patient profiles	(a) literature review; focus group discussions (b) survey of patients
7. Regulatory arrangements	Review of policies and legislation
8. Assessment of regulatory requirements	Assessment of data from Components 1–6 against AHMAC criteria and NCP criteria

### **3. Key findings and recommendations**

The conclusions and recommendations for the report as a whole reflect the consensus of the research group responsible for the project. The key findings and recommendations are summarised below.

#### **3.1 Definition of practice and scope of study**

Numerous therapeutic practices can be grouped under the umbrella term ‘complementary and alternative medicine’. This term is often used interchangeably with such terms as ‘natural therapies’, ‘complementary healthcare’, ‘holistic medicine’, and other variations. For this study, the terms ‘complementary and alternative medicine’ (CAM) and ‘complementary therapies (CT) were selected for use as generic terms (see definitions below).

This report is concerned only with naturopathy and Western herbal medicine (WHM) and does not consider a range of other practices (such as kinesiology, reflexology, iridology, reiki, Bach flower therapy, aromatherapy, ayurvedic medicine, and so on).

#### **Complementary and alternative medicine**

Complementary and alternative medicine is a group of diverse medical and healthcare systems and therapies that are based on theories or explanatory mechanisms that are not in keeping with the orthodox biomedical model (Bensoussan 1999). CAM systems generally hold medicine to be a science of the human person, and understand disease as involving a systemic dislocation of the whole person (Foss, in Robson 2003, p.2). Major CAM systems include naturopathy, Western herbal medicine (WHM), Chinese medicine, ayurveda and homeopathy.

#### **Complementary therapies**

Complementary therapies (CTs) are non-conventional therapies that are used together with conventional healthcare. The list of what are considered by conventional medicine practitioners to be complementary therapies changes continually, as those therapies that are proven to be safe and effective become adopted into conventional health care and as new approaches to health care emerge (National Center for Complementary and Alternative Medicine 2002). Examples of therapies used to complement conventional healthcare are nutritional medicine, meditation and massage. Also, consumers may choose to complement conventional healthcare with a wide range of non-conventional therapies, sometimes independently of medical advice.

#### **Naturopath**

For this study, a naturopath was taken to be a practitioner whose practice and modalities have been defined by the National Training Package (introduced in 2002, see Appendix 1.1)—that is, a practitioner having core training in naturopathic principles and philosophy, and in at least three of four practice modalities: (i) herbal medicine; (ii) nutritional medicine; and (iii) either massage or homeopathy. It is recognised that the modalities encompassed by naturopathy might be practised as single modalities, that is, either naturopaths or other practitioners may have a practice consisting of only one modality. However, this report does not address those practitioners whose training and practice are in the single modalities of massage, nutritional medicine (sometimes called ‘clinical nutrition’), or homeopathy.

#### **Western herbal medicine practitioner**

For this study, a WHM practitioner was taken to be a health practitioner who engages in extemporaneous compounding of herbs for therapeutic purposes for individuals under his or her care, and who has satisfied the core training requirements in herbal medicine principles, philosophy, and practice, as defined by the National Health Training Package (Australian National Training Authority 2002, Appendix 1.1) for WHM.

#### **3.2 Growing use of naturopathy and WHM**



Community demand for complementary and alternative healthcare has increased significantly over the past 20 years—both in Australia and in other countries (MacLennan, Wilson & Taylor 1996, 2000; Kellner & Wellman 1997; Eisenberg, Davis, Ettner, Appel, Wilkey, Van Rompay & Kessler 1998; Ernst 2000; Williamson, Fletcher & Dawson 2003). Australian survey data show that use is widespread in both sexes and across all ages and conditions (MacLennan, Wilson & Taylor 1996, 2002; De Visser, Ezzy & Bartos 2000; Adams, Sibbritt, Easthope & Young 2003, MacLennan, Myers & Taylor 2005). Use may be greater among younger people and women, but it is sufficiently prevalent and well established to warrant scrutiny in public policy.

People who use naturopaths and herbal therapists do so for a range of reasons. These include:

- seeking effective treatment for health problems;
- seeking treatment for a chronic or serious illness or condition;
- maintenance of health and wellness approaches; and
- having values compatible with the philosophy and practice of naturopathy and WHM.

At the same time, mainstream healthcare practitioners are expanding their armamentarium for providing care. In the United States of America (USA) and Australia, medical practitioners are expressing interest in training in alternative therapies (Pirotta, Farish, Kotsirilos, & Cohen 2000; Levine, Weber-Levine & Mayberry 2003). Indeed, approximately 11% of naturopaths and WHM practitioners have another health qualification—such as nursing, physiotherapy, medicine, and so on (Bensoussan, Myers, Wu & O'Connor 2004).

The consumers of naturopathy and WHM represent the broad spectrum of society. According to the patient survey reported in the present study, 48% worked in managerial or professional sectors, and 35% were employed in trade, service, or clerical work; 46% of patients were tertiary educated (including technical and private colleges), whereas 44% had high school education or less. These results are different from those of earlier studies, which showed most use by educated middle class women and little use by low income groups, although tertiary educated women remain disproportionately represented.

The majority of patients surveyed in the present study were self-referred (72.5%), but 5% were referred by medical practitioners. Psychological, gynaecological, and endocrine disorders were the most common reasons for seeking treatment, and 78% reported that they were receiving treatment for a chronic or recurrent complaint. More than 60% had previously consulted another health practitioner (with nearly 50% of those being medical practitioners) and 34% continued to see other practitioners. However, communication between practitioners had occurred for only 27% of the patients.

Victorian consumers involved in this study as focus group participants sought the advice of CAM practitioners for a similar range of reasons to those reported in the literature:

- holistic care (attention to the whole person);
- treatment and support for chronic conditions;
- mitigation of the effects of pharmaceuticals; and
- maintenance of well-being.

Overall, the majority of focus group participants were very satisfied, although this appeared to be dependent on their finding the 'right' practitioner. Some people reported 'shopping around' and 'trying out' various practitioners until they found a suitable practitioner. One person felt experimented upon, and others were concerned about the knowledge and experience of practitioners.

Satisfaction was linked to:

- quality of the relationship;
- time for discussion, and being listened to;
- knowledge and skills of the practitioner; and
- opportunity to participate in their healthcare.

The importance of a good relationship with a practitioner was emphasised. However, this is an aspiration of all consumers of healthcare, and is frequently mentioned in any evaluation research (Draper and Hill 1996). CAM practitioners are able to offer a sought-after approach to healthcare, and they generally provide sufficient consultation time to establish a good relationship.

Some users of complementary healthcare, although not all, participate actively in their healthcare and appear to be avid seekers of information—using the Internet, books, and magazines as important sources of information. This demonstrates a need for high quality information to be readily accessible.

### **3.3 Growing recognition of naturopathy and WHM**

The increased use of CAM modalities is recognised by private health funds—the majority of which offer rebates for consultations with approved practitioners. Given the growth in payments for CAM treatments, private funds are preparing guidelines for accrediting practitioners. These guidelines include assessment on the basis of qualification and experience.

The services of naturopaths are allowable under some workers' compensation schemes. In most states and territories, recommendation or referral by a medical practitioner is required for workers' compensation cover.

Professional indemnity insurance is readily available to practitioners, and premiums are low compared to those of medical practitioners. Most insurers accept membership of a professional association as a criterion for eligibility.

For the purposes of exemption from the requirements of the goods and services tax (GST), the Australian Taxation Office recognises a practitioner who is a member of a 'recognised professional association' (of which there are more than 20).

Healthcare practitioner registration boards are beginning to recognise the growing adoption by their registrants of CAM modalities, and the dual use of conventional and CAM services by consumers. Guidelines have been produced for medical practitioners, nurses, and pharmacists, and both the Australian Medical Association and the Royal Australian College of General Practitioners have developed policies supporting integrative medicine, provided that the approach is evidence-based and that doctors are appropriately qualified in the practices they offer.

In addition to its use in home and community settings, CAM is also used by consumers in institutional settings such as hospitals and residential aged care. However, apart from a few specific instances, such institutions have been slow to adopt policies that recognise changing consumer practices. This raises concerns about patient safety.

The use of, and referral for, some complementary therapies (such as acupuncture and massage) by general practitioners (GPs) can be considered a mainstream practice. In the national sample of GPs surveyed in this study, the majority (84%) agreed that acupuncture and massage were moderately or highly effective, and a large percentage was likely to refer patients to massage and acupuncture (87% and 83% respectively). GPs are using herbal medicines as well as making referrals to CAM practitioners, although a majority still see naturopathy and homeopathy (71% and 83% respectively) as being not effective or seldom effective. GPs report concerns about adverse events related to complementary medicine, with a majority perceiving Chinese herbal medicine and WHM to be occasionally harmful or frequently harmful (67% and 62% respectively). GPs reported interest in practising CAM

therapies (51% for herbal medicine, 53% for vitamin and mineral therapy), but their own training tends to be relatively limited (self-taught or through introductory workshops).

Given these trends in consumer use and practitioner adoption, there is increased scientific and regulatory interest in CAM around the world. This is reflected in the increased number of citations, the number of Cochrane protocols and reviews, and the development of policies and regulatory strategies in various countries. The World Health Organization (WHO), the USA, Canada, the United Kingdom (UK), and New Zealand have also had major policy reviews in recent years. In Australia, the most significant policy review to date is the Expert Committee on Complementary Medicines in the Health System, which reported in 2003 and recommended a number of measures to tighten the regulatory net and to improve the surveillance system and the evidence base (Expert Committee 2003).

### **3.4 Benefits of naturopathy and WHM**

There is little literature on the benefits of the ‘whole practice’ approach of naturopathy and WHM. Whole practice research is an emerging field which assesses the way that practitioners actually practice. In clinical practice, naturopaths and Western herbalists use multiple therapeutic tools accompanied by dietary and lifestyle assessment and advice, patient education, and counselling. Research to date has focused mainly on the ‘tools of trade’. However, researching a single herb or nutrient does not reflect whole practice and consumers often opt for CAM practitioners for reasons beyond the specific procedures or products.

Because of the lack of literature on the benefits of the whole practice approach of naturopathy and Western herbal medicine, a review was undertaken of the effectiveness of herbal and nutritional medicine. A literature search suggested a dramatic increase over the past three to four decades in the number of publications devoted to examining the efficacy of naturopathic and Western herbal medicines. A citation search using 20 commonly used items (10 herbal medicines and 10 nutritional supplements) found 152,925 citations between 1966 and 2003.

A review of 77 systematic reviews published between 2001 and 2003 suggested that there is now evidence of the benefits of naturopathy and WHM for almost every body system and all major illnesses. It can be concluded that the ‘tools of the trade’ of naturopathy and WHM can be effective, and that the practice of naturopathy and WHM is therefore potentially effective.

Levine et al. (2003) have confirmed the findings of the present study that medical practitioners believe that certain CAM practices are efficacious or offer benefit.

CAM is now one of the largest fields within the Cochrane Collaboration network. Even allowing for the highly reductionist approach of Cochrane reviews, the potential benefits are compelling. However, if the potential benefits are to be realised, the practitioners must be properly trained, and they must participate in continuing professional education with respect to this evolving body of evidence.

### **3.5 Risks of naturopathy and WHM**

Research reported in Chapter 2 found that risks to the public from naturopathy and WHM can be divided into two major categories:

- risks associated with the clinical judgment of the naturopath or WHM practitioner, and
- risks associated with the consumption of herbal and nutritional medicines.

The risks from acts of commission by practitioners of naturopathy and WHM relate to direct and inappropriate actions during treatment—such as inappropriate prescribing, failure to be aware of contraindications, inappropriate dosage, and inappropriate duration of therapy. The risks from acts of omission arise when practitioners have inadequate skills or are unaware of the limits of their practice. Misdiagnosis, failure to detect significant underlying pathology, and failure to refer patients on to other appropriate healthcare providers can all lead to adverse events.

Herbal and nutritional medicines produce both predictable and unpredictable effects. These include toxicity related to overdose, interaction with Western pharmaceuticals, allergic and anaphylactic reactions, and idiosyncratic reactions. The practice of herbal medicine is a greater risk in this regard than other modalities of naturopathy. The official reporting of adverse events is likely to be an underestimation of the real number of adverse events—given that the Therapeutic Goods Administration (TGA) Adverse Drug Reactions Advisory Committee (ADRAC) database cannot be analysed in terms of component ingredients (Expert Committee 2003). However, the literature does identify a wide range of adverse reactions associated with herbs and nutrients. Interaction between herbal medicines and Western pharmaceuticals is increasingly reported in the literature.

A survey of the naturopathic and WHM workforce (Bensoussan et al. 2004) suggested that, on average, practitioners experienced one adverse event every 11 months of full-time practice, and 2.3 adverse events every 1000 consultations (excluding mild gastro-intestinal events). The most common adverse events reported in relation to both herbal medicines and nutritional medicines were more severe gastrointestinal symptoms, headaches, menstrual irregularities, and skin reactions. However, the research was unable to determine whether these adverse events are a result of poor practice (including inappropriate prescribing) or a result of the medicines themselves. Nevertheless, the research suggests that the practices do have potential for toxic effects.

The survey of GPs undertaken for this study indicates that GPs perceive a large number of adverse events to be associated with CAM therapies. The survey estimates that GPs see one adverse event arising from CAM therapies every 125 GP consultations. The therapies reported as responsible for the greatest number of adverse events were, in order, chiropractic, herbal medicine, naturopathy and vitamin/mineral therapy, and Chinese herbal medicine. GPs attributed adverse events to several causes—including ineffective treatment, wrong diagnosis, allergic reaction, drug interaction, and profit motive overriding clinical judgment.

The survey of patients reported in this study showed that 34% of patients who consumed herbal medicine were concurrently taking pharmaceutical medications. This is a cause for concern because there are increasing reports of interactions between herbs and pharmaceutical products.

Complementary healthcare is used by a significant proportion of the population (MacLennan, Wilson & Taylor 2002), many of whom also use conventional medical services. Naturopathy and WHM are, therefore, an integral part of the primary healthcare system. Although there is a smaller number of CAM users who do not wish to use conventional medicine unless necessary, the data reported in surveys and focus groups suggest that people have to navigate two systems. This produces difficulties and potential dangers if consumers do not feel that they can discuss with all practitioners their use of particular services, or if they choose not to inform all practitioners. Poor communication between GPs and naturopaths and WHM practitioners is of particular concern given that a majority of CAM patients seek care for chronic conditions (and are therefore likely to be frequent and routine users of both CAM and mainstream medical services). The reporting of adverse effects of treatments or medications in conventional medicine has received much scrutiny in recent times, and the emphasis on quality and safety could be extended in policy-making to naturopathy and Western herbal medicine.

A review of coroners' records, reports from professional associations, data from the health services commissioner, and media reports shows that:

- there have been some deaths related to inappropriate clinical advice; and
- there are popular concerns about interactions between pharmaceuticals and herbal medicines.

Complaints brought by patients to professional associations are more likely to be triggered by communication problems than by concerns with interventions. Other issues related to professional practice—such as hygiene and ethical conduct—have also been of concern to consumers.

The evidence from this study suggests that the risks of naturopathy and WHM arise from both the 'tools of trade' and the primary care practice context. Given that the number of people in Australia using naturopathy and WHM as a form of primary care is greater than those using Chinese Medicine, the primary care context of usage (particularly the lack of communication between users and the parallel providers) is of particular concern.

### **3.6 Characteristics of the naturopathy and WHM workforce**

It is difficult to calculate the actual number of practicing naturopaths and WHM practitioners. Two methods are reported in the present study. Chapter 4 reports that there are approximately 1778 practicing naturopaths and Western herbalists in Australia, based on the national database of the Grand United Health Fund (Bensoussan et al. 2004). The majority of these practitioners were located in NSW, Victoria, and Queensland. Chapter 6 reports findings based upon membership of associations, which resulted in substantially higher numbers (naturopaths 4217; WHM practitioners 2469) because half of the workforce belongs to two or more professional associations (Bensoussan et al. 2004). The membership data were used to re-calculate the numbers reported by associations, resulting in a finding of 1219 naturopaths and 1752 WHM practitioners (totalling 2971 practitioners). Up to 16% of these practitioners may not currently be in practice (Chapter 4). The number of practitioners can be expected to increase, given the number of training institutions that have been established from 1990 to 2004 and a general trend towards annual increases in graduates (Chapter 5)—although some graduates of these institutions apparently indicate that they undertake training for self-help, rather than to qualify as a practitioner. It was difficult to quantify particular segments of the workforce because most practitioners used several titles to describe their practice, and most practised a range of overlapping modalities (although 'naturopath' and 'herbalist' were the most common titles, and herbal medicine and nutrition were the most common practice modalities, see Chapter 4). A significant proportion (11%) had a prior qualification in another clinical health profession.

There was wide variation in the hours spent in practice, client loads, and incomes of naturopaths and WHM practitioners. They each spent, on average 24 hours per week in clinical practice, representing 22 consultations per week. Extrapolated across the whole workforce in Australia, this represents 1.9 million consultations per annum. Total turnover in consultation fees in Australia was estimated to be more than \$85 million in 2003.

Most practitioners have at least three years education in herbal or naturopathic practice. However, the length of time required to acquire various qualifications is variable and practitioners feel under-prepared in some areas (see 3.7). The average clinical experience of practitioners was 9 years, and 75% received patients through word of mouth. Only 7% worked in multidisciplinary environments that include medical practitioners. Approximately two fifths of naturopaths and WHM practitioners used medical tests at least 50% of the time to guide clinical practice, and some reported that they guide their interventions by using diagnostic approaches specific to naturopathic and herbal practice.

GPs expressed interest in incorporating CAM in their practices. The demographics of GPs who practise complementary medicine reflect the overall demographic profile of GPs (Pirodda et al. 2002). The findings of the present study point to a high level of acceptance and use of CAM by the medical profession. GPs believe that inclusion of complementary therapies in medical undergraduate curricula is important, and were interested to receive training in acupuncture, herbal medicine, vitamin and mineral therapy, hypnosis, massage, meditation, and yoga. Although they thought that demand for complementary therapies is increasing, cross-referrals between GPs and naturopaths and WHM practitioners remain limited—in part because GPs are uncertain about how to identify qualified CAM practitioners.

Despite some convergence, there remain distinctive differences between orthodox medicine and CAM in philosophical outlook and in practice. In particular, the link between prescribing and dispensing is seen within naturopathy and WHM as central to the

individuation of therapeutic intervention, whereas that link was severed during the twentieth century for medical practitioners.

### **3.7 Training of practitioners**

Research reported in Chapter 5 indicates that the number of institutions providing education and training in naturopathy and WHM in Australia has increased significantly since the beginning of such education in the 1940s. In 2003, there were 47 naturopathy and WHM education providers in Australia, offering a total of 104 undergraduate and postgraduate courses. Of all courses identified, 49% had emerged since 2000 and continued growth is likely, with 19 campuses planning new undergraduate and/or postgraduate courses in the next five years. The estimated number of undergraduate enrolments in the present study was 3500, with about 500 graduates annually (350 naturopaths and 150 WHM practitioners). It would appear that the workforce is likely to expand considerably, although many graduates do not establish a viable practice. The reason for this is not clear and further research is required.

Developments in this field within the VET sector in general, and the health training package (2002) in particular, were important steps towards the establishment of uniform educational standards, but there remain significant variations among various courses in content and approach. In this study, courses in naturopathy and WHM were found to range from 2 years to 4.5 years. Mean course contact hours also varied. For example, for naturopathy, science content ranged from 300 hours to 1275 hours, and clinical training ranged from 198 hours to 1275 hours; for WHM, science content ranged from 507 hours to 923 hours, and clinical experience ranged from 100 hours to 441 hours. The number of clinical contact hours is especially low compared with institutions in the USA and Canada.

There is a trend towards a higher level of qualification since the first bachelor's degree course commenced in 1995, but there is no significant movement towards alignment of curricula. There are presently ten universities that offer undergraduate and/or postgraduate degree programs (including conversion of diplomas to bachelor's degrees), but some of these courses appear to be subject to less external scrutiny than courses in the VET or private higher education sectors. Current competitive pressures in higher education have the potential to encourage some institutions to exploit their self-governing status for commercial gain.

The proliferation of education providers has had several consequences that are problematic for raising the standard of the professions. These include:

- a lack of appropriate academic teaching staff;
- fragmentation and lack of critical mass of academics;
- a limited research environment (and few people with research qualifications); and
- variable arrangements for clinical training.

The teaching is primarily undertaken by sessional staff, who make up 89% of the reported academic workforce. Of a total of 821 reported academic staff, only eight (all from universities) had published papers in peer reviewed journals during the period 1999–2003.

Findings from the workforce survey reported in Chapter 4 (Bensoussan et al. 2004) were that the length of undergraduate training or first qualification for naturopaths and WHM practitioners ranges from six months to six years, with an average of 3.1 years. Twenty-two

percent of practitioners reported that they felt under-prepared in clinical training, and nearly half felt that they were inadequately prepared for inter-professional communication (Bensoussan et al. 2004).

Participation in continuing education is high in the professions, with 89% of the survey respondents attending seminars and higher degree programs (Bensoussan et al. 2004). The extent to which continuing education—for these practitioners as well as for GPs—is provided by product manufacturers is not clear. Chapter 6 reveals that only five of 14 associations provided seminars in 2002. It is highly likely that product manufacturers are the major providers of continuing education.

### **3.8 Organisation of the professions**

There are five major professional associations that represent naturopaths and WHM practitioners in Australia—the Australian Naturopathic Practitioners Association (ANPA), Australian Natural Therapists Association (ANTAsn), Australian Traditional Medicine Society (ATMS), Federation of Natural and Traditional Therapists (FNTT), and National Herbalists Association of Australia (NHAA)—and a large number of smaller groups. The oldest professional association was formed in 1920 (NHAA). There was a proliferation of groups in the 1990s, with half of the fourteen organisations surveyed in this study having been formed between 1990 and 2003. There has also been a tendency for groups to form and then to split from federated arrangements. As a result, the numbers of organisations within the two major federations—Federation of Natural and Traditional Therapists (FNTT) and Complementary Medicines Practitioner Association Council (CMPAC)—have been reduced compared with their original numbers. This has weakened their ability to represent unified professions with respect to the policy and regulatory requirements of government. As indicated in section 3.6 above, about half of the practitioners report membership of two or more associations (Bensoussan et al. 2004).

The various associations have different entry criteria and different definitions of membership categories, as well as different approaches to the maintenance of ethical standards and investigation of complaints. Their main activities are of a representational nature, such as providing a vehicle for formal recognition of practitioners, policy lobbying, and providing membership services (such as eligibility for professional indemnity insurance), and receiving and handling complaints. Most associations are not active in professional development activities, such as continuing education and the development of practice guidelines.

Associations have separate arrangements for the recognition of qualifications. These include:

- formal accreditation of courses;
- acceptance of any government accredited qualification;
- individual assessment of applicants; and
- various combinations of the above.

The associations also have diverse views about the educational standards that are required now, and in the future. Varying requirements for accreditation of practitioners weaken attempts at self-regulation.

Each association has its own mechanism for handling complaints, although not all promote their availability to consumers. They receive few complaints, and do not appear to liaise with each other regarding the question of practitioners who have been removed from one association wishing to join another. The research group was unable to detect circumstances in which associations routinely reported complaints to relevant authorities, although some complaints submitted to ATMS were being handled by the police. In the constitutions of some associations, there was a lack of clear process regarding how complaints were to be handled. The research group was unable to identify whether the people involved in complaint resolution were appropriately trained or qualified for this task.

In effect, there is no real self-regulation of naturopathy and WHM. The numerous associations constitute an *ad hoc* and inconsistent system compared with mainstream health professions where professional representation is generally consolidated. Attempts to develop a coherent approach across the professions have been frustrated by variation among associations with respect to educational standards and attitudes to regulation.

The administrative arrangement that has been put in place to register practitioners for the purpose of GST-exemption cannot be considered a form of occupational regulation, nor does it provide incentives for industry self-regulation because it reinforces current fragmented arrangements.

### 3.9 Occupational regulation

Internationally, increasing attention is being given to the question of whether the CAM professions should be regulated. The UK, the USA, Canada, and New Zealand have all undertaken reviews of policy and legislation in relation to the regulation of CAM practitioners. Statutory self-regulation with title protection is under discussion in the UK, Ontario (Canada) and New Zealand, and has already occurred in California (USA). The US White House Commission considered that ‘the heterogeneous array of education, training and qualifications’ makes it difficult to target recommendations about who to regulate (White House Commission on Complementary and Alternative Medicine Policy 2002).

Although the professions are unregulated in Australia, naturopathy and WHM practitioners and practices are subject to a diverse range of state and federal government legislation and regulation, including:

- therapeutic drugs legislation (related to registration, advertising, and labelling of products);
- drugs and poisons legislation (and schedules) in relation to prescribing rights — which prevents access by naturopaths and WHM practitioners to some ‘tools of trade’;
- quarantine legislation (in relation to importation and use of certain products);
- GST legislation (in relation to GST exemption for their services);
- Commonwealth and state health acts (in relation to rebates from private health funds and infectious diseases regulations); and
- health complaints commissioners, for example the Health Services Commissioner in Victoria.

The training and education of practitioners are subject to state and federal legislation governing education and training, but accreditation of courses remains voluntary.

Current arrangements for the accreditation of courses and the setting of professional standards are *ad hoc* and inconsistent. The legislative infrastructure does not support consistent standards of education and consistent professional standards for herbal medicine practitioners and naturopaths. The legislative framework, including *A New Tax System (Goods and Services) Act 1999*, encourages this situation. The Expert Committee (2003, p. 134) has recommended that the Australian government should ‘give consideration to revising the definition of organizations whose members satisfy requirements for “recognised professionals” for the provision of GST-free services’.

The professional associations are divided with respect to the desirability of statutory regulation of naturopathy and WHM. Most associations believe that self-regulation is not working and some actively support statutory regulation, but others believe that ‘government monitored self-regulation’ is to be preferred to statutory regulation—which is perceived as ‘government interference’. However, the nature of the government’s monitoring role is not clear and the liability issues have not been explored. There is some concern about the cost and administrative burdens associated with statutory regulation.

In their workforce survey, Bensoussan et al. (2004) reported that a majority of practitioners perceived regulation to be positive for professional status, standards of practice, standards of (and access to) education and research, access to scheduled herbs and products,



quality of herbs and products, and definition of occupational boundaries. However, these practitioners had concerns about potential negative effects of regulation on litigation, freedom of practice, and medical influence on practice.

A significant majority (77%) of GPs surveyed in the present study believed that CAM practitioners should be regulated. In relation to specific therapies, GPs strongly supported regulation for acupuncture (87% of respondents), Chinese herbal medicine (80%), herbal medicine (77%), naturopathy (73%), homeopathy (66%), and vitamin and mineral therapy (66%).

According to enquiries made for the present study, private health funds strongly support statutory registration. Their responses indicate concerns about education, professional standards, dubious claims and costs, and the time and administration costs of having to deal with multiple professional associations.

### **3.10 Consumers' expectations**

Victorian consumers involved in this study had mixed views about regulation, although the majority of participants thought that there should be some form of regulation. A number of focus group participants felt that consumers put a lot of trust in practitioners, and are often vulnerable, and that practitioners should therefore have an appropriate qualification and should be regulated. The consumers who thought that there should be regulation said it was needed to:

- raise the standard of practitioners;
- ensure consistency of care; and
- stop unethical practice.

There was some confusion about the benefits that regulation would confer on consumers, but the focus group discussions indicated that quality of care and continuing education were issues. Quality of care encompassed the relationship with the provider, the importance of communication, and the knowledge and technical competence of the provider.

Some participants felt that regulation would ensure a greater degree of protection for consumers, but others were concerned about the potential for increased medical influence or control. However, it was felt that this should be balanced against the need for the two systems (conventional medicine and complementary healthcare) to work together. Comments made in the focus groups suggest that regulation of naturopaths and WHM practitioners would enable consumers to navigate the systems more easily, and that it would enable better communication between practitioners.

The potential for 'false' consultations is an issue of concern if people believe that assistants in health food shops are qualified naturopaths. This is a safety issue, given that many of the people who participated in the present survey were active in self-prescribing.

### **3.11 Regulation of naturopathy and WHM in Victoria**

There are six general models of occupational regulation of the health workforce (DHS 2003 p.20):

- *Self-regulation* – A practitioner's voluntary membership of a professional association indicates that the practitioner is suitably qualified, safe to practise and subject to a disciplinary scheme.
- *Negative licensing* – A practitioner may practise in a self-regulated profession unless listed on a register of persons who are ineligible to practise because of a finding of poor practice.
- *Co-regulation* – Members of a professional association are regulated by that association and government.
- *Reservation of title only* – A statutory registration board registers members of a profession and reserves the use of specific titles for those who are registered.

- *Reservation of title and core practices* – Certain risky procedures within the defined scope of practice of a profession are restricted via legislation to members of the registered profession and other specified registered health professions.
- *Reservation of title and whole practice restriction* – This model restricts the use of reserved titles, broadly defines the scope of practice of a profession, and prohibits unregistered practitioners from practising the profession.

Occupational regulation in Australia is framed by the Mutual Recognition Agreement signed by the Commonwealth and the states and territories in 1992. In 1995, the Australian Health Ministers' Advisory Council (AHMAC) adopted a general policy of limited government involvement in professional regulation. The following criteria, known as the 'AHMAC criteria', must be satisfied if a profession is to be regulated:

- Is it appropriate for Health ministers to exercise responsibility for regulating the occupation in question, or does the occupation more appropriately fall within the domain of another ministry?
- Do the activities of the occupation pose a significant risk of harm to the health and safety of the public?
- Do existing regulatory or other mechanisms fail to address health and safety issues?
- Is regulation possible to implement for the occupation in question?
- Is regulation practical to implement for the occupation in question?

In 1995, Australian governments also adopted the principles of the National Competition Policy (NCP), which necessitated a further criterion:

- Do the benefits to the public of regulation clearly outweigh the potential negative impact of such regulation?

In considering the application of the six models for health workforce regulation to the current state of naturopathy and WHM use and practice in Australia, the research group came to the following conclusions in relation to the AHMAC criteria.

1. It is appropriate for Health Ministers to exercise responsibility for regulating naturopathy and WHM as they are professions that offer health services to the general public.
2. The activities, the scope of practice, and the practice context of naturopathy and WHM pose a significant risk of harm to the health and safety of the public. Minimisation of the risks should be a priority of both government and the professions.
3. Existing regulatory mechanisms—by government and the professions—are inadequate in safeguarding and protecting the public as consumers of naturopathy and WHM. Statutory regulation would provide a higher standard of complaints process with regard to access, transparency, and equity; moreover, disciplinary actions would be given the force of statute, and an appeals process would be provided.
4. Naturopathy and WHM are defined professions, with defined modalities and established educational provision, for which regulation is possible to implement. There are complexities in relation to naturopathy—because of the diversity of practices adopted by the profession and the fact that some practitioners specialise in only some modalities and do not practise others. However, similar complexities have been addressed successfully in Victoria in designing the registration scheme for the Chinese medicine profession.
5. Occupational regulation is not without some practical difficulties, but there are models in other jurisdictions in Australia and experience in relation to registration of Chinese medicine practitioners that can be drawn upon to design and implement a suitable regulatory scheme.

6. The benefits of promoting public safety outweigh the potential negative impacts of occupational regulation.

The research group found that statutory regulation is warranted because:

- there is a level of risk comparable to other regulated professions;
- there is a particular risk related to interaction of herbal medicines and pharmaceutical drugs, and the need for appropriate clinical guidelines;
- there is no legally enforceable regulatory framework governing the prescribing of drugs and poisons by naturopaths and WHM practitioners;
- there are significant variations in standards for professional education and membership among professional associations, and the professional associations have been unable to agree upon a common arrangement for self-regulation;
- there are significant variations in standards among education and training institutions and no evidence of movement towards common standards—including the failure of current regulatory frameworks for education to ensure minimum standards; and
- existing regulatory frameworks provide insufficient protection for consumers against professional misconduct.

Statutory regulation of the naturopathy and WHM professions would be expected to:

- facilitate the development of communication and referral mechanisms between conventional medical providers and CAM providers;
- provide incentives for health services to maintain accurate records of patients' medications;
- provide an incentive for the development of uniform minimum educational standards;
- provide system incentives to develop appropriate policies for the reporting of adverse drug reactions by CAM practitioners, with the aim to increase practitioner reporting of adverse reactions to herbs and supplements;
- establish transparent and independent complaints mechanisms, particularly in relation to matters of professional misconduct;
- improve public education regarding the communication of risks to consumers;
- encourage citizen engagement with policy development and implementation;
- establish quality standards and safety protocols for the use of naturopathic and Western herbal medicines; and
- provide the same protection to consumers of naturopathy and WHM as is currently available to consumers of conventional medical services.

There would inevitably be some costs associated with regulation. These would largely be borne by the professions in the form of registration fees, costs to practitioners of upgrading qualifications, and costs to educational institutions of upgrading courses and accreditation processes. Barriers to entry to the professions would be established, and some existing practitioners might face difficulty in gaining registration if their qualifications and experience proved to be insufficient. However, the research group found that there would be a net public benefit from occupational regulation.

A further potential benefit was identified regarding the public health workforce. Naturopathy and WHM graduates represent an untapped workforce at a period when severe workforce shortages are projected in healthcare; these graduates are not being utilised by the public health system, in part because of the lack of regulation and the absence of minimum enforceable standards.

### 3.12 Recommendations for regulatory requirements

The research group recommends that an independent regulatory body be established to determine uniform minimum professional and educational standards and to provide effective complaints handling mechanisms and sanctions relating to professional misconduct. A fair and transparent ‘grandparenting’ system should exist for a limited number of years to allow applicants to meet educational and other requirements set by the regulating body.

In reviewing the current situation against the AHMAC and NCP criteria, the research group concluded that:

- naturopathy and WHM are appropriately within the responsibility of the Health Ministers;
- the use of ingestibles in general (and herbal medicines in particular) in naturopathy and WHM practice poses a significant risk of harm;
- existing regulatory mechanisms are inadequate for safeguarding and protecting consumers;
- there are definable modalities within naturopathy and WHM for which it is possible and desirable to implement regulation, specifically herbal medicine and nutritional medicine;
- the multiple titles used by practitioners (particularly naturopaths), and the overlapping range of modalities they practise, pose a challenge for occupational regulation; however, the National Health Training Package does provide a definition for naturopathy and two of its core modalities, Western herbal medicine and nutritional medicine, present a level of risk that is of concern;
- the benefits of protecting public safety through occupational regulation outweigh the potential negative impacts.

The major complexity in considering whether occupational regulation should be imposed relates to the question of how best to define the professions. WHM is easily definable as a practice, a profession, and with regard to its ‘tools of trade’. It is clear that as a profession it entails risk to the public and should be regulated. Naturopathy is more diverse, having core training in the modalities of herbal medicine and nutritional medicine, plus either massage or homeopathy or both. It therefore entails a wider scope of practice. It should be noted that herbal medicine is a core practice for naturopaths (as defined by the National Health Training Package), and this modality does carry risk. In addition, nutritional medicine is a second core practice for naturopaths, and it also poses some risks. For these reasons, the research group recommends the regulation of *both* WHM and naturopathy. The need to ensure appropriate access to restricted substances is another reason for regulating both WHM practitioners and naturopaths.

In the interests of protecting public health and safety, it is recommended that the following titles be protected:

- herbal medicine practitioner;
- Western herbal medicine practitioner;
- herbalist;
- Western herbalist;
- medical herbalist;
- phytotherapist;
- phytotherapy practitioner;
- naturopath;
- naturopathic physician;
- naturopathic medicine practitioner; and
- ND (naturopathic doctor/doctorate, naturopathic diploma).

Protection of title could have unintended consequences for practitioners of herbal medicine in other traditions—such as ayurvedic medicine. It would be important for these professions to be granted exemptions from the offence provisions, or for them to ensure that any titles which they use do not suggest that they are practising WHM or naturopathy.

Protection of title could also have adverse effects on naturopaths who have been in practice for many years but who: (i) do not use herbal medicine; and/or (ii) have limited training. It would be important to include in any legislation a ‘grandparenting’ provision that recognises these practitioners.

Occupational regulation would require some educational institutions to upgrade their courses. Sufficient time would have to be allowed for appropriate changes to be made.

Although this study examined some aspects of the practice of multiple modalities (the naturopathic modalities of herbal medicine, nutritional medicine, and massage or homeopathy, as defined by the National Health Training Package), the question of whether some of these single modalities should be subjected to occupational regulation has not been considered.

There is insufficient evidence of risk to warrant protection of the following titles at this time and it is recommended that they not be protected:

- nutritional medicine practitioner;
- homeopath;
- massage therapist;
- body work therapist;
- relaxation therapist;
- natural therapist;
- complementary therapist.

There is little research on the risks associated with nutritional medicine and homeopathy, but given that the risks for naturopathy and WHM appear to be comparable to those of Chinese medicine, further research is recommended in relation to the risks and regulatory requirements of nutritional medicine and homeopathy, as well as ayurvedic medicine.

The homeopathic profession in Australia has agreed upon minimum standards and established a national register of accredited homeopaths. The Australian Register of Homeopaths (AROH) is the national registration body for professional homeopaths, and is the receiver and arbiter of complaints from the public against registered members. The Board of AROH registers homeopaths who are qualified to government endorsed standards. Registered homeopaths are bound by AROH's code of professional conduct and standards of practice. The purpose of the Register is to protect the public by accrediting only practitioners who meet these standards (Australian Register of Homeopaths 2003).

Current legislation that encourages the proliferation of standards warrants review. In particular, the implementation of the *A New Tax System (Goods and Services) Act 1999*, which provides criteria for an exemption from the requirement to levy GST on certain services has, possibly unintentionally, supported a proliferation of educational and professional standards for naturopaths and herbal medicine practitioners.

### **3.13 Additional recommendations**

The following recommendations are consolidated from the research findings in various chapters of this report.

#### **Understanding and reducing risks**

- Institutions that provide education and training in naturopathy and WHM should ensure that adequate training is available for these practitioners to minimise the specific adverse events identified in this report, and to promote the ability of practitioners to deal with these adverse events and initiate appropriate referral practices.
- Professional associations, in conjunction with relevant government agencies, should identify and promote a centralised agency for the reporting and recording of adverse events related to nutritional and herbal medicine practice.
- The current TGA Adverse Drug Reaction Reporting System (ADRS) database should be strengthened to increase its usefulness to the complementary medicine profession and the public.
- Professional associations and educational institutions should promote awareness among practitioners of the importance of reporting adverse events related to practice.
- National funding bodies—such as the National Health and Medical Research Council (NHMRC) should allocate funding for research into areas such as the quantification of adverse events in nutritional and herbal medicine, and the interactions between herbal medicines and Western pharmaceutical drugs.
- Further research should be undertaken on the nature of complaints made to various bodies, the types of action taken, and the effectiveness of complaints-handling mechanisms.
- Protocols for managing adverse events related to nutritional and herbal medicines in Australian hospitals should be reviewed, and new protocols developed if required.
- Associations should be encouraged to develop further guidelines for professional practice, for example, guidelines for referral to other practitioners, the reporting of adverse events, infection control, drug-herb interactions, the safe use of potentially toxic herbs, and adequate standards of record-keeping and advertising.
- Medical practitioners should encourage patients to disclose consumption of complementary medications.

#### **Understanding and maximising benefits**

- In view of the substantial annual increases in published CAM research from 1966-2003, professional associations, education providers and regulatory bodies should ensure that the minimum educational standards for naturopathy and WHM provide for up-to-date skills in: (i) literature acquisition and evaluation; (ii) critical reasoning and research methodologies; and (iii) evidence-based practice.
- Continuing professional education should be made mandatory by regulatory bodies.
- A form of regulation is required that enables practitioners who are appropriately qualified in herbal medicine to gain access to scheduled herbs, to improve the therapeutic benefit for patients.

- The NHMRC should commission a systematic evaluation of the extent and quality of the evidence in herbal and nutritional medicine, and should develop practice guidelines accordingly as a resource for health professionals. The NHMRC should also encourage and fund research to assess the application of evidence in naturopathic and WHM clinical practice.
- The NHMRC should fund further research—especially ‘whole-practice’ research in naturopathy and WHM, and translational research (how evidence is translated into practice).
- The quality of Australian clinical trials should be improved through training of researchers and the establishment of quarantined research funding by the NHMRC that supports the mentoring of naturopathy and WHM researchers.
- State and federal bodies should ensure that naturopathic and WHM interventions with a high level of evidence be assessed for cost effectiveness as part of an evaluation of their potential for incorporation into the public sector healthcare system.

### **Improving the standard of education and training**

- The professions of naturopathy and WHM should work towards a bachelor’s degree as the minimum requirement for entry into practice.
- A body, independent of but informed by the professions, should be established to develop educational standards and curriculum requirements to bachelor’s degree level for naturopathy and WHM, and to accredit these courses.
- Education providers should review undergraduate courses and conversion courses to bachelor’s degrees on the basis of the WHO guidelines (WHO 2004) for education and quality assurance in traditional medicine. This would assist providers to identify areas in need of improvement—such as inter-professional communication, clinical training and skills in the interpretation of published research.
- Clinical education in naturopathy and WHM should be urgently reviewed and minimum standards should be set to ensure that: (i) graduates attain core competencies; (ii) assessment processes are rigorous; (iii) clinical teachers have a minimum of five years full-time equivalent experience; (iv) all student clinics have a protocol manual; and (v) all students and staff members working in clinics have adequate first aid qualifications.
- Educational institutions should work with professional bodies in offering continuing professional education, particularly in the areas of evidence-based practice, to increase the quality and availability of continuing professional development.
- Research should be undertaken by the academics in the field, including the institutions and professional bodies in the following areas to assist developments in education: (i) the structure, cost, aims, and outcomes of conversion courses; (ii) graduate outcomes and destinations; (iii) distance education; (iv) clinical education; (v) guidelines for clinical practice in naturopathy and WHM; and (vi) international students in Australian natural therapy courses.
- Honours programs should be developed by education providers offering approved bachelor’s degrees to expedite entry of postgraduate students into doctoral programs.
- Education providers should develop policies on minimum staff qualifications, the clinical experience of clinical teachers, and best practice in recruitment to strengthen faculty development.

- All education providers should consider increasing the numbers of full-time and/or part-time academic staff to facilitate course development, coordination, and review, and encourage faculty members to undertake postgraduate study to support scholarship, research, and publication.
- Universities that offer naturopathy and WHM courses should develop appropriate academic staff, scholarship, and research.
- Education providers should include a wider range of expertise on course committees—for example educators from other sectors, representatives of the large professional associations, and a wider variety of industry stakeholders.

### **Enhancing professional representation**

- All associations purporting to represent practitioners should do so through a democratic, transparent and accountable process.
- Associations should amalgamate or work cooperatively towards establishing a single peak professional body.
- Associations should be encouraged to hold or support conferences to provide open forums, independent of product manufacturers, for the dissemination of research, and to promote the debate of issues that are important to the professions.
- Government committees that deal with complementary healthcare issues require expert representation from the complementary healthcare professions.

### **Improving mainstream health services**

- Institutions responsible for approval of suitably qualified practitioners (including government, public, and private institutions) should work together to develop greater standardisation across jurisdictions to benefit their own interests and those of consumers.
- Institutions that make decisions about funding CAM should become more acquainted with the evidence base in the interests of informed and up-to-date decision-making. Decision-making processes should be transparent.
- Hospitals or hospital associations should develop policies regarding the use and consumption of complementary medicines in hospitals by patients, and the practice of CAM in hospitals by clinical staff.
- GPs and practitioners of naturopathy and WHM should be encouraged through their professional bodies and health authorities to collaborate in the care of patients, particularly patients with chronic illnesses. Extension of ‘MedicarePlus’ could be a useful mechanism to achieve this end.
- Medical practitioners should be required by a regulatory authority to meet minimum educational standards before prescribing herbal and nutritional products, and medical education should expose undergraduates to CAM.
- GPs should be encouraged to undertake continuing education to increase their understanding of CAM, as a basis for improving interdisciplinary communication as well as appropriate advice for their patients.

### **Improving access to accurate information**

- All centralised web-based health information providers (for example, HealthInsite and BetterHealth Channel) should be reviewed to ensure that up-to-date and evidence-based information is provided on commonly used CAM treatments.
- A public education campaign should be undertaken by the registration board to inform consumers about the significance of titles, unprotected titles, and titles used by practitioners—including common titles and terms, and ‘umbrella’ terms.
- Community education should be undertaken by consumer and professional bodies to: (i) inform consumers about the different roles of general practitioners and CAM practitioners; (ii) encourage disclosure of use of complementary medicines;



and (iii) ensure that appropriate medical diagnosis for any underlying conditions is obtained.

- Government funding should be provided to develop a high quality evidence-based CAM information system that is accessible to doctors, natural therapists, education providers, health organisations, and the public.

### Improving the legislative framework

- Legislation that encourages the proliferation of standards for entry to and practice of the professions should be reviewed (for example, *A New Tax System [Goods and Services] Act 1999*).
- State and Territory governments should consider mechanisms to ensure a consistent and fair approach to complaints management and unprofessional conduct.
- A uniform approach should be adopted with respect to therapeutic goods legislation.
- State, Territory, and Commonwealth governments should give consideration to the risks arising from the absence of coverage of raw herbs used as starting materials in the current legislative regime for therapeutic goods.

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# 1. Introduction to the Project

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## 1.1 Introduction

In June 2003, the Victorian Department of Human Services (DHS) contracted with the School of Public Health, La Trobe University, to coordinate research on the benefits, risks, and regulatory requirements for the professions of naturopathy and Western herbal medicine (WHM).

The overall aims of the project were: (i) to investigate and understand the practice of naturopathy and WHM in Australia; and (ii) to make recommendations on the need, if any, for measures to protect the public.

In pursuit of these overall aims, the specific objectives of the study were to:

- identify the scope and nature of practice of the professions of naturopathy and WHM in Australia, and the characteristics of the workforce in these professions;
- understand the reasons patients choose naturopathy and WHM, and any concerns or issues they might have;
- understand the risks and benefits associated with the practice of naturopathy and WHM;
- identify the extent to which practitioners of mainstream medicine are adopting naturopathic and WHM modalities, and their training in these modalities;
- identify referral patterns and links between practitioners of naturopathy and WHM and other healthcare providers;
- profile the education and training available to persons entering and practising the professions of naturopathy and WHM, and to assess the adequacy of such education and training;
- understand the aims and activities of professional associations that represent practitioners of naturopathy and WHM;
- identify the extent of institutional recognition of naturopathy and WHM in Australia;
- assess the impact of regulatory arrangements on the practice of naturopathy and WHM in Australia and overseas;
- assess the professions of naturopathy and WHM against the Australian Health Ministers' Advisory Council (AHMAC) 'Criteria for Assessing the Need for Statutory Regulation of Unregulated Health Occupations'; and
- explore models of regulation and other measures to protect consumers of naturopathy and WHM.

Although the Australasian Association of Ayurveda requested consideration of ayurveda by the research group, ayurveda did not fall within the scope of the DHS remit for the project.

This introductory chapter provides an overview of the scope and organisation of the project. A brief history of naturopathy and Western herbal medicine is offered to set the context, along with definitions of the professions studied in this project. The chapter concludes with an overview of how the report is organised.

## 1.2 National and international context

Demand for complementary and alternative medicine (CAM) appears to have increased dramatically over the past 20 years (Lloyd, Lupton, Wiesner & Hasleton 1993; Fisher & Ward 1994; Eisenberg, Davis, Ettner et al. 1998; MacLennan, Wilson & Taylor 2002). In 2000 in Australia, one in every two people had used at least one non-medically prescribed complementary medicine, and one in five had attended a non-medically trained therapist (MacLennan, Wilson & Taylor 2002). From 1993 to 2000, the amount spent by the public on alternative medicines and services increased from \$AU930 million to \$AU2.3 billion (MacLennan, Wilson & Taylor 2002). While the amount spent on pharmaceutical drugs doubled in that period, the amount spent on alternative medicines almost tripled (Department of Health and Ageing 2001; MacLennan, Wilson & Taylor 2002).

Australia has a sizeable workforce of naturopaths and WHM practitioners. The present study identified 2,618 active practitioners, and found that approximately 350 naturopaths and 150 WHM practitioners graduate annually. Naturopaths and WHM practitioners represent an untapped workforce in the healthcare sector, which could be utilised within the public healthcare system if a framework for minimum educational and professional standards, and barriers to entry to the professions, were established. For example, some women's health clinics in community settings employ naturopaths or WHM practitioners. No data could be found on the actual number employed, although it is thought to be small.

In the United Kingdom (UK), choice of healthcare is a common-law right. In contrast, in most European countries and in the United States of America (USA), few healthcare activities are allowed without specific state authorisation (Mills 2001). The USA has traditionally been hostile to natural therapies, and these have been made illegal by the expansive scope of statutory Acts governing medical practice in each state. As a consequence, specific legislation must now be enacted for the provision of choice (Josefek 2000).

In the UK, although the legislative environment is generally benign, some regulatory measures are in place. Nevertheless, most standards are set by non-government associations. As a result, there is still wide variation in professional and educational criteria and complaints processes (Mills 2001). The House of Lords Select Committee in Science and Technology (2000) recommended statutory regulation for herbal medicine and acupuncture in the UK based on the possibility of harm, their robust voluntary self-regulation systems (essential for the working of a regulatory body), and the credible evidence base. The committee also recommended that the numerous associations should make determined efforts to amalgamate and develop a clear structure, and that bodies representing other healthcare providers (such as doctors and nurses) should set standards for the practice of complementary and alternative medicine (CAM) comparable to those set by relevant CAM regulatory bodies to ensure that patients receive high standards of care. It was also recommended that associations should develop essential clinical guidelines on various aspects of practice—for example, on how to deal with patients who do not have a medical diagnosis (Mills 2001).

In the USA, the National Center for Complementary and Alternative Medicine (NCCAM) reported in May 2004 that more than one-third of American adults now use some form of CAM (Barnes et al. 2004). However, the traditional climate of medical and legislative hostility to alternative therapies in the USA has led to CAM evolving along a different path. To gain legal standing and community acceptance, a section of the naturopathic profession deemed that a level of education similar to that required for medical education was necessary. Examinations are set by licensing boards (currently established in 14 states), and candidates must have attended one of five accredited naturopathic colleges. Other naturopathic colleges, presumably with lower requirements for practice, also exist. The result is a two-tiered system whereby some practitioners are said to be qualified, but others not (Croasdale 2002). A major national body, the American Association of Naturopathic Physicians, grants full membership only to naturopaths who are eligible for state licensing by

virtue of their qualifications from accredited courses, and the White House Commission on Complementary and Alternative Medicine Policy (2002) made educational recommendations only in respect of such accredited courses.

On an international scale, the World Health Organization (WHO) has recognised the important role that traditional medicine<sup>1</sup> plays in healthcare. The WHO's Traditional Medicines Strategy 2002–2005 has noted a number of challenges that require action. These include:

- a lack of official recognition for providers and their roles;
- inadequate or non-existent regulation;
- lack of access,
- inequitable distribution of benefits; and
- inadequate allocation of resources for development, capacity building, and research (World Health Organization 2002).

The widespread use of a large and often ignored healthcare sector is a public health issue, and no comprehensive picture exists of the kind of healthcare that is actually being provided (Eisenberg et al. 1998).

The overall international trend is towards stronger regulation. This will facilitate the implementation of certain essential strategies—an increase in transparency of regulatory schemes and the application of standards, and an increase in public scrutiny (which are essential to quality care), a gradual integration of various forms of complementary medicine into mainstream healthcare, and an increase in funding for research and capacity building. Underlying these strategies is a need to improve educational and professional standards in this area of healthcare practice.

## **1.3 Scope and organisation of the project**

### **1.3.1 Project components**

The structure of the present project, and the members of the research group responsible for various components of it, are outlined in Table 1.1.

### **1.3.2 Public consultation**

Public consultation regarding the project was achieved by:

- a project website; and
- a project reference group.

The first of these, the *project website* for Risks and Regulatory Requirements for Complementary Healthcare (RRRCH), was created as part of the website of the School of Public Health at La Trobe University <[www.latrobe.edu/public health/rrrch](http://www.latrobe.edu/public%20health/rrrch)>. The information on this website was made available for others to use. For example, an initial RRRCH 'newsletter' was published in the Australian Traditional Medicine Society (ATMS) newsletter. Some of the survey questionnaires used for the project's research were also posted on the website.

The second of these consultative mechanisms, the *project reference group* was comprised of representatives of the National Herbalists Association of Australia (NHAA), the Federation of Natural and Traditional Therapists (FNTT), the Australian Traditional Medicine Society (ATMS), the Australian Natural Therapists Association (ANTAsn), the Australian Naturopathic Practitioners Association (ANPA), and DHS. The group met twice in Melbourne. At the first meeting, the background to the project was presented and the leader of each component outlined how research would be undertaken in that component, and the current status of work. A second meeting presented preliminary findings and sought feedback from the reference group.

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<sup>1</sup> 'Traditional medicine' is the term used by the WHO to denote indigenous natural medicine systems.

**Table 1.1 Components of the project and leaders responsible**

Component	Leader
1. Risks	Professor Alan Bensoussan, University of Western Sydney (UWS)
2. Benefits	Professor Stephen Myers, Australian Centre for Complementary Medicine Education and Research (ACCMER), University of Queensland/Southern Cross University
3. Workforce (a) Naturopathy and WHM  (b) Western medicine	National Herbalists Association of Australia (NHAA) and Federation of Natural and Traditional Therapists (FNTT) workforce study. (NHAA represented by Ms Susan Dean) Professor Marc Cohen, RMIT University
4. Education and training	Dr Pauline McCabe, La Trobe University
5. Professional associations and institutional recognition	Dr Pauline McCabe, La Trobe University
6. Consumers (a) Opinions (b) Patient profile	Dr Sophie Hill, La Trobe University Professor Alan Bensoussan, UWS
7. Regulatory arrangements	Ms Genevieve Howse, La Trobe University
8. Project coordination and communication	Professor Vivian Lin, La Trobe University

## 1.4 Evolution of the practice of naturopathy and Western herbal medicine

Numerous therapeutic practices can be grouped under the umbrella of the term ‘complementary and alternative medicine’. This term is often used interchangeably with such terms as ‘natural therapies’, ‘complementary healthcare’, ‘holistic medicine’, and other variations.

Contemporary naturopathy evolved from the Austro-Germanic ‘return to nature’ movement of the 1850s. Nature cure, as it was known, combined ancient Hippocratic methods such as diet, rest and fasting in a rejection of the ‘heroic’ medicine of the time—which included bleeding, blistering, purging, and potent drugs (for example, mercury, opium and antimony) (Lindlahr 1918; Pizzorno & Snider 2001; van der Zee 1997). Sanatoria for nature cure developed in various European countries, and natural approaches to healing were exported to England, the USA, and Australia in the late nineteenth and early twentieth centuries (Myers, Hunter, Snider & Zeff 2003).

In the early twentieth century there were tens of thousands of natural therapists in the Western world, particularly in the USA. The rise, decline and later resurgence of the use of natural therapies in the twentieth century has been well documented by naturopaths, historians, and sociologists (Myers et al. 2003; van der Zee 1997; Willis 1989). Willis (1989) noted that non-orthodox practitioners in Australia were suppressed politically in the early twentieth century because orthodox medicine was believed to be a superior form of care, despite there being little scientific evidence to support such an assumption. Political suppression was later reinforced by the discovery of antibiotics—which led to active campaigns against natural therapists, who were identified as ‘quacks’ and ‘zealots’ for their use of natural approaches to healthcare (van der Zee 1997).

WHM is grounded in the British and European folk and professional tradition of herbal medicine. As such, it predates naturopathy. European settlers to Australia brought their herbs and their herbal knowledge. Evidence of the importance of medicinal plants to the fledgling colony is provided by the fact that a herb garden was established in the Rocks area of Sydney

by March 1788, within two months of the arrival of the First Fleet (Australian Journal of Medical Herbalism 1990).

Martyr (1998, 2002) has documented the lay use of domestic plants by early settlers, as well as the activities of professional herbalists, from at least the mid-nineteenth century. Formal professional associations of herbalists have existed in Australia since at least the 1880s, and early Acts to register medical practitioners were opposed by groups of herbalists and other opponents (Willis 1989). The archives of the National Herbalists Association of Australia (NHAA) show that political activity was continuous throughout the twentieth century in Queensland, New South Wales, Victoria, and South Australia—as herbalists attempted to ensure the maintenance of their livelihood through their continuing right to practise.

Herbal medicine was integrated into practice by many of the early naturopaths in Australia. It thus became a core modality in naturopathic education (Jacka 1977), while simultaneously maintaining its identity as a stand-alone profession.

Naturopathy and WHM steadily increased in popularity in Australia during the 1970s, thus drawing the attention of government. A number of early actions taken by governmental and parliamentary bodies led to the profession mobilising to defend itself. These initiatives included the Federal Committee of Inquiry into Chiropractic, Osteopathy, Homeopathy, and Naturopathy in 1977, the Victorian Parliament's Dietetic Bill in 1980, and a Draft Standard on Vitamins and Minerals proposed by the National Health and Medical Research Council and the National Therapeutic Goods Committee in 1981 (Jacka 1998). These actions produced a legacy of suspicion among practitioners with respect to government intervention—which was perceived to be attempting to suppress alternative approaches to health and healthcare.

The core of the naturopathic approach is a belief that a return to health is best achieved through the use of natural agents that stimulate the body's self-curative processes (Myers et al. 2003). Naturopathy has evolved from an early focus on diet to the integration of a range of other therapies (such as herbal medicine, homeopathy, and massage) that are compatible with its central thesis. The naturopathic perspective is grounded in *health*, rather than *disease*—and it can therefore be utilised both as 'a way of life' to support good health and as a healing approach to improve poor health. It therefore holds itself to be distinct from the approach of orthodox medicine, which has a primary focus on disease and pathology.

The term 'naturopathy' was coined in the United States in about 1895 (Pizzorno & Snider 2001). The literal meaning of the term is 'nature disease'. The American Association of Naturopathic Physicians (1989) formulated the following description of naturopathic medicine, principles, and practitioners:

Naturopathic medicine is a distinct system of primary health care: an art, science, philosophy and practice of diagnosis, treatment and prevention of illness. Naturopathic medicine is distinguished by the principles which underlie and determine its practice. These principles are based upon the objective observation of the nature of health and disease, and are continually re-examined in the light of scientific advances. Methods used are consistent with these principles and are chosen upon the basis of patient individuality. Naturopathic physicians are primary health care practitioners, whose diverse techniques include modern and traditional, scientific and empirical methods.

The six major principles that inform the practice of naturopathy are (Myers et al. 2003, pp. 50–1):

- work with the healing power of nature (*vis medicatrix naturae*), understood as the inherent self-organising and healing processes of living systems;
- identify and treat the causes (*tolle causam*), rather than suppress symptoms, as the latter generally interferes with the healing process;
- first do no harm (*primum non nocere*)—choose restorative, low harm therapies wherever possible; recognise the limits of naturopathic care and refer as necessary;
- doctor as teacher (*docere*)—educate the patient and utilise the therapeutic potential of the practitioner–patient relationship;
- treat the whole person—consider mind, body, emotions, and environment; and
- prevention—the prevention of disease and the attainment of optimal health are primary objectives of naturopathic health care, which also supports sustainability and the health of communities and the natural world.

Naturopathy has evolved to include five main therapeutic streams: (i) nutrition; (ii) herbal medicine; (iii) homeopathy; (iv) soft tissue bodywork; and (v) counselling (Myers et al. 2003). These are utilised in accordance with the philosophy and clinical tradition of naturopathy, and, increasingly, in accordance with scientific evidence (Myers et al. 2003).

The definition of natural therapies and their practices has evolved historically, reflecting the change in perception from ‘alternatives’ *in opposition to* orthodox medicine, to being recognised as *complementary to* orthodox medicine, thereby providing consumers with a comprehensive healthcare system. Naturopaths and WHM practitioners now see patients from all demographics and treat the full spectrum of health complaints—thus acting as providers of primary care alongside general practitioners (GPs).

## 1.5 Definitions used in this report

Numerous therapeutic practices can be grouped under the umbrella term ‘complementary and alternative medicine’. This term is often used interchangeably with such terms as ‘natural therapies’, ‘complementary healthcare’, ‘holistic medicine’, and other variations. For this study, the terms ‘complementary and alternative medicine’ (CAM) and ‘complementary therapies (CT) were selected for use as generic terms.

The present report is concerned only with naturopathy and Western herbal medicine, and it therefore does not consider a range of other practices (such as kinesiology, reflexology, iridology, Reiki, Bach flower therapy, aromatherapy, ayurvedic medicine, and so on).

### Complementary and alternative medicine

Complementary and alternative medicine (CAM) is a group of diverse medical and healthcare systems that are based on theories or explanatory mechanisms that are not in keeping with the orthodox biomedical model (Bensoussan 1999). CAM systems generally hold medicine to be a science of the human person and understand disease as involving a systemic dislocation of the whole person (Foss, in Robson 2003, p.2). Major CAM systems include naturopathy, Western herbal medicine (WHM), Chinese medicine, ayurveda and homeopathy.

### Complementary therapies

Complementary therapies (CTs) are non-conventional therapies that are used together with conventional healthcare. The list of what are considered by conventional medicine practitioners to be complementary therapies changes continually, as those therapies that are proven to be safe and effective become adopted into conventional health care and as new approaches to health care emerge (NCCAM 2002). Examples of therapies used to complement conventional healthcare are nutritional medicine, meditation and massage.



Also, consumers may choose to complement conventional healthcare with a wide range of non-conventional therapies, sometimes independently of medical advice.

### **Naturopath**

A ‘naturopath’ is understood in the present study to be a practitioner whose practice and modalities have been defined by the National Training Package (introduced in 2002, see Appendix 1.1)—that is, a practitioner having core training in naturopathic principles and philosophy, and in at least three of four practice modalities: (i) herbal medicine; (ii) nutritional medicine; and (iii) either massage or homeopathy. It is recognised that the modalities encompassed by naturopathy might be practised as single modalities, that is, either naturopaths or other practitioners may have a practice consisting of only one modality. However, this report does not address those practitioners whose training and practice are in the single modalities of massage, nutritional medicine (sometimes called ‘clinical nutrition’), homeopathy or counselling.

### **Western herbal medicine practitioner**

For the purposes of the present study, a ‘Western herbal medicine practitioner’ is understood to be a health practitioner who engages in extemporaneous<sup>2</sup> compounding of herbal medicines for therapeutic purposes for individuals under his or her care. Such a WHM practitioner will have satisfied core training in the principles, philosophy, and practice of herbal medicine, as defined by the National Health Training Package for WHM (introduced in 2002, see Appendix 1.1).

## **1.6 Organisation of the report**

The findings and recommendations of the study are presented in subsequent chapters, as outlined below.

### **Chapter 2: Risks Associated with the Practice of Naturopathy and WHM**

To assess the scale and severity of risk presented by the practices of naturopathy and WHM, this chapter includes a systematic review of the literature and relevant databases, and findings from two national workforce surveys: a survey of naturopathy and WHM practitioners, and a survey of general medical practitioners.

A range of resources was investigated—including: (i) biomedical databases; (ii) drug information services; (iii) medical bibliographies; (iv) legal databases; (v) reports of complaints bodies; (vi) print media; and (vii) national surveys of naturopaths, WHM practitioners, and GPs.

### **Chapter 3: Review of Reviews of the Benefits Associated with the Practice of Naturopathy and WHM**

This chapter presents a review of systematic reviews of the benefits attributed to naturopathy and WHM.

The review identified clinical trials of herbal medicine and nutritional medicine, and the nature and extent of pharmacological research activities in herbal medicine. A total of 72 systematic reviews published between 2001 and 2003 was reviewed. A separate review of homeopathy was also conducted. The paucity of literature on whole-of-practice benefits meant that this set of issues could not be systematically explored. That is, the review focussed on herbal medicine and nutrition as tools of trade of naturopathy and WHM.

### **Chapter 4: A Workforce Study of Naturopathic and Western Herbal Medicine Practitioners in Australia**

This chapter reports on the workforce data from a 2003 study funded by the National Herbalists Association of Australia and the Federation of Natural and Traditional Therapists,

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<sup>2</sup> Extemporaneous preparations are those prescribed as part of a consultation for an individual patient.

with financial support from the Commonwealth Department of Health and Ageing. (Bensoussan, Myers, Wu & O'Connor 2004).

These data included: (i) the number and qualifications of practitioners; (ii) the location of practices; (iii) the diagnostic methods used; (iv) the treatments, modalities, and technologies employed; (v) record-keeping procedures; (vi) knowledge and use of infection control procedures; (vii) professional indemnity insurance arrangements; (viii) participation in continuing professional development activities; and (ix) attitudes to regulation.

## **Chapter 5: Arrangements for the Education of Professionals in Naturopathy and WHM**

This chapter reports on the quality and extent of education in naturopathy and WHM in Australia through a survey of education providers who offer entry level qualifications (award and non-award programs) for practitioners of naturopathy and WHM.

The survey also sought information on conversion courses (upgrade to bachelor's degree) and postgraduate courses. The survey identified: (i) the types of institutions that provide education in naturopathy and WHM in Australia; (ii) the programs offered; (iii) course accreditation mechanisms and standards; (iv) course content in terms of basic and medical sciences, the theory and practice of naturopathy and WHM, and clinical and research subjects; (v) student profiles and graduating practitioner numbers; (vi) staffing profiles; (vii) consultative mechanisms regarding courses, and other quality assurance arrangements; (viii) the extent and nature of research activities; and (ix) views on education in naturopathy and WHM.

## **Chapter 6: Representation of Naturopathy and WHM through Professional Associations**

This chapter presents a profile of the organisations that represent practitioners of naturopathy and WHM in Australia, including groups that represent other health occupations that have adopted naturopathy and WHM treatment modalities.

A survey of identified professional associations was carried out and data were collected in the following areas: (i) the types of association and their legal status and aims; (ii) the size, number, and types of members in each state of Australia; (iii) the criteria for membership; (iv) requirements for continuing education; (v) protocols for dealing with complaints and discipline; (vi) codes of ethics and practice guidelines; (vii) course accreditation standards and processes; (viii) quality assurance processes; (ix) affiliations; and (x) views on the role of government in the regulation of naturopathy and WHM.

## **Chapter 7: Institutional Recognition of Naturopathy and WHM**

This chapter presents findings on the extent of institutional (government and non-government) support for (or involvement in) the practice of naturopathy and WHM.

Data were collected on the policy positions of various bodies including: (i) third party insurers (such as private health funds, the Health Insurance Commission, and workers' compensation and traffic-accident insurers); (ii) Commonwealth and state health authorities (including the Department of Veterans' Affairs and the Commonwealth Rehabilitation Service); (iii) professional indemnity insurers; (iv) the Australian Taxation Office; (v) statutory registration boards and professional associations of mainstream healthcare providers; (vi) statutory education authorities; (vii) the National Health and Medical Research Council; and (viii) public hospitals.

## **Chapter 8: Naturopathy, WHM, and General Practice: The primary healthcare system context**

This chapter presents findings from a survey of general practitioners carried out across Australia to assess the extent to which practitioners of Western medicine use naturopathy and WHM, or are involved in cross-referrals with practitioners of naturopathy and WHM.

The survey built upon comparable studies conducted in the late 1990s (Hall & Giles-Corti 2000; Pirotta, Cohen, Kotsirilos & Farish 2000), and considered such issues as: (i) the nature of use and the modalities employed; (ii) perceptions of risks and effectiveness of various complementary modalities; (iii) referral practices; (iv) attitudes to occupational regulation; (v) the use of complementary modalities and ‘over-the-counter’ products; and (vi) interest in, and extent of, professional development.

## **Chapter 9: Profile of Consumer Views on the Practice of Naturopathy and WHM**

This chapter reports on patient profiles, and on consumer use of (and satisfaction with) naturopathy and WHM. These issues were explored through three different projects:

1. a review of the Australian and international literature on the subject, including reports from complementary healthcare research units and consumer organisations;
2. a profile of patients (conducted as part of the workforce survey reported in Chapter 4); and
3. consumer focus groups conducted in Victoria.

The patient profile collected data on: (i) the demographics of patients who use naturopathy and WHM; (ii) the educational levels and employment status of patients; (iii) the health insurance coverage of patients; (iv) the level of inter-referral and dual patient care with other healthcare workers; (v) the nature of medical conditions; (vi) the frequency and cost of consultations; (vii) the form of treatment administered; and (viii) any pharmaceutical medication concurrently used.

The key issues explored in the focus groups included: (i) the extent of use of naturopathy and WHM; (ii) the reasons for use of naturopathy and WHM; (iii) how practitioners were selected; (iv) satisfaction with naturopathy and WHM services; (v) issues related to the use of ‘over-the-counter’ medications and self-prescribing; (vi) issues related to concurrent use of conventional and complementary healthcare providers; (vii) issues related to concurrent use of Western pharmaceuticals and WHM; and (viii) views on the need (if any) for increased consumer protection and government regulation.

## **Chapter 10: Regulatory Arrangements in Australia and International Trends Related to the Practice of Naturopathy and WHM**

This chapter describes regulatory arrangements relevant to naturopathy and WHM in Australia, as well as general trends in selected overseas countries.

A literature search was carried out to identify: (i) the nature of regulatory frameworks existing in other countries for the regulation of naturopathy and WHM (in particular in the European Community, the UK, Canada, the USA, and New Zealand; and (ii) the nature of current regulatory controls in Australia (at the Commonwealth level and in the states and territories) including the federal Therapeutic Goods Administration (herbal preparations), practitioner registration and/or licensing, and state-based powers to regulate potentially toxic or dangerous herbs through drugs and poisons regulations.

## Chapter 11: Assessment of Regulatory Requirements against the AHMAC Criteria

The final chapter brings together the evidence from previous chapters and considers this against the criteria adopted by AHMAC for regulation of the health workforce. Specifically, the criteria are:

- Is it appropriate for Health Ministers to exercise responsibility for regulating the occupation in question, or does the occupation more appropriately fall within the domain of another Ministry?
- Do the activities of the occupation pose a significant risk of harm to the health and safety of the public?
- Do existing regulatory or other mechanisms fail to address health and safety issues?
- Is regulation possible to implement for the occupation in question?
- Is regulation practical to implement for the occupation in question?
- Do the benefits to the public of regulation clearly outweigh the potential negative impact of such regulation?

In addition, the chapter considers the appropriateness of various options for regulation for naturopathy and WHM—including an assessment of the suitability of: (i) self-regulation; (ii) government monitored self-regulation; (iii) negative licensing; and (iv) statutory registration.

The chapter concludes with the research group's recommendations regarding the regulation of naturopathy and WHM in Victoria.

### Acknowledgment

The authors acknowledge assistance from Sue Evans (School of Natural and Complementary Medicine, Southern Cross University, Lismore, NSW) for her contribution on the history of WHM in Australia.

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## 2. Risks Associated with the Practice of Naturopathy and Western Herbal Medicine

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### 2.1 Introduction

In assessing the need for further regulation of naturopathy and Western herbal medicine (WHM), a key objective of the present report is to determine whether the practice of naturopathy and WHM poses a significant risk of harm to public health and safety. This chapter identifies the health risks associated with naturopathy and WHM as practised in Australia.

The report analyses the literature on adverse effects of naturopathy and WHM, supplemented by reports made to Australian authorities or recorded on databases of adverse events. Data on adverse events obtained from a workforce survey of naturopathic and WHM practice in Australia have been published previously (Bensoussan et al. 2004).

### 2.2 Methodology

The following resources were searched to locate naturopathic and WHM adverse effects to December 2003.

- *Computerised literature searches*: These were carried out in Medline<sup>®</sup> and EmBase<sup>®</sup> using MeSH terms and the free-text strategy outlined in Appendix 2.1. The search was restricted to articles published between 2000 and 2003. Case reports, case series, and reviews reporting adverse effects of herbal medicines, nutritional supplements, and homeopathy were included. Only English language articles available in Australia were reviewed. Emphasis was given to articles in which causality could be well established.
- *Bibliography searches*: Where possible the bibliographies of relevant articles were searched and the original references obtained.
- *Newspapers*: Various local and international newspapers were searched via LexisNexis, the F2 network (media-based website network), and other direct newspapers online.
- *Litigation search, coroners' reports, court records*: Several legal databases were utilised for these searches with a limited number of cases found. Legal databases included Casebase, LexisNexis, Austlii, APAIS (Public Affairs), Scaleplus, and various legal and government websites. The litigation search strategy is described in Appendix 2.2.
- *Adverse Drug Reactions Advisory Committee (ADRAC)*: The ADRAC database does not have specific search terms for naturopathy and WHM. Systematic retrieval of relevant adverse events was therefore too difficult. However, some key examples are cited.
- *Drug information services (DISs)*: Drug information services were contacted in Victoria for information on adverse reactions related to naturopathy and WHM.

- *State healthcare complaint agencies:* Agencies throughout Australia were approached for information. Numerous government and surveillance-body websites were also searched. These are listed in Appendix 2.3.
- *Professional associations:* Naturopathy and WHM professional associations were approached for relevant data.
- *Practitioner workforce surveys:* A comprehensive survey questionnaire was developed in consultation with the profession. This was distributed nationally to all members of the naturopathic and WHM workforce. Data were collected from practitioners of naturopathy and WHM, including data on adverse events. A second survey instrument was also prepared and distributed to medical practitioners. The survey methods and response rates are described in Chapter 4.

## 2.3 Categories of risk

Risks to the public from naturopathy and WHM can be divided into two major categories:

- risks associated with the exercise of clinical judgment of the naturopath or WHM practitioner; and
- risks related directly to the consumption of naturopathic or herbal medicines.

A schema for the classification of potential risks identified in the practice of naturopathy and WHM is given in Table 2.1. The following sections expand upon these categories in detail.

**Table 2.1 Schema for the classification of potential risks identified in the practice of naturopathy and WHM**

Category of risk	Major risks	Principal types
Clinical judgment of the practitioner	Acts of commission	Removal of therapy Incorrect prescribing
	Acts of omission	Misdiagnosis Failure to refer Failure to explain precautions
Consumption of herbal and nutritional medicines	Predictable toxicity (type A reactions)	Direct overdosage Interaction between herbal medicines Interaction with pharmaceuticals
	Unpredictable reactions (type B reactions)	Allergy/anaphylaxis Idiosyncratic reactions
	Failure of good handling and manufacture	Misidentification Lack of standardisation Contamination Substitution

## 2.4 Risks associated with the clinical judgment of the practitioner

Risks of commission and omission are inherent in the practice of any healthcare occupation, including Western medicine. Some concerns have been raised regarding these risks in relation to naturopathy and WHM.

In general, complaints about herbal, homeopathic, and nutritional products can be directed to both state and Commonwealth agencies, which each have some legislative responsibility for therapeutic goods.

Naturopathic and WHM practitioners fall under state jurisdiction, and complaints related to practitioners can be directed to state authorities.

There is currently no distinct and formal reporting system for adverse effects of herbal, homeopathic, and nutritional medicines, although product related adverse effects are

supposed to be reported to the Adverse Drug Reactions Advisory Committee (ADRAC) of the Therapeutic Goods Administration (TGA), and practitioner related adverse events are normally reported to state based healthcare complaints units.

Sections 2.4.1 - 2.4.5 summarise relevant reports from government agencies, electronic databases, and media.

### 2.4.1 Acts of commission

Acts of commission relate to direct and inappropriate acts undertaken by a practitioner during treatment. Examples include recommending that a person with epilepsy cease taking anti-epileptic medication, or that a post-thyroidectomy patient cease taking thyroid replacement hormone. This can lead to loss of the potential benefit of the therapy, increased morbidity, and loss of life.

Other examples and associated risks include:

- *poor prescribing*: prescribing of preparations that are inappropriate for the patient's condition;
- *failure to observe contraindications*: for example, prescribing *Glycyrrhizin* species (licorice root) in individuals who have hypertension can result in an exacerbation of the condition due to the mineralocorticoid-like action of the preparation;
- *inappropriate dosage*: some preparations are well tolerated at certain dosages (the 'therapeutic window'), but can be toxic at higher dosages. For example, the herb *Ephedra* (currently a scheduled substance), which contains ephedrine, can be used as a bronchodilator in the management of asthma; however, at higher doses, it has amphetamine-like properties that can cause nervousness, tachycardia, hypertension, seizures, and psychosis;
- *inappropriate duration of therapy*: adverse effects can be related to duration of exposure; for example, safe use of some herbs over prolonged periods might require monitoring of liver function; and
- *failure to identify and avoid known interactions with pharmaceuticals*.

### 2.4.2 Acts of omission

Risks of acts of omission arise when practitioners have inadequate skills, or are unaware of the limits of their practice. They generally fall into the following categories:

- *failure to detect significant underlying pathology*: this might increase morbidity by allowing a disease process to progress; delaying access to conventional medical treatment might also increase mortality, for example in conditions such as atypical myocardial infarction or cancer;
- *misdiagnosis*: this is often associated with failure to refer a patient to an appropriate healthcare practitioner, and can be further compounded by incorrect prescribing;
- *failure to refer*: not referring a patient to a medical practitioner or other appropriate healthcare practitioner can also occur if a practitioner fails to recognise the limits of his or her clinical practice; in such cases, the diagnosis might be correct, but the practitioner falsely assumes that the treatment will be effective;
- *failure to disclose*: this occurs if a practitioner does not advise a patient of the known potential adverse effects of a treatment; this can equate to failure to obtain informed consent.



Based on the search strategies described in Appendix 2.1, the number of adverse event citations reported in Medline each year rose from 88 citations in 1966 to 1186 citations in 2002. Cases were identified in relation to each category, as described in Table 2.1. Some cases are presented below.

### 2.4.3 State healthcare complaint agencies

Health complaints agencies around Australia were contacted regarding complaints concerning alternative health practitioners and/or their remedies. The various organisations were contacted by written application and/or through their websites. The agencies that were approached are listed in Appendix 2.3.

**Table 2.2 Number of complaints registered by Health Care Complaints Commissioners related to alternative healthcare (not necessarily naturopathy or WHM)**

State	Classification	Year	Number of complaints reported (% in brackets)
New South Wales	Alternative health providers	2002–03	4 (0.2)
		2001–02	7 (0.4)
		2000–01	6 (0.3)
		1999–2000	7 (0.4)
		1998–99	11 (0.8)
Victoria	Alternative therapists	2002–03	12
		2001–02	9
		2000–01	10
		1999–00	17
		1998–99	21
		1997–98	12
		1996–97	7
Queensland	Complementary Alternative health	2002–03	27
		2001–02	8
		2000–01	13
Western Australia	Other providers	2002–03	(1)
	Alternative providers	2001–02	(1)
	Alternative providers	2000–01	(1.3)
Australian Capital Territory	Individual provider	2002–03	(9)
	Other	2001–02	(16)
		2000–01	(9)
		1999–2000	(13)
		1998–99	(16)
		1997–98	(16)
South Australia*	N/A	N/A	N/A
Tasmania*	N/A	N/A	N/A
Northern Territory*	N/A	N/A	N/A

\*Note: Tasmania, South Australia, and the Northern Territory made no mention of alternative or other providers

Sources: Health Care Complaints Commission (NSW) Annual Reports 2000–01, 2001–02, 2002–03; Office of the Health Services Commissioner (Victoria) Annual Reports 1998–99, 1999–00, 2000–01, 2001–02, 2002–2003; Health Rights Commission Annual Reports (Queensland) 2000–01, 2001–02, 2002–03; Office of Health Review (Western Australia) Annual Reports 2000–01, 2001–02, 2002–03. Health Services Complaint Commissioner (ACT) Annual Reports 2002–03

Each state healthcare complaints agency in Australia releases an annual report, which includes statistical data of complaints made. The number and percentage of complaints reported are listed in Table 2.2. Further detailing for some of these cases was provided by the Health Rights Commission (Qld) (2003) (see Table 2.3).

**Table 2.3 Nature of complaints against naturopaths in Queensland**

Nature of complaint	Number recorded in two years to February 2004	Number recorded in ten years to February 2004
<b>Queensland Naturopaths</b>		
Quackery	-	2
Discourtesy	1	1
Misinformation	-	1
Billing Practices	1	1
Fraud	-	1
Inadequate Information About Costs	-	1
Sexual Misconduct	1	3
Diagnoses	1	1
Medication	2	3
Misdiagnoses	1	2
Painful Treatment	-	1
Treatment Negligent	1	2
Wrong Treatment	1	1
<b>Total</b>	<b>9</b>	<b>20</b>
<b>Queensland Homeopaths</b>		
Hygiene	-	1
Sexual Misconduct	-	3
Medication	-	1

#### 2.4.4 Professional association records

Each of the major professional associations that represent naturopaths and WHM practitioners was contacted for data on practitioner complaints and/or adverse event reports. Four associations supplied data on the number and type of complaints (see Chapter 6). The largest number of complaints related to inadequate communication by practitioners. Most complaints were associated with the practice of WHM (see Table 2.4). The Australian Traditional Medicine Society (ATMS) Ltd reported two cases of death that occurred in Australia. These are detailed in section 2.4.5.

**Table 2.4 Number of complaints against naturopaths and WHM practitioners recorded by four professional associations 1998–2002 by category of complaint**

Category	Naturopaths	WHM practitioners	Uncategorised
Access	0	5	
Treatment	2	3	
Communication	2	8	
Costs	1	1	
Rights	0	0	
Administration	0	0	
Uncategorised			9
<b>Totals</b>	<b>5</b>	<b>17</b>	<b>9</b>
<b>Overall Total</b>	<b>31</b>		

### **2.4.5 Litigation searches, coroners' reports, and court records**

Although few cases of relevance were identified, cases had been processed within the Westmead (New South Wales) and Perth (Western Australia) courts. Newspaper reports of these cases were also identified. Two principal cases of death attributed to following the directions of a naturopath were found within Australia. In both cases the naturopaths have faced various criminal charges regarding their actions.

A New South Wales (NSW) naturopath, who was treating an 18 day old baby for congenital heart disease, instructed the child's parents not to allow the baby to undergo urgent heart surgery, as recommended by a cardiologist. The naturopath inappropriately recommended supplements as an alternative to surgery. The baby died and the naturopath was found guilty of manslaughter.

A second NSW naturopath was charged with several counts relating to repeated illegal use of medical titles and medical practices. The naturopath faced 22 charges under the *Fair Trading Act 1987* (including false advertising and pretending to be a doctor in 2002) and three offences under the *Business Names Act 1962*. The naturopath, who used 'live blood cell analysis', stated that he was able to diagnose conditions such as cancer. He was successfully prosecuted by the NSW Department of Fair Trading. A coronial inquest is currently pending into the death of a 37 year old man treated by the same naturopath. The patient, who had chronic renal failure, ceased continuous ambulatory peritoneal dialysis while under inpatient care which was considered by the pathologist to be the cause of death.

## **2.5 Risks associated with the consumption of nutritional and herbal medicines**

Any pharmacologically active agents that have the capacity to change physiological function can have adverse effects. Like pharmaceuticals, WHMs can have two types of reactions (Rawlins 1981):

- *predictable (Type A) reactions*: extensions of the pharmacological effects, generally dose-dependent, and usually less severe; and
- *idiosyncratic (Type B) reactions*: not predicted by pharmacology, occur infrequently, are not related to dose, and can cause significant morbidity or death.

### **2.5.1 Drug information services**

Information services on drugs and poisons provide an avenue for the detection and/or reporting of adverse effects of Western pharmaceuticals. In Australia there is an established network of state and regional drug information services at major teaching hospitals. Each one stated that it recorded all cases with the ADRAC database and could offer no further information or statistics other than those found through ADRAC directly.

### **2.5.2 Adverse Drug Reactions Advisory Committee (ADRAC)**

Searches on the ADRAC database did not provide sufficient detail for analysis because the ADRAC database does not have specific search terms for naturopathy and WHM. Using herbal medicines as a general term yielded more than 500 products that had been reported to have been associated with adverse events. ADRAC suggests that this might be a significant underestimate of the number of adverse reactions to herbal medicine in Australia. This appears to be confirmed by the findings of the naturopathic and WHM Workforce Survey (Bensoussan et al. 2004). Factors leading to under-reporting could include:

- lack of knowledge by practitioners of ADRAC and its reporting mechanisms
- a perception that ADRAC is interested only in drugs (and not herbal products);
- no clear and known mechanism available for reporting by non-medical practitioners; and
- reluctance by non-medical practitioners to report effects because of fear of litigation or admitting some failure in their practice.

### 2.5.3 Predictable (type A) adverse reactions to herbal medicines, nutritional substances, and homeopathic substances

Some agents in herbal medicine have direct toxicity and predictable adverse effects. Some are considered to be sufficiently toxic to be included under the federal government's Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP). An example of a predictable adverse effect is that caused by mineralocorticoids.

Liquorice root (*Glycyrrhiza* spp.) and its extracts are often used in herbal medicine. They contain glycyrrhizic acid and glycyrrhithic acid, both of which have mineralocorticoid-like actions. Adverse effects of mineralocorticoid excess include oedema, hypertension, and electrolyte imbalances. It has been reported that these problems occur in up to 20% of patients taking large doses of liquorice root, or on long term therapy with these substances (Chang & But 1986). Bryer-Ash et al. (1987) reported an American patient who developed torsades de pointes (a cardiac arrhythmia) following ingestion of a herbal medicine containing liquorice root. It was postulated that this could be related to electrolyte imbalances, specifically hypokalaemia.

Numerous adverse reactions to herbal and nutritional medicines were identified in the literature. The results are summarised in Table 2.5 (by herb), Table 2.6 (by nutrient), and Table 2.7 (by body system). Relatively few adverse reactions have been reported to have occurred with homeopathy (see Table 2.8). In many reports of adverse events, it is difficult to be certain of any causality; and if causality *is* suggested, the *degree* of causality can vary substantially from case to case. In each case cited below, there is sufficient suspicion of some degree of causality for it to be reported.

**Table 2.5 Adverse reactions to herbal substances listed by herb name**

Herb	Adverse reaction
Bitter melon ( <i>Momordica charantia</i> )	Hypoglycaemic convulsions in children (Basch, Gabardi & Ulbricht 2003)
Black cohosh ( <i>Cimicifuga racemosa</i> )	Review of safety (Huntley & Ernst 2003; Dog, Powell & Weisman 2003) Hepatotoxicity (Whiting, Clouston & Kerlin 2002)
Cascara sagrada	Hepatotoxicity (Nadir, Reddy & Van Thiel 2000)
Chamomile ( <i>Anthemis nobilis</i> )	Eczema (Giordano Labadie, Schwarze & Bazex 2000) Anaphylactic reactions (Miller 1998)
Chaparral ( <i>Larrea tridentata</i> or <i>L. divaricata</i> )	Hepatotoxicity (Stickel, Egerer & Seitz 2000; Stedman 2002)
Chinese red rice	Myopathy (Smith & Olive 2003) Contact dermatitis (Etxenagusia et al. 2000)
Combinations of herbs, minerals, and vitamins	Anaphylactic reaction (Boullata, McDonnell & Oliva 2003) Hepatotoxicity (Sleeper & Kennedy 2003; Whiting, Clouston & Kerlin 2002; Fraquelli et al. 2000; Favreau et al. 2002; Wurtz et al. 2002; Gow et al. 2003; Bajaj et al. 2003; Lontos et al. 2003) Cardiovascular reactions (Scheinost 2001; Cannon, Cooke & McCarthy 2001; Zabihi & Abdollahi 2002b; Dieter & Vorperian 2000; Baghkhani & Jafari 2002) Metrorrhagia (Palop et al. 2000) Acute renal failure (Adesunloye 2003) Mental status changes (Chen et al. 2002; Machado Vieira, Viale & Kapczinski 2001; Spinella & Eaton 2002; Jacobs & Hirsch 2000) Lithium toxicity (Pyeovich & Bogenschutz 2001) Diabetic ketoacidosis (Case & Maldonado 2002) Acute eosinophilic pneumonia (Chu et al. 2001) Seizures (Kockler, McCarthy & Lawson 2001) Nicotinic toxicity (Rao & Hoffman 2002) Hyperthyroidism (Bauer et al. 2002) Acute myoglobinuria (Donadio et al. 2000)

	Ischaemic stroke (Kaberi Otarod et al. 2002; Vahedi et al. 2000) Ischaemic colitis (Ryan, Reamy & Rochester 2002) Acalculous eosinophilic cholecystitis (Adusumilli et al. 2002) Rhabdomyolysis (Scroggie, Harris & Sakai 2000) Photosensitivity (Palanisamy, Haller & Olson 2003) Changes in blood coagulation (D'Amico et al. 2002; Yue & Jansson 2001; Hoffman 2001)
Comfrey ( <i>Symphytum officinale</i> )	Veno-occlusive disease (Stickel & Seitz 2000)
<i>Coriandrum sativa</i>	Endocrinotoxicity (Zabihi & Abdollahi 2002a)
Dong Quai ( <i>Angelica sinensis</i> )	Gynaecomastia (Goh & Loh 2001)
Echinacea	Leukopaenia (Kemp & Franco 2002) Anaphylactic reactions (Mullins & Heddle 2002; Soon & Crawford 2001) Asthma (Mullins & Heddle 2002) Maculopapular rash (Mullins & Heddle 2002) Changes in blood coagulation (Ananthanarayan & Urbach 2000)
Ephedra/Ma Huang	Review of safety (Haller & Benowitz 2000; Bent et al. 2003; Samenuk et al. 2002) Mental status changes (Jacobs & Hirsch 2000; Traboulsi, Viswanathan & Coplan 2002; Walton & Manos 2003) Cerebral infarction (Foxford, Sahlas & Wingfield 2003) Hearing loss (Schweinfurth & Pribitkin 2003) Hepatotoxicity (Borum 2001) Exertional heatstroke (Oh & Henning 2003) Cardiovascular reactions (Traub, Hoyek & Hoffman 2001; Wettach & Falvey 2002)
Fig leaf ( <i>Ficus carica</i> )	Burns (Bollero et al. 2001; Ozdamar, Ozbek & Akin 2003)
Garlic ( <i>Allium sativum</i> )	Burns (Baruchin et al. 2001; Rafaat & Leung 2000)
<i>Ginkgo biloba</i>	Bleeding complications (Hauser, Gayowski & Singh 2002) Stevens–Johnson syndrome (Davydov & Stirling 2001) Cardiovascular reactions (Cianfrocca et al 2002) Haematoma (Miller & Freeman 2002; Benjamin et al. 2001) Seizures (Granger 2001) Acute retrobulbar haemorrhage (Fong & Kinnear 2003)
Ginseng	Review of safety (Coon & Ernst 2002; Miller 1998) Mental status changes (Vazquez & Aguera Ortiz 2002; Engelberg, McCutcheon & Wiseman 2001)
Golden germander ( <i>Teucrium polium</i> )	Hepatotoxicity (Polymeros, Kamberoglou & Tzias 2002)
Greater celandine ( <i>Chelidonium majus</i> )	Hepatotoxicity (Stedman 2002; Stickel et al. 2003)
Kava ( <i>piper methysticum</i> )	Review of safety (Denham, McIntyre & Whitehouse 2002) Hepatotoxicity (Russmann et al. 2003; Campo et al. 2002; Humberston, Akhtar & Krenzelok 2003; Brauer et al. 2003; Escher, Desmeules & Giostra 2001) Anaphylactic reaction (Schmidt & Boehncke 2000)
Liquorice ( <i>Glycyrrhiza glabra</i> )	Hypokalaemia (Hussain 2003; Elinav & Chajek Shaul 2003; Lozano et al. 2000; Satko & Burkart 2001) Oedema (Negro et al. 2000) Hypertension (Woywodt et al. 2000; Russo et al. 2000)
Linseed ( <i>Linum usitatissimum</i> )	Anaphylactic reaction (Leon, Rodriguez & Cuevas 2002)
Noni juice ( <i>Morinda citrifolia</i> )	Hyperkalemia (Mueller et al. 2000)
Nutmeg ( <i>Myristica fragrans</i> )	Psychosis (Kelly et al. 2003)
<i>Passiflora incarnata</i>	Cardiovascular and gastrointestinal reactions (Fisher, Purcell & Le Couteur 2000)

Pollen mixture	Anaphylactic reaction (Crivellaro et al. 2000)
Propolis	Anaphylactic reaction (Horiuchi 2001) Granulomatous contact dermatitis (Teraki & Shiohara 2001)
<i>Polygonum multiflorum</i>	Hepatotoxicity (Park, Mann & Ngu 2001)
Psyllium	Anaphylactic reaction (Khalili, Bardana & Yunginger 2003)
Saw palmetto ( <i>Serenoa repens</i> )	Prolonged bleeding time (Cheema, El Mefty & Jazieh 2001)
Senna	Melanosis coli (Ahmed & Gunaratnam 2003)
Spearmint ( <i>Mentha spicata</i> )	Contact dermatitis (Bonamonte et al. 2001)
St John's wort ( <i>Hypericum perforatum</i> )	Photosensitivity reactions (Cotterill, J.A. 2001; Lane Brown 2000) Review of safety (Bilia, Gallori & Vincieri 2002; Rodriguez Landa & Contreras 2003) Hypertension (Zullino & Borgeat 2003; Patel, Robinson & Burk 2002) Delayed emergence from anaesthesia (Crowe & McKeating 2002) Withdrawal syndrome (Dean, Moses & Vernon 2003) Cardiovascular collapse during anaesthesia (Irefin & Sprung 2000) Serotonin syndrome (Parker et al. 2001) Hair loss (Parker et al. 2001) Anxiety and nausea (Sultana, Peindl & Wisner 2000)
Tea tree ( <i>Melaleuca alternifolia</i> )	Dermatitis (Perrett, Evans & Russell Jones 2003; Khanna, Qasem & Sasseville 2000) Anaphylactic reaction (Mozelsio et al. 2003)
<i>Viola tricolour</i>	Haemolysis (Behmanesh & Abdollahi 2002)
Wintergreen	Vomiting and tinnitus (Bell & Duggin 2002)

**Table 2.6 Adverse reactions to vitamins, minerals, and nutritional substances**

<b>Nutrient</b>	<b>Adverse reaction</b>
Castor oil ( <i>Ricinus communis</i> )	Uterine rupture (Sicuranza & Figueroa 2003)
Creatine	Rhabdomyolysis (Robinson 2000)
Folate	Anaphylactic reaction (Dykewicz, Orfan & Sun 2000)
Glucosamine/chondroitin sulphate	Exacerbation of asthma (Tallia & Cardone 2002)
Niacin	Anaphylactic reaction (Grouhi & Sussman 2000) Macular oedema (Callanan, Blodi & Martin 1998)
Silver	Argyria (Hori et al. 2002; Gulbranson, Hud & Hansen 2000; McKenna, Hull & Zone 2003) Toxicity (McIntyre et al. 2001)
Vitamin A	Toxicity (Coghlan & Cranswick 2001)
Vitamins B6 & B12	Rosacea fulminans (Jansen et al. 2001)
Vitamin B2	Anaphylactic reaction (Ou, Kuo & Huang 2001)
Vitamin B6	Photosensitivity (Kawada et al. 2000)
Vitamin C	Iron overload (Mallory, Sthapanachai & Kowdley 2003) Acute renal failure (Mashour, Turner & Merrell 2000)
Vitamin D	Hypercalcaemia (Ashizawa et al. 2003; Evliyaoglu et al. 2003; Koutkia, Chen & Holick 2001; Nordt, Williams & Clark 2002; Bereket & Erdogan 2003) Hepatotoxicity (Croquet et al. 2000; Doyle, Conlon & Royston 2000) Hepatic hydrothorax (Miksad et al. 2002)
Zinc	Zinc-induced copper deficiency (Hein 2003; Igic et al. 2002; Irving et al. 2003; Porea, Belmont & Mahoney 2000) Hepatotoxicity (Castilla-Higuero et al. 2000)

**Table 2.7 Adverse reactions summarised by body system**

<b>System</b>	<b>Includes</b>	<b>Herb</b>
Anaphylactic reactions		Willow bark (Boullata, McDonnell & Oliva 2003) Echinacea (Mullins & Heddle 2002) Folic acid (Dykewicz et al. 2000) Linseed (Leon, Rodriguez & Cuevas 2002) Pollen mixture (Angiola, Crivellaro et al. 2000) Psyllium (Khalili, Bardana & Yunginger 2003) Skullcap (Takeshita et al. 2001) Tea tree oil (Mozelsio et al. 2003) Vitamin B2 (Ou et al. 2001)
Cardiovascular	Hypertension, bradycardia, palpitations, hypotension, ischaemic stroke, myocardial infarction, cerebral infarction, arrhythmia, cardiovascular collapse	Combination (Yates, O'Connor & Horsley 2000; Cannon, Cooke & McCarthy 2001; Baghkhani & Jafari 2002; Yates, O'Connor & Horsley 2000; Cannon, Cooke & McCarthy 2001; Baghkhani & Jafari 2002; Zabihi & Abdollahi 2002b; Scheinost 2001) Ephedra (Traub, Hoyek & Hoffman 2001; Wettach & Falvey 2002; Foxford, Sahlas & Wingfield 2003; Samenuk et al. 2002; Dieter & Vorperian 2000; Haller & Benowitz 2000; Vahedi et al. 2000; Kaberi Otarod et al. 2002; Rezkalla et al. 2002; Enders, Dobesh & Ellison 2003) Ginkgo biloba (Cianfrocca et al. 2002) Ginseng (Coon & Ernst 2002) Liquorice (Sigurjonsdottir et al. 2001; Woywodt et al. 2000; Russo et al. 2000) Passiflora incarnata (Fisher, Purcell & Le Couteur 2000) St John's Wort (Zullino & Borgeat 2003; Irefin & Sprung 2000; Patel, Robinson & Burk 2002)
Dermatological	Contact dermatitis, photosensitivity, rash, erythema nodosum, burns, Stevens–Johnson syndrome, phototoxic reaction, rosacea fulminans, erythema multiforme, melanosis, keratosis, argyria	Chamomile (Giordano Labadie, Schwarze & Bazex 2000) Greater celandine (Etxenagusia et al. 2000) Combination (Palanisamy, Haller & Olson 2003) Echinacea (Mullins & Heddle 2002; Soon & Crawford 2001) Fig (Bollero et al. 2001; Ozdamar, Ozbek & Akin 2003) Garlic (Baruchin et al. 2001; Rafaat & Leung 2000) Ginkgo biloba (Chiu, Lane & Kimball 2002; Davydov & Stirling 2001) Homeopathy (Nanda, Pandhi & Reddy 2003; Chakraborti et al. 2003) Iron (Ortega et al. 2000) Kava (Schmidt & Boehncke 2000) Propolis (Teraki & Shiohara 2001; Horiuchi 2001) Silver (Hori et al. 2002; McKenna, Hull & Zone 2003; Gulbranson, Hud & Hansen 2000) Spearmint (Bonamonte et al. 2001) Laurel oil (Ozden et al. 2001) St John's Wort (Cotterill 2001; Sultana, Peindl & Wisner 2000; Lane Brown 2000) Tea tree oil (Perrett, Evans & Russell Jones 2003; Khanna, Qasem & Sasseville 2000; Varma et al. 2000) Lavender oil (Varma et al. 2000) Vitamin B6 (Kawada et al. 2000) Niacin (Grouhi & Sussman 2000)

		Vitamins B6 & B12 (Jansen et al. 2001)
Haematological	Coagulation disorder, leukopaenia, haemorrhage, haematoma, metrorrhagia, cerebral haemorrhage, haemolysis, anaemia and neutropaenia	Combination (Yue & Jansson 2001; Norred & Finlayson 2000; Burton & Kaczmarek 2003; Hoffman 2001) Echinacea (Kemp & Franco 2002; Ananthanarayan & Urbach 2000) Ginkgo biloba (Benjamin et al. 2001; Fessenden, Wittenborn & Clarke 2001; Hauser, Gayowski & Singh 2002; Fong & Kinnear 2003) Ginseng (Palop Larrea et al. 2000) Saw palmetto (Cheema, El Mefty & Jazieh 2001) Viola tricolour (Behmanesh & Abdollahi 2002) Zinc (Irving et al. 2003, Igc et al. 2002, Porea, Belmont & Mahoney 2000, Hein 2003)
Hepatotoxic	Hepatitis, jaundice, liver failure, hepatic hypervitaminosis A	Black cohosh (Whiting, Clouston & Kerlin 2002) Cascara sagrada (Nadir, Reddy & Van Thiel 2000) Greater celandine (Stickel et al. 2003) Combination (Sleeper & Kennedy 2003, Fraquelli et al. 2000, Bajaj et al. 2003, Lontos et al. 2003, Favreau et al. 2002, Wurtz et al. 2002) Ephedra (Borum 2001) Golden germander (Polymeros, Kamberoglou & Tzias 2002) Kava (Gow et al. 2003, Brauer et al. 2003; Escher et al. 2001; Denham, McIntyre & Whitehouse 2002; Russmann et al. 2003; Campo et al. 2002; Teschke, Gaus & Loew 2003; Humberston, Akhtar & Krenzelok 2003; Russmann, Lauterburg & Helbling 2001) Polygonum multiflorum (Park, Mann & Ngu 2001) Vitamin A (Miksad et al. 2002, Doyle, Conlon & Royston 2000; Croquet et al. 2000) Zinc (Castilla Higuero et al. 2000)
Neurological	Mental status changes, mania, seizures, hypomania, suicide attempt, psychosis, delirium, serotonin syndrome, anxiety, subdural hematoma, hearing loss	Valerian & Ginkgo biloba (Chen et al. 2002) Combination (Kockler, McCarthy & Lawson 2001; Machado Vieira, Viale & Kapczynski 2001; Spinella & Eaton 2002) Ephedra (Jacobs & Hirsch 2000; Traboulsi, Viswanathan & Coplan 2002; Walton & Manos 2003; Schweinfurth & Pribitkin 2003; Boerth & Caley 2003) Ginkgo biloba (Granger 2001; Miller & Freeman 2002) Ginseng (Engelberg, McCutcheon & Wiseman 2001; Vazquez & Aguera Ortiz 2002) Nutmeg (Kelly et al. 2003) St John's Wort (Patel, Robinson & Burk 2002; Parker et al. 2001; Brown 2000)
Metabolic	Hypoglycaemia, diabetic ketoacidosis, hyperthyroidism, hypokalaemia, oedema, hypercalcaemia, endocrinotoxicity	Combination (Case & Maldonado 2002; Bauer et al. 2002) Coriandrum sativa (Zabihi & Abdollahi 2002a) Liquorice (Hussain 2003; Elinav & Chajek Shaul 2003; Negro et al. 2000; Satko & Burkart 2001; Yoshida & Takayama 2003; Lozano et al. 2000) Vitamin D (Evliyaoglu et al. 2001; Ashizawa et al. 2003; Koutkia, Chen & Holick 2001, Bereket & Erdogan 2003; Nordt, Williams & Clark 2002)
Renal	Renal failure,	Combination (Adesunloye 2003)



	hyperkalaemia	Noni juice (Mueller et al. 2000) Vitamin C (Mashour, Turner & Merrell 2000)
Other	Uterine rupture	Castor oil (Sicuranza & Figueroa 2003)
	Myopathy and joint pain	Chinese red rice (Smith & Olive 2003)
	Lithium toxicity	Combination (Pyeovich & Bogenschutz 2001)
	Acute respiratory failure	Combination (Chu et al. 2001)
	Nicotinic toxicity	Combination (Rao & Hoffman 2002)
	Rhabdomyolysis	Combination (Scroggie, Harris & Sakai 2000; Prasad et al. 2002; Donadio et al. 2000) Creatine (Robinson 2000)
	Acalculous eosinophilic cholecystitis	Combination (Adusumilli et al. 2002)
	Gynaecomastia	Dong quai (Goh & Loh 2001)
	Asthma	Echinacea (Mullins & Heddle 2002) Glucosamine-Chondroitin (Tallia & Cardone 2002)
	Exertional heatstroke	Combination (Oh & Henning 2003)
	Breast symptoms	Ginseng (Coon & Ernst 2002)
	Melanosis coli	Senna (Ahmed & Gunaratnam 2003)
	Withdrawal syndrome	St John's Wort (Dean, Moses & Vernon 2003)
	Delayed emergence from surgery	St John's Wort (Crowe & McKeating 2002)
	Hair loss	St John's Wort (Parker et al. 2001)
	Vitamin A toxicity	Vitamin A (Coghlan & Cranswick 2001)
	Salicylate toxicity	Oil of Wintergreen (Bell & Duggin 2002)
	Iron overload	Vitamin C (Mallory, Sthapanachai & Kowdley 2003) Ginkgo seed (Kajiyama et al. 2002)
	Ischaemic colitis	Combination (Ryan, Reamy & Rochester 2002)
	Silver toxicity	Colloidal silver (McIntyre et al. 2001)

**Table 2.8 Adverse reactions to homeopathic substances**

Homeopathic substance	Adverse reaction
Arsenic	Melanosis and keratosis (Chakraborti et al. 2003).
Mercury present in homeopathic substance	Systemic allergic contact dermatitis characterised by a widespread erythema favouring the major flexures (Audicana et al. 2001)
Rauwolfia	Bradycardia (Wadhwa 2000).
Homeopathic treatment for a cough	Erythema multiforme in nine day old neonate (Nanda, Pandhi & Reddy 2003)
Various	Review of adverse effects (Dantas & Rampes 2000)

### 2.5.4 Interactions with Western pharmaceuticals

Interactions between preparations can be classified scientifically into two main types:

- *pharmacokinetic interactions*: in which one agent alters the absorption, distribution, or elimination of another; for example, in Western medicine, the enzyme inhibitor ketoconazole alters the elimination of drugs (such as terfenadine) that are metabolised by the cytochrome P450 enzyme system; and
- *pharmacodynamic interactions*: in which the effect of one agent augments or diminishes the effect of the other without altering the pharmacokinetics; for example, additive central nervous system (CNS) depression with hypnotics and tricyclic antidepressants.

The Australian naturopathic and herbal medicine Patient Profile (see Chapter Nine) showed that 34% of patients consuming herbal medicine were concurrently taking pharmaceutical medications (excluding vitamins and mineral supplements). It is therefore important to consider the significant potential for these interactions.

There is now substantial documentation that preparations of St John's wort (*Hypericum perforatum* L.) can result in drug–herb interactions. Pharmacokinetic interactions have been noted to occur between this preparation and numerous conventional drugs—including warfarin, digoxin, theophylline, cyclosporin, HIV protease inhibitors, anticonvulsants, and oral contraceptives (Barnes, Anderson & Phillipson 2001; Mills et al. 2004). St John's wort can affect the systemic bioavailability of pharmaceutical drugs by inducing specific cytochrome P450 drug metabolising enzymes (Barnes, Anderson & Phillipson 2001; Mills et al. 2004). Table 2.9 summarises examples of case reports of interactions between herbal substances and pharmaceuticals, and Table 2.10 summarises interactions of vitamins, minerals, and nutritional substances with pharmaceuticals.

**Table 2.9 Interactions of herbal substances with pharmaceuticals**

<b>Herb/Nutrient</b>	<b>Interactions</b>
Black pepper	Propranolol (Harkness & Bratman 2003)
Danshen (Salvia miltiorrhiza)	Warfarin (Harkness & Bratman 2003)
Devils Claw (Harpagophytum procumbens)	Warfarin (Shaw et al. 1997)
Dong Quai (Angelica sinensis)	Warfarin (Page & Lawrence 1999)
Ephedra/Ma Huang	Phenelzine (Harkness & Bratman 2003)
Fenugreek (Trigonella foenum-graecum)	Warfarin (Lambert & Cormier 2001).
Foxglove	Digoxin (Harkness & Bratman 2003)
Garlic (Allium sativum)	Protease inhibitors ((Harkness & Bratman 2003) Warfarin (Harkness & Bratman 2003; Miller 1998, Myers 2002)
Geranium/ginseng	Frusemide (Harkness & Bratman 2003)
Ginkgo biloba	Ibuprofen (Meisel, John & Roots 2003) Warfarin (Harkness & Bratman 2003) Trazodone (Fugh Berman & Ernst 2001) Aspirin (Fugh Berman & Ernst 2001)
Ginseng	Digoxin (Harkness & Bratman 2003) Warfarin (Miller 1998; Myers 2002) Phenelzine (Miller 1998; Fugh Berman & Ernst 2001) Frusemide (Harkness & Bratman 2003)
Green tea (Camellia sinensis)	Warfarin (Taylor & Wilt 1999).
Kava (Piper methysticum)	Levodopa (Fugh Berman & Ernst 2001).
Licorice (Glycyrrhiza glabra)	Digoxin (Harada et al. 2002) Prednisolone (Harkness & Bratman 2003) Spironolactone (Harkness & Bratman 2003)
	Antihypertensive agents (Sigurjonsdottir et al. 2001)
Psyllium	Orally administered drugs (Harkness & Bratman 2003)
Seaweed	Warfarin (Bartle, Madorin, P. & Ferland 2001)
Soy	Levothyroxine (Bell & Ovalle 2001)
St John's wort (Hypericum perforatum)	Cyclosporine (Ahmed, Banner & Dubrey 2001; Ruschitzka et al. 2000; Barone et al. 2000; Karlova et al. 2000; Turton Weeks et al. 2001; Bauer et al. 2003; Moschella & Jaber 2001; Mai et al. 2000; Harkness & Bratman 2003) Digoxin (Harkness & Bratman 2003) Indinavir (Piscitelli et al, 2000, Harkness & Bratman 2003)

	$\delta$ -aminolaevulinic acid (Ladner et al. 2001) Tacrolimus (Bolley et al. 2002) Amitriptyline (Johne et al. 2002) Simvastatin (Sugimoto et al. 2001) Theophylline (Fugh Berman & Ernst 2001) Sertraline (Barbenel et al. 2000) Buspirone (Dannawi 2002)
Wintergreen	Warfarin (Joss & LeBlond 2000)

**Table 2.10 Interactions of vitamins, minerals, and nutritional substances with pharmaceuticals**

Vitamin, mineral, nutrient	Interactions
Calcium	Thiazide diuretics (Harkness & Bratman 2003) Thyroid hormone (Harkness & Bratman 2003) Verapamil (Harkness & Bratman 2003)
Coenzyme Q10	Warfarin (Myers 2002)
Folate	Methotrexate ((Harkness & Bratman 2003) NSAIDs (Harkness & Bratman 2003) Trimethoprim/Sulfamethoxazole (Harkness & Bratman 2003) Capecitabine (Clippe et al. 2003)
Iron	Levodopa/carbidopa (Harkness & Bratman 2003) Methyldopa (Harkness & Bratman 2003) Penicillamine (Harkness & Bratman 2003). Thyroid hormone (Harkness & Bratman 2003)
Potassium	ACE inhibitors (Harkness & Bratman 2003)
Vitamin B6	Isoniazid (Harkness & Bratman 2003)
Vitamin B12	Nitrous oxide (Harkness & Bratman 2003)
Vitamin C	Warfarin (Myers 2002).
Vitamin D	Heparin (Harkness & Bratman 2003)
Vitamin K	Warfarin (Harkness & Bratman 2003; Myers 2002)

### 2.5.5 Unpredictable reactions to herbal medicines

As can occur with pharmaceuticals, rare (often idiosyncratic) reactions have been reported with herbal medicines. Case reports in the literature do not allow estimation of risk, and they vary in the analysis of preparations and identification of the constituents of the preparations. The majority of unpredictable reactions are due to allergy.

### 2.5.6 Failure of good handling and manufacture of nutritional and herbal medicines

Problems related to handling and manufacturing processes can include:

- misidentification;
- lack of standardisation;
- contamination with heavy metals or toxins;
- inadvertent (or deliberate) substitution of other herbs; and
- adulteration with Western pharmaceutical products.

In addition, modern manufacturing techniques can generate new forms of herbal medicines with profiles of compounds not present in the traditional form. This can be problematic because the original claims regarding efficacy and safety will have been based on the traditional herbal preparation. However, modern manufacturing methods are more likely to generate improved quality and concomitant safety and, in some cases, might generate new therapeutic claims.

## Misidentification

It is important that plant material in herbal medicine be correctly identified. However, the nomenclature that is used can vary and thus complicate interpretations of the literature. For example, the herb known in English as ‘Ginseng’ is also known as ‘ren-shen’ (transliteration), ‘Radix ginseng’ (Latinised pharmaceutical name), and ‘*Panax ginseng*’ (binomial scientific name). It can be difficult to trace these various common names, transliterations, and pharmaceutical names to the source species—which can result in erroneous identification. The use of the binomial scientific name is recommended (But 1993).

## Lack of standardisation

Various factors affect the constituents of medicinal plants. These include:

- *genetic variation*: both interspecies and intraspecies;
- *environmental factors*: such as climate, altitude, and growing conditions;
- *time of harvesting*;
- *part of the plant used*;
- *storage conditions*; and
- *processing treatments*.

To ensure batch-to-batch reproducibility of commercially produced herbal medicines, identification tests are required to confirm the presence of the active constituents. If an assay method is available, it should be used to quantify these constituents. If they are quantifiable, constituents should meet the minimum proportion identified in the literature as having a pharmacological effect. If the active constituents have not been identified, a chromatographic ‘fingerprint’ of the plant can provide batch-to-batch comparability. However, such standards are currently not compulsory in Australia. Lack of standardisation can lead to sub-potent (and possibly super-potent) therapeutic preparations being available, and this can compromise herbal treatment. Failure of herbal treatment might place some individuals at risk.

Cui et al. (1994) compared the ginsenoside content of 50 brands of ginseng sold in 11 countries. Ginsenoside is a glycosylated steroid to which most of the biological activity of ginseng (*Panax ginseng*) has been ascribed. The concentration ranged from 1.9 to 9 %w/w in 44 of these products, and six contained no ginsenosides. One of these six contained large amounts of ephedrine. Consequently, a Swedish athlete who thought he was taking ginseng ingested ephedrine and was accused of ‘doping’.

## Contamination

Potential contaminants of herbal medicines include microorganisms, microbial toxins, pesticides, fumigation agents, radioactivity, and heavy metals. Potential contaminants are listed in Table 2.11.

**Table 2.11 Potential contaminants that require monitoring in the quality control of herbal medicines**

Type of contaminant	Examples
Microorganisms	<i>Staphylococcus aureus</i> , <i>Escherichia coli</i> (certain strains), <i>Salmonella</i> , <i>Shigella</i> , <i>Pseudomonas aeruginosa</i>
Microbial toxins	Bacterial endotoxins, aflatoxins
Pesticides	Chlorinated pesticides (e.g., DDT, dieldrin), organic phosphates, carbamate insecticides and herbicides, dithiocarbamate fungicides, triazin herbicides
Fumigation agents	Ethylene oxide, methyl bromide, phosphine
Radioactivity	Cs-134, Cs-137, Ru-103, I-131, Sr-90
Metals	Lead, cadmium, mercury, arsenic

Cases of heavy metal toxicity from herbal medicine have been reported in overseas jurisdictions. The reports include poisoning with cadmium, lead, arsenic, mercury, and

thallium (De Smet 1992; Brown & Ede 1996). Apart from heavy metals there were no other cases of contamination cited in the literature. Other contaminants have not been the focus of any extensive investigation and it is possible that they may be present in some herbal medicines. Good manufacturing practice for the identification of contaminants in manufactured herbal products requires detection of only microorganisms, and the estimation of other contaminants is left to the discretion of manufacturers.

### **Substitution of materials used in herbal medicines**

The overseas literature cites inadvertent or deliberate substitution of the constituents of Chinese herbal preparations. For example, cheaper substitutes—such as Siberian ginseng (*Eleutherococcus senticosus*), American ginseng (*Panax quinquefolium*), or Japanese ginseng (*Panax pseudo-ginseng*)—have been substituted for Korean or Chinese ginseng (*Panax ginseng*) (Chan & Critchley 1996; But 1994). Sometimes the substitute has had much greater toxicity than the original (Bensoussan & Myers 1996).

The following case has been documented in Australia. A 56 year old woman presented in August 2002 with fatigue, nausea, and increasing jaundice (Gow et al. 2003). Apart from a past history of benign monoclonal gammopathy diagnosed 12 months previously, she had no previous medical history. She had no known risk factors for viral hepatitis, there was no family history of liver disease, and her alcohol intake was minimal. Acting on the recommendation of a naturopath, the patient had, for three months, taken a herbal supplement containing a solvent extraction of kavalactones (60 mg), *Passiflora incarnata* (50 mg), and *Scutellaria lateriflora* (100 mg). No medications were being taken other than vitamin and mineral supplements.

Examination in hospital revealed deep jaundice without any stigmata of chronic liver disease. Intensive tests showed no cause for liver failure. Tests performed in the days immediately after admission showed non-specific hepatitis, and subsequent tests showed such deterioration that the patient was listed for an urgent liver transplant. Seventeen days after admission the transplant proceeded, but the patient died as a result of complications, including major haemorrhage. The causes of death were listed as progressive blood loss, hypotension, and circulatory failure. Tests of the herbal product revealed that one listed ingredient, *Scutellaria lateriflora*, was absent, but that a further unidentified ingredient was present.

This was the first case reported in Australia of fulminant hepatic failure caused by an intake of a product containing Kava and *Passiflora incarnata*. (It is not known if *Passiflora* or the unknown ingredient were also implicated in the adverse reaction, but unpublished data [present author, SM] suggest that the *Passiflora* was unlikely to be the cause of the hepatic failure and that the kava content was more likely to be the cause). Approximately 68 cases have been reported worldwide of suspected hepatotoxicity associated with the use of Kava-related products, including six that resulted in liver transplantation, and three that resulted in death.

### **Adulteration with Western pharmaceuticals**

There are several reports in the literature regarding the intentional adulteration of Chinese herbal medicines with Western pharmaceuticals (Bensoussan & Myers 1996); however, no cases were found related to WHM. The adulterants identified included non-steroidal anti-inflammatory agents, corticosteroids, paracetamol, and sedatives (such as diazepam) (De Smet 1992; Bensoussan & Myers 1996).

## 2.6 Practitioner-reported adverse events in herbal medicine and naturopathy

### 2.6.1 Naturopaths and WHM practitioners

A survey of the practitioner workforce in naturopathy and herbal medicine was undertaken in 2003. This is reported in Chapter 4 (Bensoussan et al. 2004). Five questions in the workforce survey requested information on adverse events. Three main questions listed common adverse events related to herbal medicines, nutritional medicines, and homeopathic medicines respectively. Practitioners were asked to indicate the number of times each adverse event had occurred during their practice lifetimes. The total responses to these questions are given in Table 2.12. If practitioners indicated that more than five adverse events of a particular kind had occurred, unless specified otherwise this was taken (conservatively) to represent seven adverse events. In the final row of Table 2.12 the raw numbers of adverse events are extrapolated for the whole workforce, based on response rates to the survey.

**Table 2.12 Adverse events identified by practitioners, occurring during their practice lifetimes through the use of herbal, nutritional, and homeopathic medicines**

Adverse events	Number of occasions reported			
	Herbal medicine	Nutritional medicine	Homeopathy	Total
Mild gastrointestinal symptoms (nausea, discomfort)	1952	1,023	178	3,053
Severe gastrointestinal symptoms (vomiting, diarrhoea, or pain)	296	150	23	469
Significant skin reaction	307	127	244	678
Severe fatigue	144	74	73	291
Jaundice	4	4	0	8
Fainting or dizziness	110	53	31	194
Headache	870	434	171	1,475
Menstrual irregularities	322	56	72	450
Palpitations	128	52	27	207
High blood pressure	42	14	7	63
Psychiatric disturbance	12	6	27	45
Hepatotoxicity (as identified by blood tests)	9	1	0	10
Renal toxicity (as identified by blood tests)	2	1	0	3
Significant respiratory disturbance	9	8	16	33
CNS effects (e.g., numbness, palsy)	17	11	5	33
Referral to medical practitioner or hospital	82	14	17	113
Death	0	1	0	1
Missing to all	75	97	123	295
<b>Total adverse events</b>	<b>4,306</b>	<b>2,029</b>	<b>891</b>	<b>7,226</b>
<b>Adverse events extrapolated to the total workforce *</b>	<b>9,633</b>	<b>4,539</b>	<b>1,993</b>	<b>16,165</b>

\* Note: Based on the adjusted response rate of 44.7%

The most common adverse events reported for *herbal medicines* were mild gastrointestinal symptoms (n = 1952), headaches (n = 870), menstrual irregularities (n= 322), significant skin reactions (n = 307), and severe gastrointestinal symptoms (n = 296). Serious

adverse events reported included CNS effects (n = 17), hepatotoxicity (n = 9), and significant respiratory disturbance (n = 9). In all, 82 adverse events were significant enough to warrant referral of the patients to medical practitioners or hospitals, although no deaths were reported.

The most common adverse events reported associated with *nutritional medicines* were mild gastrointestinal symptoms (n = 1,023), headache (n = 434), and severe gastrointestinal symptoms (n = 150). Serious adverse events reported included CNS effects (n = 11), significant respiratory disturbance (n = 8), renal toxicity (n = 1), and one death. In all, 14 adverse events were significant enough to warrant referral of the patients to medical practitioners or hospitals.

More research is needed on the use of nutritional supplements by nutritional medicine practitioners. Evaluation of risks for this profession was not part of the brief for the current study.

The most common adverse events reported for *homeopathic medicines* were significant skin reactions (n = 244), mild gastrointestinal symptoms (n = 178), and headache (n = 171). Serious adverse events reported included CNS effects (n = 5) and significant respiratory disturbance (n = 16). In all, 17 adverse events were significant enough to warrant referral of the patients to medical practitioners or hospitals, although no deaths were reported. The reporting of adverse events to homeopathic medicines was more problematic for practitioners of this discipline, as evidenced by the significant increase in missing responses (123) for this item. (Some physiological responses are considered by homeopaths to be part of the healing process, and are therefore not necessarily viewed as 'adverse'.)

Approximately one third of practitioners (33%) indicated that they usually report adverse events. However, fewer (27%) were aware of the Australian reporting procedures for adverse drug reactions. Practitioners indicated that adverse events related to products are usually reported to the manufacturer (22%), the supplier (14%), a professional association (13%), ADRAC (4%), the TGA (1%), or other groups (3%), including mentors, professional supervisors, and other healthcare providers.

The overall number of adverse events recorded is substantial, particularly in association with the use of WHMs and nutritional medicines. Practitioners report substantially fewer adverse events associated with homeopathy. This workforce survey suggests that practitioners will encounter a significant number (and wide range) of adverse events during their practice lifetimes. Extrapolated to all Australian naturopathic and WHM practitioners, an estimated 16,165 adverse events related to herbal, nutritional, and homeopathic interventions have occurred during their combined practice lifetimes.

It is impossible to estimate the rate of adverse events for herbal and nutritional medicines from case reports and case series alone—because the total exposure to a particular medicinal substance is unknown. There are currently insufficient data to quantify, in detail, the risks to a population presented by the consumption of herbal and nutritional medicines.

However, the data reported by practitioners on adverse events associated with herbal, nutritional, and homeopathic medicines can be combined to provide rates of adverse events for the practice of herbal medicine and naturopathy. Two variables were calculated to generate two measures of rates of adverse events—using years in full-time practice and total consultations from the workforce data. These variables were: (i) adverse events per year of full-time practice; and (ii) adverse events per number of patient consultations. To facilitate a focus on potentially *more serious* adverse reactions that might be distinctly associated with naturopathic or herbal medicine practice, mild reactions (specifically mild gastrointestinal reactions) were excluded from both calculations.

The adverse events per year of full-time practice were calculated for each practitioner who responded to the workforce survey. Total adverse events reported by a practitioner were divided by the practitioner's equivalent full-time years of practice. The mean rate of adverse events per year of full-time practice was then calculated for each respondent.

The adverse events per number of patient consultations were derived for each practitioner by dividing the total adverse events reported by that practitioner by an estimation of total consultations for the same practitioner. Total consultations were calculated by multiplying average consultations per week by 48 weeks per year by equivalent full-time years of practice. This calculation is less reliable because it assumes that the number of patients seen by practitioners in the survey period remained static throughout their practice lifetimes. The mean rate of adverse events per number of patient consultations was then calculated. This figure can be used only as a crude measure of the frequency of adverse events.

Table 2.13 gives figures for these two variables for the whole of the workforce. The number of adverse events per year of full-time practice was 4,073 (excluding mild gastrointestinal effects). The data suggest that a full-time practitioner will experience one adverse event each 11 months of full-time practice, with 2.3 adverse events per 1,000 consultations. This figure includes adverse events related to herbs, nutritional medicines, and homeopathic medicines.

**Table 2.13 Total adverse events extrapolated to the whole workforce: adverse events per year of full-time practice, adverse events per consultation, and consultations per adverse event for practitioners (mild gastrointestinal effects excluded)**

Adverse event figures and rates	Herbalists	Naturopaths	Total
Total adverse events (excluding mild gastrointestinal effects)	3,760	3,237	4,073
Adverse events per year of full-time practice	1.1 (SD 2.0)	1.2 (SD 2.9)	1.1 (SD 2.7)
Adverse events per consultation	0.0020 (SD 0.0060)	0.0025 (SD 0.0087)	0.0023 (SD 0.0078)
Consultations per adverse event	500	400	357

## 2.6.2 Adverse events reported by medical practitioners

In a separate workforce study, medical practitioners were surveyed to identify reports of adverse events associated with complementary medicine in general, interactions between complementary therapies and conventional treatment, and potential withdrawal from conventional treatment or delay in diagnosis associated with intervention by a complementary medicine practitioner. Details of the survey instrument and process are described in Chapter 8.

General practitioners (GPs) were asked how many patients they had seen in the previous four weeks who had encountered:

- an adverse event as a result of a complementary therapy;
- an interaction between a complementary therapy and a medical therapy;
- inappropriate withdrawal of a medical therapy by a complementary therapist; or
- a delay in diagnosis or treatment due to inappropriate use of a complementary therapy.

A total of 402 doctors answered this question, generating 1,548 adverse events (including interactions, withdrawals, delays in diagnosis, and inappropriate treatment) over a designated four week period. However many doctors commented that it was difficult to recall actual patient numbers, so these data must be treated with caution. They are likely to underestimate the actual number of events during this period because recall is not as comprehensive as continuous gathering of data. Furthermore, these figures include an assumption of causality. Nevertheless, the data do provide a useful basis for comparison of the relative percentage of adverse events between therapies in the given period. Caution must also be exercised when interpreting these figures because some therapies are more widely



used than others, which influences the number of adverse events seen by doctors relating to each particular therapy.

The therapies with the greatest number of adverse events were chiropractic (17.8%), herbal medicine (15.6%), naturopathy (13.2%), vitamin and mineral therapy (13.2%), and Chinese herbal medicine (7.4%) (see Table 2.14). When doctors were asked to indicate whether these events were mild (self-limiting, requiring little or no intervention) or serious (potentially dangerous, requiring active intervention), the greatest number of serious events was associated with chiropractic (4.7%), followed by herbal medicine (4.1%), and naturopathy (3.6%).

**Table 2.14 Adverse events reported by medical practitioners: frequency of adverse events, interactions between complementary therapies and conventional treatment, withdrawal from conventional treatment, or delays in diagnosis due to a complementary therapy during a four week period**

Note: All numbers expressed as ‘Total/Mild/Serious’

	Adverse events	Inter-action	Withdrawn from treatment	Delay in diagnosis	Total events	Percentage of all events
Chiropractic	141/113/28	20/9/11	29/21/8	86/60/26	276/203/73	17.8/13.1/4.7
Herbal medicine	72/60/12	82/61/21	39/28/11	48/29/19	241/178/63	15.6/11.5/4.1
Naturopathy	33/23/10	34/29/5	67/52/15	71/46/25	205/150/55	13.2/9.7/3.6
Vitamin and mineral therapy	132/129/3	23/22/1	17/14/3	33/29/4	205/194/11	13.2/12.5/0.7
Chinese herbal medicine	38/30/8	41/30/11	16/13/3	19/14/5	114/87/27	7.4/5.6/1.7
Massage	47/45/2	5/5/0	6/6/0	48/41/7	106/97/9	6.8/6.3/0.6
Homoeopathy	16/11/5	18/16/2	34/26/8	23/16/7	91/69/22	5.9/4.5/1.4
Acupuncture	25/21/4	6/6/0	9/8/1	16/15/1	56/50/6	3.6/3.2/0.4
Osteopathy	14/12/2	1/1/0	8/3/5	25/21/4	48/37/11	3.1/2.4/0.7
Meditation	18/16/2	8/7/1	5/5/0	16/13/3	47/41/6	3.0/2.6/0.4
Spiritual healing (e.g., Reiki)	11/9/2	3/3/0	10/7/3	15/13/2	39/32/7	2.5/2.1/0.5
Aromatherapy	11/8/3	4/2/2	9/3/6	12/8/4	36/21/15	2.3/1.4/1.0
Reflexology	5/5/0	7/7/0	10/6/4	10/7/3	32/25/7	2.1/1.6/0.5
Yoga	16/12/4	1/1/0	5/5/0	4/4/0	26/22/4	1.7/1.4/0.3
Hypnosis	12/12/0	5/5/0	1/1/0	8/7/1	26/25/1	1.7/1.6/0.1

On average, medical practitioners reported seeing 121 patients per week. This generates an approximate rate of one adverse event per 125 consultations, or one adverse event per week.

Of particular interest in this question were the medical practitioners’ handwritten comments relating to serious cases that stood out in memory. Only naturopathy, chiropractic, herbal medicine, massage, and acupuncture featured in these comments. All comments relating to serious events are shown in order of severity in Table 2.15. Overall, GPs considered the harmfulness of complementary and alternative medicine (CAM) to be related more to the scope of practice (the broad range of clients and conditions treated, coupled with lack of recognition of the limitations to practice, which might contribute to incorrect, inadequate, or delayed diagnoses) than to the specific risks of the therapies themselves.

Naturopathy and WHM can be considered to offer an ‘alternative’ service to that offered by GPs—in that therapists in this group are primary care practitioners who see patients from all demographics who are suffering from the full spectrum of health complaints, including potentially life-threatening illnesses. As primary care practitioners, naturopaths and WHM practitioners are involved with diagnosis and subsequent treatment (see Chapter 9).

**Table 2.15 Medical practitioner comments relating to serious adverse events**

<b>Discipline</b>	<b>Medical practitioner comments</b>
Naturopathy	Death from superficial melanoma treated by naturopath Naturopath delayed conventional breast cancer treatment for nine months—now inoperable Woman with widespread breast cancer metastases had ineffective naturopathy and herbal treatment instead Wrong diagnosis by naturopath Inappropriate investigations suggested by naturopath Allergic reaction from naturopathy Serious allergic skin reaction from naturopathy Two cases of detox reaction by naturopath using homoeopathy Severe cystic acne as a result of diet manipulation by naturopath
Chiropractic	Death from spinal tumour—chiropractor just kept manipulating Many serious injuries from chiropractic treatment, including vertebral artery damage, strokes, and one case of blindness Spinal malignancy undiagnosed by chiropractor Chiropractor damaged spine and told patient to cease physiotherapy Bilateral sacral fracture not effectively treated by chiropractor Manipulation aggravated torn joint ligaments Worsening of pain
Herbal medicine	Herbal interactions with contraceptive pill Aplastic anaemia after taking kelp tablets Serious interaction between Ginkgo and aspirin/NSAID causing iron-deficiency anaemia and angina requiring hospital admission and transfusion Two near-fatal reactions to St John’s Wort in combination with Ginkgo reported to ADRAC Serious interaction between St John’s Wort and warfarin
Massage	Sudden onset of severe back pain after massage; took two weeks to correct Over-enthusiastic massage caused neck problems
Acupuncture	Acupuncturist withdrew patient from prescription treatment for arthritis—resulting in worsening symptoms
General comments	Many serious reactions due to complementary therapies too difficult to remember Many delayed or incorrect diagnoses due to complementary therapies Many patients do not tell doctors what complementary medications they are taking Some doctors requested a database of interactions between herbal and traditional medicines Some doctors suggested that profit motive overrides clinical judgment in complementary therapies

## 2.7 Summary of results

### 2.7.1 Risks associated with practice

- Risks to the public can arise from the clinical judgment of practitioners. These risks can arise from acts of commission or acts of omission. These types of risks exist in all healthcare practices.
- Cases of adverse events related to commission and omission have been reported; however, this does not appear to represent widespread malpractice.
- Twice as many complaints by patients to professional associations were triggered by communication problems with practitioners than by concerns with intervention itself.
- Although there are many reports by practitioners of adverse events related to the use of herbal medicine and interventions with nutritional supplements, it is difficult to determine whether these adverse events are a result of poor practice (including inappropriate prescribing) or whether they are a result of the medicines themselves.
- Although GPs did report severe adverse reactions from complementary and alternative medicine, overall GPs considered the harmfulness of CAM, including naturopathy and WHM, to be related more to the scope of practice (the broad range of clients and conditions treated, coupled with lack of recognition of the limitations to practice, which might contribute to incorrect, inadequate, or delayed diagnoses) than to the specific risks of the therapies themselves.
- There is clearly, *prima facie*, risk associated with a workforce of clinicians who consult directly with patients who present with a full range of health conditions.
- There is also, *prima facie*, risk associated with practitioners whose principal tools of trade involve ingestible medicines.

### 2.7.2 Risks associated with the consumption of herbal and nutritional medicines

- Like Western medicines, herbal and nutritional medicines can produce both predictable and unpredictable effects. Cases were identified in each of the areas.
- Predictable effects can include direct toxicity, toxicity related to overdose of a preparation, and toxicity associated with interaction with Western pharmaceuticals. Unpredictable effects can include allergic and anaphylactic reactions to herbal medications, and idiosyncratic reactions.
- Several herbs are well documented as causing toxic reactions. Especially toxic substances are restricted by current legislation. However, a number of less toxic substances is available to practitioners for use in prescriptions.
- Risks can also be associated with the inappropriate handling or manufacture of herbal and nutritional medicines. Few examples of this exist in Australia or overseas.
- Herbal and nutritional medicines have potential to interact with pharmaceutical drugs, and numerous cases have been reported.
- It is impossible to estimate the rate of adverse events for herbal and nutritional medicines from case reports and case series alone—because the total exposure to a particular medicinal substance is unknown. There are currently insufficient data to quantify the risks presented by naturopathic or herbal medicines in any detail.
- The profile of risks to the consumer is changing as a result of the concurrent use of pharmaceutical medicines, manufacturing techniques that alter potency of products, the application of herbal and nutritional medicines to a wide range of illnesses, and growing use of these therapies.

### 2.7.3 Australian workforce data

- The number of adverse events associated with herbal and nutritional medicines recorded in Australia is substantial, and the types of events reported are considered significant. The Australian workforce data suggest that practitioners will experience one adverse event every eleven months of full-time practice, and 2.3 adverse events for every 1,000 consultations.
- There appears to be significant under-reporting to government agencies of adverse events associated with herbal and nutritional medicines—possibly due, in part, to practitioners' lack of awareness of avenues for such reporting.
- The current TGA Adverse Drug Reaction Reporting System (ADRS) database is limited in its usefulness and applicability to complementary medicines. The reporting system is not sufficiently widely utilised by unregistered practitioners.
- Further research needs to be undertaken to provide a more accurate assessment of these risks. The minimising of such risks should be a priority for both government and the profession.

## 2.8 Discussion

The number of adverse events associated with WHMs and nutritional medicines recorded in Australia is significant. The types of events reported are considered significant—for example, severe gastrointestinal symptoms, palpitations, and hepatotoxicity. The workforce survey data suggest that practitioners will experience one serious adverse event every 11 months of full-time practice, and 2.3 adverse events for every 1,000 consultations (excluding mild gastrointestinal effects).

Overall, one third of practitioners reported that they notify adverse events to a variety of agencies, although it is of concern that these reports were largely provided back to the manufacturer or supplier of the product, rather than to the Commonwealth's ADRAAC. Reporting of adverse events by the herbal medicine and naturopathy professions needs to be strengthened through appropriate centralisation of data using the established processes of the Australian reporting procedures for adverse drug reactions. The professions need to work with the Adverse Drug Reactions Unit (ADRU) of the TGA to increase awareness of the reporting mechanisms among their members.

Approximately half (ten of the 22 categorised complaints from patients) recorded by professional associations related to poor communication by practitioners. It is of interest that this was perceived to be a more significant problem than problems arising from the intervention itself (which generated only five of the 22 categorised complaints). This pattern of complaints is likely to represent significant under-reporting, and thus signals a need to train graduates in this field. Professional associations should explore, in detail, the nature of these consumer complaints, with a view to strengthening relevant practitioner attributes.

The Expert Committee on Complementary Medicines in the Health System (2003) endorsed the earlier findings of Bensoussan & Myers (1996) that the utility of many adverse reaction reports involving complementary medicines on the TGA's ADRS database appears to be limited because a lack of recorded product information does not allow an unequivocal determination of the identity of the product. Moreover, the ADRS database does not support searching for individual ingredients in multi-ingredient products (such as most herbal and naturopathic medicines). It is of concern that neither of these issues, as reported in Bensoussan & Myers (1996), has been addressed.

A wide range of adverse events has been reported in the literature, and some recognisable trends are present for some herbal medicines. However, the available data (both the published cases and the naturopathy and WHM practitioner reports in the workforce survey) are likely to be significant underestimates of the risks presented. Cases reported to the manufacturers (the most common direction for reports) are very unlikely to be published or reported to the ADRU of the TGA. Furthermore, cases that are published are dependent on

the enthusiasm of the reporting practitioners, and require sufficient detail (or novelty) to be of interest to readers. Finally, the retrospective workforce survey was subject to the recall bias of practitioners and is likely to be an underestimate, because recall is not as comprehensive as continuous data gathering. The summary provided here is therefore likely to underestimate the true risks to the public.

A brief comparison of the present study with an earlier study of the risks presented by the practice of traditional Chinese medicine (TCM) highlights some similarities and differences (Bensoussan & Myers 1996). There were considerably more detailed reports of herb toxicity in TCM, including hospital admissions. It appears that the herbs available in WHM present fewer risks of direct poisoning. In both forms of practice there exist a few cases of misdiagnosis of patients and removal from care. However, with the growth in use of complementary medicines in parallel with pharmaceutical drugs there are now increased reports of interactions between pharmaceutical drugs and WHMs.

No prospective study of the risks presented by naturopathic and WHM practice has been undertaken. However, a recent prospective study in the United Kingdom of adverse drug reactions (ADRs) as a cause of admission to hospital did not report any reactions due to complementary medicines (Pirmohamed et al. 2004). This is to be contrasted with 1,225 hospital admissions related to a pharmaceutical ADR (prevalence 6.5%), resulting in a substantial burden on the health budget. The adverse events associated with nutritional medicines and homeopathy represent those reported by practitioners of naturopathy and WHM (Chapter 4). These data might not reflect adverse events in clients of other practitioners using these substances.

It is also important to note the potential changing profile of risks to the public. For example, herbal manufacturers are developing and utilising new extraction methods to optimise recovery of key compounds in herbal ingredients, with the aim of increasing the potency of the final herbal product. The Herbal Working Party within the TGA is aware of these issues and is developing guidelines to manage the assessment of new (and old) manufacturing technologies. These changing product potencies might represent an additional risk to consumers. With the growth in use of complementary medicines, it is very likely that patients will use them for an increasingly wide range of illnesses, and might do so concomitantly with conventional drugs. In the case of new pharmaceuticals, practitioners have little experience with which to predict potential interactions.

The degree of risk to public health and safety established in the current review warrants consideration of the practices of WHM and nutritional medicine in terms of effective occupational regulation. The minimisation of risks should be a priority of the herbal and naturopathic professions working with government policy makers. This might involve more formalised statutory or self-regulatory arrangements to provide enforceable minimum education and clinical practice standards. Enforceable education and practice standards should help reduce predictable adverse events through improved use of medicines and better management of those adverse events. A prospective study of adverse events is required to provide a more accurate assessment of the risks involved in the practice of these disciplines.

## **2.9 Recommendations**

Based upon the findings of the above research, the following recommendations are made.

- Given the substantial risks presented by the practices of WHM and naturopathy, there is a need to review and revise relevant regulatory mechanisms with a view to minimising risks to the public.
- Naturopathic and WHM education institutions should ensure adequate training is available to minimise the specific adverse events identified, to promote the ability of practitioners to deal with these adverse events, to initiate appropriate referral practices, to report adverse events, and to recognise the limitations of practice.

- Professional associations, in conjunction with relevant government agencies, should identify and promote a centralised location for reporting and recording of adverse events related to nutritional and herbal medicine practice.
- The current TGA ADRS database should be substantially modified to increase its usefulness in assessing adverse events related to complementary medicine.
- Professional associations and educational institutions should work to engender a consciousness among the profession of the need to report adverse events related to practice.
- National funding bodies (such as the National Health and Medical Research Council) should allocate funding for research into the quantification of adverse events in nutritional and herbal medicine, and the interactions of preparations used in these disciplines with Western pharmaceutical drugs.
- Hospital associations, in conjunction with clinical colleges and medical administrators, should review (or develop if necessary) hospital protocols for managing adverse events related to herbal and nutritional medicines.
- The DHS should commission reviews of nutritional medicine and homeopathy to ascertain the nature of the workforce and the risks and benefits to the public.

### Acknowledgment

Contributions are acknowledged from Professor Marc Cohen (RMIT University) and Dr Pauline McCabe (La Trobe University).

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## **3. A Review of Reviews of the Benefits of Naturopathy and Western Herbal Medicine**

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### **3.1 Introduction**

The purpose of this chapter is to evaluate the current scientific literature on the benefits of naturopathy and Western herbal medicine (WHM). Such an evaluation is important as it provides an understanding of the current state of the science, and the scientific literature, that underpin the two professions under review. Discussion about the risks of an intervention or therapy should not occur outside an understanding of its attendant benefits. The coupling of risks and benefits in a scientific setting provides an appropriate context in which to examine the value of interventions and therapies.

In 2003, the manufacturing licence of Pan Pharmaceuticals was suspended by the Therapeutic Goods Administration (TGA), and more than 1600 therapeutic products were recalled, of which the majority were complementary medicines. The ensuing public debate was vigorous, and there were many accusations that little evidence existed regarding the benefits of complementary medicine. Senior members of the medical profession and a state premier expressed their doubts about the benefits of complementary medicine and their concern about the lack of evidence to support its practice. Proponents of complementary medicine countered these accusations by citing specific evidence that demonstrated benefits. In response to the recall and the ensuing public debate, an expert committee was established by the Commonwealth government to review complementary medicines in the Australian health system (Commonwealth of Australia 2003). This review did not set out to establish the benefits of complementary medicine. Rather, the review was constrained to issues within the province of the Commonwealth government. To date, no objective review of the evidence for the benefits of naturopathy and WHM has been undertaken by any Australian government body, and the present review is therefore a first step in establishing constructive dialogue within the field.

A major difficulty in determining the benefits of naturopathy and WHM is that these disciplines have not been subject to systematic investigation of the manner in which the disciplines are practised in the community. Whole practice (or whole systems) research assesses the way that practitioners actually practice. In clinical practice, naturopaths and Western herbalists use multiple therapeutic tools accompanied by dietary and lifestyle

assessment and advice, patient education, and counselling. Researching a single herb or nutrient does not reflect the whole of practice.

Whole practice research is an emerging research field within complementary medicine (Ritenbaugh et al. 2003), and although several projects are currently being planned and implemented, there are no data available about the efficacy or safety of these disciplines within an holistic model. In the absence of these data, the only way to evaluate these disciplines effectively and objectively is to focus on their major therapeutic tools. The limitation of this approach is that the effectiveness of a specific therapeutic tool (such as a nutrient or a herbal medicine) is an inadequate indication of the complex clinical interactions that occur in a whole-practice setting. The major therapeutic tools used by naturopaths and Western herbalists include Western herbal medicines, nutritional supplements, and homeopathic preparations. In the present study, these specific therapeutic tools were the subject of a systematic literature evaluation, which is outlined in this chapter. A more detailed review of the literature can be found in the accompanying appendices.

It is important to note that the specific therapeutic tools reviewed in this chapter are not used exclusively by naturopaths and Western herbalists. The use of these substances falls under the purview of many health professions, and research in this area has generally been undertaken outside the context of specific professional boundaries.

Homeopathy is included in this review because it is controversial within scientific circles. Because it uses diluted preparations (and, in some cases, ultra-diluted preparations), it is generally considered to be safe. However, because of the dilution there is concern, and in some cases frank scepticism, about its capacity to provide any benefits. In comparison with the lack of literature on the risks associated with homeopathy, there is a growing body of clinical evidence that has assessed its efficacy. For these reasons, it was considered prudent to review this literature.

This chapter thus reviews the benefits of the tools of practice of naturopathy and WHM, and is divided into four sections: (i) a general citation review; (ii) an evaluation of the extent of pharmacological research in herbal medicine; (iii) a literature review of herbal medicine and nutritional supplements research; and (iv) a literature review of homeopathic research. The methodologies used are described in each section.

## 3.2 General citation review

The resources available for the present study did not permit a full evaluation of the literature pertaining to all WHMs and nutritional supplements. Early evaluation of the literature revealed thousands of references that would have to be included if such a comprehensive review were to be undertaken. However, to demonstrate the extent of the literature in these two fields, a general citation review was undertaken.

### 3.2.1 Methods

The Complementary Healthcare Council, one of the peak bodies representing the complementary medicines industry in Australia, was approached to provide a list of the ten most popular (widely utilised) herbal medicines and the ten most popular nutritional supplements in Australia in 2004. The following list was provided:

- *Herbal medicines*: *Echinacea* species; *Ginkgo biloba*; *Hypericum perforatum* (St John's wort); *Oenothera biennis* (evening primrose oil); *Allium sativa* (garlic); *Valeriana officinalis* (valerian); *Serona repens* (saw palmetto); *Panax ginseng*; *Mentha piperita* (peppermint oil); and *Melaleuca alternifolia* (tea-tree oil);
- *Nutritional supplements*: fish oils; glucosamine; chondroitin; vitamin E; vitamin C; folic acid; calcium; iron; magnesium; zinc.

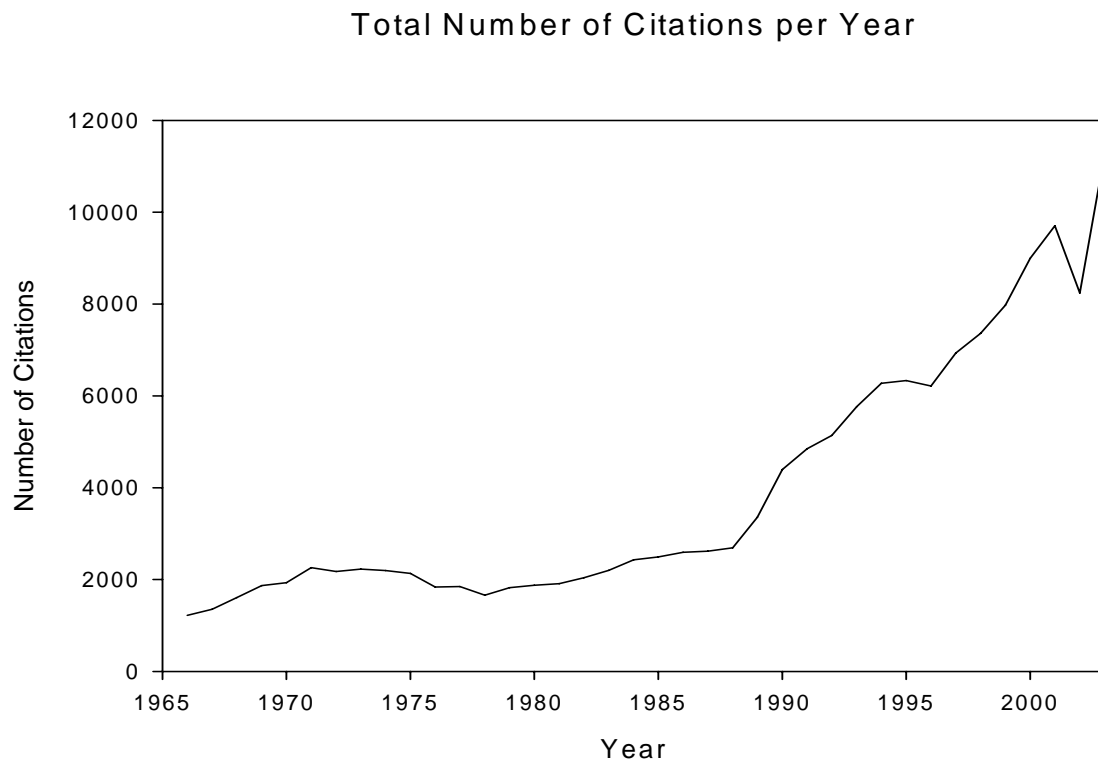
Searches were performed using the electronic medical databases Medline and EMBASE Drugs and Pharmacology. Specific search terms were used for each database (see

Appendix 3.1). The search strategy is outlined in Appendices 3.3 and 3.4. The searches were saved as text files and imported into Endnote citation management software, so that duplicates could be removed. Yearly searches were then performed using the Endnote libraries. It should be noted that Medline incorporates citations from 1966 and EMBASE incorporates citations from 1990. Searches included references up to the last complete year (2003).

### 3.2.2 Results

The citation search resulted in 152,925 citations being identified from 1966 until 2003 on the 20 items listed above. The ten nutritional supplements accounted for 136,014 citations and the ten herbal medicines for 16,991 citations. Figure 3.1 shows the total number of citations per year covering the 20 items. The total number of citations for each of the items is summarised in Table 3.1.

**Figure 3.1 Total number of citations per year for selected herbal medicine and nutritional supplements (1966–2003)**



**Table 3.1 Number of citations on selected herbal medicines and nutritional supplements (1966–2003)**

<b>Herbal medicine or nutritional supplement</b>	<b>Citations</b>
<i>Echinacea</i> species	689
<i>Ginkgo biloba</i>	2,849
<i>Hypericum perforatum</i> (St John's wort)	1,805
<i>Oenothera biennis</i> (evening primrose oil)	819
<i>Allium sativa</i> (garlic)	2,908
<i>Valeriana officinalis</i> (valerian)	682
<i>Serona repens</i> (saw palmetto)	394
Panax ginseng	3,055
<i>Mentha piperita</i> (peppermint oil)	376
<i>Melaleuca alternifolia</i> (tea-tree oil)	255
<b>Sub-total herbal medicine</b>	<b>16,991</b>
Fish oils	6,834
Glucosamine	12,880
Chondroitin	12,035
Vitamin E	31,424
Vitamin C	33,777
Folic acid	22,221
Calcium	9,331
Iron	4,345
Magnesium	1,048
Zinc	2,129
<b>Sub-total nutritional supplements</b>	<b>136,014</b>
<b>Total citations</b>	<b>152,925</b>

### 3.2.3 Discussion

As noted above, the 20 chosen items represent the most popular nutritional supplements and herbal medicines on the Australian market. However, the number of nutritional supplements and herbal medicines used by naturopaths and Western herbalists is significantly more extensive than these 20 items.

The number of citations found on these 20 items was 143,026. The large number of citations on these 20 items alone represented an impractical task if these were to be acquired and reviewed. However, this preliminary assessment of the quantity of literature in these fields assisted the study team to establish reasonable parameters for an achievable scope of work for the review of benefits.

The major limitation of a general citation review is that the nature of the specific papers that make up the citations remains undetermined. To appreciate what the literature represented, a more specific citation review of the pharmacological literature was undertaken for herbal medicine alone.

### 3.3 Evaluation of pharmacological research in herbal medicine

To characterise the nature of citations found in the medical database searches, a review of the types of literature on specific herbal medicines was undertaken—with the specific intention of evaluating the extent of pharmacological research in this area. Using the delimiters available in the electronic medical databases, an estimate of various broad areas of pharmacological investigation could be separated.

### 3.3.1 Methodology

Two samples were chosen for this review.

- *Sample 1*: This consisted of the ten popular herbs chosen by the Complementary Healthcare Council that were included in the general citation review (see above).
- *Sample 2*: This consisted of the ten randomly selected herbs from the *Materia Medica* 'A-list' of the National Herbalists Association of Australia's *Herbal Medicine Curriculum and Course Accreditation Guidelines*. This list identifies herbal medicines that must be taught as part of an NHAA-accredited course. It contains 98 herbs. The herbs in the list were numbered 1 to 98 and an on-line random number generator was used to generate the sample. Herbs randomly chosen for inclusion in the review were: albizia (*Albizia lebbek*); black cohosh (*Cimicifuga racemosa*); myrrh (*Commiphora molmol* spp.); clivers (*Galium aparine*); greater plantain (*Plantago major*); rhubarb (*Rheum officinale*, *R. palmatum*); danshen (*Salvia miltiorrhiza*); sage (*Salvia officinalis*); stinging nettle (*Urtica dioica*); and bilberry (*Vaccinium myrtillus*).

Searches were performed using both the Medline and EMBASE Drugs and Pharmacology databases. The search strategy is outlined in Appendix 3.2.

A Medline search allowed identification of the number of citations under the broad areas of laboratory (*in vitro*) studies, animal studies, and human clinical trials. The EMBASE Drugs and Pharmacology search was used to determine the spread of research in pharmacology and toxicology.

In addition to searching these databases, major international pharmacopoeiae were searched to determine if monographs on any of the herbs were included. The pharmacopoeiae included: the British Pharmacopoeia 2002; European Pharmacopoeia 5th edition (2005); United States Pharmacopoeia 27-National Formulary 22 (2004); and the Pharmacopoeia of the People's Republic of China (English Edition 2000). In addition the WHO Monographs on Selected Medicinal Plants Vol. 1 (1999) and Vol. 2 (2002) were searched.

### 3.3.2 Results

#### Sample 1

The results of this analysis demonstrated that nine of the popular herbal medicines had multiple monographs; the only exception was evening primrose oil, which had only one.

The Medline search on these herbs found 4,531 citations. These included 973 *in vitro* studies (22%), 2,960 animal studies (65%), and 598 clinical trials (13%).

The EMBASE search found 8,423 citations, of which 4,308 (51%) could be limited to either pharmacology (3,935) or toxicology (371). The pharmacological investigation of these herbs was nine times greater than the toxicological investigation in this citation review.

A full analysis of the data can be found in Table 3.2.

#### Sample 2

The results of this analysis demonstrated that five of the randomly chosen herbal medicines had multiple monographs, two had only one monograph, and three had no monographs.

The Medline search on these herbs found 655 citations. These included 180 *in vitro* studies (27%), 424 animal studies (65%) and 51 clinical trials (8%).

The EMBASE search found 683 citations of which only 439 (65%) could be limited to either pharmacology (407) or toxicology (32). The pharmacological investigation of these herbs was twelve times greater than the toxicological investigation in this citation review.

A full analysis of these data can be found in Table 3.3.

**Table 3.2 Scope of pharmacological research identified for the ten most popular herbal medicines in Australia**

	Monographs	MEDLINE			EMBASE		
		In vitro	Animal	Clinical Trials	Total hits	Pharmacology	Toxicology
Echinacea (Echinacea spp.)	USP, WHO-I	50	76	32	523	204	21
Ginkgo biloba	BP, EP, USP, PPRC, WHO-I	179	557	173	2225	1009	60
St John's wort (Hypericum perforatum)	BP, EP, USP, WHO-II	121	266	99	513	244	20
Evening primrose oil	WHO-II	28	191	68	618	184	19
Garlic (Allium sativum)	BP, EP, USP, WHO-I	285	849	87	1647	755	118
Valerian (Valeriana officinalis)	BP, EP, USP, WHO-I	24	67	31	507	231	28
Saw palmetto (Serenoa repens)	EP, USP, WHO-II	15	21	36	330	153	4
Korean ginseng (Panax ginseng)	BP, EP, USP, PPRC, WHO-I	218	874	25	1606	924	81
Peppermint oil	BP, EP, USP, WHO-II	11	36	30	265	165	10
Tea-tree oil	BP, EP, WHO-II	42	23	17	189	66	12

Notes: BP: British Pharmacopoeia 2002; EP: European Pharmacopoeia 5th edn (2005); USP: United States Pharmacopoeia 27-National Formulary 22 (2004); PPRC: Pharmacopoeia of the People's Republic of China (English Edition 2000); WHO-I: WHO Monographs on Selected Medicinal Plants Vol 1 (1999); WHO-II: WHO Monographs on Selected Medicinal Plants Vol 2 (2002).

**Table 3.3 Scope of pharmacological research identified for a random sample of ten herbal medicines frequently used by WHM practitioners in Australia**

	Monographs	Medline			Total hits	EMBASE	
		In vitro	Animal	Clinical trials		Pharmacology	Toxicology
Albizia ( <i>Albizia lebb eck</i> )		2	9	0	5	2	1
Black cohosh ( <i>Cimicifuga racemosa</i> )	WHO-II	22	33	7	30	22	2
Myrrh ( <i>Commiphora molmol et spp.</i> )	BP, EP, USP	5	32	5	24	15	4
Clivers ( <i>Galium aparine</i> )		0	3	0	3	1	0
Greater plantain ( <i>Plantago major</i> )		9	20	1	13	10	2
Rhubarb ( <i>Rheum officinale, R. palmatum</i> )	BP, EP, WHO-I	18	31	6	135	65	5
Danshen ( <i>Salvia miltiorrhiza</i> )	PPRC	66	198	19	320	221	12
Sage ( <i>Salvia officinalis</i> )	BP, EP	18	15	2	57	16	2
Stinging nettle ( <i>Urtica dioica</i> )	USP, WHO-II	30	50	9	41	22	3
Bilberry ( <i>Vaccinium myrtillus</i> )	BP, EP	10	33	2	55	33	1

Notes: BP: British Pharmacopoeia 2002; EP: European Pharmacopoeia 5th edn (2005); USP: United States Pharmacopoeia 27-National Formulary 22 (2004); PPRC: Pharmacopoeia of the People's Republic of China (English Edition 2000); WHO-I: WHO Monographs on Selected Medicinal Plants Vol 1 (1999); WHO-II: WHO Monographs on Selected Medicinal Plants Vol 2 (2002)



### 3.3.2 Discussion

The purpose of this review was to identify broad categories of research that made up the literature pertinent to nutritional supplements and herbal medicine. The results suggest that the major research activity on these preparations has occurred in either laboratory studies or animal models. These two categories made up approximately 90% of the citations. This was reflected in both the sample of popular herbs and the sample of those randomly chosen.

The majority of the investigations was undertaken in animal models—which represented 65% of both citation lists. Given the general policy of much of the complementary medicines industry to avoid animal testing of their products, this result might be considered surprising. However, much of the work had been undertaken in research laboratories investigating potential new compounds for use in the pharmaceutical industry, or by research groups interested in the biological activity of these substances.

In both samples, the amount of work on the pharmacological activity of the herbs was substantially greater than research on their toxicology. This was because a large proportion of the research was investigation of the biological activity and mechanism of action of specific compounds derived from these plants—as a first step in their potential pharmacological development. Research on the toxicology of the crude plant or its constituents generally occurs *after* the biological activity has been established.

Clinical trials of these herbs reflected their popularity. The popular herbs represented 13% of the citations of clinical trials and the random herbs represented 8%. Every herb in the popular list had more than ten clinical trial citations. Four had more than 30 citations, and another four had more than 50 citations. In contrast, nine of the randomly chosen herbs had fewer than ten clinical trials. Two had no trial citations, and another three had one or two citations. Only one herb in the randomly chosen list had more than ten citations. This was *Salvia miltiorrhiza* (Dan Shen), an increasingly popular herb, which had 19 citations.

### 3.4 Evaluation of the literature on nutritional supplements and herbal medicine

The aim of this component of the project was to evaluate the literature on nutritional supplements and herbal medicine. As noted above, initial literature searches revealed that the total number of citations on nutritional supplements and herbal medicines was beyond the scope of the time and funding available for the project. Accordingly, it was decided that a sub-set of these citations would be required for this evaluation. In choosing the sub-set, several guiding principles were established. The first principle was that this component of the project be undertaken with a clearly delineated methodology that could be duplicated by other researchers. The second principle was that all citations assessed needed to demonstrate benefits of the substances reviewed. The study was therefore limited to systematic reviews that reported on the benefits of nutritional supplements and herbal medicines in humans, and which had used rigorous clinical trial methodology. Other limitations are described below.

### 3.4.1 Review methods and citation numbers

Searches were performed using the electronic medical databases Medline and EMBASE Drugs and Pharmacology. Specific search terms were used for each database. The search strategy is outlined in Appendices 3.3 and 3.4. The searches were saved as text files and imported into Endnote citation management software so that duplicates could be removed.

The first approach to limit the review was to shorten the time over which citations were chosen and to review only human randomised controlled trials (RCTs). Limiting the years of the search to 2001–2003 and searching for RCTs located 4,118 papers on nutritional supplements and 585 on herbal medicine (a total of 4,703 citations). All the titles and abstracts of these citations were screened, and the number of citations was limited to ensure that they fell within the purview of naturopathy and WHM. For example, the intravenous use of vitamins was excluded, as were herbs that did not fall into the category of those used by a Western herbalist or naturopath. This reduced the citations to 1,401 for nutritional supplements and 470 for herbal medicine (a total of 1,871 citations). Because this number was still considered to be beyond the resources of the project, the search was further refined. Limiting the searches to references cited only in 2003 reduced the numbers substantially—to 420 for nutritional supplements and 128 for herbal medicine (a total of 548 citations). There was a general concern that commenting only on the RCTs undertaken in a given year would not necessarily reflect the totality of the current body of science.

The second approach to reduce the number of citations to a manageable quantity was to search for systematic reviews only—because the authors of these reviews would have evaluated the literature pertinent to their specific questions and would have made a determination on its methodological quality. An additional benefit of the strategy of limiting this review to systematic reviews was that it helped to overcome the problems imposed by the time limitation. Systematic reviews are more broadly reflective of the totality of the literature. They reflect the literature pertinent to the research questions, and are not time limited.

The initial search for systematic reviews was limited to a ten year period from 1993 to 2003. This found 4,018 papers on nutritional supplements and 4,406 papers on herbal medicine (a total of 8,424 citations). These citations were screened for relevance and were reduced to 136 references on nutritional supplements and 147 references on herbal medicine (a total of 383 references). These were further reduced by limiting the search to the period 2001 to 2003, which resulted in 84 references on nutritional supplements and 74 references on herbal medicines (a total of 158 references). It was decided that this method would be used to undertake the review.

The search strategy was rerun on 24 February 2004 to capture any additional papers added to the database in the interim, and the citation search was considered complete. The final number of citations found for the review was 114 on nutritional supplementation and 100 on herbal medicine (a total of 214 citations). These 214 papers were obtained and reviewed for appropriateness for inclusion. Papers were excluded if they were: (i) reviews other than systematic reviews; (ii) reviews of complementary medicine treatments other than herbal or nutritional medicine; (iii) reviews of orthodox medical treatments outside the scope of naturopathic or WHM practice; (iv) repeat papers published in different journals; (v) reviews on the safety of nutritional supplements or herbal medicines; (vi) annotated bibliographies; or (vii) reviews published in foreign language journals. This resulted in 76 papers being excluded from the 114 papers on nutritional supplements and 66 papers being excluded from the 100 papers on herbal medicines. This left 38 meta-analyses and systematic reviews on nutritional supplements and 34 meta-analyses and systematic reviews on herbal medicines.

The final methodological step was a review for methodological quality. The 72 remaining papers were assessed using a questionnaire designed to abstract information from systematic reviews. All the papers had the information systematically abstracted to a cover sheet to allow for cross-checking by another team member. The ten questions used to abstract information from each of the reviews were:

- Did the authors of the work have a written protocol?
- Had the authors defined the research question clearly?
- Had the authors described the search strategy and how studies were chosen for inclusion?
- How did the authors assess the quality of the individual studies?
- How did the authors abstract the information from the individual studies?
- Had the authors provided adequate details of the subjects included in the studies being analysed?
- Had the authors plotted their results?
- Had the authors inspected their data for heterogeneity of outcome?
- How did the authors calculate a summary estimate of the effect of the intervention?
- Had the authors inspected the data for evidence of publication bias?

No papers were excluded on the basis of poor methodological quality—leaving 72 papers included for assessment (38 papers on nutritional supplements and 34 on herbs). A flowchart of the literature methods and citation numbers is given in Figure 3.2.

To assist in the presentation of the data, the papers were clustered into the body system most appropriate to their research question, and summarised for inclusion in this report.

### **3.4.2 Results**

The central research question of this review was to assess the current evidence to support the benefits of naturopathy and WHM. Therefore, only papers that showed positive benefit were included in this chapter. A summary of *all* papers (positive, negative, and inconclusive) can be found in Appendix 3.5. What follows is a selected review of the key papers that reported clinically relevant benefits, clustered in major body systems. These are summarised in Tables 3.4 and 3.5.

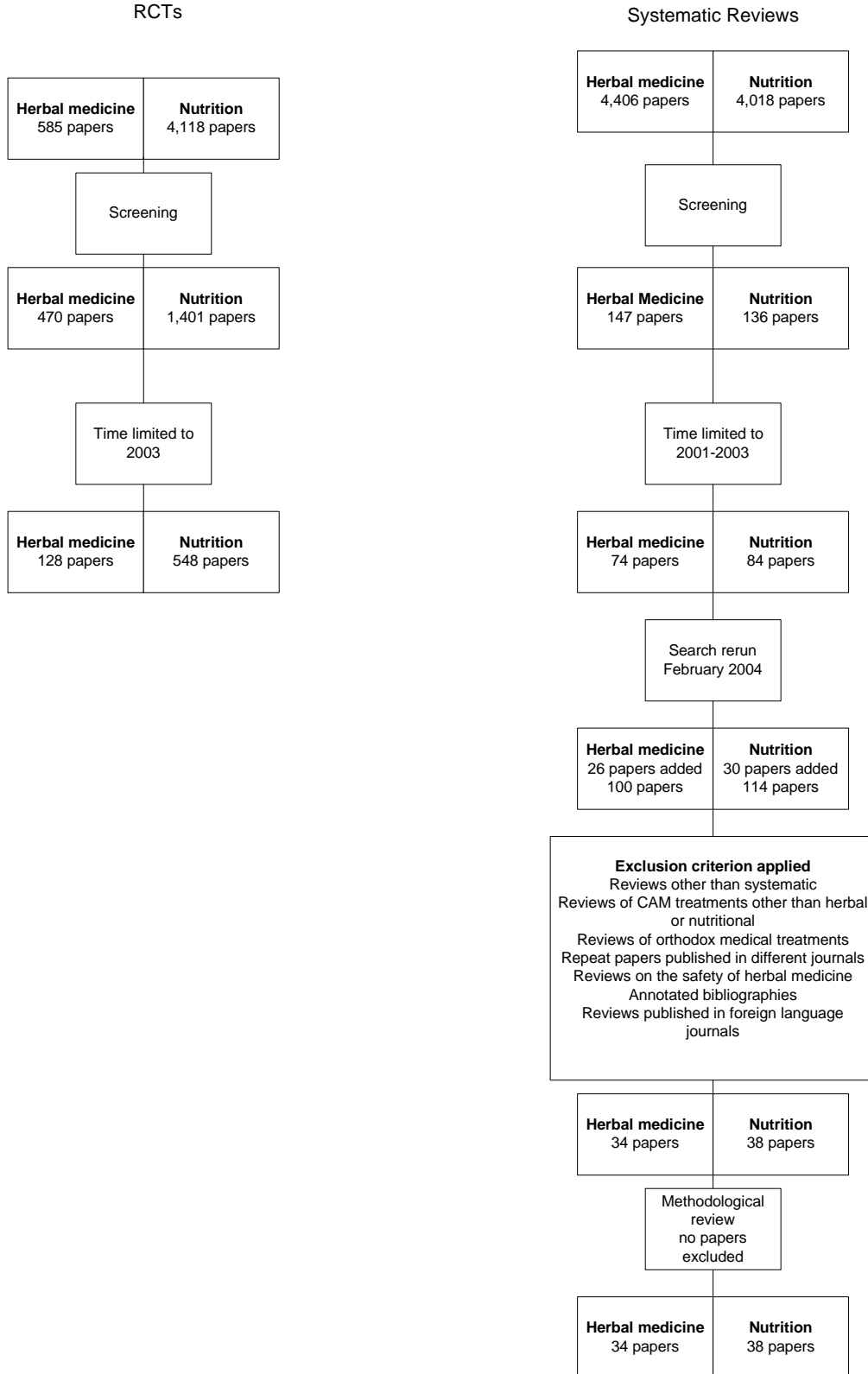
#### **Cardiovascular system**

A meta-analysis of the effects of N-3 polyunsaturated fatty acids on coronary artery disease demonstrated that they lowered the risk of fatal myocardial infarction (30%), sudden death (30%), and overall mortality (20%) (Bucher et al. 2002).

A systematic review (Hermansen et al. 2003) of the evidence for the effect of soy and other natural products on lipid parameters (including a meta-analysis of 38 RCTs on soy products) demonstrated that these products decreased levels of total cholesterol, LDL, and triglycerides by 9%, 13%, and 11% respectively. Seven clinical trials of soy products with high levels of active constituents reported significant reductions in LDL cholesterol from 4% to 21%. Positive results were also found for psyllium (6–7% reduction in LDL), oat bran with high levels of beta-glucan (2–17% reduction in LDL), and plant sterols (4–18% reduction in LDL). Only small reductions in LDL were found from a meta-analysis of 67 clinical trials on dietary fibre.

A systematic review of the effect of artichoke extract on total cholesterol levels found only two studies that fulfilled inclusion criteria (Pittler et al. 2002). One study demonstrated an 18% reduction in total cholesterol. The authors concluded that further work needs to be undertaken to verify this effect.

**Figure 3.2 Flowchart of the literature methods and citation numbers.**



**Table 3.4 Summary of systematic reviews of nutritional supplements**

Year	First author	Condition	Treatment studied	RCTs and subjects	R	Primary outcome	Principal findings
<b>Cardiovascular system</b>							
2003	Vivekanathan DP	Cardiovascular disease prevention	Antioxidant vitamins	RCT=12 (n=219,901)	-	Mortality and cardiovascular death	Lack of a salutary effect consistently for various doses of vitamins in diverse populations. The results, combined with a lack of mechanistic data for efficacy of vitamin E, do not support routine use of vitamin E.
2002	Bucher HC	Coronary heart disease	n-3 polyunsaturated fatty acids	RCT=11 (n=15,806)	+	Fatal and non-fatal myocardial infarction and overall mortality	Intake of n-3 polysaturated fatty acids reduces overall mortality due to myocardial infarction and sudden death in patients with coronary heart disease.
2002	Gelenijnse JM	Hypertension	Fish oil	RCT=36 (n=2114)	+	Blood pressure	High intake of fish oil might lower BP, especially in older and hypertensive subjects
2003	Hermansen K	LDL:HDL ratio and other lipid parameters	Soy and other natural products	RCT=145 (n=7105)	~	Lipid levels	The new soy-based supplements might play a role in reducing cardiovascular risk
<b>Gastrointestinal system</b>							
2002	Cremonini F	Antibiotic-associated diarrhoea	Probiotics	RCT=7 (n=811)	+	Presence/absence of diarrhoea	Results suggest benefit of probiotic administration on antibiotic-associated diarrhoea. Further data required.
2002	D'Souza AL	Antibiotic-associated diarrhoea	Probiotics	RCT=9 (n=not reported)	+	Number of subjects in absence of diarrhoea	Probiotics can be used to prevent antibiotic-associated diarrhoea. Further data required for treatment of antibiotic-associated diarrhoea.
2002	Huang JS	Acute diarrhoea	Probiotics	RCT=18 (n=1917)	+	Duration of diarrhoea in days	Bacterial probiotic therapy shortens duration of acute diarrhoeal illness in children by approx. one day
2002	Van Niel CW	Acute infectious diarrhoea	Lactobacillus	RCT=8 (n=765)	+	Clinical course of diarrhoea	Results suggest lactobacillus is safe and effective as treatment for children with acute infectious diarrhoea.
<b>Neurological system</b>							
2001	Arnold LE	Adults with attention-deficit hyperactivity	24 alternative therapies	Not reported	~	Behavioural and psychosocial measures	Some alternative treatments effective but mainly in certain patients. More research required.

		disorder					
2001	Benton D	Intelligence in children	Micro-nutrients	RCT=22 (n=4428)	~	Verbal and non-verbal measures of intelligence	Only children with deficiencies benefit from supplementation.
2003	Higgins JPT	Dementia and cognitive impairment	Lecithin	RCT=12 (n=376)	~	Dependency, global impression, functional performance, behavioural, quality of life, cognitive function, effect on carer and death	Evidence from randomised trials do not support use of lecithin in treatment of patients with dementia, although some moderate effects were found.
2002	Nye C	Autism	Vitamin B6 and magnesium	RCT = 2 (n=20)	~	Compulsive behaviour, obsessive-compulsive behaviour, hyperactivity, impulsivity	Due to small number of studies, quality of studies, and small sample sizes, no recommendation advanced.
2003	Montgomery SA	Mild cognitive impairment and mild Alzheimer's disease	Acetyl-L-carnitine	RCT=21 (n=1479)	+	Cognitive measures	Significant benefit at 3 months (increasing over time) in both clinical scales and psychometric tests; treatment well tolerated.
2001	Olde Rikkert MGM	Insomnia	Melatonin	RCT=6 (n=95)	+	Sleep latency, sleep efficiency, wake time during sleep	Low doses of melatonin improve initial sleep quality in selected elderly insomniacs. Further data required.
<b>Musculoskeletal system</b>							
2001	Hauselmann HJ	Knee osteoarthritis	Nutripharmaceuticals	RCT = 20 (n=1515)	~	Pain	Glucosamine sulphate and chondroitin sulphate provide a small-to-moderate improvement in pain and function compared with placebo; comparable to NSAIDs without adverse effects. Soybean/avocado unsaponifiable residues had modest effect on pain but require further data.
2002	Papadimitropoulos E	Osteoporosis	Vitamin D	RCT=25 (n=4017)	+	Bone density and fractures	Vitamin D decreases vertebral fractures and might decrease nonvertebral fractures.
2003	Richy	Knee osteoarthritis	Glucosamine and chondroitin	RCT=15 (n=1775)	+	Joint space narrowing, WOMAC, Lequesne Index, visual analogue scale pain, mobility and responding status	Demonstrates structural efficacy of glucosamine and indistinguishable symptomatic efficacies for glucosamine and chondroitin. Further data required.

2002	Shea B	Postmenopausal osteoporosis	Calcium	RCT=15 (n=1806)	+	Bone densities and fractures	Calcium supplementation alone has small positive effect on bone density.
2002	Soeken KL	Osteoarthritis	S-adenomethionine	RCT=11 (n=1442)	+	Pain, functional limitation and AEs	SAME is as effective as NSAIDs in reducing pain and improving function limitation in patients with OA without adverse effects associated with NSAIDs.
2003	Holdcraft LC	Fibromyalgia and related syndromes	Physical, homeopathic, nutritional and alternative treatments	RCT=22 (n=1116)	~	Stiffness, pain, quality of life	Some herbal and nutritional supplements have evidence for effectiveness with FMS
<b>Female reproductive system</b>							
2003	Villar J	Prevention and treatment of maternal morbidity and preterm delivery	Calcium, magnesium, fish oil, vitamins E and C, iron and folate, and vitamin A,	RCT=123 (n=not reported)	+	Pre-eclampsia, pregnancy hypertension, anaemia and haemorrhage related outcomes, maternal infection and obstructed labour/caesarean section	Iron and folate reduce anaemia. Calcium given to women at high risk of hypertension during pregnancy or low calcium intake reduced the incidence of preeclampsia and hypertension. Vitamins E and C and fish oil promising for preventing preeclampsia and preterm delivery. Vitamin A and beta-carotene reduced maternal mortality in a large study. Further data required.
2001	Stevinson C	Premenstrual syndrome	Herbal, physical & nutritional supplements	RCT=27 (n=1872)	~	Subjective rating, MDQ, POMS, dairies and symptom scales	On basis of evidence, no complementary/alternative therapy can be recommended as treatment for premenstrual syndrome
2003	Hofmeyr GJ	High blood pressure and related maternal and fetal neo-natal adverse outcomes during	Calcium	RCT=11 (n=6864)	+	High blood pressure, pre-eclampsia, preterm delivery, low birth weight	Calcium appears beneficial for women at high risk of gestational hypertension and in communities with low dietary calcium intake. Further data required.

		pregnancy					
<b>Systemic disorders</b>							
2001	Pittler MH	Weight reduction	Guar Gum	RCT=11 (n=174)	-	Body weight	Guar gum not efficacious for reducing body weight.
2003	Pittler MH	Weight reduction	Chromium picolinate	RCT=10 (n=473)	~	Body weight	Meta-analysis suggests relatively small effect of chromium picolinate for reducing body weight.
2001	Oppenheimer SJ	Iron-deficiency anaemia	Iron	RCT=11 (n=4536)	~	Type and number of infections	Oral iron given as a supplement in nonmalarious areas might reduce infectious morbidity in disadvantaged populations. Oral iron supplementation in the tropics in children has been associated with increased risk of clinical malaria and other infections.
2003	Schwedhelm E	Systemic oxidative stress	Antioxidants	Not reported	~	Antioxidant status, lipid peroxidation, DNA damage, protein damage	Antioxidants mainly derived from dietary sources show greatest benefits in epidemiological surveys. In clinical trials several drugs and micronutrients have potential to prevent further harm in secondary prevention. Further research is required.
2003	Branch JD	Body composition variables & performance tasks	Creatinine	RCT=100 (n=1847)	+	Body composition variables and performance tasks	Short-term creatinine more effective for lean body mass with isometric, isokinetic, isotonic, and upper body exercise. Creatinine does not improve running or swimming performance.
2002	Brown KH	Growth in children	Zinc	RCT=37 (n=2637)	+	Body weight and height	Zinc supplementation improves height and weight measures
2002	Dempsey RL	Strength	Creatinine	RCT=16 (n=414)	+	Strength	Oral creatine supplementation combined with resistance training increases maximal weight lifted in young men. No evidence for older or female groups.
2003	Nissen SL	Lean mass and strength gains	Creatinine, HMB, chromium, androstenedione/ DHEA	RCT=48 (n=1044)	+/-	Lean mass and strength	Creatine and HMB have data supporting use to augment lean mass and strength gains with resistance training.
2003	Latham LK	Preventing falls and improving physical function of	Vitamin D	RCT=13 (n=2496)	~	Measures of strength, physical function or measure of fall frequency	Insufficient evidence for vitamin D alone for improvement of physical performance of older people; some data suggest a benefit from vitamin D combined with calcium supplementation. Further data required



		older people					
<b>Cancer</b>							
2002	Gorsky M	Premalignant oral lesions	Topical retinoids	RCT=4 (n=61)	+	Clinical response to medication	Direct application of higher concentrations of retinoic acid results in suppression of oral leukoplakia; use in treatment of recurrent and persistent lesions might be justified. Further data required.
<b>Endocrinology</b>							
2002	Althuis MD	Glucose intolerance and type 2 diabetes	Chromium	RCT=15 (n=618)	~	Glucose, insulin and glycated haemoglobin concentrations after intervention	No effect on non-diabetic subjects; inconclusive results on diabetics.
2003	Yeh G.Y. et al	Glycemic control in diabetes	Chromium, magnesium, vanadium, vitamin E, $\alpha$ -lipoic acid	Chromium (RCT=8, n=486) Magnesium (RCT=7, n=276) Vanadium (CT=3, n=21) Vitamin E (CT=6, n=179, $\alpha$ -lipoic acid (CT=1, n=74)	~	Various glycemic control markers	Evidence for chromium and magnesium inconclusive. Evidence for Vitamin E mixed and inconclusive. Evidence for vanadium and $\alpha$ -lipoic acid limited and requires further elucidation of function.

Legend:

R = result; + positive; - negative; ~ inconclusive.

**Table 3.5 Summary of systematic reviews of herbal medicines**

Year	First author	Condition	Treatment	RCTs and subjects	R	Primary outcome	Principal findings
<b>Cardiovascular system</b>							
2002	Pittler MH	Hypercholes- -teraemia	Artichoke leaf	RCT=2 (n=167)	~	Reduction in total serum cholesterol	Limited evidence of efficacy and safety
2002	Pittler MH	Chronic venous insuf- ficiency	Horse chestnut seed extract	RCT=14 (n=941)	+	CVI-related symptoms, leg volume, ankle and calf circumference, oedema, pain, sensation of tension, swelling, leg fatigue and heaviness, calf cramps and itching	HCSE appears to be a safe and effective treatment for CVI
2002	Siebert U	Chronic venous insuf- ficiency	Horse chestnut seed extract	RCT=13 (n=1051)	+	CVI-related symptoms, leg volume, ankle and calf circumference, oedema, pain, sensation of tension, swelling, leg fatigue and heaviness, calf cramps and itching	Reduced leg volume and some effect on leg pain; adverse events mild; further long-term observational studies required to test efficacy
2003	Pittler MH	Chronic heart failure	Hawthorn extract	RCT=8 (n=632)	+	Mean change in maximal workload	Hawthorn has significant benefit as adjunct treatment in chronic heart failure
2003	Thompson Coon JS	Hypercholes -teraemia	Herbal medicine products	RCT=25 (n=1430)	+	Reduction in total cholesterol between 10 and 33%	Potential hypercholesterolaemic activity for herbal medicines tested; high safety profile for all herbs tested
<b>Gastrointestinal system</b>							
2001	Liu JP	Hepatitis B	Chinese medicinal herbs	RCT=3 (n=307)	+	Viral and serum markers	Jianpi Wenshen recipe showed significant effects compared with interferon in clearing viral markers
2001	Liu JP	Hepatitis B	Genus phyllanthus	RCT=22 (n=1947)	+	Serum HBV markers, conversion of HbeAg to anti-Hbe, biochemical response, liver histopathology and quality of life	Phyllanthus species had a positive effect in clearance of serum HbsAg; validity of evidence reduced due to poor trial quality
2002	Thompson Coon JS	Non-ulcer dyspepsia	Herbal medicine	RCT=17 (n=1808)	+	Changes in GIT symptoms	Potential for some of herbs trialled for relief of non-ulcer dyspepsia
2002	Jacobs BP	Liver disease	Milk thistle	RCT=14 (1209)	~	Liver biopsy histology, biochemical markers and mortality data	

2002	McCulloch MB	Chronic hepatitis B	Chinese herbs	RCT=27 (n=not given)	-	Seroreversion of HbsAg, HbeAg, HBV DNA	
2003	Liu JP	Hepatitis C	Medicinal herbs	RCT=13 (n=818)	-	Virological and biochemical response, improvement of histological activity index, and quality of life	
2003	Spanier JA	IBS	Herbal medicines	RCT=7 (n=259)	-	None recorded	No therapy supported by results
2003	Gundermann KJ	Functional dyspepsia	Iberogast	RCT=4 (n=592)	+	Changes in GIS sum score	Highly significant overall therapeutic effect of Iberogast
<b>Neurological system</b>							
2001	Whiskey E	Depression	Hypericum perforatum	RCT=22 (n=2736)	+	Hamilton depression scale	St John's wort significantly more effective than placebo but not significantly different in efficacy compared with anti-depressants. Less side effects with St John's wort compared with antidepressants
2001	Evans JR	Macular degeneration	Ginkgo biloba	RCT=1 (n=20)	+	Changes in CGI scale, changes in ADL, changes in mood and emotional function	Some evidence of improvement in cognition with use of Ginkgo biloba
2002	Birks EV	Cognitive impairment and dementia	Ginkgo biloba	RCT=33 (n=3278)	+	Clinical global improvement scale measuring cognitive function, functional performance, behavioural disturbance, global impression, quality of life, dependency, acceptability of treatment and safety	Promising evidence of improvement in cognitive function associated with Ginkgo biloba
2002	Kasper S	Depression	Hypericum extract	RCT=3 (n=544)	+	Hamilton rating scale	Hypericum effective in reducing core somatic symptoms of depression and insomnia and anxiety associated with depression more effectively than placebo
2003	Pittler MH	Anxiety	Kava extract	RCT=11 (n=645)	+	Hamilton anxiety scale	Kava safe and effective short-term treatment in management of anxiety

<b>Musculoskeletal system</b>							
2001	Little CV	Osteo- arthritis	Herbal medicines	RCT=5 (n=471)	+	Changes in pain, mobility, grip strength and usage of NSAIDs, changes in serum lipids and fatty acid levels, QOL measures	Convincing evidence for the efficacy and safety of avocado-soybean unsaponifiables; other treatments not recommended
2001	Long L	Osteo- arthritis	Herbal medicine	RCT=12 syste- matic reviews= 2 (n=1063)	~	Global symptom score, VAS pain, joint stiffness, tenderness, and swelling	Some herbal treatments showed potential for efficacy
2003	Soeken K	Rheumatoid arthritis	Herbal medicine	RCT=14 (n=645)	+	Global symptom score, VAS pain, joint stiffness, tenderness, and swelling	Moderate evidence to support use of gamma-linolenic acid
<b>Female reproductive system</b>							
2001	Stevinson C	Premenstrual syndrome	Herbal medicine	RCT=7 (n=592)	-	MDQ, PMTS scale, VAS	
2001	Kelly AJ	Childbirth	Castor oil	RCT=1 (n=100)	-	Vaginal delivery not achieved within 24 hours, uterine hyperstimulation and increases in foetal heart rate, caesarean section and maternal or foetal death	Clinical efficacy of <i>C. ramosa</i> not proven
2002	Borrelli F	Menopause	Cimicifuga ramosa	RCT=4 (n=226)	-	Improvements in the Kupperman menopause scale and Hamilton anxiety scale; changes in the biochemical markers of menopause	No convincing evidence found
2002	Kronenberg F	Menopause	Herbal medicine	RCT=10 (n=962)	+	Serum hormone levels, intensity of hot flushes and the Kupperman index	Only black cohosh demonstrated efficacy in relieving hot flushes
2003	Huntley AL	Menopause	Herbal medicine	RCT=18 (n=1295)	~	Physical and psychological symptoms of menopause	No conclusive evidence of efficacy; however black cohosh provided promising results
<b>Male reproductive system</b>							
2002	Wilt T	Prostatic hyperplasi a	Serenoa repens	RCT=21 (n=3139)	+	Urological symptom scores, urodynamic measures, residual urine volume, changes in prostate size, nocturia, overall improvement in health	Serenoa repens provided mild to moderate improvement in urinary symptoms and flow measures; long term effects unknown
2002	Wilt T	Prostatic	Pygeum	RCT=18	+	Change in urinary symptom scale	Might be useful in treatment of prostatic

		hyperplasia	africanum	(n=1562)		scores	hyperplasia
<b>Urinary system</b>							
2001	Jepson RG	Urinary tract infection	Cranberries	RCT=7 (n=604)	~	Number of UTI in each group, microbiological confirmation of UTI	Might reduce symptoms of UTI; however, evidence is unclear
<b>Respiratory system</b>							
2003	Hofmann D	Bronchial asthma	Dry extract of ivy leaves	RCT=3 (n=75)	+	Body plethysmographic and spirometric tests	Ivy-leaf extract improved respiratory function in children with chronic bronchial asthma; data insufficient to provide conclusive evidence; long term efficacy unproven
<b>Oncology</b>							
2003	Ernst E	Cancer	Mistletoe	RCT=10 (n=2470)	-	Clinical outcome measures, biochemical markers, survival rate, quality of life	Studies did not demonstrate efficacy of mistletoe
2003	Kienle GS	Cancer	Mistletoe	RCT=16 (n=2495) Quasi RCT=2 (n=155) Non- RCT=5 (n=1896)	~	Clinically relevant outcomes including survival rate, quality of life, remission rate, disease-free survival	Poor methodological quality; however, some statistically relevant outcomes in 12 studies
<b>Infectious disease</b>							
2003	Martin KW	Antiviral agents	Herbal medicine	RCT=33 Non- RCT=8 (n=3306)	+	Changes in serum levels HbsAg, HbeAg, HBV DNA, pain scores and healing of lesions	Overall positive results from herbs trialled; negative trials might not have been published
<b>Endocrinology</b>							
2003	Yeh GY	Glycemic control (diabetes)	Herbal medicine products	RCT=58 Other trials=0 (n=4565)	-	Fasting and postprandial plasma glucose, glucose tolerance test response, insulin and C peptide levels, protein glycosylation, clinical insulin requirements	Insufficient evidence to show efficacy; however, herbs had high safety profile

A meta-analysis of eight RCTs using hawthorn (*Crataegus oxycantha*) extract to assess its effect on congestive cardiac failure demonstrated that it was more effective than placebo in maximal workload using bicycle ergometry (Pittler et al. 2003). The adverse events were mild and the authors concluded that hawthorn extract was a safe and effective adjunctive treatment for congestive cardiac failure.

A meta-analysis of 13 RCTs was undertaken on horse chestnut seed extract (HCSE) in the treatment of chronic venous insufficiency (Pittler & Ernst 2002). The study demonstrated that HCSE reduced leg volume by 46.4 mL, increased the likelihood of improvement in leg pain by 400%, and increased the probability of improvement in oedema (150%) and itching (170%) in comparison with a placebo. The evidence was not sufficient to show improvements in leg fatigue or calf cramps. Adverse events were mild.

### **Gastrointestinal system**

A meta-analysis of RCTs on the role of probiotics in the prevention of antibiotic-associated diarrhoea was undertaken using nine studies (D'Souza et al. 2002). It found a 60% reduction in relative risk.

A meta-analysis of 18 RCTs on the use of probiotics in the management of acute diarrhoea in a paediatric population demonstrated that probiotics reduced the duration of diarrhoea by 0.8 days (Huang et al. 2002). Another meta-analysis investigated studies specifically undertaken on *Lactobacillus* for the same condition and population (Van Niel et al. 2002). It found that *Lactobacillus* supplementation reduced the duration of diarrhoea by 0.7 days, and reduced the frequency of diarrhoea on day 2.

A meta-analysis of the use of a proprietary herbal preparation (Iberogast) in the treatment of functional dyspepsia included four RCTs (Gundermann et al. 2003). A significant therapeutic effect was found, with minimal side effects.

A systematic review of herbal medicines in the treatment of non-ulcer dyspepsia was undertaken in 17 trials (13 on combination herbs and four on single herbs) (Thompson, Coon & Ernst 2002). There was an improvement in symptom scores ranging from 60% to 95% compared with baseline, placebo, and a comparison drug. There were few reports of adverse events.

### **Neurological system**

The efficacy of acetyl-L-carnitine in the treatment of mild cognitive impairment and mild Alzheimer's disease was assessed by Montgomery et al. (2003) using a meta-analysis of 21 RCTs. The authors combined all the clinical and psychometric tests to produce an 'All Scales Effect Size', which showed a significant positive effect for acetyl-L-carnitine over placebo.

A systematic review of the efficacy of melatonin in the treatment of insomnia in elderly subjects included six RCTs (Olde Rikkert and Rigaud, 2001). Sleep latency (time between subject's self-appointed sleep time and sleep onset) decreased significantly in four studies, and sleep efficiency (the percentage of time that the subject was in bed following sleep onset that was spent asleep) increased in three of the studies. The authors recommended that larger, more generalised studies needed to be undertaken.

A two-stage meta-analysis was undertaken of 22 RCTs on the effects of St John's wort (*Hypericum perforatum*) in treating depression (Whiskey et al. 2001). In stage 1, all data from studies using the Hamilton Depression Scale (HAM-D) were included. This showed that St John's wort was significantly more effective than placebo, but did not show a significant improvement in efficacy when compared with standard antidepressants. In the second stage, a sub-analysis of studies that fulfilled the intention to treat analysis and adhered to predefined inclusion criteria (age, diagnosis, HAM-D scores) was analysed (n = 6 placebo, and n = 4 active comparator trials). This sub-analysis in more rigorous studies demonstrated that St John's wort was more effective than placebo, and equally effective as standard

antidepressants. Adverse events were mild and transient, and there were fewer reports of adverse effects than for standard antidepressants.

A meta-analysis of the effects of *Ginkgo biloba* on cognitive impairment and dementia was undertaken on 33 RCTs (Birks et al. 2002). The analysis showed benefits associated with *Ginkgo* (dose less than 200 mg daily) compared with placebo at less than 12 weeks when measuring clinical global improvement (15.32, 95% CI 5.9–39.8,  $p < 0.0001$ ). Benefits were also noted at 24 weeks using a dose greater than 200 mg/day. The authors concluded that *Ginkgo* appeared to be clinically safe, and that there was encouraging evidence of efficacy (especially in improving cognition and function).

A meta-analysis of was undertaken on 11 RCTs of the use of *Kava* extract for treating anxiety (Pittler and Ernst 2003). This analysis showed a significant reduction in anxiety in subjects who received the study treatment compared with those who received placebo, as measured by the Hamilton Anxiety Scale.

### **Musculoskeletal system**

A meta-analysis of 15 RCTs was undertaken to determine the efficacy of glucosamine sulphate and/or chondroitin sulphate on knee osteoarthritis (Richy et al. 2003). A significant positive effect was found for glucosamine when compared with placebo for the radiological evolution of osteoarthritis. No corresponding high quality data were available for chondroitin. In measuring pain and physical function outcomes, the results for glucosamine and chondroitin were combined—because there was no significant difference between them. The agents were effective across a range of validated measures.

The prevention of postmenopausal osteoporosis by calcium supplementation was examined in a meta-analysis of 15 RCTS (Shea et al. 2002). The change from baseline was significant after two years for total bone density (BD), for lumbar spine BD, for hip BD, and for distal radius BD. The relative risk of fractures between placebo and calcium was not significant.

A meta-analysis of 11 RCTs on the safety and efficacy of S-adenomethionine (SAME) for the treatment of osteoarthritis was undertaken by Soeken et al. (2002). The analysis found that SAME produced an improvement in physical function, but produced no significant change in pain when compared with placebo. When SAME was compared with non-steroidal anti-inflammatory drugs (NSAIDs), they were found to be equivalent for both pain and physical function. A review of safety found that subjects treated with SAME were 58% less likely to experience side effects when compared with subjects taking NSAIDs.

A systematic review (Soeken et al. 2003) of herbal medicine in rheumatoid arthritis found 14 RCTs that met the inclusion criteria—most of which were single studies of individual herbs. A meta-analysis on two studies of gamma-linolenic acid (GLA) showed significant improvements in pain, tender joint count, swollen joint count, and stiffness compared with placebo. Only the swollen joint count failed to reach significance. The review concluded that GLA has ‘moderate’ support in the treatment of RA.

A systematic review of herbal medicines for the treatment of osteoarthritis found 12 RCTs and two systematic reviews that fulfilled the inclusion criteria (Long et al. 2001). The results showed promising evidence for the efficacy of Articulon-F, capsaicin, devil’s claw, reumalex, and willow bark in osteoarthritis, and a reduction in the consumption of NSAIDs as a result of the use of an extract of avocado and soya bean. Adverse events were mild and transient—including gastrointestinal tract symptoms, pruritus, and headache. Capsaicin caused temporary burning pain on application in some patients. It was concluded that the herbal remedies reviewed could offer a viable alternative in the treatment of osteoarthritis.

### **Female reproductive system**

Eleven randomised, placebo-controlled studies were reviewed in a meta-analysis to define the effect of calcium supplementation in the prevention of pre-eclampsia (Hofmeyr et al. 2003). It was found that calcium significantly reduced the risk of high blood pressure by 19%. This effect was higher (55%) in women who had a high risk of hypertension and who had low

baseline calcium levels. Calcium also significantly decreased the risk of pre-eclampsia by 32%. There was a greater effect in subjects with high risk of hypertension and low calcium levels. A smaller number of babies with a birth weight less than 2.5 kg was born to subjects who were supplemented with calcium.

A review of RCTs and systematic reviews investigated the role of nutritional interventions during pregnancy in reducing maternal morbidity, mortality, and preterm labour (Villar et al. 2003). This revealed that vitamin A and  $\beta$ -carotene reduce maternal mortality, that calcium supplementation is beneficial for women with low calcium intake and a high risk of pre-eclampsia, that fish oil and magnesium might prevent preterm labour, and that iron and folate are effective in preventing and treating severe anaemia, even postpartum.

### **Male reproductive system**

A meta-analysis of the effects of saw palmetto (*Serenoa repens*) on benign prostatic hyperplasia identified 21 RCTs that met the inclusion criteria (Wilt et al. 2002a). Results showed that treatment with *Serenoa repens* improved urinary symptoms and flow measures compared with placebo. Adverse events were mild, transient, and infrequent.

A meta-analysis of the effects of *Pygeum africanum* on benign prostatic hyperplasia identified 18 RCTs that met the inclusion criteria (Wilt et al. 2002b). Subjects taking the study medication were twice as likely to report an improvement in urological symptoms, with a 19% reduction in nocturia, 24% reduction in residual urine volume, and a 23% increase in peak urine flow for individuals taking *Pygeum africanum* compared with placebo.

### **Urinary tract**

A systematic review of the effect of cranberry products in preventing urinary tract infections (UTIs) found seven RCTs that met the inclusion criteria (Jepson et al. 2001). They included studies on cranberry juice (5), cranberry tablets (1), and both juice and tablets (1). The reviewers concluded that cranberry products might reduce the number of symptomatic UTIs in adult women over a 12 month period. However, the evidence was unclear in other groups—such as elderly men, elderly women, and children.

### **3.4.3 Discussion**

There is a substantial body of literature on clinical trials assessing the effects of nutritional supplementation and herbal medicine on a wide range of conditions.

One possible approach to the review was to choose specific nutritional supplements and herbal medicines that were generally known to have a favorable body of evidence and concentrate on providing the evidence about these specific preparations. While the concept of putting the best foot forward might be tempting to advocates of naturopathy and WHM, it was decided that a more systematic approach to the literature would provide a more objective understanding of the type and range of literature demonstrating benefits for nutritional supplementation and herbal medicine. It was apparent from the outset that the review could not be fully inclusive and would only be able to provide a specific time-limited window on the totality of the literature. The systematic approach would also be more random in identifying papers which appeared appropriate for an objective review of the literature. The development of an objective methodology which could be replicated independently was chosen for these reasons.

The present study revealed that a range of nutritional supplements and herbal medicines have demonstrable benefits at the highest level of evidence—systematic reviews of RCTs. These benefits are spread across a range of conditions and body systems. It is reasonable to suggest that a more exhaustive review of the literature would reveal further examples of validated reports of positive benefits within the fields of nutritional and herbal medicine. The evidence that was found during the present evaluation demonstrates that some of the ‘tools of trade’ of naturopaths and Western herbalists have proven efficacy. In addition, the safety profile of many of these preparations was addressed within the systematic reviews and found to be good, with minor adverse events reported.



An important component of the evaluation of any therapy is a determination of its potential benefits in comparison with its potential risks. The most appropriate method to undertake this assessment is to note the specific benefits of an intervention or therapy on a target population (that is, individuals with a specific health condition) and to compare these with the specific risks of that intervention or therapy in that target population. In conventional medicine the determination of risk to benefit can often be underpinned with hard data—such as the proportion of individuals who achieve a benefit compared with the proportion of people who experience an adverse event. In complementary medicine such hard data are often unavailable. Many complementary medicine interventions and therapies have yet to be assessed in rigorous clinical trials, and very few of these interventions and therapies have been the subject of systematic investigations of safety. Pragmatic issues challenge researchers working in this field. For example, although it might be possible to capture data on adverse events associated with a specific complementary medicine, it is difficult to determine accurately the community exposure to that medicine. In conventional medicine, prescription numbers are monitored by a central government agency, thus allowing a denominator to be found to determine the rate of adverse events in a given time. Until these issues can be addressed, specific analysis of risks to benefits will remain problematic in studying complementary medicines.

A major limitation of this review was the relevance of the evidence to the clinical practice of naturopathic and Western herbal medicine. The principal limitation is that the use of these nutritional supplements and herbal medicines reflects only a component of the whole-practice approach of naturopaths and Western herbalists. Although it is possible that the additions of the other components of practice—such as lifestyle and dietary assessment and advice, counselling and ancillary modalities (such as tactile therapies, aromatherapy and homeopathy)—might result in *decreased* effectiveness of proven nutritional supplements and herbal medicine, it is also possible that the combination of these components into an individualised management plan might lead to *increased* effectiveness. The assessment of this latter hypothesis needs to be considered a major priority in the research agenda for naturopathy and WHM.

Another limitation of this approach to assessing the benefits of naturopathy and WHM is that there is no evidence of the application of either the positive or negative literature to clinical practice. The converse is also true—that is, there is no evidence to suggest that this literature is *not* included in clinical practice. The review of educational curricula (reported in Chapter 5 of this report) suggests that all the major educational programs contain components in which such evidence should be reviewed. This is a critical issue—because evidence-based complementary medicine needs to be included in undergraduate and postgraduate curricula (and in continuing professional education) to ensure that the naturopathic and WHM professions remain up to date with the developing scientific base of their practice. Provided that current educational practice *does* include evidence-based information, there is a high likelihood, based on the positive effects of the supplements reviewed in the present study, that therapists trained in this way will be effective clinicians.

### **3.5 Evaluation of the literature on homeopathy**

Homeopathy is the most controversial of the therapeutic modalities that constitute naturopathic medical practice. Some homeopathic preparations are manufactured to a dilution which is beyond (or below) Avogadro's number. At such a dilution it can be argued that preparations no longer have any molecules of the active starting preparation, rendering them no better than placebo. Proponents of homeopathy argue that the clinical trial literature demonstrates the effectiveness of homeopathy in comparison with placebo. Opponents counter this by arguing that the clinical trial methodology must be at fault. Unfortunately, many homeopaths are of the opinion that clinical trial methodology cannot reflect the 'real world practice' of homeopathy, and reject any negative result from such trials.

In assessing these contrary views, two factors should be taken into account. First, it should be noted that not all homeopathic medicines are at dilutions beyond Avogadro's

number. Homeopathic ‘mother tinctures’ are generally, but not exclusively, prepared from herbal starting materials with an aqueous alcohol solvent manufactured in a ratio of one part of herbal material to 8–10 parts of solvent. These homeopathic ‘mother tinctures’, which form the ‘starting point’ of homeopathic prescribing, are far from being ‘ultra-dilute’ (beyond Avogadro’s number). It is therefore inappropriate to dismiss all homeopathy on the basis of an argument that condemns ‘ultra-dilute’ solutions. Secondly, evidence from rigorous clinical trials of homeopathic preparations (whatever the dilution) should not be dismissed out of hand without evaluating that evidence, and the rigour with which the trials were conducted.

### **3.5.1 Methods**

Searches were performed using both the Medline and EMBASE Drugs and Pharmacology databases and the free text word ‘homeopathy’ (or ‘homoeopathy’). RCTs between 2000 and 2003 were selected for inclusion in this review.

### **3.5.2 Results**

The searches identified 28 RCTs of homeopathy. These were acquired and evaluated for quality. A full description of the findings is provided in Appendix 3.6, and a complete summary of the papers in Appendix 3.7.

Of the 28 studies, eight (28%) demonstrated a positive result.

Of the 28 studies, 11 (39%) were of ‘high’ methodological quality, and three of these 11 (27%) showed a positive effect for homeopathy in the treatment of childhood diarrhoea, acute otitis media, and chemotherapy-induced stomatitis.

Of the 28 studies, 14 (50%) were of ‘medium’ methodological quality, and three of these 14 (21%) showed a positive effect for homeopathy in the treatment of plantar fasciitis, premenstrual syndrome, and seborrheic dermatitis.

Of the 28 studies, three (11%) were of ‘low’ methodological quality, and two of these three (66%) showed a positive effect for homeopathy in the treatment of high altitude mountain sickness and attention-deficit hyperactivity disorder (ADHD).

### **3.5.3 Discussion**

This review demonstrated evidence that several clinical conditions were positively affected by homeopathy in comparison with placebo. To determine the value of this evidence, it needs to be placed in the context of the systematic reviews and meta-analyses conducted in this field.

Kleijnen, Knipschild and ter Riet (1991) assessed 107 controlled studies for the efficacy of homeopathic intervention. These reviewers concluded that, despite the shortcomings of the research methods of individual trials, the meta-analysis demonstrated evidence for the efficacy of homeopathy. The authors emphasised the need for greater rigour when designing trials in homeopathy, with a clear description of methodology.

A meta-analysis by Linde et al. (1997) examined 89 of 186 identified trials. The selected trials covered more than 10,500 patients. The authors concluded that the results of the meta-analysis were “not compatible with the hypothesis that the clinical effects of homeopathy are completely due to placebo”. However, the study suggested that there are few, if any, implications for clinical practice because “there was insufficient evidence that homeopathy is clearly efficacious for any single clinical condition”.

Cucherat et al. (2000) provided a wide ranging literature review that identified all published and unpublished RCTs of homeopathy up to June 1998. Of 118 trials, only sixteen satisfied the inclusion criteria. These criteria included: (i) a comparison of homeopathic efficacy with placebo or a treatment without an active constituent; (ii) a dilution greater than one part in a million; and (iii) a clearly defined primary outcome. This represented 17 comparisons. Blinded and unblinded trials were included. The aim of this review was to demonstrate evidence of efficacy of homeopathic treatment in patients with any condition. The broad nature of this approach meant that conventional statistical methods used in meta-analysis were difficult to apply. To overcome this, significance levels (*p* values) were

combined. Using this approach, the null hypothesis that was tested was that homeopathic efficacy is not demonstrated in any one of the included trials. The combined  $p$  value for the 17 comparisons was 0.000036. This changed to 0.082 when only the five highest quality trials were included. In accordance with the null hypothesis, this result showed that in *at least one* trial homeopathic treatment was more efficacious than placebo. It did not demonstrate efficacy in all trials. Like Linde (1997), Cucherat et al. (2000) observed an inverse relationship between trial quality and significance. The authors concluded that the strength of the evidence supporting homeopathic efficacy was low due to the overall low quality of the trial designs and of reporting.

One of the major limitations of homeopathic research is the lack of replications of high quality positive trials. Duplication of results in clinical research is essential for the highest class of evidence. Until this duplication is undertaken, homeopathy will have difficulty in moving beyond the conclusion of Linde et al. (1997)—that the evidence is incompatible with the hypothesis that the clinical effects of homeopathy are completely due to placebo; however, the evidence is insufficient to confirm the effectiveness of homeopathy in any single clinical condition.

### 3.6 Summary of results

The focus of Chapter 3 was to assess the nutritional supplements and herbal medicines that are the primary ‘tools of trade’ of naturopaths and Western herbalists. The main findings from the review were as follows.

- There is a substantial number of citations on nutritional supplements and herbal medicines in the biomedical literature. The citation search for the top ten nutritional medicines and top ten herbal medicines on the Australian market resulted in 152,925 citations from 1966 to 2003.
- A review of the pharmacological literature on specific herbal medicines demonstrated that there is a substantial body of literature covering both popular and randomly selected herbal medicines.
- A time limited review of systematic reviews was undertaken in herbal medicine and nutritional supplements. This review assessed the results of more than 1,338 RCTs involving 375,462 subjects. The review demonstrated that there is clear evidence that herbal medicines and nutritional supplements provide real benefits in a broad range of diseases.
- A review of homeopathy demonstrated that a body of clinical research is building in this discipline area. A total of 28 RCTs was identified over the period 2000–2003. The systematic reviews of this discipline have concluded that it is unlikely that the observed effect is due to a placebo; however, further evidence is required to support the role of homeopathy in any specific condition.

### 3.7 Synthesis of review findings

This review of the benefits of nutritional substances, herbal medicines, and homeopathic medicines has demonstrated that a substantial body of scientific literature exists on nutritional supplements and herbal medicines. This ranges from basic laboratory and animal research to randomised controlled trials. A thorough evaluation of the nature of this evidence was undertaken using an objective methodology that can be replicated by other investigators. Pragmatic issues of time and resources meant that the review was limited to systematic reviews of randomised controlled trials published within a two year period (2001-2003). These reviews demonstrated that a number of nutritional supplements and herbal medicines have first class evidence for their effectiveness. It is reasonable to propose that a more exhaustive review of the totality of the literature would uncover additional examples of nutritional supplements and herbal medicines with such evidence.

A major limitation of the review was that this evaluation relates to components of the practice of these professions and does not represent the practices in their totality. There is

currently a lack of scientific evidence of the efficacy of the whole practice of these professions, and their overall efficacy when practised within their holistic paradigm can only be inferred by an assessment of some of their ‘tools of trade’. Despite this limitation, the findings of the review demonstrate that several of the tools of trade of naturopathy and WHM have substantiated benefits. Although it is possible that these benefits are negated or diminished by inappropriate practice of these professions, it is also possible that the addition of other elements of their practice enhances clinical effectiveness.

A review of the educational curricula of these professions (presented in Chapter 5) demonstrates that professional naturopaths and Western herbalists receive training in counselling, dietary and lifestyle prescriptions, and other health disciplines. Appropriate teaching of these subjects should include an assessment of the available scientific evidence on effectiveness and safety of herbal medicines and nutritional supplements. This study has demonstrated that such evidence is available, and therapists educated in this way can be expected to be effective clinicians.

A review of the benefits of homeopathy was included in this chapter because it is a scientifically controversial therapy. The results of a number of systematic reviews demonstrated that homeopathic treatment is more efficacious than placebo. However, there was concern that the overall quality of the trials was poor and that first class evidence for the treatment of any specific condition has not been established. The lack of replication of trials was a weakness in the body of evidence.

### 3.8 Recommendations

Based upon the findings of the above reviews, it is recommended that:

- the minimum educational standard for naturopathy and WHM should provide for up-to-date skills in: (i) literature acquisition and evaluation; (ii) critical reasoning and research methodologies; and (iii) evidence-based practice.
- the educational institutions involved in naturopathy and WHM should provide undergraduate and postgraduate courses in research methods to increase the skills base in research methodology and research interpretation;
- any regulatory schema should include a requirement for mandatory continuous professional education (CPE) in evidence-based complementary medicine because the evidence base is continually expanding;
- funding should be provided by state and federal governments for a systematic evaluation of the state of the evidence in herbal and nutritional medicine as a resource for health professionals;
- state and federal government bodies should encourage and fund research to assess the extent which naturopaths and WHM practitioners apply scientific evidence in their clinical practice;
- state and federal government bodies should encourage and fund further research, especially whole-practice research, in complementary medicine; and
- a national strategy should be developed to ensure that Australian complementary medicine researchers maintain a high standard in the overall quality of clinical trials in complementary medicine.
- State and federal bodies should ensure that naturopathic and WHM interventions with a high level of evidence be assessed for cost effectiveness as part of an evaluation of their potential for incorporation into the public health system.

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# 4. A Workforce Study of Naturopathy and Western Herbal Medicine Practitioners in Australia

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## 4.1 Introduction

Various forms of complementary and alternative medicine are being increasingly used by the Australian public (MacLennan, Wilson & Taylor 2002). Aromatherapy and Chinese medicine (CM) have exhibited steady growth. However, the growth of naturopathic practices is more difficult to monitor because of their eclectic nature (MacLennan, Wilson & Taylor 2002). Naturopathic practices include Western herbal medicine (WHM), homeopathy, tactile therapies (including massage), nutrition, and lifestyle advice. Our group has previously surveyed the Australian traditional Chinese medicine workforce (Bensoussan & Myers 1996). However, no comprehensive national study has been undertaken of the naturopathic and WHM component of the healthcare workforce.

The purpose of the current study was to develop an understanding of the nature of the practice of naturopathy and WHM, with particular reference to the characteristics of its workforce. Section 195-1 of the Act governing the goods and services tax (*A New Tax System (Goods and Services Tax) Act 1999*) states that GST-free services may be provided only by a 'recognised professional'. In the absence of statutory regulation, a 'recognised professional' is a member of a professional association that has uniform national registration requirements relating to the supply of the services. The present study surveyed naturopathic and WHM practitioners, irrespective of the professional association to which they belonged. This chapter reports on the characteristics of these professionals.

The findings of the Australian Naturopathy and Western Herbal Medicine Workforce Survey (Bensoussan, Myers, Wu & O'Connor 2004) are summarised here. Data were collected from practitioners of naturopathy and WHM. These data included:

- basic demographics;
- consultation fees;
- patient management and referral processes;
- private health fund rebate status;
- level of utilisation of Western medical diagnosis;
- nature and standards of education;
- compliance with current regulations (including prescribing and/or dispensing of drugs and poisons);
- adverse events;
- level of support for a system of uniform national accreditation; and

- extent and type of membership of professional associations.

## 4.2 Methodology

Before undertaking a national survey of practitioners across various representative professional associations, collaboration was sought with a major health insurance provider. Grand United Health Fund ('Grand United') was one of the first insurers to provide benefits to its members for complementary and alternative medicine (CAM) services, and it holds a comprehensive national database of practitioners. This method overcame a number of difficulties, including:

- the assumed extensive overlap in membership lists across the various peak professional associations;
- the anticipated reluctance of some professional associations regarding the merging of mailing lists to establish a central mailing list;
- the absence of incentives for professional associations to encourage participation by their members (due, in part, to competition between the peak professional associations); and
- the potential for bias that would have existed if individual professional associations had commissioned surveys of only their own members.

The list of practitioner providers held by Grand United was revised and, whenever possible, updated with membership lists provided by relevant professional associations. Four categories of providers were available on the Grand United list: herbalists, naturopaths, homeopaths, and nutritionists. Although the present project did not set out to collect data on homeopaths or nutritionists, these practitioners were included in the initial mailout to cover cases in which a naturopath might be listed only as a 'homeopathic provider'. This survey was interested in homeopaths and nutritionists only if they also practised as naturopaths, or if their practices incorporated at least two naturopathic modalities. Practitioners identified by the single modality of 'massage' were not surveyed.

Grand United undertook a direct mailout to practitioners. Approximately three weeks later, practitioners were sent a reminder postcard encouraging them to complete the survey instrument.

### 4.2.1 The questionnaire

A comprehensive questionnaire was developed in consultation with the National Herbalists Association of Australia and the Federation of Natural and Traditional Therapists (see Appendix 4.1). This contained 84 items over eight pages and was designed to address the lack of available data on the characteristics of the naturopathic and WHM workforce. The survey instrument was piloted with a sample of 13 practitioners in New South Wales (NSW), and was then modified in response to feedback from the pilot. The survey required no practitioner-identifying data, and included an accompanying explanatory letter and a reply-paid envelope. The Human Ethics Committee, University of Western Sydney, granted ethics approval for the study.

### 4.2.2 Response rate

In total, 3,540 survey forms were mailed out to practitioners. Of these, 423 surveys were returned to sender and the practitioners could not be contacted to resend the survey. This left an effective mailing list of 3,117 practitioners.

Verbal reports suggested that a number of practitioners, despite being on professional association mailing lists, were not currently in practice. To check the accuracy of the mailing list, 100 names were randomly selected (after returns to sender had been excluded), and efforts were made to make direct telephone contact with these practitioners. Telephone numbers were checked with professional association listings, and with published telephone directories. Over a two week period of continuous attempted contact (including at least five attempted calls during day, night, and weekends), 76 were contacted: 73 (96%) were currently



practising, and three (4%) were no longer practising. Of the remaining practitioners who could not be contacted (24), it was assumed that 50% were out of practice.

Therefore, of 3,117 practitioners on the mailing list it was assumed that 16% were not currently in practice. This generated an active mailing list of 2,618 practitioners. The survey responses totalled 859—providing an initial response rate of 33%.

This initial response rate was considered to be artificially low—as a result of the inclusive enrolment strategy that had been undertaken, whereby surveys were sent to homeopaths and nutritional practitioners who might not be naturopaths or Western herbalists. A second response rate was therefore calculated—compensating for the over-inclusive enrolment. During analysis of the data, practitioners who indicated that they practised only as homeopaths, nutritionists, or massage therapists were removed from the final database (64 cases). An adjusted response rate was calculated, with these cases removed from the final database (numerator), and with the remaining number of homeopaths and nutritionists who were sent a survey form removed from the initial mailout count (denominator). An effective mailing list of 1,778 herbalists and naturopaths was generated, which allowed for 16% not in practice. Calculated on 795 responses, the adjusted response rate was 44.7%.

This response rate is similar to the response rate obtained for the above-mentioned workforce survey of traditional Chinese medicine practitioners (Bensoussan & Myers 1996). The overall response rate was deemed adequate for analysis, and the database thus established was considered to be satisfactory for the purposes of drawing conclusions about the Australian naturopathic and WHM workforce.

## 4.3 Demographics

### 4.3.1 Who practices naturopathy and WHM?

Practitioners were asked which of a number of titles best described their practice (Question 3). Responses are summarised as follows:

- 489 practitioners (61.5%) identified ‘herbalism’ as one of their practice descriptors;
- 604 practitioners (76.0%) identified ‘naturopathy’ as one of their practice descriptors; and
- 54 (6.8%) respondents were also members of conventional and registered health professions: three were qualified medical specialists, twelve were general medical practitioners, ten were pharmacists, 28 were nurses, and one was a physiotherapist.

Table 4.1 summarises the descriptors selected by respondents to describe their practices. The table also illustrates the range of allied health practitioners who used one or more of the modalities included in naturopathic practice. Most practitioners (76.1%) identified more than one title to describe their practice.

Of 604 practitioners who practised naturopathy, 351 (58.1%) also described their practices as using herbal medicine. Additional titles selected by herbalists and naturopaths (by self-identification in Question 3) are summarised in Table 4.1. This indicates the extent to which these professions overlapped in the modalities practised—with naturopaths including herbal medicine in their practice up to 44% of the time, and herbalists regularly practising both homeopathy and nutritional medicine (see Table 4.2).

**Table 4.1 Titles selected by respondents to describe their practices**

Nature of practice	Number (total 795); percentages in brackets
Herbalist	489 (61.5%)
Naturopath	604 (76.0%)
Homeopath	208 (26.2%)
Nutritionist	315 (39.6%)
Massage therapist	277 (34.8%)
Aromatherapist	32 (4.0%)
Bach flowers practitioner	175 (22.0%)
Meditation/relaxation (including yoga, qi gong)	50 (6.3%)
Medical specialist	3 (0.4%)
General medical practitioner	12 (1.5%)
Pharmacist	10 (1.3%)
Chiropractor	6 (0.8%)
Osteopath	9 (1.1%)
Physiotherapist	1 (0.1%)
Nurse	28 (3.5%)
Counsellor	59 (7.4%)
Psychologist	5 (0.6%)
Traditional Chinese medicine practitioner	20 (2.5%)
Acupuncturist	41 (5.2%)
Other	141 (17.7%)
Missing	11 (1.4%)

**Table 4.2 Practice time devoted to disciplines**

Practice devoted to (Q4)	Herbalists (Q3)	Naturopath (Q3)	Total (Q3)
Herbal medicine	53.1 ± 27.1	43.7 ± 25.6	46.7 ± 27.3
Nutritional medicine	41.7 ± 26.0	42.5 ± 25.7	41.6 ± 25.9
Massage and tactile therapies	28.9 ± 24.5	31.0 ± 24.1	31.6 ± 25.4
Homeopathy	22.4 ± 23.7	24.6 ± 23.8	26.2 ± 26.4
Other *	37.5 ± 27.9	36.0 ± 27.0	38.6 ± 28.2

Notes:

1. Numbers represent mean percentages of practice time (with standard deviations in brackets)
2. \* Other includes iridology and aromatherapy

### 4.3.2 Basic demographics of practitioners

Questions 73 and 74 sought information on the age and gender of respondents. The average (mean) age of the naturopathic and WHM workforce was 44.1 years (standard deviation 10.4 years). Females made up 76.1% of the workforce.

Distribution of practitioners by location (Question 1) is summarised in Table 4.3 and Figure 4.1. Approximately twice as many practitioners practised in metropolitan areas as practised in country areas.

**Table 4.3 Numbers of practitioners by location**

<b>Location</b>	<b>Herbalists</b>	<b>Naturopaths</b>	<b>Total</b>
<b>NSW and ACT</b>			
Sydney Metropolitan area	125 (25.6%)	132 (21.9)	192 (24.2)
NSW Country	70 (14.3%)	60 (9.9)	109 (13.7)
ACT	9 (1.8%)	7 (1.2)	12 (1.5)
Total NSW and ACT	204 (41.7%)	199 (32.9)	313 (39.4)
<b>Victoria</b>			
Melbourne Metro. area	71 (14.5%)	121 (20.0)	139 (17.5)
Vic Country	26 (5.3%)	41 (6.8)	45 (5.7)
Total Victoria	97 (19.8%)	162 (26.8)	184 (23.2)
<b>Queensland</b>			
Brisbane Metropolitan area	50 (10.2%)	66 (10.9)	76 (9.6)
Queensland Country	51 (10.4%)	65 (10.8)	82 (10.3)
Total Queensland	101 (20.7%)	131 (21.7)	158 (19.9)
<b>South Australia</b>			
Adelaide Metropolitan area	25 (5.1%)	34 (5.6)	36 (4.5)
SA Country	3 (0.6%)	6 (1.0)	6 (0.8)
Total South Australia	28 (5.7%)	40 (6.6)	42 (5.3)
<b>Western Australia</b>			
Perth Metropolitan area	19 (3.9%)	27 (4.5)	29 (3.6)
WA Country	4 (0.8%)	6 (1.0)	8 (1.0)
Total Western Australia	23 (4.7%)	33 (5.5)	37 (4.7)
<b>Tasmania</b>			
Hobart Metropolitan area		1 (0.2)	1 (0.1)
Tasmania Country	3 (0.6%)	1 (0.2)	3 (0.4)
Total Tasmania	3 (0.6%)	2 (0.3)	4 (0.5)
<b>Northern Territory</b>			
Darwin Metropolitan area			
NT Country			1 (0.1)
Total Northern Territory			1 (0.1)
Missing	33 (6.7%)	37 (6.2)	56 (7.0)
<b>Totals</b>	<b>489 (100%)</b>	<b>604 (100%)</b>	<b>795 (100%)</b>

**Figure 4.1 Numbers of practitioners by location (state, rural, metropolitan)**

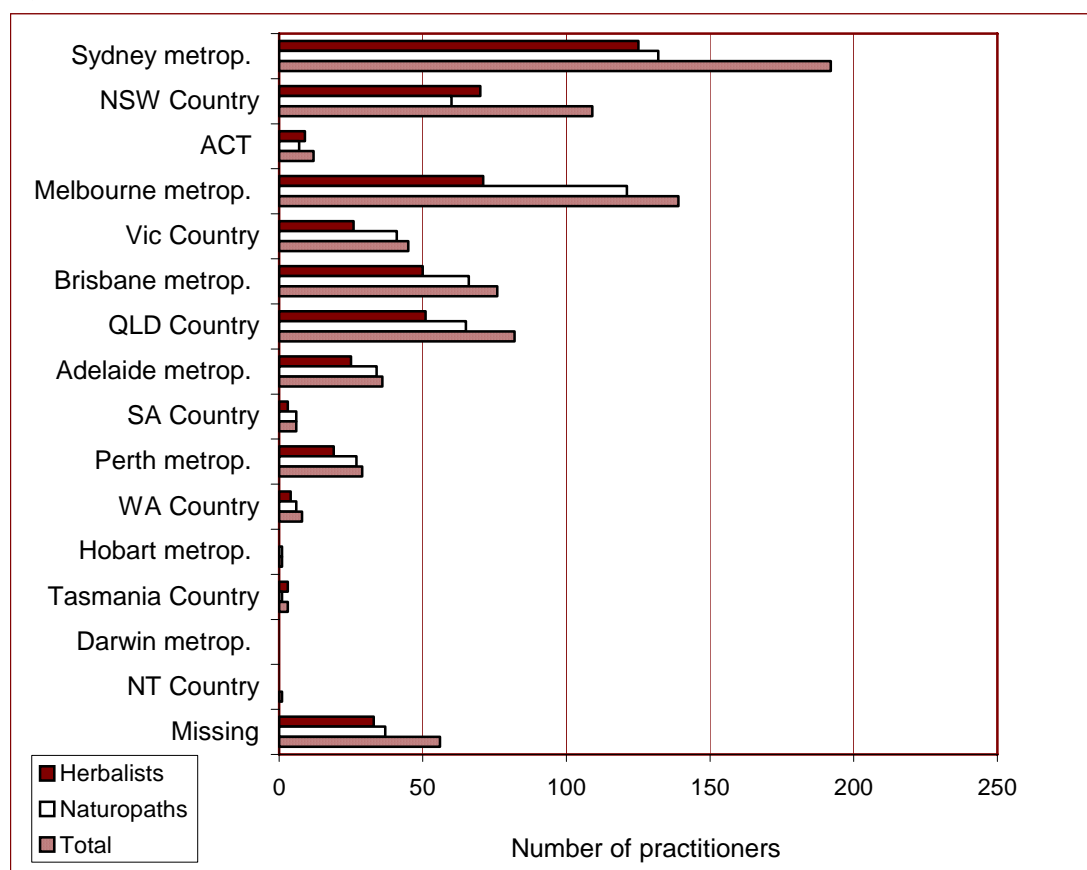


Table 4.4 identifies the number of practice locations at which practitioners saw patients. One in four practitioners used two different practice locations.

**Table 4.4 Number of practice locations**

Number of practice locations	Herbalists	Naturopaths	Total
1	323 (66.1%)	391 (64.7%)	515 (64.8%)
2	118 (24.1%)	161 (26.7%)	202 (25.4%)
3	22 (4.5%)	23 (3.8%)	31 (3.9%)
4 or more	10 (2.0%)	17 (2.8%)	18 (2.3%)
Missing	16 (3.3%)	12 (2.0%)	29 (3.6%)
<b>Total</b>	<b>489 (100%)</b>	<b>604 (100%)</b>	<b>795 (100%)</b>

## 4.4 Nature of practice

### 4.4.1 Work practices and consultations

Practitioners were asked a range of questions about time spent in various aspects of their practice (Questions 7-9).

Practitioners undertook an average of 22.3 naturopathic or herbal medicine consultations per week, although this figure varied widely from only one consultation per week to 250 consultations per week. The hours spent in clinical practice, and the duration of initial consultations and follow-up consultations, are reported in Table 4.5. To calculate the average (mean) hours worked in clinical practice, including initial and follow-up

consultations, midpoints were used for the time interval categories in Questions 7 and 9 in the workforce survey.

**Table 4.5 Average hours in practice per week, with duration of initial and follow-up consultations**

	<b>Herbalists</b>	<b>Naturopaths</b>	<b>Total</b>
Hours spent in clinical practice per week	23.9 ± 13.3 hours	24.2 ± 13.1 hours	23.8 ± 13.3 hours
Face-to-face contact—initial consultation	22.7 ± 5.9 minutes	23.0 ± 5.7 minutes	23.0 ± 5.8 minutes
Face-to-face contact—follow-up consultation	13.1 ± 6.2 minutes	12.9 ± 6.0 minutes	13.4 ± 6.3 minutes

Note: Numbers above show average times and standard deviations

The mean number of consultations per year for naturopathic and WHM practitioners was calculated by multiplying consultations per week for these groups by 48 weeks. This figure was used to estimate the total consultations per year provided by the naturopathic and WHM workforce (mean total yearly consultations multiplied by estimated number of practitioners). The extrapolated figure revealed that the workforce as a whole was expected to undertake approximately 1,900,981 consultations in 2003. This figure is consistent with other estimates made through patient surveys (MacLennan, Wilson & Taylor 2002).

**Table 4.6 Estimated total number of consultations performed per year**

<b>Practitioner group</b>	<b>Average total consultations per year per practitioner (responders only)</b>	<b>Estimate of total consultations per year for workforce (extrapolated to whole workforce)</b>
Herbalists	1088.4 ± 1128.6 *	—
Naturopaths	1097.7 ± 1167.6 *	—
<b>Total</b>	<b>1069.0 ± 1129.4 *</b>	<b>1,900,981</b>

Note: \*With removal of 5% of extreme values, the standard deviation is reduced to 628.8 for the total workforce

#### 4.4.2 Diagnostic tests used by practitioners

##### Western diagnostic tests

Practitioners were asked to about their use of *Western medical tests* (such as pathology and radiology) to guide clinical practice (Question 10). Results were as follows.

- Diagnostic tests (either self-initiated or provided by patients or colleagues) were used by 38.0% of all practitioners to guide their clinical practice 50% or more of the time.
- 47.7% of practitioners claimed to use diagnostic tests ‘occasionally’.

##### Western medical diagnoses

Practitioners were also asked about their use of *Western medical diagnoses* (Question 11). Results were as follows:

- 47.2% of practitioners reported that they used Western medical diagnoses to guide their naturopathic or herbal medicine treatments in 50% or more of patient cases; and
- 45.2% claimed to use Western medical diagnoses ‘occasionally’.

##### Diagnostic tests specific to naturopathic practice

Diagnostic tests *specific to naturopathic practice* were used more widely. For example:

- 80.6% of practitioners indicated that they used iris diagnosis in their practice; and

- 62% performed physical assessments.

The use of these diagnostic tools or methods in clinical practice is reported in Table 4.7.

**Table 4.7 Numbers of practitioners using various diagnostic tools or methods in their practices**

Diagnostic tools or methods	Herbalists (N = 489)	Naturopaths (N = 604)	Total (N = 795)
<b>Physical examinations</b>			
Examination of blood pressure, auscultation, palpation, etc.)	289 (59.1%)	399 (66.1%)	493 (62.0%)
<b>Pathological testing</b>			
Functional pathology (e.g., salivary tests, stool analysis)	109 (22.3%)	146 (24.2%)	177 (22.3%)
Hair testing	121 (24.7%)	140 (23.2%)	172 (21.6%)
<b>Traditional testing</b>			
Iris diagnosis	412 (84.3%)	524 (86.8%)	641 (80.6%)
Tongue diagnosis	310 (63.4%)	363 (60.1%)	454 (57.1%)
Oriental diagnosis	49 (10.1%)	50 (8.3%)	68 (8.6%)
Face diagnosis	82 (16.8%)	102 (16.9%)	130 (16.4%)
<b>Alternative testing</b>			
Electro-dermal screening (e.g., LISTEN, Vega)	51 (10.4%)	79 (13.1%)	94 (11.8%)
Muscle-testing	100 (20.4%)	117 (19.4%)	160 (20.1%)
Haemaview/live blood analysis	52 (10.6%)	77 (12.7%)	95 (11.9%)
Other	108 (22.1%)	136 (22.5%)	172 (21.6%)
Missing	8 (1.6%)	4 (0.7%)	14 (1.8%)

#### 4.4.3 Record-keeping by practitioners

Responses to questions on record-keeping of patient consultations (Questions 13–15) indicated that 99.4% of practitioners made notes on each new patient consultation and that 98.4% of practitioners made notes on each and every subsequent visit.

Records and notes were kept on:

- paper or cards alone (77.2% of practitioners);
- a combination of paper/cards and computers (19.5% of practitioners); and
- computers alone (2.6% of practitioners).

#### 4.4.4 Referrals between naturopathic/WHM practice and other practices

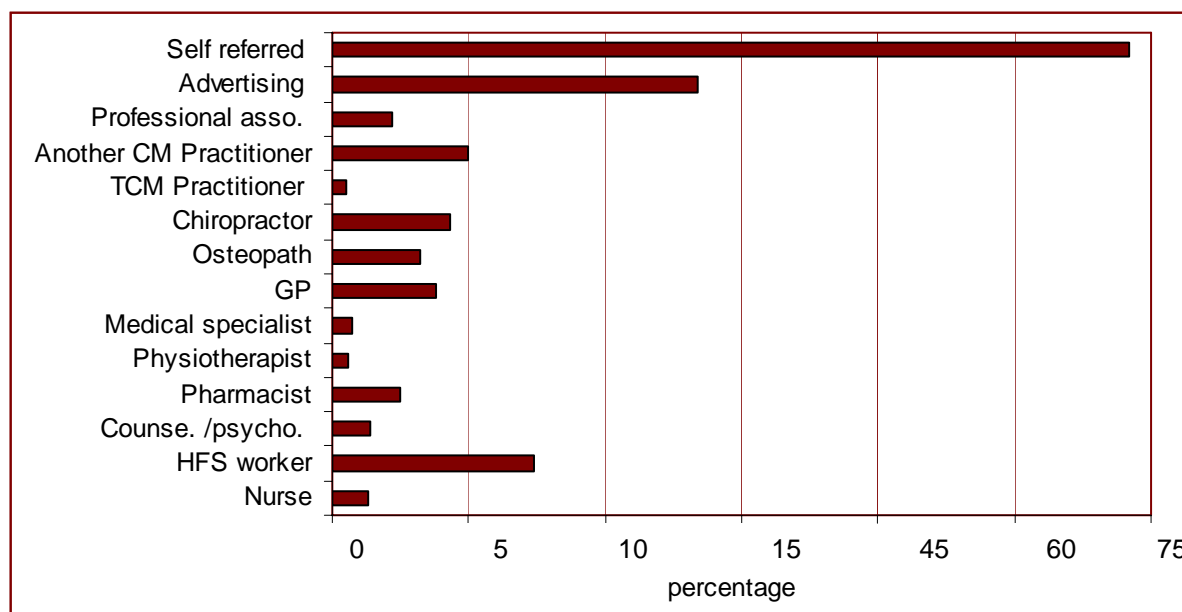
##### Sources of referrals

Practitioners were asked to identify the *sources* of patient referral, and how frequently their patients were referred from each source (Questions 30–44). The referral patterns to naturopathic and WHM practitioners are summarised in Table 4.8 and Figure 4.2.

**Table 4.8 Referral sources and frequency of referral from each source**

Referral source	Never or almost never	Occasionally	Referral in about half the cases	Frequent referral	Always or almost always referral
Self referred (including friends, other patients)	4 (0.5%)	91 (11.4%)	103 (13.0%)	353 (44.4%)	237(29.8%)
Advertising (including 'Yellow Pages')	170 (21.4%)	370 (46.5%)	93 (11.7%)	86 (10.8%)	21 (2.6%)
Professional association	400 (50.3%)	286 (36.0%)	15 (1.9%)	15 (1.9%)	2 (0.3%)
Another complementary medicine practitioner	150 (18.9%)	502 (63.1%)	38 (4.8%)	35 (4.4%)	5 (0.6%)
Traditional Chinese medical practitioner (including herbs and acupuncture)	536 (67.4%)	108 (13.6%)	3 (0.4%)	3 (0.4%)	1 (0.1%)
Chiropractor	340 (42.8%)	297 (37.4%)	21 (2.6%)	28 (3.5%)	6 (0.8%)
Osteopath	417 (52.5%)	233 (29.3%)	14 (1.8%)	19 (2.4%)	6 (0.8%)
General medical practitioner	309 (38.9%)	349 (43.9%)	21 (2.6%)	24 (3.0%)	6 (0.8%)
Medical specialist	534 (67.2%)	112 (14.1%)	7 (0.9%)	5 (0.6%)	1 (0.1%)
Physiotherapist	504 (63.4%)	156 (19.6%)	11 (1.4%)	5 (0.6%)	0
Pharmacist	463 (58.2%)	181 (22.8%)	12 (1.5%)	19 (2.4%)	1 (0.1%)
Counsellor or psychologist	345 (43.4%)	326 (41.0%)	14 (1.8%)	9 (1.1%)	2 (0.3%)
Health food store worker	236 (29.7%)	384 (48.3%)	34 (4.3%)	51 (6.4%)	8 (1.0%)
Nurse	420 (52.8%)	238 (29.9%)	15 (1.9%)	10 (1.3%)	0

**Figure 4.2 Percentage of referral sources frequently, always, or almost always used**



The majority of practitioners (74.2%) indicated that their patients were frequently or almost always referred by word of mouth, which includes referral from other patients and

friends. A smaller proportion (43.9%) of practitioners indicated that they occasionally received referrals from general practitioners (GPs), and a further 14.1% stated that they occasionally received referrals from medical specialists.

Approximately one third of practitioners (30.3%) worked in a multidisciplinary clinical environment, and 7.2% of respondents indicated that their multidisciplinary team included a GP or medical specialist.

### Forward referrals

*Forward referral* to another health practitioner was not as common. Only 7.4% of practitioners stated that they referred on to a GP in about half or more of cases, whereas 72.8% of practitioners stated that they ‘occasionally’ referred their patients on to GPs. Instances of forward referral are summarised in Table 4.9.

**Table 4.9 Onward referral destinations and frequency of referrals**

Onward referral destination	Never or almost never	Occasionally	Referral in about half the cases	Frequent referral	Always or almost always referral
Another complementary medicine practitioner	113 (14.2%)	558 (70.2%)	29 (3.6%)	24 (3.0%)	6 (0.8%)
Chinese medicine practitioner (including herbs and acupuncture)	324 (40.8%)	321 (40.4%)	12 (1.5%)	19 (2.4%)	1 (0.1%)
Chiropractor	235 (29.6%)	397 (49.9%)	39 (4.9%)	27 (3.4%)	5 (0.6%)
Osteopath	223 (28.1%)	408 (51.3%)	45 (5.7%)	26 (3.3%)	3 (0.4%)
General medical practitioner	61 (7.7%)	579 (72.8%)	59 (7.4%)	51 (6.4%)	1 (0.1%)
Medical specialist	386 (48.6%)	251 (31.6%)	15 (1.9%)	21 (2.6%)	0
Physiotherapist	437 (55.0%)	201 (25.3%)	7 (0.9%)	4 (0.5%)	0
Pharmacist	494 (62.1%)	128 (16.1%)	5 (0.6%)	5 (0.6%)	1 (0.1%)
Counsellor or psychologist	142 (17.9%)	512 (64.4%)	37 (4.7%)	23 (2.9%)	1 (0.1%)
Health food store worker	530 (66.7%)	91 (11.4%)	12 (1.5%)	8 (1.0%)	1 (0.1%)
Nurse	588 (74.0%)	37 (4.7%)	2 (0.3%)	1 (0.1%)	0

### 4.4.5 Clinical experience

Practitioners were asked how many years of full time clinical experience they had had (Question 66). Clinical experience in naturopathy and WHM varied widely—ranging from recent graduates with little experience to practitioners with 47 years of clinical experience. The average (mean) duration of clinical experience of respondents is summarised in Table 4.10.



**Table 4.10 Average (mean) clinical experience by nature of practice**

	<b>Herbalists (N = 485)</b>	<b>Naturopaths (N = 602)</b>	<b>Total (N = 790)</b>
Either full-time or part-time (Q64)*	8.8 years (SD 6.7)	8.7 years (SD 7.1)	9.1 years (SD 7.3)
Condensed full-time equivalent (Q65)*	6.6 years (SD 5.8)	6.6 years (SD 6.2)	6.7 years (SD 6.1)

Notes:

1. Means of experience are expressed in years (standard deviations in brackets)
2. \* Questions refer to items on Workforce Survey. For conversion of part-time to equivalent full-time a mean ratio of 0.75 was calculated for the whole workforce.

#### 4.4.6 Cost of treatment and practitioner income

Practitioners were asked to indicate their average fees for initial and follow-up consultations (Questions 16 and 17), the gross annual income generated by their natural therapy practice (Question 75), and the percentage of their gross total income (all sources) derived from their natural therapy practice (Question 77).

The average fee charged for an initial consultation was AUD\$61.70 (SD \$26.50) with little variation between naturopaths and herbalists (Table 4.11). The average fee charged for follow-up consultations was \$42.10 (SD \$17.00). Using the average fee of \$45.00 per consultation (allowing for initial consultation fees), the naturopathic and herbal workforce turned over approximately \$85 million in 2003 in consultation fees (based on previous estimate of 1,900,981 consultations; see Table 4.6). This does not include the cost of herbal products, nutritional supplements, and homeopathic medicines that might be prescribed by the practitioner during the consultation and dispensed directly to the patient.

**Table 4.11 Incomes by nature of practice**

	<b>Herbalists (Q3)</b>	<b>Naturopath (Q3)</b>	<b>Total</b>
Average (mean) initial consultation fee	\$59.80 (SD 23.60)	\$61.20 (SD 23.90)	\$61.70 (SD 26.50)
Average (mean) follow-up consultation fee	\$41.20 (SD 14.90)	\$41.50 (SD 13.60)	\$42.10 (SD 15.20)

Note: Numbers are expressed in Australian dollars (AUD\$)

The overall income generated from naturopathic or herbal medicine practice is summarised in Table 4.12, along with the percentage that this represents of gross practitioner income. In summary, from their WHM or naturopathic practices:

- 21.6% of the workforce stated that they earned less than \$20,000;
- 44.6% stated that they earned \$20,000–\$60,000; and
- approximately 4% of practitioners stated that they earned more than \$100,000.

**Table 4.12 Income earnings and percentage of gross income from practice by nature of practice**

	<b>Herbalists</b>	<b>Naturopaths</b>	<b>Total</b>
<b>Income</b>			
Less than \$20,000	105 (21.5%)	118 (19.5%)	172 (21.6%)
\$20,001–40,000	81 (16.6%)	104 (17.2%)	137 (17.2%)
\$40,001–60,000	137 (28.0%)	171 (28.3%)	218 (27.4%)
\$60,001–80,000	51 (10.4%)	56 (9.3%)	72 (9.1%)
\$80,001–100,000	30 (6.1%)	46 (7.6%)	55 (6.9%)
More than \$100,000	13 (2.7%)	25 (4.1%)	30 (3.8%)
<b>Percentage of gross income</b>			
Less than 20%	74 (15.1%)	83 (13.7%)	129 (16.2%)
21–40%	65 (13.3%)	81 (13.4%)	99 (12.5%)
41–60%	65 (13.3%)	83 (13.7%)	114 (14.3%)
61–80%	72 (14.7%)	83 (13.7%)	106 (13.3%)
81–100%	199 (40.7%)	258 (42.7%)	323 (40.6%)

When asked what percentage of gross total income was derived from this practice, 16.2% stated that their income represented 20% or less of their gross earnings, with 40.6% indicating that it represented more than 80% of their gross earnings. These figures are also summarised in Table 4.12. It is of interest that approximately half (47.5%) of responding practitioners felt that they were fully employed in their practice. At the time of the survey, 68% of practitioners were registered with the Australian Taxation Office for the purposes of collecting goods & services tax (GST)—which is obligatory if business income exceeds \$50,000 per annum.

## **4.5 Safety in practice**

### **4.5.1 Adverse events in WHM and naturopathy**

Five questions in the workforce survey requested information on adverse events. Three main questions (Questions 18, 19, and 20) listed common and adverse events related to herbal medicines, nutritional medicines, and homeopathic medicines respectively. These data are reported in Chapter 2 (section 2.6.2) along with information on the agencies to which naturopaths and WHM practitioners reported adverse events.

### **4.5.2 Use of restricted herbs**

Practitioners were asked whether they prescribed any of a list of specified herbs in any preparation (Question 23). The list included several substances that are restricted due to their inclusion in the Standard for Uniform Scheduling of Drugs and Poisons that is adopted in state and territory drugs and poisons legislation. These substances and their frequency of usage are identified in Table 4.13. The data indicate that practitioners occasionally used a number of scheduled substances—suggesting either a lack of awareness of the legal restrictions that apply or a lack of willingness to comply with the law. The high use of kava might be a reflection of the fact that restrictions on the availability of kava have only recently been introduced.

**Table 4.13 Selected scheduled (restricted) herbs prescribed for oral and external use by practitioners**

Substance	External use	Oral use
<i>Aconitum</i> spp (Aconite, Monkshood, Wolfsbane)	9 (1.1%)	22 (2.8%)
<i>Acorus calamus</i> (Sweet flag or Sweet sedge)	2 (0.3%)	5 (0.6%)
<i>Aristolochia</i> spp (Chinese fairy vine)	2 (0.3%)	1 (0.1%)
<i>Atropa belladonna</i> (Deadly nightshade)	1 (0.1%)	14 (1.8%)
<i>Borago officinalis</i> (Borage)	13 (1.6%)	20 (2.5%)
<i>Colchicum autumnale</i> (Autumn crocus or Meadow saffron)	2 (0.3%)	14 (1.8%)
<i>Convallaria</i> spp (Lily of the valley)	3 (0.4%)	16 (2.0%)
<i>Datura</i> spp (Jimson weed or Thorn apple)	2 (0.3%)	4 (0.5%)
<i>Digitalis</i> (Foxglove)	2 (0.2%)	12 (1.5%)
<i>Ephedra</i> spp (Ma huang)	1 (0.1%)	32 (4.0%)
<i>Gelsemium</i> spp (Yellow jasmine)	1 (0.1%)	19 (2.4%)
<i>Hyoscyamus niger</i> (Henbane)	1 (0.1%)	8 (1.0%)
<i>Piper methysticum</i> (Kava)	10 (1.3%)	189 (23.8%)
<i>Lobelia inflata</i> (Indian tobacco)	5 (0.6%)	32 (4.0%)
<i>Mandragora officinalis</i> (Mandrake)	1 (0.1%)	3 (0.4%)
<i>Melilotus officinalis</i> (Sweet clover)	1 (0.1%)	25 (3.1%)
<i>Pulmonaria</i> spp (includes Lungwort)	1 (0.1%)	13 (1.6%)
<i>Rauwolfia</i> spp (Indian snake root)	1 (0.1%)	8 (1.0%)
<i>Senecio</i> spp	1 (0.1%)	5 (0.6%)
<i>Symphytum</i> spp (Comfrey)	356 (44.8%)	26 (3.3%)
<i>Tanacetum vulgare</i> (Tansy)	6 (0.8%)	47 (5.9%)
<i>Tussilago farfara</i> (Coltsfoot)	4 (0.5%)	31 (3.9%)

Practitioners were asked to indicate if there were herbs, homeopathics, or nutritional medicines which are currently restricted from use, but which practitioners believed would be beneficial in their practices (Question 24). Such substances (including, for example, ephedra and coltsfoot) were identified by 69.6% of practitioners. A significant majority (82.3%) of practitioners were of the opinion that suitably qualified practitioners should be granted the legal right to prescribe herbal or homeopathic medicines that are currently restricted by the scheduling arrangements.

Approximately one third of practitioners (33.4%) indicated that they usually reported adverse events. However, fewer (27.1%) were aware of the Australian procedures for reporting adverse drug reactions. Practitioners indicated that adverse events related to products were usually reported to manufacturers (21.7%), suppliers (13.7%), professional associations (12.9%), the Australian Drug Advisory Committee (4.0%), the Therapeutic Goods Administration (1.2%), or other groups (2.8%), including mentors, professional supervisors, and other healthcare providers.

### 4.5.3 Form and labelling of preparations

Although nutritional medicines are usually prepared commercially, there is variation in the methods of preparation and dispensing of herbal medicines and homeopathic medicines. Question 26 asked practitioners which forms of herbal or homeopathic medicines they prescribed. Approximately one half of practitioners indicated that they mixed or combined 90% or more of their herbal medicines in their own clinics using standardised source material provided by suppliers. The forms of herbal medicines and homeopathics most commonly prescribed are listed in Table 4.14.

**Table 4.14 Forms of herbal and homeopathic medicines prescribed by practitioners**

Forms	Herbal medicines	Homeopathics
Tablets/capsules/pills	542 (68.2%)	144 (18.1%)
Pillules	24 (3.0%)	271 (34.1%)
Tea infusions	394 (49.6%)	4 (0.5%)
Extracts/tinctures	655 (82.4%)	33 (4.2%)
Creams	502 (63.1%)	114 (14.3%)
Pessaries	104 (13.1%)	14 (1.8%)
Granules/powders	159 (20.0%)	10 (1.3%)
Raw herb decoctions	102 (12.8%)	1 (0.1%)
Glycerol preparations	269 (33.8%)	5 (0.5%)
Liquid single homeopathics	19 (2.4%)	313 (39.4%)
Liquid homeopathic complexes	39 (4.9%)	351 (44.2%)
Radionically prepared homeopathics	7 (0.9%)	91 (11.4%)

Table 4.15 summarises the frequency with which various forms of medicines are prepared from raw materials by individual practitioners. Table 4.16 summarises the details published on dispensing labels with regard to any herbal or homeopathic medicines prepared and dispensed from private practices.

**Table 4.15 Frequency with which various forms of natural medicines are prepared from raw materials by individual practitioners**

Form	Never	Occasionally	Half the time	Frequently	Always
Herbal extracts or tinctures	530 (66.7%)	125 (15.7%)	12 (1.5%)	33 (4.2%)	37 (4.7%)
Infused oils	506 (63.6%)	146 (18.4%)	5 (0.6%)	13 (1.6%)	9 (1.1%)
Pessaries	590 (74.2%)	33 (4.2%)	0	3 (0.4%)	7 (0.9%)
Creams or ointments	324 (40.8%)	244 (30.7%)	38 (4.8%)	76 (9.6%)	40 (5.0%)
Tablets	625 (78.6%)	21 (2.6%)	4 (0.5%)	8 (1.0%)	4 (0.5%)
Homeopathics	551 (69.3%)	77 (9.7%)	9 (1.1%)	23 (2.9%)	25 (3.1%)

**Table 4.16 Information recorded on labels of herbal or homeopathic medicines prepared and dispensed by practitioners**

Information	Herbal medicines	Homeopathics
No label	1 (0.1%)	0
Clinic name	516 (60.9%)	281 (35.3%)
Practitioner name	565 (77.1%)	260 (32.7%)
Patient name	672 (84.5%)	350 (44.0%)
Date	671 (84.4%)	357 (44.9%)
Formula name	444 (55.8%)	324 (40.8%)
Partial list of ingredients	80 (10.1%)	48 (6.0%)
Full list of ingredients	249 (31.3%)	172 (21.6%)
Proportions of ingredients	67 (8.4%)	29 (3.6%)
Exact amount of ingredients	78 (9.8%)	28 (3.5%)
Potency	86 (10.8%)	301 (37.9%)
Dosage regimen	680 (85.5%)	367 (46.2%)
Storage details	461 (58.0%)	207 (26.0%)
Expiry date	453 (57.0%)	186 (23.4%)
Batch number	193 (24.3%)	78 (9.8%)
Clinic contact details	552 (69.4%)	288 (36.2%)
Australian Business Number	123 (15.5%)	53 (6.7%)

## 4.6 Education

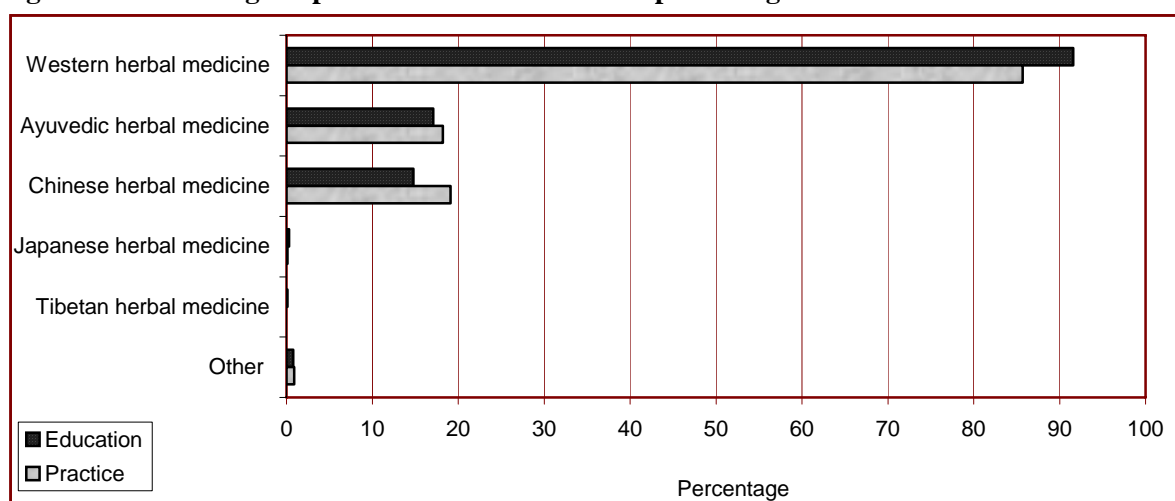
### 4.6.1 Length and type of education

Practitioners were asked the tradition of herbal medicine in which they had been educated, and the tradition in which they now practised most frequently (Question 5). Responses are summarised in Table 4.17. Figure 4.3 indicates that, although there was an emphasis on WHM training, a significant proportion of practitioners were educated in, and practised, other traditions of herbal medicine—particularly ayurvedic (18.2%) and Chinese herbal medicine (19.1%).

**Table 4.17 Number of practitioners educated in various traditions of herbal medicine and tradition most frequently practised**

Tradition of herbal medicine	Education	Practice
Western herbal medicine	728 (91.6 %)	681 (85.7 %)
Ayurvedic herbal medicine	136 (17.1 %)	145 (18.2 %)
Chinese herbal medicine	118 (14.8 %)	152 (19.1 %)
Kampo (Japanese herbal medicine %)	2 (0.3 %)	1 (0.1 %)
Tibetan herbal medicine	1 (0.1 %)	0
Other	6 (0.8 %)	7 (0.9 %)
Not applicable	35 (4.4 %)	

**Figure 4.3 Percentage of practitioners educated and practising in various traditions**



The reported duration of undergraduate study for first herbal or naturopathic qualification for practitioners ranged from six months to six years, with an average of 3.1 years (see Table 4.18). Approximately 31% of herbal and naturopathic practitioners held no naturopathic qualifications, with approximately one third of these (11% overall) having qualifications in other healthcare disciplines. Table 4.18 also summarises non-naturopathic qualifications (undergraduate or postgraduate) held by practitioners.

**Table 4.18 Average duration in years of undergraduate (initial) training, and non-naturopathic qualifications held by practitioners**

Qualifications held	Herbalists	Naturopaths	Total
<b>Length of study</b>			
Average duration of undergraduate study for first qualification	3.0 years (SD 1.1)	3.2 years (SD 1.1)	3.1 years (SD 1.2)
<b>Non-naturopathic qualifications held</b>			
Any health discipline	57 practitioners (11.7%)	67 practitioners (11.1%)	82 practitioners (10.3%)
Arts	53 practitioners (10.8%)	61 practitioners (10.1%)	74 practitioners (9.3%)
Science or engineering	41 practitioners (8.4%)	51 practitioners (8.4%)	61 practitioners (7.7%)
Law	1 practitioner (0.2%)	1 practitioner (0.2%)	1 practitioner (0.1%)
Social sciences	4 practitioners (0.8%)	4 practitioners (0.7%)	6 practitioners (0.8%)
Other	13 practitioners (2.7%)	20 practitioners (3.3%)	22 practitioners (2.8%)

#### 4.6.2 Preparation for practice

Practitioners were asked whether their primary naturopathic and herbal courses adequately prepared them for professional practice. The majority of practitioners reported that they had been ‘adequately prepared’ or ‘well prepared’ for practice in all aspects of theoretical and clinical training—except for inter-professional communications, in which 43.6% felt that they were poorly prepared (Table 4.19). In addition, 22% of practitioners felt that they were poorly prepared in the area of clinical training.

**Table 4.19 Perception of preparation for professional practice**

Component of training	Poorly prepared	Adequately prepared	Well prepared
Clinical training	175 (22.0%)	378 (47.5%)	222 (27.9%)
Theoretical training: natural therapies component	27 (3.4%)	355 (44.7%)	386 (48.6%)
Theoretical training: medical sciences component	77 (9.7%)	423 (53.2%)	269 (33.8%)
Theoretical training: Western diagnosis component	198 (24.9%)	387 (48.7%)	168 (21.1%)
Inter-professional communications	347 (43.6%)	311 (39.1%)	85 (10.7%)

#### 4.6.3 Participation in continuing education

Practitioners were asked whether they were currently undertaking any formalised continuing education (Question 59). Participation in continuing education in naturopathy or herbal medicine was reported by 88.8% of the workforce. This included seminar attendance (80.5% of the workforce) and postgraduate studies (24 students undertaking master’s and PhD degrees). More than 80% of practitioners felt that participation in continuing education was very important. Current first aid certification (Question 61) was held by 85.3% of the workforce.

## 4.7 Professional context

### 4.7.1 Cross-membership of associations

Practitioners were asked to list the professional associations of which they were members—in order of importance to themselves (Question 79). Table 4.20 lists respondents by the number of associations to which they belonged. Half of the respondents reported that they belonged to two or more professional associations. A very large number of small associations (115) was identified.

**Table 4.20 Number of memberships of professional associations held by practitioners**

Number of associations of which respondents were members	Number of respondents (percentage)
1	771 (97.0%)
2	395 (50.0%)
3	120 (15.1%)
4	44 (6.0%)

Each respondent was asked to identify his or her primary association. The number of respondents for eleven primary associations is listed in Table 4.21.

**Table 4.21 Eleven primary associations identified by respondents**

Professional association	No. of responding members
Australian Traditional Medicine Society (ATMS)	402
National Herbalists Association of Australia (NHAA)	330
Australian Natural Therapists Association (ANTA)	157
Australian Naturopathic Practitioner Association (ANPA) *	107
Federation of Natural and Traditional Therapists (FNTT) (peak body)	50
Australian Homeopathic Association (AHA)	45
Australian Register of Homeopaths (AROH)#	20
Australian Kinesiology Association (AKA)	20
Complementary Medicine Association (CMA)	19
Victorian Herbalists Association (VHA)	18
Australian Acupuncture and Chinese Medicine Association (AACMA)	15

\*ANPA is also included under the Federation of Natural and Traditional Therapists (FNTT)

#AROH is not a professional association, but was listed as such by some respondents to this question.

### 4.7.2 Government regulation

Practitioners were invited to identify the positive and negative implications of possible government regulation of herbal medicine or naturopathic practice (Question 67). Their views are summarised in Table 4.22.

Overall, in contemplating greater government regulation, practitioners perceived more positive implications than negative implications—in terms of professional status, standards of practice, standards of education, access to research infrastructure, postgraduate education, access to scheduled herbs and products, quality of herbs and products, and definition of occupational boundaries.

Practitioners were unsure of the likely effect of government regulation of practice on patient costs, practitioner income, and litigation (legal cases brought against practitioners). Practitioners perceived that, overall, regulation would have a negative effect on medical influence on practice and were either unsure or negative regarding freedom of practice. These responses were consistent, irrespective of professional association membership.

**Table 4.22 Practitioners' perceptions of potential government regulation of practice**

	Positive change	Negative change	Unsure
Professional status	625 (78.6%)	37 (4.7%)	100 (12.6%)
Standards of practice	580 (73.0%)	53 (6.7%)	123 (15.5%)
Standards of education	578 (72.7%)	55 (6.9%)	127 (16.0%)
Access to research infrastructure	464 (58.4%)	34 (4.3%)	254 (31.9%)
Practitioner income	212 (26.7%)	80 (10.1%)	446 (56.1%)
Litigation	99 (12.5%)	212 (26.7%)	429 (54.0%)
Postgraduate education	474 (59.6%)	43 (5.4%)	222 (27.9%)
Patient costs	158 (19.9%)	170 (21.4%)	407 (51.2%)
Quality of herbal medicines, nutritional supplements, and homeopathics	370 (46.5%)	76 (9.6%)	301 (37.9%)
Access to scheduled herbs, homeopathics, nutritional substances	439 (55.2%)	121 (15.2%)	191 (24.0%)
Definition of occupational boundaries	328 (41.3%)	157 (19.7%)	252 (31.7%)
Freedom of practice	172 (21.6%)	273 (34.3%)	299 (37.6%)
Medical influence on practice	100 (12.6%)	352 (44.3%)	292 (36.7%)

Table 4.23 lists practitioners' views on the main functions of a national accreditation body (Question 68). The three most important in order of priority were maintenance of national register of qualified practitioners, establishment of standards of training and accreditation of training courses and assessment of practitioner qualifications.

If a state-based or national accreditation system were in place (Question 70), three in every four practitioners reported that they would retain their professional association membership. Practitioners were divided on the question of whether their interests would be served by a single accreditation board covering all naturopaths, Western herbalists, homeopaths, nutritionists and tactile therapists.

**Table 4.23 Practitioners' views on the main functions of a national accreditation body**

Main functions of a national accreditation body	Number (percentage%)
Assessment of practitioner qualifications	537 (67.5%)
Maintenance of national register of qualified practitioners	658 (82.8%)
Receipt of complaints against registered practitioners and responsibility for disciplinary proceedings if necessary	467 (58.7%)
Establishment of standards of training and accreditation of training courses	613 (77.1%)
Issuing codes of standards of practice	439 (55.2%)
Monitoring compliance with continuing professional education requirements	372 (46.8%)
Examination of practitioners trained overseas	423 (53.2%)
Public education	463 (58.2%)
Other *	54 (6.8%)

Note: \* 'Other' includes media responses to negative events, and protection of practitioner rights.

### 4.7.3 Health fund provider rebate status

Practitioners were asked about their registration as 'providers' with health funds (Question 80). Most practitioners (73.3%) estimated that they were registered with six or more health insurance providers (Table 4.24).



**Table 4.24 Number of health insurance funds with which practitioners were registered as providers**

Number of health insurance providers	Herbalists (N = 489)	Naturopaths (N = 604)	Total (N = 795)
1–5	123 (25.2%)	107 (17.7%)	181 (22.8%)
6–10	164 (33.5%)	216 (35.8%)	275 (34.6%)
11–20	107 (21.9%)	152 (25.2%)	180 (22.6%)
>20	77 (15.7%)	111 (18.4%)	128 (16.1%)
Missing	18 (3.7%)	18 (3.0%)	31 (3.9%)

#### 4.7.4 Professional indemnity insurance arrangements

Questions 82 and 83 sought information on forms of professional indemnity insurance held by practitioners.

Professional indemnity insurance was arranged through their professional associations for 70% of practitioners. Another 19% arranged insurance independently. Surprisingly, 2.4% had no cover. That is, 24 in every thousand practitioners did not hold any professional indemnity insurance. The amount of indemnity cover held is listed in Table 4.25.

**Table 4.25 Level of professional indemnity insurance held by practitioners**

Amount of professional indemnity insurance held	Herbalists (N = 489)	Naturopaths (N = 604)	Total (N = 795)
\$1 million	168 (34.4%)	232 (38.4%)	300 (37.9%)
\$2 million	168 (34.4%)	199 (32.9%)	257 (32.3%)
\$5 million	85 (17.4%)	107 (17.7%)	136 (17.1%)
\$10 million	47 (9.6%)	49 (8.1%)	69 (8.7%)
Missing	21 (4.3%)	17 (2.8%)	33 (4.2%)

## 4.8 Summary of results

- Most practitioners identified more than one title to describe their practice, with significant overlap between naturopathy and herbal medicine. The most common titles used were ‘naturopath’ and ‘herbalist’.
- The workforce was predominantly female.
- There was significant variation in intensity of clinical practice with a mean of 24 hours per week (representing 22 consultations per week). Extrapolated across the whole naturopathic and WHM workforce in Australia this represented 1.9 million consultations in 2003.
- A significant proportion (38%) of naturopathic and WHM practitioners used medical tests at least 50% of the time to guide clinical practice. More than 80% of practitioners guided their interventions by using diagnostic approaches specific to naturopathic practice.
- Most practitioners (75%) received patients through word of mouth, and almost half also acknowledged occasional referrals from medical practitioners. Only 7% of practitioners worked in multidisciplinary environments that included medical practitioners.
- The average (mean) clinical experience of practitioners was nine years.
- The cost of treatment was modest with average fees for an initial consultation being AUD\$61.70, and for follow-up consultations AUD\$42.10.
- Average practitioner income was between \$20,000 and \$60,000. Total turnover in consultation fees in Australia was estimated at more than \$85 million in 2003.
- One third of practitioners usually reported adverse events, but not to ADRAC.

- The reported duration of education ranged from six months to six years. Most practitioners had at least three years of education in herbal or naturopathic practice, and an additional 11% held other health qualifications. However, almost half felt that they were inadequately prepared for inter-professional communication, and almost a quarter that their clinical training was inadequate. Participation in continuing education was high (88%).
- Half of the workforce belonged to two or more professional associations. There was a very large number of small associations (115).
- The majority of practitioners viewed government regulation as having more positive implications than negative implications, and most supported more practitioner regulation.
- The majority of practitioners were registered with health insurance funds as providers. Most held professional indemnity insurance, but a small number had no such insurance.

## 4.9 Discussion

The findings of this study indicate that the practices of herbal medicine and naturopathy make a substantial contribution to the Australian healthcare sector, with approximately 1.9 million consultations annually and an estimated turnover of \$85 million in consultations (excluding the costs of medicines). This is consistent with the high levels of usage reported by an Australian survey of consumers of complementary medicine (MacLennan, Wilson & Taylor 2002).

The herbal and naturopathic workforce was predominantly female (76%). The workforce consisted of a diverse cohort of practitioners, particularly in terms of length and nature of education and clinical experience. Primary professional qualifications varied from six months to six years in duration, raising issues with regard to practitioners' preparedness for practice. In fact, 22% of practitioners felt that they were poorly prepared in terms of clinical training. It might be unrealistic for practitioners to expect otherwise if they had received only several months of study in the field. However, irrespective of the field of study and the quality of education, a sense of being deficient might not be unusual among graduates of any healthcare discipline. Nevertheless, more than one in five practitioners in the present study viewed their clinical training as inadequate in preparing them for practice. The concerns expressed by practitioners in this survey should be considered seriously by relevant education providers.

Practitioners, on average, worked approximately 24 hours per week in clinical practice and had 6.7 years of equivalent full-time experience—although this varied from recent graduates to practitioners with 47 years in practice. Practitioners used a wide variety of conventional and non-conventional diagnostic tests. In some cases, the clinical value of these tests has not been proven.

There appeared to be some integration with registered sectors of the healthcare workforce, mainly with GPs. Approximately 8% of herbalists and naturopaths received referrals from GPs or medical specialists for half or more of their patients. Of the herbal and naturopathic workforce, 11% were qualified in another healthcare discipline—including general practice, medical specialty, physiotherapy, pharmacy, or nursing. It is of significance that 30% of practitioners reported that they worked in a multidisciplinary healthcare facility. However, many practitioners (43.6%) felt that they were poorly prepared for inter-professional communications. A large proportion of patients was referred to practitioners by word of mouth.

The overall number of consultations provides evidence of the high degree of utilisation of Western herbal and naturopathic practice in Australia. There was wide recognition of these practices by health insurers for the purposes of patient rebates—with three-quarters of practitioners having provider status with six or more funds. This might reflect pressure on

insurers from members of the public wishing to exercise choice. However, the annual earnings associated with herbal and naturopathic practice appeared to be modest.

The study revealed indicators that naturopaths and herbalists take their responsibilities to consumers seriously. These indicators included: (i) the significant proportion of practitioners who identified continuing professional education as a priority (and participated in it); (ii) widespread participation in first aid training; and (iii) almost universal coverage in professional indemnity insurance.

It is interesting that practitioners reported membership of a very large number of small associations (115). Although the majority of practitioners reported membership of one of the four principal associations, the findings confirm the fragmented and underdeveloped nature of professional representation in the field, and the need for government intervention to promote more uniform educational and practice standards and other mechanisms to ensure public protection. Overall, practitioners were strongly supportive of any potential government regulation of WHM or naturopathic practice.

## 4.10 Recommendations

Based upon findings from the survey of the naturopathic and WHM workforce, the following recommendations are made.

- In view of the current fractured representation by a large number of professional associations, there is an urgent need to consolidate professional representation of the workforce. Given the apparent inability of the profession to achieve this, statutory regulation should be seriously considered to ensure consistency of training and clinical practice, and enforce minimum standards for education and professional practice.
- Inconsistency in educational and professional standards should be rectified by an independent body with the authority to mandate the minimum standards for naturopaths and WHM practitioners
- Educational institutions should carefully review their programs of study to prepare graduates more adequately for inter-professional communication and to strengthen provision of clinical training.
- The professional associations should work together to develop a public education campaign to inform consumers about the titles used by practitioners—including common titles and terms, umbrella terms, and what they signify.

## Acknowledgment

This study was funded by the National Herbalists Association of Australia and the Federation of Natural and Traditional Therapists, with financial support from the Commonwealth Department of Health and Ageing. The collaboration of Grand United Health Fund is acknowledged. Parts of this chapter have been reprinted with permission from Bensoussan et al. (2004).

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# 5. Tertiary Education in Naturopathy and Western Herbal Medicine

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## 5.1 Introduction

Historically, knowledge of naturopathy and Western herbal medicine (WHM) was obtained by self-teaching or apprenticeship. Education in these disciplines is now available in three education sectors: private colleges, vocational education and training (VET), and universities. In the early twentieth century, herbalists could gain admission to the National Herbalists' Association of Australia (NHAA, established 1920) by examination (Kirby 1990). The first recorded naturopathy course was conducted by the British and Australian Institute of Naturopathy in the 1940s (Jacka 1998).

Early growth in the number of colleges was slow, but colleges proliferated following the Parliament of Victoria Social Development Committee's report (1986), which found that naturopathy did not require statutory registration. The VET sector entered education in naturopathy and WHM during the late 1990s. Many colleges subsequently became registered training organisations (RTOs) and restructured their courses utilising VET health training packages and competencies.

The first degree course in naturopathy commenced in 1995 at Southern Cross University (SCU), New South Wales (NSW), and bachelor's degrees are now available in both the public and private sectors (with private providers applying for accreditation with the appropriate state office of higher education). Since 1995 the number of universities entering the field of tertiary education in naturopathy and WHM has steadily grown.

In 2004 the World Health Organization released its 'Guidelines for Quality Assurance of Traditional Medicine Education in the Western Pacific Region' (WHO 2004), which provided a timely benchmark for education in natural therapies. The past three decades have seen a period of growth, instability, and diversity in education in natural therapies in Australia. Some of the schools established in this time are likely to meet many of the WHO guidelines, but others might have difficulty in finding the necessary resources to address areas of weakness.

This chapter presents the findings of a 2003 survey of Australian naturopathy and WHM education providers. The chapter describes the range of education providers, the status of education in naturopathy and WHM, and the views of education providers on a range of issues relevant to education in naturopathy and WHM.

## 5.2 Methodology

The objectives of the study were:

- to develop a comprehensive picture of education in naturopathy and WHM in Australia; and
- to compare standards of education offered by various providers of naturopathy and WHM education.

A survey instrument, based on that used for similar research by Bensoussan & Myers (1996), was developed and trialled. Approval for the research was obtained from the Human Ethics Committee, La Trobe University.

Australian providers of training programs for practitioners in naturopathy and WHM were identified via professional associations, advertising media including websites, industry publications, and the informal natural therapy network. The criterion adopted for participation in the study was that a course provider must have offered a course in naturopathy or WHM in 2003. This criterion allowed the inclusion of new courses being offered in 2003 for commencement in 2004. Providers of relevant education to medical doctors were included for comparison.

The questionnaire (see Appendix 5.1) sought information on:

- course type and structure;
- entry requirements;
- number of students;
- methods of assessment;
- clinical policies and procedures;
- outcomes;
- teaching and staffing;
- quality assurance; and
- important educational issues.

The findings that are summarised in this chapter are based on responses to the questionnaire, which have not been subjected to stringent verification. However, the findings have been reviewed by experienced naturopathy and WHM professionals and academics, and the research group is confident that the broad findings do reflect an accurate picture of naturopathy and WHM education in Australia.

Questionnaires were sent to all relevant education providers identified in Australia. From these 43 providers, 30 questionnaires were returned. Because one respondent had ceased to offer a relevant course before 2003, only 29 questionnaires were deemed to be valid. The 29 questionnaires represented 33 campuses across Australia, producing a 70.2% response rate by campus. Data were received on 65 courses, representing 62.5% of the total number of courses identified.

A breakdown of response by course revealed that the lowest response was in the area of diploma courses (11.11%), whereas a 100% response rate was obtained for all bachelor's degree courses and one advanced diploma conversion course. The response rate for the most common courses (advanced diplomas) was good: naturopathy 69%; WHM 62%.

### **5.3 Overview of education providers and awards identified in Australia (participant and non-participant)**

This section presents an overview of the education providers and the naturopathy and WHM courses offered by those providers. It includes both participant and non-participant providers. Information in this section was obtained from the public record (see Methodology above) and from returned questionnaires.

#### **5.3.1 Education providers identified in Australia**

Forty-three providers of education in naturopathy and WHM were identified in Australia. One company, the Australian College of Natural Medicine Pty. Ltd., had five campuses—located in Melbourne (2), Queensland (2) and Western Australia—making a total of 47 campuses offering naturopathy and/or WHM courses in 2003. Appendix 5.2 lists all 47 identified campuses and the 104 courses offered in 2003.

#### **5.3.2. Breakdown of participant and non-participant campuses by provider type**

All tertiary education sectors (university, TAFE and the private sector) offered courses in naturopathy and WHM in 2003.

An analysis of provider types and participation in the current research study is shown in Table 5.1. There was a high response rate from the TAFE sector (100%) and the university sector (91%), but a relatively low response rate from private colleges (59%). Reasons given for non-participation included: (i) that the information requested was ‘confidential’; (ii) that the questionnaire was too long; and (iii) that the institution was concerned about the potential effects of more stringent regulation of education. Non-respondent providers were more likely to offer courses at the lower award levels of certificate and diploma.

Table 5.1 sets out the number of participating and non-participating campuses by provider type.

**Table 5.1 Breakdown of participant and non-participant campuses by provider type**

	Total	Participant	Non-participant
Private colleges	32 (68%)	19 (59%)	13 (41%)
TAFE colleges	4 (8.5%)	4 (100%)	0
Universities	11 (23.5%)	10 (91%)	1 (9%)

### 5.3.3 Characteristics of the participant education providers

Twenty-nine education providers returned questionnaires which included data on courses offered at 33 campuses—one of the participating private providers had five campuses located in three states. Full details of the participants are provided in Appendix 5.3.

The responding education providers included:

- ten universities;
- four TAFE institutions; and
- fifteen private providers (of whom twelve were ‘for-profit’ companies, two were ‘non-profit’ organisations, and one was unspecified).

### 5.3.4 Total awards available in Australia (participant and non-participant providers)

The total number of awards identified in Australia (from both participant and non-participant providers) was 104 (undergraduate and postgraduate), see Appendix 5.2.

Of the 104 identified courses, analysis of the range of awards (Table 5.2) revealed that:

- 9 (9%) were diploma courses;
- 56 (54%) were advanced diploma courses;
- 17 (16%) were bachelor’s degrees (11 undergraduate programs in naturopathy; one in WHM; and five conversion courses for diplomates);
- 13 (13%) were postgraduate awards; and
- 7 (7%) were certificate level courses (usually offered as the first year of a diploma and/or as a retail assistant course).

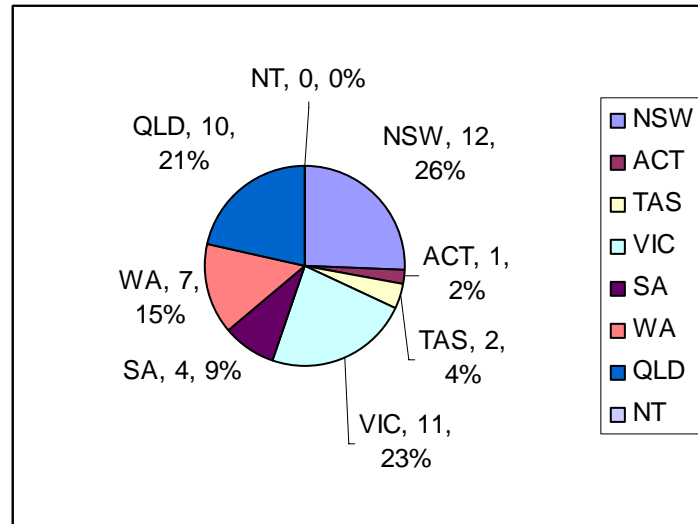
**Table 5.2 Courses by award and discipline (participant and non-participant providers)**

Course level	Naturopathy	WHM	Generic	Total
Certificate	0	1	0	1
Certificate IV	3	2	1	6
Diploma	2	7	0	9
Advanced diploma	32	24	0	56
Advanced diploma conversion	1	0	0	1
Bachelor’s degree	11	1	0	12
Bachelor’s degree conversion	1	0	4	5
Graduate certificate	0	0	4	4
Graduate diploma	0	2	3	5
Master’s degree	0	2	2	4
Unknown	1	0	0	1
<b>Total</b>	<b>51</b>	<b>39</b>	<b>14</b>	<b>104</b>

### 5.3.5 Location of education providers (participants and non-participants)

Most education providers were located in the eastern states. Of all states and territories, only the Northern Territory had no providers. NSW had the most providers (26%), followed by Victoria (23%) and Queensland (21%). Figure 5.1 indicates the number of providers per state or territory (in brackets) and percentages of the total.

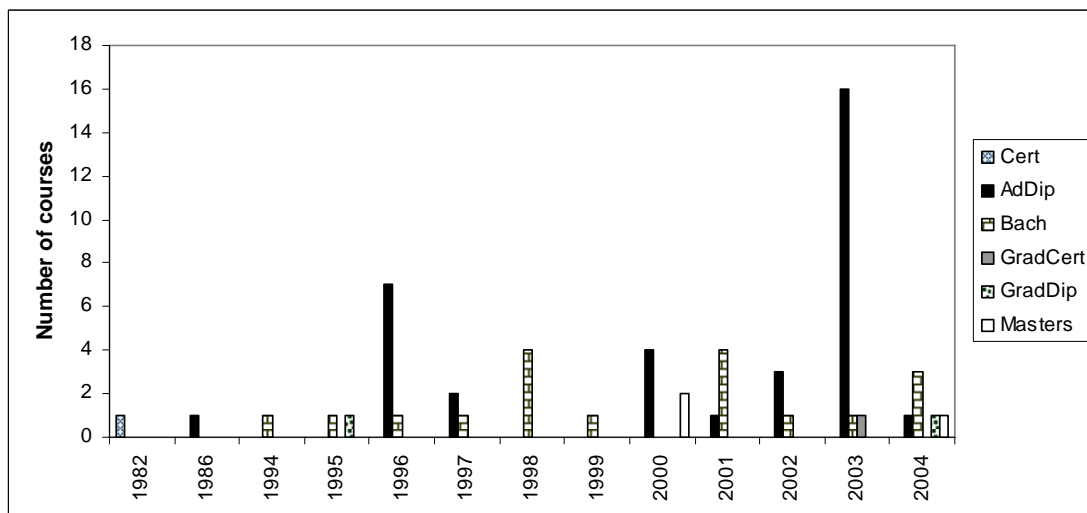
**Figure 5.1 Percentage of education providers by state and territory (combined participant and non-participant providers)**



### 5.3.6 Growth and evolution of education in naturopathy and WHM

The number of diplomas offered by responding education providers slowly increased from 1961 to 1989. The shift from private provider courses to government accredited (VET) advanced diplomas commenced in earnest in 1996, and accelerated in 2003 when national health training packages began to replace the state packages. (Figure 5.2 indicates the large number of advanced diplomas (16) which were established in 2003). Growth in the past decade was further enhanced as new TAFE and university providers entered the market.

**Figure 5.2 Number and type of awards 1982-2004 (Naturopathy and WHM)**



Providers had begun to move away from the 'lower' awards in response to community and professional demands for higher educational standards. The first university course was

established in 1995 (in naturopathy), and several larger private providers have been accredited since then to award bachelor's degrees. In 2003, bachelor's and postgraduate degrees made up 40% of all courses in the participant group.

Unregulated growth and competition have resulted in an array of awards across all three education sectors. Indeed, of all courses identified by the survey group, 49% had emerged since 2000.

### 5.3.7 Affiliations with other education providers

Sixteen campuses (48%) had affiliations with other providers of education in natural therapies in Australia, and twelve had overseas affiliations (Appendix 5.4). Most local affiliations consisted of arrangements that fed diplomates into the university sector to convert their original qualification to a bachelor's degree, thereby also providing a pathway to higher education and research.

## 5.4 Courses offered by participating education providers

### 5.4.1 Overview of reported courses

The total number of naturopathy and WHM awards offered by participating education providers was 65, representing 62.5% of the total number of courses available in Australia (Table 5.3).

**Table 5.3 Total combined courses by discipline (participant providers)**

Course level	Naturopathy	WHM	Generic	Total
Diploma	0	1	0	1
Advanced Diploma	22	15	0	37
Advanced diploma conversion	1	0	0	1
Bachelor's degree	11*	1*	0	12
Bachelor's degree conversion	1	0	4	5
Graduate certificate	0	0	2	2
Graduate diploma	0	2	1	3
Master's degree	0	2	2	4
<b>Total</b>	<b>35</b>	<b>21</b>	<b>9</b>	<b>65</b>

\* Note: Several months after completion of the survey, the NSW Office of Higher Education accredited two new bachelor's degrees (one in naturopathy and one in WHM) to be offered by a private provider, taking the total number of bachelor's degrees to 14.

For ease of dealing with the complexity of data, courses were divided into four categories:

- full undergraduate<sup>1</sup> courses (practitioner preparation);
- conversion courses (upgrade of diplomas and advanced diplomas to bachelor's degrees);
- undergraduate distance education; and
- postgraduate courses.

Representative subject tables were developed for these four areas. These can be found as Appendices 5.5, 5.7, 5.8 and 5.10.

<sup>1</sup> Data represented in this category were received for advanced diploma and bachelor's degree courses only. No data were received for diploma courses, which are still recognised by most professional associations as adequate for practitioner preparation in naturopathy and WHM.



## 5.4.2 Undergraduate courses

The questionnaire sought information on the contact hours and curriculum content in the areas of theory, clinical education, and medical sciences (see Table of undergraduate subjects, Appendix 5.5).

### Course contact hours

There was a wide range of total contact hours, with some courses having twice or three times the contact hours of others (see Table 5.4). The most notable difference was in the advanced diploma of naturopathy courses in which the range of total contact hours was 1240 hours to 4018 hours.

**Table 5.4 Range of course contact hours for naturopathy and WHM full-time undergraduate courses**

Course	Number of courses	Range of contact hours	Mean hours
Bachelor's degree in naturopathy	11	1492–3220	2216
Bachelor's degree in WHM	1	1550	1550
Advanced diploma in naturopathy	22	1240–4018	2314
Advanced diploma in WHM	14	1274–3060	1837

Note: This table does not include conversion courses

Information was also sought on the number of teaching contact hours for three course areas: theoretical subjects, clinical subjects, and biomedical and social sciences. The range of hours was again wide in each of these three core areas (see Table 5.5).

**Table 5.5 Range of teaching hours by course type and content area for undergraduate courses**

Course type	Theory		Clinical		Biomedical and social sciences	
	Number	Teaching hours	Number	Teaching hours	Number	Teaching hours
Advanced diploma naturopathy	13	706–1850	14	198–800	12	300–840
Advanced diploma WHM	10	462–2376	12	100–272	11	507–923
Bachelor's degree naturopathy	10	533–2550	10	280–765	11	416–930
Bachelor's degree WHM	1	635	1	100	1	815

### Naturopathy and WHM theory

The naturopathic curricula were generally consistent in demonstrating that a course in naturopathy should include the history and philosophy of naturopathy, nutrition, herbal medicine, naturopathic health assessment, communication and counselling, naturopathic clinical medicine, ethical and legal studies, and practice management (see Table of subjects, Appendix 5.5). However, the number of therapies taught as part of naturopathy varied, with the traditional four core modalities—nutrition, herbal medicine, homeopathy and bodywork (soft tissue therapies)—being reduced to three, or two plus an elective modality in some courses. The National Health Training Package (VET, Appendix 5.6) identifies nutrition and herbal medicine as core subjects for naturopathy, with either homeopathy or massage as a compulsory elective third modality. Reduced modality content might account in part for the wide range of theory hours (Table 5.6).

Although information was not directly sought on the philosophy informing the course, few of the course materials offered by providers included a clearly articulated philosophy or indicated how relevant philosophy might be integrated into the overall aims of the course and

graduate outcomes. Providing a philosophy subject (as most courses did) does not necessarily mean that the philosophy informs the overall curriculum and desired graduate outcomes in a coherent and structured manner.

### Comparison of modality offerings in naturopathy

The four traditional core modalities were compulsory in 63% of advanced diploma courses in naturopathy and 90% of bachelor's degree courses. Reduction in core modalities appears to have occurred more frequently at advanced diploma level than at bachelor's degree level. Reasons for this might include the nature of the health training packages (which provide for optional modalities) (see Table 5.6) and the more competitive commercial nature of education at this level. It might be argued that optional modalities cater to student choice and preferences. However, a college might decide to offer either homeopathy or a soft tissue therapy as an elective, but not both, thereby limiting both costs and choice.

**Table 5.6 Major modalities in naturopathy**

Courses	4 core modalities	3 core modalities	2 core modalities plus 1 compulsory elective
Advanced diploma in naturopathy (19 courses)	12 courses (63%): nutrition, WHM, homeopathy, massage	5 courses (26.5%): nutrition, WHM, massage	2 courses (10.5%): WHM & nutrition, plus either homeopathy or massage
Bachelor's degree in naturopathy (10 courses)	9 courses (90%): nutrition, WHM, homeopathy, massage	1 course (10%): nutrition, WHM, homeopathy	0

### Comparison of modality offerings in WHM

The WHM curricula were generally consistent in providing a range of relevant subjects—including traditions of herbal medicine, botany, *materia medica*, pharmacognosy<sup>2</sup>, clinical herbal medicine, manufacturing, and herbal prescription. There were significant differences in the range of other complementary therapies included in the WHM courses. The most common addition was nutrition in 81% of courses (see Table 5.7), but other examples were homeopathy, massage, flower essences, aromatherapy, and tissue salts. Some also included naturopathic approaches to health assessment and philosophy.

Because there have been complaints made against herbalists in the area of communication (see Chapter 2), the level of content of communication or counselling in curricula was assessed. The findings are included in Table 5.7. Of the 16 WHM courses, 14 (87%) had a subject that might include communication skills, but the extent and quality of this content could not be determined.

**Table 5.7 Number of courses including selected subjects in WHM curricula**

Courses	Nutrition	Communication or counselling	Ethics or legal issues
All undergraduate WHM courses (16)	13 (81%)	14 (87%)	3 (19%)

Only three undergraduate WHM courses (19%) included a unit devoted to ethics and legal issues. However, it is recognised that health training package competencies (such as 'Develop Professional Expertise') require some ethical and legal content. It was difficult to

<sup>2</sup> The knowledge of drugs, especially as a branch of natural history relating to medicinal substances in their natural or unprepared state (Oxford English Dictionary).

determine the actual content and quality of ethical or legal education in courses assessed in this survey.

### **Clinical teaching**

Schools must ensure that students acquire sufficient clinical knowledge and skills to prepare them for the responsibility of primary contact practice (WHO 2004). To achieve this, patient contact is expected to begin early in the course and clinical skills should be introduced and structured according to the stage of the course (WHO 2004). Clinical teaching in this survey was characterised as clinical observation and student clinic.

The absence of an enforceable standard for clinical teaching hours has resulted in wide variation in the hours reported for this critical area of teaching (see Table 5.5). The range of reported clinical hours across all courses that prepare undergraduates for practice was 100–272 hours for WHM and 198–800 hours for naturopathy (see Appendix 5.5). Advanced diplomas of naturopathy reported a range of 198–800 clinical hours, with 57% of respondents reporting 400–500 hours of clinical teaching (see Appendix 5.5).

Advanced diplomas of WHM reported a range of 100–272 clinical hours, with 78% of respondents providing 200–272 hours of clinical education.

The naturopathy bachelor's degrees also demonstrated significant variation in hours of clinical teaching. The lowest number of clinical hours was 280 in a three year undergraduate university course, but this was supplemented with a compulsory fourth year of part-time clinical practice (number of additional hours not specified). The majority of bachelor's degrees in naturopathy (62%) reported 400–600 clinical hours in their courses, and the highest was 765 clinical hours in a four year program (see Appendix 5.5).

The nature of the clinical experience was not clear from this survey. However, it can apparently vary from *observation* to *supervised undergraduate practice* plus a compulsory postgraduate internship. Distance education programs might entail disadvantages in this regard if much of the clinical time is spent in observation in private clinics (in which the actual management of patients by students under supervision is generally not available). In naturopathy and WHM courses, clinical requirements usually refer to the number of hours spent in a clinic, rather than to the number and types of patients or cases with whom students must deal before graduation. If patient numbers are low in some clinics, actual clinical experience would be limited in terms of number of cases and variety of problems and patient ages.

This study was not able to provide a detailed picture of the nature, structure, and timing of clinical programs. However, the limited number of clinical hours in many courses is a cause for concern. Further research is warranted in this area. In the meantime, schools are referred to the WHO guidelines on traditional medicine education (WHO 2004).

### **Biomedical and social sciences**

All courses included a range of sciences—such as anatomy, physiology, chemistry, biochemistry, pathophysiology, psychology, symptomatology, and clinical diagnosis. Significant findings were as follows.

- Reported contact hours for the sciences ranged from 300 hours to 923 hours for advanced diplomas, and from 416 hours to 930 hours for bachelor's degrees (see Table 5.5).
- A specific research unit was evident in approximately half of the advanced diploma courses, whereas all but one university had a compulsory research subject.
- The incidence of pharmacology units was lowest in the bachelor's degrees in naturopathy (73%), but it is possible that some information might be integrated into other subjects.
- Health sociology was not evident in any of the undergraduate subject lists; a surprising omission in view of the social and political factors affecting the naturopathy and WHM professions.

### Normal full-time length of courses

The normal full-time length of advanced diplomas varied considerably—from 2 years to 4.5 years. This is indicative of the lack of an agreed educational standard for the preparation of naturopaths and WHM practitioners as primary contact practitioners (see Table 5.8).

The majority of advanced diplomas were three year courses: 13 of 20 courses (65%) for naturopathy, and 11 of 15 courses for WHM (73%). Two advanced diplomas in naturopathy (10%) were only two years in length, and two advanced diplomas in WHM (13.3%) were only two years in length.

The length of bachelor's degrees in naturopathy varied from three years to five years—with six of ten (60%) being four year courses, three (30%) being three year courses, and one being part of a five year double degree program. There was only one bachelor's degree course in WHM available in 2003; this was a three year program.

**Table 5.8 Undergraduate programs: normal full-time length**

Course	2 years	3 years	3.5 years	4 years	4.5 years	5 years
Advanced diploma in naturopathy (n = 20)	2 (10%)	13 (65%)	1 (5%)	3 (15%)	1 (5%)	0
Bachelor's degree in naturopathy (n = 10)	0	3 (30%)	0	6 (60%)	0	1 (10%)*
Advanced diploma in WHM (n = 15)	2 (13.3%)	11 (73.3%)	0	1 (6.6%)	1 (6.6%)	0
Bachelor's degree in WHM (n = 1)	0	1 (100%)	0	0	0	0

\* Note: Double degree in nursing and naturopathy

### Average contact hours per week

The widest range of weekly contact hours was 11–25—in the advanced diplomas of naturopathy (see Table 5.9).

**Table 5.9 Range of contact hours per week for naturopathy and WHM courses**

Course	Number of courses	Range of contact hours per week
Bachelor's degree in naturopathy	7	15–25
Bachelor's degree in WHM	1	20
Advanced diploma in naturopathy	18	11–25
Advanced diploma in WHM	13	15–21

### Completion times

To ensure that knowledge and skills are current at graduation, it is good practice to set a maximum time for completion of a course. Five private providers offering advanced diplomas did not set a maximum time for completion.

### Honours programs

Only one education provider (a university) reported having an honours program. This was a one year course of research training conducted after completion of a bachelor's degree.

### 5.4.3 Conversion courses

Conversion courses offer graduates who hold diplomas or advanced diplomas opportunities to upgrade their awards. Most courses are for conversion to bachelor's degrees, but one TAFE institute offered an upgrade from diploma to advanced diploma. The University of New England (UNE) in NSW was the first university (1994) to offer a conversion to a bachelor's degree. The availability of such conversion courses was an important development that created a pathway for naturopathy and WHM graduates into higher education and research. Several of the courses are generic—that is, not specific to naturopathy or WHM—thereby enabling diplomates from a range of complementary healthcare professions to apply.

Five Australian universities now offer a conversion course for graduates of diploma or advanced diploma courses (Appendix 5.7). Analysis of the curricula revealed that:

- the number of subjects ranged from four to nine;
- content varied considerably and, in some courses, appeared to be largely drawn from generic health science subjects;
- research, pathophysiology, and social sciences were frequent components;
- three of the five courses appeared to contain no units specific to naturopathy or WHM; and
- only two of the five courses included components designed to develop clinical practice skills.

Further clinical experience is not currently mandatory because students have already completed the requisite clinical hours for diploma or advanced diploma education and are accredited to practice by professional associations. However, considering the findings on clinical education above, it could be argued that advanced level clinical experience should be included in all conversion courses to support higher order clinical skills. It is notable that 22% of respondents in a recent workforce survey (see Chapter 4) indicated that clinical preparation in their primary courses was poor (Bensoussan, Myers, Wu & O'Connor 2004).

Conversion programs would benefit from further research to determine the most appropriate curricula, and to assess the aims of the courses and their outcomes from the perspectives of students, the profession, and industry.

### 5.4.4 Distance education courses

Distance education (DE) is a controversial issue because it may be argued that it is an inadequate mode of delivery for preparation of a primary contact practitioner. However, flexible, online DE options are increasingly part of tertiary education, and natural therapy educators who offer DE have attempted to address the concerns.

Significant findings included the following.

- Eight campuses (24%) offered part of an undergraduate program by DE to allow flexible study (Appendix 5.8).
- Complete naturopathy and/or WHM advanced diploma programs by DE were offered by two providers, one of which is a dedicated DE provider.

The quality of clinical education is a concern with DE courses (as it is with on-campus courses). Although the major DE providers operated student clinics, it was not clear what proportion of clinical time was spent in private practitioner clinics—where experience may consist largely of observation and discussion rather than supervised practice.

### 5.4.5 Short courses

None of the providers supplied information on the questionnaire on any short courses in naturopathy or WHM that they might offer. However, information on short courses was obtained from websites and prospectuses.

Many private providers offered short courses in naturopathy and/or WHM. Short courses can usually be completed within one or two years part-time. They fall into the following categories:

- general interest courses: self-help and family health care;
- introductory courses: usually subjects without prerequisites that can be credited towards a full program;
- certificate courses (not accredited by VET or professional associations); and
- VET-accredited certificates III and IV: usually designed for retail or clinic assistants.

No prerequisites are required for attendance at short courses, which can be open to the general public and might provide a benefit in terms of personal health education. Some short courses have no formal assessment; whereas, in others, assessment can be compulsory or optional. Some short courses can be credited towards an award.

Short courses are also provided by product manufacturers—who have a significant role in providing postgraduate education in naturopathy and WHM in Australia. It is not known whether attendees are always required to be qualified practitioners.

There is anecdotal evidence that some practitioners in the community have attended only short courses, and might not have an adequate grounding in the basic medical sciences, pathophysiology, and clinical training. This has been the experience of the Chinese Medicine Registration Board of Victoria in assessing the qualifications of applicants for registration. The extent to which short courses in naturopathy and WHM might be credited towards formal training, the type of assessment in these courses, and the information given to the public about their purpose, need to be critically reviewed by education providers.

#### **5.4.6 Postgraduate courses**

The postgraduate area is small but growing, and includes programs ranging from graduate certificates to master's degrees. Four universities and two private providers offered postgraduate courses (Appendix 5.10). Some were generic, and thus allowed natural therapists from varying disciplines to apply, whereas others were specific to herbal medicine.

Whereas the growth area at the level of *bachelor's degrees* has been in naturopathy programs, four of the nine *postgraduate* courses were specific to herbal medicine, reflecting strong research interest in this area.

#### **5.4.7 Course accreditation and recognition**

The accreditation or recognition of courses by professional associations is an important factor in the eligibility of graduates for membership of an association. In turn, membership of a 'recognised professional association' determines the status of members as providers of GST-free services with the Australian Taxation Office, which is held to be part of the current self-regulatory framework (Chapter 6). It is good practice in established professions that a course be designed with input from professional associations, and also be accredited by an independent education authority to ensure that the course reflects the educational standard indicated by its award level.

Most courses in the present study were independently accredited by government authorities (the VET sector or a state office of higher education) or by a university. However, it is still possible for courses that have not been independently accredited by an education authority to be formally recognised by a professional association. It is not known how many non-participant providers offer courses in this category. The status of courses offered by participants at the time of the survey is set out in Appendix 5.9.

Providers reported that 38 of 39 undergraduate courses (97%) in the present study had formal accreditation or approval through the VET sector, universities, or state offices of higher education. Of the 37 advanced diplomas and one diploma reported in this survey, 36 (95%) were accredited within the VET sector.

All bachelor's degree and postgraduate awards were approved either by universities or the relevant state office of higher education.

Of the 39 undergraduate courses, 30 (77%) were formally recognised by a professional association, and applications were in progress for several others.

Of the five conversion courses, four were not recognised by a professional association. Some universities argued that the students were practitioners whose previous qualifications had already been recognised by professional associations. Nevertheless, lack of involvement by professional associations in the design and oversight of conversion courses may hinder universities in developing informed relationships with the naturopathy and WHM professions that they serve.

The accreditation status of courses provided by schools that did not participate in the survey is unknown.

#### **5.4.8 Admission requirements**

Admission requirements for undergraduate programs were reported by 17 private campuses. Of these campuses:

- twelve of the 17 (70%) based admission on an interview to assess academic ability and suitability;
- five of the 17 campuses (29%) required completion of Year 12; and
- none required a background in sciences (although three provided bridging courses in this area).

Four universities cited university admission scores between 75 and 85—indicating that there was competition for places. This resulted in enrolment of students with a history of moderate to high academic achievement.

Some providers advised informally that international students were also enrolling in private natural therapy schools, but little is known about this group—including the number of applicants and enrolments, how they are assessed for enrolment, what English language requirements are applied, whether they are studying by distance education, the level of student support available, and their outcomes or graduate destinations. Research in this area could be carried out by education providers or professional associations, and would assist the education sector and prospective international students.

### **5.5 Educational approaches**

Participants were asked to provide information on educational strategies—including assessment, policies and procedures in clinics, and student guidelines.

#### **5.5.1 Assessment**

Providers were asked to indicate the forms of assessment used for the herbal medicine subjects. There was a heavy reliance on closed-book examinations and case studies as the major forms of assessment, reflecting a limited approach to assessment in some courses.

Forms of assessment that were not used at all for herbal medicine assessment in some schools included:

- open-book or take-home examinations;
- oral examinations;
- literature reviews or critical reviews;
- annotated bibliographies;
- essays of more than 1500 words;
- projects;
- reports;
- clinical demonstrations; and
- journals or log books.

A limited approach to assessment types can disadvantage some students and may also indicate lack of awareness of good educational practice.

## 5.5.2 Clinical policies and procedures

Twenty-seven campuses offered undergraduate programs. Of these, 24 had a student clinic, two were developing clinics, and one used the clinic of a partner provider.

Participants were asked about the availability of a range of clinical policies and student guidelines, and whether clinical staff members were required to have first aid training. Full details of the availability and types of clinical policies and guidelines can be found in Appendix 5.11.

Clinical policies and guidelines that were least often available for students were on the clinical management of patients taking pharmaceutical drugs, and advice or information about medical immunisation (Table 5.10).

Providers were advised that the research team would welcome copies of policies or guidelines, but none was received. It was therefore not possible to assess the quality of the documents that had been developed by providers.

**Table 5.10 Availability of clinical policies and guidelines**

Policy or guideline	Number of student clinics (n = 24)
Requirement that all clinic staff and students have a first-aid certificate	21 (87.5%)
Dispensing of naturopathic and herbal remedies	22 (91.5%)
Notification of adverse reactions	21 (87.5%)
Handling and follow-up of incidents (such as accidents and emergencies)	21 (87.5%)
Referrals to other healthcare practitioners	21 (87.5%)
Clinical management of patients taking pharmaceutical drugs	9 (37.5%)
Advice and information provided to patients about medical immunisation	2 (8%)

## 5.6 Student body

### 5.6.1 Applications and enrolments

In advanced diploma courses there was little difference between the number of applications and the number of enrolments—indicating that most applicants received places. However, for bachelor’s degrees, university places are limited by funding and selection was therefore more competitive. Table 5.11 compares applications and enrolments across four course types.

**Table 5.11 Comparison of undergraduate applications and enrolments by course type**

Course type	Applications			Enrolments		
	Number of Courses	Number of Applicants (Range)	Mean Number of Applicants per Course	Number of Courses	Number of Enrolments (Range)	Mean Number of Enrolments per Course
Adv. diploma naturopathy	11	1–260	53.7	13	5–150	45.5
Adv. diploma WHM	8	1–120	41.8	9	2–68	31.7
B. degree naturopathy	5	0–350	192.6	6	0–393	139.7
B. degree WHM	1	NP	-	1	-	40

Notes:

1. 2003 data
2. Table does not include conversion programs
3. NP = Data not provided

### 5.6.2 Student age, numbers and gender by course type



The total number of students enrolled in undergraduate and postgraduate programs in the participant group of education providers in 2003 was 3,719.

### Undergraduate

In 2003, naturopathy and WHM undergraduate programs (full practitioner preparation) were provided on 26 campuses of the 33 represented in the survey. Of these 26 campuses, data on student enrolments were provided by 23 campuses (88.5%), with all the major providers responding to this question. Data were provided for 21 advanced diploma courses and six bachelor's degrees. This represented 37.5% and 50% respectively of all similar awards identified in Australia (see Table 5.2).

In 2003 the total number of undergraduate enrolments, across all years, for the 27 courses, was 3014 (Table 5.12). Of these, 1602 (53%) were in advanced diplomas, and 1412 (47%) in bachelor's degrees.

**Table 5.12 Number of student enrolments in 2003 across all years of courses**

Course type	Number of campuses	Advanced diploma enrolments	Bachelor's degree enrolments	Postgraduate enrolments	Total enrolments
Advanced diploma in naturopathy	17	1254			
Advanced diploma in WHM	12	348			
<b>Total advanced diploma</b>		<b>1602</b>			
Bachelor's degree in naturopathy	7		1372		
Bachelor's degree in WHM	1		40		
<b>Total bachelor's degree</b>			<b>1412</b>		
<b>Total undergraduate enrolments</b>					<b>3014</b>
Bachelor's degree conversions	4			553	
Advanced diploma conversions	1			6	
<b>Total conversion enrolments</b>					<b>559</b>
Graduate certificates	2			88	
Master's degrees	2			47	
PhD degrees	3			11	
<b>Total postgraduate enrolments</b>					<b>146</b>
<b>Overall total</b>					<b>3719</b>

Providers reported 311 undergraduate students (10.3%) who were school leavers (that is, completed secondary school in the last three years). This question was not well answered, possibly because providers had difficulty retrieving the data. However, anecdotal evidence indicates that naturopathy and WHM courses have traditionally attracted a majority of mature age students.

It was difficult to extrapolate total naturopathy and WHM undergraduate student numbers in Australia in 2003. This was because: (i) not all respondents provided data on the number of undergraduate students enrolled; (ii) the non-participant education providers tended to be the smaller institutions; and (iii) in at least two courses, students appeared to be simultaneously enrolled in both an advanced diploma of naturopathy and an advanced diploma of WHM. Taking these issues into account, the total number of naturopathy and WHM students in 2003 was conservatively estimated to be approximately 3500.

In the participant providers, there were 2626 students (87%) enrolled in naturopathy and 388 students (13%) enrolled in WHM. Overall, 1602 (53%) were enrolled in advanced diplomas and 1412 (47%) in bachelor's degrees.

WHM was substantially more popular with females than with males. In 2003, the female to male ratio for advanced diplomas in WHM was 86.5% to 13.5%, and for the one bachelor's degree in WHM the ratio was 95% to 5%. In naturopathy, the ratio between the genders was more even. In advanced diplomas of naturopathy, the female to male ratio was 54% to 46%, and in bachelor's degrees of naturopathy it was 68% to 32%.

Overall, most students in undergraduate courses in 2003 were female (65%). This finding can be compared with data reported by Bensoussan et al. (2004) from a survey of practitioners in 2004, when 76.1% of responding practitioners were female.

### **Conversion and postgraduate course numbers**

Conversion from a diploma or advanced diploma to a bachelor's degree was available at four universities in 2003, with another university offering a new course to commence in 2004. One TAFE institute offered an upgrade from a diploma of naturopathy to an advanced diploma. (See Appendix 5.7).

Demand for conversions to bachelor's degrees appeared to be strong, with 553 enrolments in 2003. Postgraduate course numbers were small, although it was difficult to ascertain actual numbers of PhD students because they might be enrolled in schools of other disciplines—such as nursing or nutrition.

### **5.6.3 Previous qualifications of students**

Of the 33 campuses, 23 (70%) supplied information on the previous qualifications of students. However, the quality of the data made quantification difficult. Previous qualifications held by students included chiropractic, Chinese medicine, dentistry, medicine, nursing, osteopathy, pharmacy, physiotherapy, and psychology. The workforce survey reported in Chapter 4 found that approximately 11% of naturopathy and WHM practitioners held qualifications in other healthcare disciplines (see 4.6.1).

### **5.6.4 School-leavers**

Entrants into naturopathy and herbal medicine have traditionally been mature age students, and this group has been preferred by education providers because of perceived higher levels of life skills. School-leavers in the 2003 intake were in the minority. Across all courses for which data were provided (n=23), school-leavers made up 26.7% of the student body.

A comparison of award types revealed that school-leavers constituted 36% of students in advanced diploma courses, and 20% of students in bachelor's degree courses.

However, further comparison of bachelor's degree courses between those offered on private campuses (n=4) and those offered by universities (n=3) revealed that 44.5% of students on the private campuses were school-leavers, while only 17% of students enrolled in bachelor's degrees in universities were school-leavers.

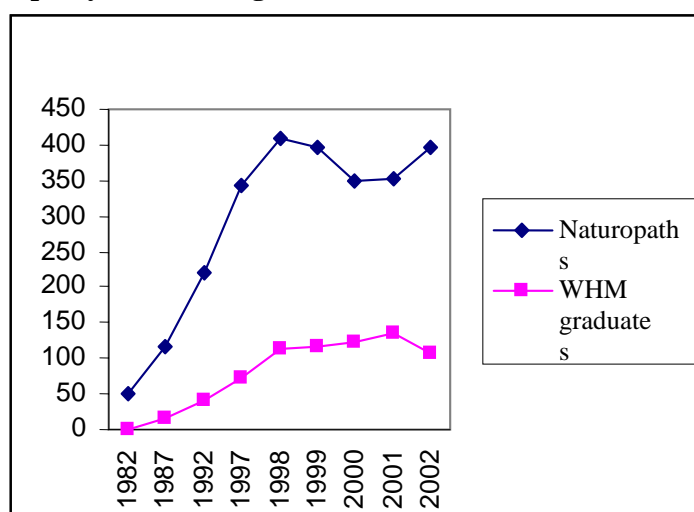
## 5.7 Graduate completions and educational trends

### 5.7.1 Graduates

The trend in graduate completions over a twenty year period was identified by requesting data for every five years from 1982 to 1997, and then for every year from 1998 to 2002 (see Figure 5.3).

The number of graduates rose from 1982 until 1998—quite markedly in the case of naturopathy, which peaked at 410 in 1998. It is of interest that the rate of increase for both disciplines slowed after 1998. For WHM, a relatively stable period followed, with a slight increase in 2001, and then a decrease in 2002. Naturopathy graduates followed a similar trend until 2001. However, whereas WHM numbers have decreased slightly since 2001, naturopathy numbers began to increase again in the period from 2001 to 2002.

**Figure 5.3 Naturopathy and WHM graduates 1982–2002**



### Implications

There is a lack of data on the number of graduates who successfully enter the workforce and secure a viable income from their practice. Many undertake other part-time employment to supplement earnings from practice. Bensoussan, Myers, Wu & O'Connor (2004) reported that 21.6% of the workforce stated that their practice income was less than \$20,000 per annum and 28.7% stated that gross income from practice was less than 40% of their total income.

Research is required to clarify several issues, including:

- the number of graduates who do not develop viable employment in the industry or profession;
- the implications of an increasing workforce;
- the cost to the community of under-utilised education; and
- whether prospective students are aware of challenges in developing a viable practice and/or securing a full-time income within the profession or industry.

### 5.7.2 Estimated workforce 2003–2007

Unfortunately the data provided were insufficient to enable an estimate to be made of future graduate numbers over the next five years. Despite this, some comment can be made by comparing the above recent graduate numbers with the existing workforce data reported in Chapter 4. Bensoussan et al. (2004) calculated an active mailing list of 2618 naturopathy and WHM practitioners. With approximately 500 practitioners graduating each year, and a conservative estimate of 3500 studying in 2003, it would appear that the workforce is likely to

expand considerably. However, a significant number of graduates apparently do not develop a viable practice (and some of these might not intend to do so).

### 5.7.3 Graduate destinations

Six education providers provided information on the employment status of graduates. Collection methods for the private colleges were either not stated, or were said to be ‘informal’ surveys. Two private colleges reported similar figures of 40–50% of graduates in either full-time or part-time practice. One added that ‘most of the remainder had an intention to practise, others were not intending but were not dissatisfied with that situation’. One private college stated that 95% were employed, but provided no information on how the data were collected. UNE reported figures collected for 1999–2002, which showed 42–56% of graduates in full-time work related to naturopathy or WHM, and 30–38% in part-time work related to naturopathy or WHM. SCU provided data from a compulsory higher education survey undertaken twelve months after graduation, which showed that 81% were employed and had an average income above \$30,000.

In the past, most graduates have had to find employment by establishing their own private practices. This situation is evolving as a growing market provides more employment opportunities, for example in multidisciplinary clinics, pharmacies, manufacturing, company representation, education, and the fitness industry.

Further research on graduate outcomes and destinations is needed to develop reliable workforce and employment data, and to understand the issues related to non-employment or under-employment in the naturopathy and WHM professions and industry.

### 5.7.4 Planned growth in educational programs

Providers were asked if they were planning any new undergraduate or postgraduate programs for naturopathy and/or WHM in the next five years. Positive responses are reported in Table 5.16. Overall, approximately one third of campuses were planning to introduce new courses in the next five years.

**Table 5.13 Planned growth in educational programs**

Course type	Private providers (n = 19 campuses)	TAFE (n = 4)	Universities (n = 10)	Combined providers (n = 33 campuses)
Naturopathy undergraduate	8 (42.10%)	1 (25%)	3 (30%)	12 (36.36%)
Naturopathy postgraduate	7 (36.84%)	0	5 (50%)	12 (36.36%)
WHM undergraduate	8 (42.10%)	1 (25%)	1 (10%)	10 (30.30%)
WHM postgraduate	7 (36.84%)	0	4 (40%)	11 (33.33%)

### Undergraduate

Continued growth in undergraduate courses appears to be likely. However, given that the available data indicate that a significant percentage of graduates might not find full-time work, consideration needs to be given to the number of undergraduate places on offer. More rigorous data on graduate outcomes are needed. In particular, data are required on the following questions:

- why students enrol in naturopathy and WHM courses;
- whether prospective students are sufficiently informed about employment prospects following graduation;
- whether courses provide adequate preparation for building a private practice or sufficient support for seeking other forms of employment; and
- whether outcomes are different for university and private college graduates.

## **Postgraduate**

The development of faculties and research capacity in naturopathy and WHM is essential to the future of the professions. Of the ten universities in the study, 50% were planning to introduce new postgraduate programs in naturopathy, and 40% in WHM. Four universities that were planning new postgraduate courses in the next five years have not previously offered postgraduate programs in either naturopathy or WHM.

## **5.8 Economic value of naturopathy and WHM education**

### **5.8.1 Comparison across the education sectors**

#### **Private and university sectors**

In the private sector, naturopathy and WHM education has been funded by students paying full fees to attend private education providers. The private sector has educated many of the practitioners who are key providers in the complementary healthcare industry, which has an annual value of approximately \$2 billion (MacLennan, Wilson & Taylor (2002).

The Department of Education, Science and Training has recently reformed the funding of higher education places. Previously, Commonwealth loans were not available to students engaged in private higher education. The Higher Education Contribution Scheme (HECS) was available to students of naturopathy and WHM enrolled in university bachelor's degrees and for some conversion degrees, but not for bachelor's degrees in the private sector. In 2003 a typical four year HECS cost was \$21,468 (Band 2), compared with full fees of \$25,000–28,000 in the private sector (Appendix 5.9). Many students would prefer a Commonwealth loan because it offers an opportunity to defer repayment. The federal government recently announced a new loan scheme, 'Fee-Help', for higher education students enrolled with a government-recognised higher education provider. Some government-accredited private providers of naturopathy and WHM bachelor's degrees have recently been included in this category (DEST 2005a).

In 2006, the total, lifetime Fee-Help limit will be \$50,950 (undergraduate plus postgraduate education). The amount will be indexed annually and a loan fee of 20% will apply to loans for undergraduate courses of study (DEST 2005b).

A significant amount of taxation has been provided to the federal government in the form of goods and services tax (GST) on education fees in the private sector and practitioner-prescribed medicines. However, almost no revenue is returned to the sector. In contrast, in New Zealand, government funding partially supports naturopathy education through a subsidy that is paid to private providers as a proportion of the student's overall fee (Cottingham 2004). New Zealand students are therefore less financially disadvantaged than their Australian counterparts, and it should be noted that Australians studying in New Zealand are eligible for the subsidy (Cottingham 2004).

#### **Bachelor's degree conversion courses**

There was a wide divergence in the cost of full fee-paying conversion courses, from \$3800 to \$10,764. In comparison, HECS cost was \$5479 (Appendix 5.7). The number of subjects in the courses varied from four to eight. Whether courses offer value for money is a matter for determination by prospective students, who might base their decisions purely on cost.

In the current climate of reduced government funding, universities are forced to find external sources of income. Funds derived from conversion courses might therefore be utilised to cover school and faculty costs unrelated to naturopathy or WHM.

## Funding in the VET sector

There was also wide divergence in TAFE fees. Two TAFE providers were operating on a cost-recovery basis only,<sup>3</sup> with total course fees being under \$3000, whereas two were charging fees that were on parity with private providers (Appendix 5.9).

VET courses in certain designated industry areas are partially subsidised by the federal government, but complementary health care is not such a designated industry. As a consequence, students enrolled in advanced diplomas of naturopathy or WHM in TAFE colleges in 2003 were full fee-paying students.

### 5.8.2 Estimated economic value of naturopathy and WHM education in 2003

Table 5.14 shows the range and mean cost of naturopathy and WHM courses in Australia. The mean cost of undergraduate education per student in 2003 was \$16,622. The economic value of naturopathy and WHM undergraduate education, calculated on a conservative estimate of 3500 students (see 5.6.2), was \$58,177,000.

Students converting to a bachelor's degree (553 students) paid a mean cost of \$4667 per course, producing an estimated total cost of \$2,580,851 to upgrade qualifications.

The postgraduate market remains small (see 5.4.6 and 5.6.2). Insufficient data were provided to enable an estimate of its economic value.

Overall, the economic value of naturopathy and WHM education was significant, contributing over \$60 million to the economy in 2003. Education also entails other costs such as textbooks, thus contributing to the publishing industry.

**Table 5.14 Cost of undergraduate courses**

Award	Range	Mean
Advanced diploma in naturopathy (private sector)	\$12,148–28,000	\$20,216
Advanced diploma in naturopathy (TAFE)	\$1010–18,000	\$9580
Advanced diploma in WHM (private sector)	\$9448–18,600	\$15,109
Advanced diploma in WHM (TAFE)	\$12,000	\$12,000
Bachelor's degree in naturopathy (all providers)	\$16,101–28,070	\$20,454
Bachelor's degree in WHM	1 course only	\$16,101
<b>Mean cost per course (n=34)</b>		<b>\$16,622</b>

## 5.9 Academic workforce in naturopathy and WHM

### 5.9.1 Comparison of workforce data across education sectors

Of 33 participating campuses, 26 (79%) provided data on the number of naturopathy and WHM lecturers in their programs. The total reported number of staff members was 821. This figure represents data from 55% of the total identified campuses in Australia, with most of the larger schools providing data. Although it is difficult to extrapolate total workforce numbers with any accuracy, the data do throw some light on the academic workforce.

Because providers usually employ the same lecturers across related subjects, no distinction could be made between staff members employed to teach naturopathy and those employed to teach WHM. To gain a clearer picture of staff members dedicated to naturopathy and WHM, lecturers in the sciences were not included in the data.

There was heavy reliance on sessional and guest lecturers, who made up 89% of the total workforce. The remainder were part-time staff members (6.5%) and full-time staff members (4.5%) (see Table 5.15).

<sup>3</sup> One of the two TAFE providers operating on a cost-recovery basis in 2003 indicated that it would not continue this model of funding. If the advanced diploma in naturopathy were to continue, fees would be on a par with those in the private sector.

**Table 5.15 Naturopathy and WHM academic workforce**

Naturopathy and WHM combined	Full-time	Part-time	Sessional	Guest	Totals
Theory	26	40	457	134	657
Clinical	11	14	132	7	164
<b>Totals</b>	<b>37</b>	<b>54</b>	<b>589</b>	<b>141</b>	<b>821</b>
<b>Percentage of total workforce</b>	4.5%	6.5%	72%	17%	100%

Note: Data refer to all providers combined (n = 26)

To allow comparisons to be made, the data in Table 5.15 were broken down by provider type:

- private provider workforce;
- university workforce; and
- TAFE workforce.

Each of these is discussed below.

### Private provider workforce

Compared with the overall figures (Table 5.15), the workforce in the private sector showed slightly higher use of sessional and guest staff members and slightly lower use of permanent staff members (Table 5.16). However, the lack of tenured staff in the private sector was striking with a 93% utilisation of sessional and guest lecturers.

**Table 5.16 Summary of reported teaching staff in private teaching institutions**

Naturopathy and WHM combined	Full-time	Part-time	Sessional	Guest	Totals
Theory	12	21	406	129	568
Clinical	5	8	125	5	143
<b>Totals</b>	<b>17</b>	<b>29</b>	<b>531</b>	<b>134</b>	<b>711</b>
<b>Percentage of total workforce</b>	2.5%	4%	74.5%	19%	100%

Note: Data refer to 13 education providers.

### University workforce

All ten universities that participated in the survey provided data on lecturers. A total of 85 individuals was participating in teaching dedicated to naturopathy and WHM. Compared with the private sector, there was significantly greater use of tenured staff. Nevertheless, well over half of the university teaching workforce (63%) consisted of sessional and guest lecturers (Table 5.17).

Universities providing conversion courses rely heavily on subjects from their sciences curricula that require no naturopathy or WHM teaching. One university had no naturopathy or WHM staff.

**Table 5.17 Summary of total reported teaching staff in universities**

Naturopathy and WHM combined	Full-time	Part-time	Sessional	Guest	Total
Theory	12	12	43	5	72
Clinical	4	3	4	2	13
<b>Total naturopathy and WHM staff</b>	<b>16 (19%)</b>	<b>15 (18%)</b>	<b>47 (55%)</b>	<b>7 (8%)</b>	<b>85 (100%)</b>

Note: Data refer to 10 education providers.

### TAFE workforce

Three of the four TAFE institutions provided data on teaching staff (Table 5.18). There was higher employment of part-time staff in the TAFE institutions. The proportion in this category (42%) approached that of sessional staff (46%).

**Table 5.18 Summary of total reported teaching staff in TAFE institutions**

<b>Naturopathy and WHM combined</b>	<b>Full-time</b>	<b>Part-time</b>	<b>Sessional</b>	<b>Guest</b>	<b>Total</b>
Theory	1.75	7	8	0	16.75
Clinical	1.25	3	3	0	7.25
<b>Total naturopathy and WHM staff</b>	<b>3 (12%)</b>	<b>10 (42%)</b>	<b>11 (46%)</b>	<b>0</b>	<b>24 (100%)</b>

Notes: Data refer to 3 institutions.

### 5.9.2 Implications of the academic workforce data

There are significant educational risks inherent in the use of a high percentage of casual staff. A lack of permanent staff members means that:

- less non-teaching academic work is carried out; this includes less attention to the coordination and regular review of courses and subjects; and
- the establishment of a scholarly faculty is impeded; such a faculty (with a focus on scholarship, research, and publication) constitutes the cutting edge of any discipline.

It would seem that income from full fee-paying conversion students might be contributing little to the development of naturopathy and WHM faculty and research in some universities.

### 5.9.3 Qualifications of teaching staff

Information was sought on the highest qualifications of staff members teaching naturopathy and WHM subjects (Table 5.19).

Only 14 (42.4%) of the 33 participant campuses responded to this question. Of the 14 that did respond, seven (50%) were universities, two (14%) were TAFE institutes, one (7%) provided postgraduate courses for doctors, and four (29%) were private natural therapy colleges. Most of those that did not respond were private providers (n = 14). The research team was concerned that private providers presented so little information on the qualifications of their staff.

In view of the poor response to this question, the available data provide only a snapshot that disproportionately represents university and TAFE staff.

Data were provided for 58 staff members—which represents only 7% of the total reported workforce of 821. Of the 58, 24 (41%) had a bachelor's degree as their highest award. Six staff members (10%) had a master's degree, and six (10%) had a PhD. Ten (42%) of the 24 bachelor's degrees were in naturopathy, and all were awarded in the period from 1999 to 2004. The remainder were in various other disciplines—including biochemistry, science, medicine, nursing, psychology, commerce, arts, and law.

Of the nine staff members whose highest award was a diploma, four (44%) were teaching in the area of homeopathy.



**Table 5.19 Qualifications of staff members teaching in naturopathy and WHM**

Qualification	Number	Naturopathy (excluding WHM)*	WHM*	Clinical teaching*
Traditional apprenticeship	1	1	1	1
Diploma	9	6	3	2
Advanced diploma	7	4	1	1
Bachelor's degree	24	11	9	8
Bachelor's degree (honours)	2	0	1	1
Graduate certificate	1	1	0	0
Graduate diploma	2	1	1	1
Master's degree	6	5	0	0
PhD	6	4	2	2
<b>Total</b>	<b>58</b>			

Note: \* Individuals might teach in more than one area

### 5.9.4 Clinical practice experience of teaching staff

Information on the length of clinical practice experience in naturopathy and WHM was obtained for 36 teaching staff members from three private providers, five universities, and two TAFE institutes. The full-time equivalent ranged from one year to 36 years, with a mean of 11.3 years and a median of 10 years.

For those actively involved in clinical teaching (n = 15) the range of clinical practice experience was from 3 years to 36 years (full-time equivalent) with a mean of 14.3 years and a median of 11 years.

Information on clinical teachers was provided by three universities, two TAFE institutes, and two private providers. Although most staff members had more than the recommended minimum of five years clinical experience, again this disproportionately represented university and TAFE staff.

### 5.9.5 Implications of the qualifications data

As noted above, private providers supplied little data on the qualifications of their academic workforce. For some of the larger private colleges with high numbers of sessional staff members it was apparently difficult to retrieve data on their qualifications and range of clinical practice experience. However, this does not fully explain why so few private natural therapy colleges responded to this question.

The following observations can be made.

- The small amount of data that was provided refers mainly to the tenured staff in universities and TAFE institutes. It is therefore not representative of private providers, and there is a concern that the qualifications of teaching staff in those organisations might be lower overall.
- The establishment of a bachelor's degree as the minimum standard for education would require a suitably qualified teaching workforce. (See Table 5.12 for data on enrolment numbers.)
- To develop an academic workforce that is skilled in scholarship, advanced clinical education, and research, all education providers need to encourage staff members to upgrade their qualifications and pursue higher education.

### 5.9.6 Publications and research grants

A total of eight academic staff members had published articles in refereed journals in the previous five years. Four of these had a strong record of publication. All were university staff members—indicating the lack of a culture of research and scholarship in the private education sector.

Three universities had received funding in the period 1999 to 2003 for research. This was in the areas of:

- evaluation of nutrition knowledge in graduates (SCU, Australian Dairy Corporation, \$20,000);
- herb–drug interactions (University of Sydney, NHMRC, \$150,000; University of Sydney, St Vincents Fairfax Foundation, \$170,000); and
- developing Armidale as a centre for health and wellbeing (UNE, Armidale Dumaresque Council, \$20,000).

One private college (Nature Care College) collaborated on the SCU project (see above), and also received separate funding for development of a module on critical analysis of nutrition information (Australian Dairy Corporation, \$10,000).

The Australian Centre for Complementary Medicine Education and Research (ACCMER) reported receiving a total of AUD\$1,118,859 in research grants in the period 1999-2003. All this funding was received from the commercial sector for contracted research. Due to confidentiality requirements, ACCMER was unable to provide any further details about the source of the funding, or disclose the nature of the research.

Total research funding reported by education providers for naturopathy and WHM in the five years from 1999 to 2003 was AUD\$1,488,859, with approximately 90.1% being provided by the private sector.

### **5.9.7 Recruitment**

Schools were asked about the number of teaching positions advertised in newspapers over the past five years. Universities were more likely to advertise nationally. Private providers, when they did advertise, used state or local advertising media. Of the 15 private providers, six (40%) reported that they had not advertised at all, or that they had approached individuals personally; four (26%) did not answer the question.

These data raise concerns about recruitment practice. Best practice involves advertising for the most highly qualified and experienced staff—rather than preferential recruitment, such as approaching recent graduates of a school to fill teaching positions. The latter approach makes it more difficult to improve educational standards and bring new ideas and approaches to a curriculum.

## **5.10 Quality assurance in naturopathy and WHM education**

Providers were asked about quality assurance procedures for courses and subjects. Responses to the questions are provided in Appendix 5.12.

### **5.10.1 Membership of course committees**

Course advisory committees, which provide guidance to faculties on teaching programs, usually include both internal and external members. External input is considered good practice because it enables advisory committees to remain current and relevant, both educationally and industrially.

Of the 29 providers, 27 (93%) stated that they were advised by a course committee. The qualitative data demonstrated that:

- academics and teaching staff made up the bulk of committee membership in all three sectors (private, TAFE, and university);
- private providers were more likely to include administrative staff and practitioners from the community; only one private provider mentioned the participation of external academics on course committees; and
- universities were more likely to include a representative of a professional association.

In general, course advisory committees tended to lack external academics and representatives of the large professional associations.

### **5.10.2 Course review and evaluation processes**

Providers were asked a series of questions about course review and evaluation. A total of 22 providers (76%) responded.

The frequency of internal review of courses ranged from six monthly to five yearly. Three private providers stated that review was carried out by a single individual. This might not provide a sufficient range of expertise or ensure responsiveness of the program to the needs of the profession and the community.

The frequency of external reviews ranged from never (two education providers) to five yearly (four education providers). Among private providers there was little use of outside expertise. The schools tended to rely on either the same team that performed internal reviews, or on the re-accreditation process carried out by the VET sector.

Regarding student evaluation of subjects, 24 providers (82.7%) replied that this occurred regularly (usually at the end of each unit).

Internal and external review of content and educational strategies is an integral part of quality assurance, and good practice involves properly constituted committees—which should include external expertise in naturopathy, WHM, education, and other areas considered relevant by the provider.

It was difficult to assess the quality of review overall. Nonetheless, it was apparent that external review mechanisms in the private sector are generally in need of improvement. This sector tended to rely on the audits built into VET and OHE accreditation processes. The Australian Quality Training Framework (AQTF) has a quality assurance focus. It notes that it is the provider's responsibility to have its educational strategies validated by the profession to determine whether the course is delivering against the expected outcomes.

Private education would also benefit from the teaching and learning expertise available from academics or consultants in the field of education.

## **5.11 Views and opinions of naturopathy and WHM education providers**

Providers were asked open questions about the regulation of naturopathy and WHM, education in naturopathy and WHM, and any other concerns regarding political, governmental, or legal issues relevant to education. Responses were analysed either quantitatively or qualitatively, as appropriate.

### **5.11.1 Regulation of naturopathy and WHM**

Of 29 providers, 19 responded to this question. Most support was expressed for statutory regulation, with ten (53%) indicating a preference for this model. A breakdown by provider type indicated the following:

- 14 private providers responded to the question, and five (36%) supported statutory regulation for naturopathy and/or WHM;
  - 4 (28.5%) supported a co-regulation model,
  - 1 (7%) supported continued self-regulation; and
  - 9 (64%) supported some form of government involvement in the regulation of practitioners.
- 5 of the 10 universities responded to this question, and all five (100%) expressed informal support for a statutory registration scheme;
- no TAFE providers expressed a position; and
- 4 responses were either unclear or ambiguous.

### **5.11.2 Educational requirements for beginning practitioners of naturopathy and WHM**

Twenty providers replied to this question. They tended to advocate the level of education they were already offering, but analysis of the comments indicated that 13 (65%) either strongly or moderately supported bachelor's level education for naturopathy and WHM. Comments indicated that:

- a bachelor's degree was necessary for practitioners who wanted to advance in research and education;
- there was a belief that a bachelor's degree will inevitably become the minimum requirement;
- education to the level of bachelor's degree is essential 'for the good of the profession', and to provide university pathways; and
- a degree is 'the responsible position for any health practitioner'.

Other findings were as follows.

- Six providers (30%) supported an advanced diploma as the minimum, but four of these also indicated support for a bachelor's degree.
- Nine (45%) supported a bachelor's degree as the minimum requirement.
- One respondent (5%) indicated that a diploma was sufficient for WHM.
- Four responses (20%) were unclear.

### **5.11.3 Future of education for naturopathy and WHM in Australia**

Providers were asked their opinion on the future of education for naturopathy and WHM in Australia. A total of 22 organisations replied to this question, which evoked detailed and sometimes passionate responses. Qualitative analysis revealed the following themes.

#### **Tertiary education**

Tertiary education would continue to develop with 'increasing uptake of bachelor degree courses and the development of postgraduate courses specific to naturopathy and WHM'. There was support for 'bachelor degree as minimum entry with standardised educational policies for registration'. Education also needed to provide better support for the interface between natural and conventional therapies by 'reflecting the contemporary care situation of scientific and integrative medicine'. Concern was also expressed about 'the level of qualifications, clinical exposure and research experience of teaching staff. It is necessary to ensure that education in these areas is consistently reviewed, upgraded, and updated.'

#### **Clinical requirements**

Inadequate clinical preparation was identified as an issue. In particular, there was concern that students should have sufficient supervised practice both before and after graduation. The concept of a residency program for graduates is rare in Australia, with only one provider mandating a clinical internship after graduation. 'There needs to be acceptable levels of education and clinical practicum. There should be a formal internship for all graduates to ensure their competency before practising alone.'

#### **Vocational education**

The adequacy of VET sector health training packages was identified as an issue. Compliance with the new national health training package created opportunities for a reduction in standards because some requirements (pertaining to performance criteria, units of competency and clinical training) were open to interpretation, causing a degree of dissatisfaction with the package: 'In future, only graduates with degrees will be able to practise. Health training packages will be phased out.'

There was qualified support for the package from some education providers, which would prefer that 'naturopathy and WHM education is retained in a vocational setting; however, the current vocational standard needs to be lifted'.

Two colleges stated that they were teaching above the health training package requirements—in order to provide sufficient preparation for practice.

### **Research**

There was strong support for research and higher degrees. This was particularly so with respect to the philosophical, theoretical, and clinical aspects of naturopathy and WHM—because these drive the holistic base of these disciplines and differentiate them from conventional medicine. However, this view of research and higher degrees was tempered with respect to evidence-based medicine, with its reductionist approach and reliance on quantitative data, because ‘it needs to be remembered that different medical interventions, as well as different classes of medicines, require different sorts of evidence’.

Anxieties about participation in research were questioned by one respondent: ‘The profession needs more courage (and data). Research into the profession needs to be supported so that projects like [*The Practice and Regulatory Requirements of Naturopathy and Western Herbal Medicine* will] be encouraged by stakeholders within the profession. There is a tendency to [withhold] support out of fear.’

### **Erosion of holistic philosophies**

A major concern expressed by private providers of naturopathy and WHM was that movement of courses into the public tertiary sector might result in a loss of traditional holistic philosophies and perspectives. The health training package was noted to be an example of this. Practitioner values were being changed because ‘imposition of scientific approaches is heading the naturopath towards the orthodox medical model’. However, the possibility of combining both approaches was supported: ‘Education in both naturopathy and WHM must embrace both traditional and evidence-based approaches. Natural medicine principles must underpin education and practice of these two approaches.’

### **Integrative medicine**

The need for better integration and cooperation between the medical profession and naturopathy/WHM practitioners was expressed by respondents from both the medical and naturopathy/WHM sectors. ‘More doctors will expand their training to include principles of naturopathy. There will be an increasing need for integrated medical and CAM education, particularly of conventional health practitioners across the fields of health, in naturopathy/WHM including nutrition.’ To facilitate this, ‘naturopathy should become a mainstream health profession and have respect as such by other health professions and the public. It should co-exist and work with the medical profession.’

It was expected that ‘increasing public interest will lead to increasing education requirements’. Therefore, the ‘future for education looks promising, but education providers will have to be flexible to endure the inevitable changes their industry will face’.

Private providers were likely to face competition from the public education sector. However, ‘the better and more dedicated private providers will continue to exist in the face of university competition’.

### **Private and public education: links and partnerships**

The continuation of education in the private sector was supported through the notion of ‘two-part education’—advanced diplomas in the private sector followed by conversion to bachelor’s degrees through established pathways. ‘The consecutive model with cooperation between private providers and universities seems to be working well and we are happy to have that continue.’ This model was also believed to safeguard the culture of naturopathy and WHM.

### **Graduate destinations**

There was a degree of pessimism about the future of graduates. ‘Training of naturopaths in the capital cities has reached saturation point. Most graduates entering the workplace in 2004–2005 will not find sustainable employment.’

There was cynicism with respect to the rationale for providing so many student places: 'Most teaching institutions continue training at current levels mainly for financial reasons. In future the number of graduates will be limited by available work.'

### **Political concerns**

There was unhappiness about ongoing conflict within the profession over both education and regulation. 'The future for education looks troubled due to conflicts within the profession over regulation.' 'We are concerned regarding some of the professional accrediting bodies not having democratic selection criteria and having non-transparent policies.' One recommendation was for standards to be set by an independent body: 'It should be government and peak body controlled. Education has to be benchmarked and taken out of commercial hands.'

On a more positive note, one respondent was encouraged by growing political acknowledgment of the role of natural therapies in Australia. 'We see the federal government paying more attention to natural therapies with a view to incorporating them into the national healthcare system.' As evidence regarding the cost and health benefits of some therapies mounts, there will be increasing pressure to make them accessible to all Australians.

## **5.12 Summary of results**

### **5.12.1 Overview**

- In 2003 there were 47 naturopathy and WHM education providers in Australia. They offered a total of 104 undergraduate and postgraduate courses in naturopathy and WHM.
- In the present survey, 47 providers of naturopathy and WHM education received questionnaires, with 33 questionnaires being returned by eligible providers. The response rate for the study was 70% (representing 62.5% of naturopathy and WHM courses in Australia).
- Of total identified courses, 56% were advanced diplomas, 16% were bachelor's degrees, 15% were diplomas and certificates, and 13% were postgraduate awards.
- Of all naturopathy and WHM courses reported by the respondents, 49% had emerged since 2000. The first bachelor's degree course commenced in 1995.
- Of all responding education providers, 15 (52%) were privately owned, four (14%) were TAFE institutes, and ten (34%) were universities.
- Twelve (80%) of the 15 private education providers were 'for-profit' companies.
- The number of naturopathy and WHM graduates had increased in reporting schools from approximately 50 in 1982 to 500 in 2003.
- An estimated 3500 students were enrolled in naturopathy and WHM programs in Australia in 2003.
- Informal surveys by providers had indicated that many graduates do not achieve full employment in the profession. However, there is a lack of reliable data on this matter. Further research on graduate outcomes and destinations is needed in the context of an education market that appears likely to continue to expand.
- Approximately one third of campuses were planning to develop new undergraduate and/or postgraduate naturopathy or WHM courses in the next five years.

### **5.12.2 Undergraduate awards and curricula**

- Length of courses in both naturopathy and WHM ranged from 2 years to 4.5 years.
- Mean course contact hours (bachelor's degrees and advanced diplomas combined) for naturopathy were 2265, and for WHM were 1693.
- Sciences content ranged from 300 hours to 930 hours in naturopathy and from 507 hours to 923 hours in WHM.
- Clinical experience ranged from 198 hours to 800 hours in naturopathy and from 100 hours to 272 hours in WHM.
- Shorter courses in naturopathy do not teach all four traditional modalities (nutrition, herbal medicine, homeopathy, and massage).
- Only one honours program was available.
- Two providers offered whole courses by distance education.
- Clinical policies and guidelines were reported to be available in most student clinics. However, because no examples were provided to the research team, the quality and extent of these remained unclear.
- 97% of courses in this study were government or university accredited.

### **5.12.3 Conversion courses**

- Five universities offered one year upgrades for diplomates to a bachelor's degree.
- One TAFE institute offered conversion of a diploma to an advanced diploma.
- Three university conversion courses consisted primarily of generic health science subjects with no advanced practice in naturopathy or WHM.

### **5.12.4 Postgraduate courses**

- Four universities and two private providers offered a total of nine postgraduate courses, ranging from graduate certificates to master's degrees.
- Four of the nine postgraduate courses were specific to herbal medicine.

### **5.12.5 Course recognition and accreditation**

- Formal accreditation through the VET sector, universities, or state offices of higher education was reported for 97% of undergraduate courses surveyed.
- Professional associations had formally recognised 77% of these undergraduate programs.

### **5.12.6 Review of courses**

Deficiencies were identified in some curricula. A review of curricula by providers and professional associations is required, particularly with regard to adequacy in the following areas:

- clinical practice;
- pharmacology and interactions among herbs, nutrients, and drugs;
- communications, counselling, ethics, and legal issues;
- critical thinking and analysis;
- basic research methods, literature reviews, and the role of evidence-based practice in holistic healthcare;
- manufacture of herbal products for extemporaneous prescribing;
- sociology of health and healthcare;
- core modalities of naturopathy and WHM;
- variety of forms of assessment; and
- input from education specialists to ensure that forms of assessment match desired outcomes with respect to subjects, courses, and graduate attributes.

### **5.12.7 Economic value of naturopathy and WHM education**

- The mean cost of undergraduate education per student in 2003 was \$16,622. This represented an estimated turnover in the tertiary sector of \$58,177,000.
- The mean cost of a conversion course was \$4,667 and students paid approximately \$2,580,851 to upgrade their awards to the level of a bachelor's degree.
- The combined economic value of naturopathy and WHM undergraduate and conversion courses was \$60,757,851.

### **5.12.8 Applications and enrolments**

- Few private education providers turned applicants away, but there was competition for the limited places available in universities.
- The majority of students were of mature age, but the proportion of school-leavers is likely to increase as more university places become available.
- International students are enrolling in naturopathy and WHM courses, but little is known about this group. Research would assist both education providers and prospective international students.

### **5.12.8 Academic workforce**

- Little data were provided on the qualifications of teaching staff, particularly in the private sector.
- Sessional staff members made up 89% of the total workforce.
- Non-teaching academic work (such as coordination, development, and regular review of courses and subjects) is likely to suffer from the lack of permanent staff.
- Some universities provide conversion courses without the establishment of a naturopathy or WHM faculty (or have made minimal progress in this regard).
- Only eight staff members (all from universities) had published in peer-reviewed journals during the period 1999–2003.
- Three universities, one teaching and research centre, and one private college had received funding for research projects in the areas of herbal medicine, nutrition, and community health. Total research funding reported by education providers for naturopathy and WHM in the five years from 1999 to 2003 was AUD\$1,488,859, with approximately 90.1% being provided by the private sector.
- Approaches to recruitment varied—with private providers being less likely to advertise widely for teaching staff and more likely to approach individuals personally.

### **5.12.9 Quality assurance**

- The frequency of internal review processes was generally adequate. However, there was little use of external expertise on review committees (particularly for content and educational strategies) in the private sector.

### **5.12.10 Regulation and educational standards**

- Overall, two thirds of education providers either strongly or moderately supported education to the level of bachelor's degree as the appropriate entry level qualification for naturopathy and WHM.
- Less than one third supported an advanced diploma as the minimum standard.
- Concern was expressed about ongoing conflict within the professions over regulation and education. Major concerns were: lack of agreement in the profession on the most appropriate mode of regulation and minimum educational standards, the commercialisation of education resulting in lowered standards, lack of democratic processes and transparent policies in some professional associations, and the need for standards to be set by an independent body.



## 5.13 Discussion

Community interest in natural therapies has fed strong growth in the education sector over the past decade, reflecting increasing public support for complementary and alternative medicine (CAM) in Australia and in other developed countries. The level of education in naturopathy and WHM is evolving, but the absence of a common standard for the preparation of practitioners contributes to lack of recognition by mainstream institutions (see Chapter 7). Debate is required to reach agreement on minimum standards for naturopathy and WHM education programs, but attempts to improve educational standards are unlikely to succeed without the support of a regulatory system that can mandate minimum education requirements.

### 5.13.1 Growth

Australia's output of naturopaths and WHM practitioners increased tenfold in the past twenty years. The graduation of 350 naturopaths per annum is similar to that for licensed naturopaths in the United States (where the number of unlicensed practitioners is not clear)<sup>4</sup> (Cooper, Laud & Dietrich 1998). It has been predicted that, in the period 1995–2010, the number of naturopaths in the United States of America (USA) would approximately triple, but that the number of medical practitioners would grow by only 16% (Cooper & Stoflet 1996).

In 2003, approximately 350 naturopaths and 150 WHM practitioners graduated in Australia. Their qualifications varied from diplomas to bachelor's degrees, and are recognised by an increasing range of associations and accrediting bodies that have differing standards. Many graduates do not appear to move into practice or succeed in establishing a viable practice, but the reasons for this are not clear. Nevertheless, growth trends indicate that the annual number of graduates is likely to increase.

Growth and competition have fostered diversity in education, confounding attempts to establish effective self-regulation with minimum entry level, qualifications and practice standards. The involvement of three educational sectors, each with its own culture and approach to education, has created an unsustainable divergence in naturopathy and WHM curricula. There is considerable variation in the amount of theory, clinical teaching, sciences, and modalities taught in naturopathy and WHM curricula, and the limited clinical training is a particular concern in some courses.

### 5.13.2 Current educational standards in Australia

The involvement of the VET sector has assisted naturopathy and WHM education by introducing an external and independent accreditation process. However, it has also introduced a tension between two philosophies of education—the competency-based model and the traditional academic model. Structuring a curriculum to support achievement of competencies is open to a degree of interpretation—for example, with respect to the number of hours required to achieve competency. In the present study, the number of hours devoted to the skills needed to *Provide Western Herbal Medicine Treatment* (course code HLTNAT2a) varied from 60 hours to 300 hours in two different TAFE institutions.

The Commonwealth government recently introduced reforms to the VET sector, which saw the abolition of the Australian National Training Authority (ANTA) in 2005. ANTA has been responsible for national coordination of VET training packages to ensure consistency of training and national recognition of awards. However, in future, the Commonwealth will deal directly with industry and providers through a new ministerial post for VET within the Department of Education, Science and Training. The implications of the restructure are unclear for VET sector education in naturopathy and WHM, but it would

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<sup>4</sup> In the United States graduates from courses without accreditation can practise. Some states without licensing systems allow naturopaths and herbalists to practise. The number of practitioners in these categories is not clear, but it is likely that the total number exceeds that of Australia. See Chapter 10 for information on licensing in the United States.

appear that present policy aims to achieve further deregulation of the education market (Wheelahan 2004).

It is acknowledged that all courses need not be exactly the same, and that schools might offer some variation in their approaches. Nevertheless, there is a need for agreement on the minimum requirements for professional standards, and on the minimum length of time and content required in courses to prepare a graduate for practice. Educational strategies also require periodic evaluation to develop graduate outcomes and assess whether they are being met. In particular, assessment types need to be varied to develop the many skills needed in contemporary healthcare practitioners (World Health Organization 2004).

### 5.13.3 International comparison of curricula (naturopathy)

The Council for Naturopathic Medical Education (CNME) in the United States (US) is an external accrediting body that has developed a benchmark for courses that prepare naturopaths to practise in those states that offer licensing. There are four naturopathy courses in the US leading to a professional doctorate accredited by the CNME (and an unknown number of unaccredited courses). For accredited degrees, the standard premedical baccalaureate is the preferred prerequisite (two years including biology, chemistry, psychology, and humanities) before entering a four year course leading to a doctor of naturopathic medicine degree (professional doctorate) (Smith & Logan 2002).

**Table 5.20 Comparison of naturopathy courses, Australia and United states**

Naturopathy Courses	Australia	United States CNME Accredited Courses
Course hours (face-to-face)	1240 - 4018	2580 - 3270
Undergraduate program length	2 - 4.5 years	4 years
Herbal medicine	30-60 hours	140 hours <sup>^</sup>
Sciences	300 - 930	1100 <sup>^</sup>
Clinical training	198 - 800	1200 - 1500

Note: 1. <sup>^</sup> number represents example from one course only

Contact time in CNME curricula range from 2580 hours to 3270 hours, compared with an Australian range of 1240 hours to 4018 hours. The herbal medicine stream at one college seeking CNME accreditation was 140 contact hours (Poorman, Kim & Mittman 2001). This compares with Australian examples (from curricula provided for the present study) of 60–300 contact hours (not including time spent on herbal medicine in clinical subjects).

Science hours in Australian courses ranged from 300 hours to 930 hours, with none equalling the 1100 hours in a US naturopathy program described by Poorman, Kim & Mittman (2001).

Some comparisons can also be made with the United Kingdom (UK)—at least with respect to herbal medicine, which is more established in the UK than naturopathy. Vickers & Zollman (1999) reported wide variation in the content and standard of herbal medicine courses. At the highest level, ‘medical herbalists’ underwent four years of preparation to the level of a bachelor’s degree. This included study of nutrition, and at least 500 hours of supervised clinical practice. There has been discussion in the UK regarding the need to standardise education in basic sciences (perhaps through joint curricula with other health professionals) and the need to establish external accreditation of complementary health courses (PW Foundation 2003).

In the area of clinical education in naturopathy, CNME curricula include 1200–1500 clinical hours, compared with the Australian range of 198–800 clinical hours. The lower end of this range is clearly inadequate and, as discussed below, would be unable to comply with

the recommended content of clinical training (WHO 2004). A benchmarking exercise is currently under way at SCU in Australia to map differences across naturopathic curricula from three schools—one in Australia, one in the USA, and one in Canada (Orrock 2004). Currently, the American and Canadian schools offer 1120 clinical hours and 1000 clinical hours respectively, compared with 765 clinical hours in the Australian course (at SCU). Although graduates are, in theory, trained as primary care practitioners, this is not readily apparent in the clinical training in any of the courses—which involve very few hospital and primary care practical placements and internships outside the education providers' own clinics (Orrock 2004).

### **5.13.4 Clinical education, placements, and residencies**

There is substantial concern regarding the adequacy of clinical education in Australia, and the disparities in the length of clinical training reflect the lack of an effective system for setting educational standards in naturopathy and WHM. Undergraduate clinical placements in Australia mainly occur in clinics run by education providers, in private clinics (which usually allow observation only), and in outpatient settings such as health clinics for the homeless where students can practice under supervision. Clinical placement programs for new graduates are almost non-existent in Australia.

Problems with clinical training are reported in the literature for both undergraduate and postgraduate placements. In the US undergraduate clinical training occurs mainly in outpatient settings but there is interest in extending placements to hospital settings and emergency care (Poorman, Kim & Mittman 2001). The expansion of clinical placement programs is expected to improve the quality of naturopathic training significantly, promote acceptance by other health professionals and the community, increase participation in research and government programs for underserved populations, provide hospital-based care, and increase state licensing of naturopathy (Neill & Hudson 2002).

Clinical placements are a vital part of preparation for new graduates. Because there is no government funding for postgraduate clinical placements in the US they are few in number and competition among naturopathic graduates for placement is strong; fewer than 10% of naturopathic practitioners gain a residency in the USA (Poorman, Kim & Mittman 2001, Neill & Hudson 2002). In Australia, only one provider in the present study mandated a postgraduate clinical placement program—100 postgraduate hours in the school's clinic.

The development of adequate clinical training is impeded by cost, the structure of curricula, the availability of quality supervision, and the difficulty of obtaining placements that deliver a high level of clinical experience to students.

As in Australia, most US graduates must establish their own practices and many work in isolation. Attempts are being made to support US graduates with informal mentoring programs (Poorman, Kim & Mittman 2001). There appear to be few mentoring programs for new Australian graduates, and it is generally the responsibility of graduates to seek out their own mentors.

The development of minimum requirements for undergraduate naturopathy and WHM education in Australia presents challenges. Determining an appropriate minimum number of clinical training hours is unlikely to occur in the absence of enforceable education standards. Further, improving the quality of supervised practice for undergraduates (in school clinics and external settings) and developing postgraduate clinical training and mentorship programs will require time and a systematic approach from professional associations and education providers. Support in the form of research on clinical training and the mentoring of naturopathy and WHM graduates would benefit education providers, the professional community and the public.

### **5.13.5 WHO guidelines for traditional medicine education**

In 2004, the World Health Organization (WHO) released a set of guidelines for educational standards and quality assurance in traditional medicine (TM) education (WHO 2004). The

guidelines are broad—in acknowledgment of diversity among TM schools and their need to respond to local requirements in defining relevant objectives.

The guidelines provide a useful template for educational objectives. Some points from the guidelines are noted below. These address issues raised by the findings of the present study, particularly with regard to overall course aims, clinical education, and quality assurance.

- A clearly articulated philosophy is essential to underpin the course and inform all course components and graduate outcomes.
- A set of course objectives and graduate outcomes is necessary to inform the design and implementation of the curriculum, and to measure whether the course achieves its aims.
- An internal curriculum committee should be appointed for the course. This should consist of a group of individuals who have expertise in TM and in education. This committee should carry out evaluation and review of the curriculum, and should oversee necessary changes. Outside experts might be part of this committee.
- A range of teaching and learning methods is required, informed by good educational practice. Forms of assessment should stimulate deep learning (such as problem solving, analysis, and organisation of knowledge), and should promote communication and lifelong learning.
- Students must have sufficient patient contact and acquire sufficient clinical knowledge and skills to assume appropriate clinical responsibility upon graduation. Components of clinical training should include: (i) early patient contact; (ii) structured clinical training; (iii) exposure to a wide range of patient demographics and disorders; (iv) appropriate health assessment skills; (v) the incorporation of health promotion and disease prevention into patient care; (vi) experience of a range of clinical settings; and (vii) the development of teamwork with other health professionals.
- Forms of assessment need to match and reinforce the goals of the program, including those that are difficult to assess by conventional means—for example problem solving and holistic activities (such as communication with patients and working as part of a healthcare team). Clinical examinations should form a significant component of the overall process of assessment.
- Students need to be exposed to a variety of clinical settings, including those of Western healthcare, to promote understanding of mainstream approaches.
- Students should meet a wide range of common problems among patients of all ages, and should experience the effects of family, community, and environment on health.
- To ensure responsiveness to the changing healthcare needs of the community, schools need to develop relationships with outside institutions (such as other TM schools, universities, community health agencies, higher education agencies, and research organisations).

The WHO guidelines also set out the elements of best practice in quality assurance (QA). A QA system consists of periodic self-review, an external QA process, accreditation systems, and adequate processes to approve new courses. The collection of data about the school and its courses is essential to the self-review process. The course aims should be compared with actual outcomes, and strengths and weaknesses should be identified.

Periodically, external QA can be carried out by inviting a group of outside peers and experts to review the course. In a confidential, professional, and collegiate manner, the external panel should assess whether the course is meeting its own objectives. Such an objective perspective can provide constructive material for course renewal (WHO 2004).

Meeting the WHO (2004) guidelines on educational standards and quality assurance would present difficulties for some private providers, particularly smaller colleges with limited resources.

### 5.13.6 Future of naturopathy and WHM education in Australia

It is clear that there is a trend to higher educational standards and that it is undesirable for primary contact practitioners—especially if seeking equality with practitioners in other healthcare disciplines—to continue to be educated only at a vocational level. Unfortunately, there is no consensus on an agreed minimum standard of education, and this means that naturopaths and WHM practitioners are vulnerable to the charge that some might not be sufficiently prepared to work independently of medical practitioners (Mills 2001). A previous federal Minister for Health and Aged Care, Dr Michael Wooldridge, emphasised that measures exempting ‘recognised professionals’ from GST requirements were only transitional, and that education to the level of a bachelor’s degree was considered by his department to be the minimum requirement for healthcare practitioners (Khoury 2000).

The public wants collaboration and integrated patient management among health professionals, but this level of practice sophistication is uncommon (Pizzorno 2002). The naturopathy and WHM professions need to develop and articulate educational and professional standards in accordance with their philosophy, and prepare for the level of transparency and accountability expected of today’s healthcare professionals (Pizzorno 2002). The different paradigms, theories, and practice protocols that characterise CAM have not been rigorously developed or tested, and they vary from one educational program to another (PPG Panel 1997). In the current era of evidence-based practice there is a pressing need for researchers and scholars trained in naturopathy and WHM to investigate, develop, and articulate a valid and distinctive paradigm.

Mills (2001) has argued that progress is most likely to be achieved through more rigorous educational curricula—which will establish a culture of enquiry, articulate the scope and limits of practice more clearly, and encourage interaction with other health professionals. The Expert Committee (2003) recommended that education in complementary medicine should be strengthened and that courses should be independently accredited, but whether Australia should follow a ‘medical model’ of education, as appears to be occurring in the US, needs debate. Practitioners must be able to identify situations that require referral to a general medical practitioner, but do not necessarily require the same diagnostic skills as medical practitioners. The demand is for well qualified natural therapists who can offer distinctive health focused care that complements the mainstream medical approach of disease intervention and pathology (Robson 2003). The opportunity exists to develop a culture of enquiry in naturopathy and WHM, and to establish a benchmark for rigorous, holistic, health oriented curricula. To nourish such a culture, and to support individuals who have an aptitude for higher education, it is necessary to: (i) establish education to the level of a bachelor’s degree as the standard qualification for naturopathy and WHM practitioners; and (ii) develop faculties of naturopathy and WHM trained in research and scholarship.

The failure of the profession to unite behind a bachelor’s degree as the minimum preparation for practitioners—a movement that began in the 1980s—has led to the present situation whereby the lack of a common educational standard contributes to ineffective self-regulation and increases the need for independent external regulation. Educational policy has, to a considerable extent, been influenced by individuals who have a commercial interest in education and who therefore have a substantial conflict of interest. Independent policy-making bodies are essential to the future of education in naturopathy and WHM.

The current political climate favours the deregulation of education. However, there is a danger that the outcome for education in naturopathy and WHM will be the continuation of certain modes of education in the private sector that do not provide graduates with the academic and clinical skills now required of health professionals—skills that will be essential if naturopathy and WHM are to become accepted as distinctive health professions.

Five issues illustrate the problems that have arisen due to delay in raising the minimum educational requirement to the level of a bachelor’s degree.

*First*, QA is underdeveloped. As a consequence, there has been delay in acknowledging and addressing areas of weakness in current curricula (such as clinical education, communication skills, and interaction with other healthcare professionals).

*Secondly*, naturopathy and WHM now lack, at a critical time in their history, the level of public presence that can be achieved by having professionals who have moved through higher education into positions of influence. The absence of such prominent professionals reduces the visibility and credibility of the professions in the mainstream of healthcare, and has led to a reliance on holistic medical doctors for public advocacy in representing and defending CAM.

*Thirdly*, there are few published articles by Australians on naturopathy and WHM in refereed journals. Courses limited to a diploma or advanced diploma level do not provide sufficient academic development to foster scholarship, research, and publication.

*Fourthly*, the distinctive body of knowledge in naturopathy and WHM is largely invisible to mainstream healthcare because there is so little research on the theory, philosophy, and whole-practice approach of the disciplines. There are many research publications on the therapies, but virtually nothing on such areas as the application of theory, health assessment, or patient management. These are currently taught by experienced clinicians, and the available textbooks are usually written by individual practitioners on the basis of their own experience. The overwhelming emphasis of research publications on *therapeutic interventions* means that naturopathy and WHM are vulnerable to the charge that they exist only as *therapies*, and not as *disciplines* that offer a distinctive perspective on human healthcare. An appropriate evidence base for naturopathy and WHM requires a significantly broader scope of research topics, carried out by researchers who are trained in the paradigms of naturopathy and WHM.

*Finally*, the current educational model (of ‘advanced diploma plus bachelor’s degree conversion year’) has not supported honours programs—which could be either embedded into a four year bachelor’s degree or structured as an additional year. Graduates of courses that do not have honours programs must take a longer route to a doctorate—via a master’s degree. This is a significant disadvantage to both postgraduate students and the professions.

The transition to education to the level of a bachelor’s degree as the minimum requirement for practice could be fostered by further development of the partnerships that exist between private providers and universities. However, the limitations of the prevalent model (of an advanced diploma followed by a conversion course to a bachelor’s degree) must be addressed. The culture of enquiry that is typical of education for a bachelor’s degree needs to be established from year one. Concurrently, a culture of holistic healthcare would need to be developed within participating universities. An appropriate standard of clinical education is required, and emphasis should be placed on developing a range of hospital and community settings for clinical practice.

The limited range of forms of assessment in some naturopathy and WHM courses, as found in the present study, indicates a failure to focus on educational strategies. Student learning in some courses would benefit from a broadening of forms of assessment because graduates require competence in problem solving, analysis, critical thinking, location of information, developing a written argument, referencing, report writing, and communication with other health professionals. In other words, desirable graduate attributes include *educational* attributes, as well as knowledge in natural therapies. A range of forms of assessment is necessary to develop such higher level educational outcomes.

Setting a bachelor’s degree as the minimum standard would require an academic workforce composed of individuals who possess at least that level of education, in addition to adequate clinical experience. The lack of data in the present study on the current qualifications and clinical experience of teaching staff, especially in the private education sector, creates uncertainty as to whether such capacity exists in the teaching workforce. Schools should encourage all teaching staff members to upgrade their qualifications, and

should ensure that those who are teaching in naturopathy and WHM subjects have adequate clinical experience.

Most affiliations between non-university institutions and universities presently consist of private schools feeding diplomates into university courses for conversion of diplomas to degrees. The availability of conversion courses has, in the past, been an important step in the evolution of education in naturopathy and WHM—by creating a pathway into higher education and research. The next phase requires a focus on scholarship and research—which will involve bachelor’s degrees preparing graduates appropriately from year one of a course. There is potential for cross-pollination between private providers and universities, but this will require willingness on both sides to foster the innovative development of the best attributes of each within the other.

In some universities, conversion courses to bachelor’s degrees presently consist largely of generic health science subjects. Also, the lack of naturopathy and WHM faculties in some conversion courses is noted. Universities need to consider whether the income derived from conversion courses could be better used to resource a culture of holistic healthcare through the dedicated development of naturopathy and WHM faculties, scholarship, and research.

### **5.13.7 Argument for independent regulation with minimum education standards**

Education providers are preparing naturopaths and WHM practitioners (an estimated 3,500 in 2003) to be primary contact practitioners attending to the healthcare of Australians. The education of such practitioners clearly requires the setting of minimum standards by an independent authority to ensure that practitioners are adequately prepared for this important role. The findings of the present study lead to concerns about deficiencies in course length, clinical experience, course content (in terms of biomedical sciences and social sciences), the provision of courses by distance education, and quality assurance. Competition appears, in some cases, to have contributed to a proliferation of courses and a lowering of the quality of education available in the marketplace.

Although many private providers have moved to advanced diploma programs, there is unsustainable inconsistency in the standard of courses offered. Furthermore, although some professional associations are upgrading practitioner requirements to the level of an advanced diploma, others continue to accept practitioners with a diploma level of education and have not required existing members to upgrade their qualifications or to demonstrate continuing professional education as a requirement for membership.

Attempts to self-regulate have not been successful in the area of education. It is therefore likely that some practitioners are poorly prepared and are not adequately attending to the health and safety of Australians. The debate about the best educational preparation for naturopaths and WHM practitioners must be free of sectional interests, and the climate of anxiety that has pervaded the professions (and clouded debate) in recent years must be addressed. An independent body, informed by the professions, but able to make rational and objective judgements, is required to set minimum educational standards.

A bachelor’s degree is recommended as the minimum standard for both naturopathy and WHM. Universities and offices of higher education in several states have identified the core requirements for such a degree, and full undergraduate practitioner preparation<sup>5</sup> at this level is currently available in five universities and on five private campuses in Australia.

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<sup>5</sup> Conversion courses are not included in this statement

### **5.13.8 Impact of a uniform educational standard**

Taking into account the time that will be required for a transition to a bachelor's degree as the minimum requirement, the present study considers that there is sufficient knowledge and infrastructure within the professions to enable the change to be made.

It is acknowledged that such a move would have an impact on private and VET providers who do not offer bachelor's degrees; they will have to decide whether to upgrade their courses, cease offering courses in naturopathy and WHM, merge with other schools, or seek partnerships with universities. The last of these have already developed between a number of universities and private providers to support upgrade of qualifications, and this model has the potential to be extended (provided that the concerns noted above are adequately addressed). The introduction of a bachelor's degree as the minimum standard might also produce further beneficial change and expansion in the university sector.

The benefits of a bachelor's degree as the mandated level of education would be significant for consumers, other healthcare professionals, and public and private institutions that have an interest in healthcare. Current causes of concern—about the quality of education and the capacity of practitioners to function safely and effectively in a primary contact role—would largely be met.

A 'grandparenting' period would be necessary to enable recent diplomates to upgrade their qualifications. Occupational regulation with higher standards of education is likely to result in fewer practitioners with a more consistent quality of training.

### **5.14 Conclusion**

Naturopaths and WHM practitioners are primary contact health professionals, but their current educational standards vary, and those training at the lower end of the scale are not likely to be adequately prepared. The degree of risk in their practice, and the need for better integration of complementary care with mainstream healthcare, require education at least to the level of a bachelor's degree. The fostering of a scholarly community of naturopaths and herbalists, which would result from such a change, would help to establish benchmarks for holistic, health-oriented curricula. Courses should be subject to external accreditation in accordance with independent standards embedded in an effective system of regulation. In particular, any future regulatory scheme needs to consider standards for clinical education.

### **5.15 Recommendations**

Based upon the findings of the above survey, the following recommendations are made.

- The professions of naturopathy and WHM should work towards a bachelor's degree as the minimum requirement for entry into practice.
- An independent body, informed by the professions but separate from professional associations and education providers, should be created to establish education standards and curriculum requirements for bachelor's degrees for naturopathy and WHM.
- Review of undergraduate courses and conversion courses to bachelor's degrees should be undertaken by education providers, utilising the WHO guidelines (WHO 2004) for education and quality assurance in traditional medicine; this would assist providers in identifying areas in need of improvement.
- Clinical education in naturopathy and WHM should be reviewed, and minimum standards should be set to ensure graduate competence. Clinical teachers should have a minimum of five years full-time equivalent experience, all student clinics should have a protocol manual, and all students and staff working in clinics should have adequate first aid qualifications.
- Education providers and professional bodies should work together in offering continuing professional education that is free of the bias that may be present in education offered by product manufacturers.



- Research should be undertaken in the following areas to assist development in education: (i) the structure, cost, aims, and outcomes of conversion courses; (ii) graduate outcomes and destinations (including those gained from distance education); (iii) clinical education; (iv) guidelines for clinical practice in naturopathy and WHM; and (v) international students in Australian naturopathy and WHM courses.
- Education providers should develop appropriate policies on minimum staff qualifications, the clinical experience of clinical teachers, and best practice in recruitment.
- All education providers should consider increasing the numbers of full-time and/or part-time academic staff to facilitate course development, coordination, and review, and should encourage staff members to undertake postgraduate study to support scholarship, research, and publication.
- Universities offering naturopathy and WHM courses should consider the need for the development of faculties, scholarship, and research (if these are not sufficiently supported at present).
- Honours programs should be developed in naturopathy and WHM bachelor's degree courses to expedite entry of postgraduate students into PhD programs.
- Education providers should consider a wider range of expertise when constituting course committees—for example, educators from other sectors, representatives of the large professional associations, and a wider variety of industry stakeholders.

### Acknowledgements

Thanks to Professors Vivian Lin and Alan Bensoussan for constructive comments during the preparation of this chapter.

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# 6. Representation of Practitioners of Naturopathy and Western Herbal Medicine by Professional Associations

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## 6.1 Introduction

Professional associations play a key role in setting professional, ethical, and educational standards, and in representing their members to government, private sector institutions, and the public. The number of associations that represent naturopathy and WHM has been an area of difficulty for government and other institutions in consulting with these professions. This chapter presents the findings of a survey of professional associations, including two medical associations whose members have an interest in complementary and alternative medicine (CAM), and an association representing both consumers and practitioners of CAM.

## 6.2 Methodology

Bensoussan, Myers, Wu and O'Connor (2004) identified 115 associations to which naturopathy and WHM practitioners belonged, with more than half of the respondents having joined two or more associations (Chapter 4). Investigation of the 115 associations prior to the current survey revealed that most did not primarily represent the professions of naturopathy and WHM.

The criteria for participation in the survey were that an association must:

- profess a key role in the representation and standards of the professions of naturopathy and/or WHM; and/or
- profess a key role in the representation of practitioners who use naturopathic and/or WHM modalities<sup>1</sup>.

Seventeen associations met the criteria for participation in this survey. These associations were identified through consultation with the profession, government reports, existing research (Bensoussan et al. 2004), websites, and information from health funds.

A comprehensive questionnaire—modelled on that developed by Bensoussan & Myers (1996) for similar research on associations representing Chinese medicine in Australia—was adapted and developed in consultation with the research team. The survey instrument was piloted by the Australian Natural Therapists Association and the National Herbalists Association of Australia, and adjustments were made following feedback from these organisations. A copy of the questionnaire is included as Appendix 6.1. The questionnaire was mailed to the 17 eligible associations, together with a letter of invitation to participate, an information sheet, and a consent form. The Human Ethics Committee, La Trobe University, granted ethics approval for the study.

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<sup>1</sup> Includes associations representing medical practitioners.

The questionnaire was mailed in the first week of November 2003. Most had not responded by the due date of 5 December 2003, so all were notified of an extension to 31 January 2004. Those that had not responded by then were followed up by telephone and email.

Information sought in the questionnaire included:

- the structure and administration of the association;
- aims and purposes of the association;
- codes of ethics and practice guidelines;
- affiliations;
- matters pertaining to membership;
- a range of policies and procedures; and
- views on appropriate models of regulation for naturopathy and WHM;
- the current concerns of the associations.

Fourteen of the 17 associations responded to the questionnaire, providing a response rate of 82.3%. Table 6.1 lists all eligible associations and the acronyms used throughout this chapter.<sup>2</sup>

Some responding associations did not answer all questions. Reasons given for this included: (i) concerns about confidentiality issues; (ii) difficulty accessing the information from databases; (iii) respondents being busy and lacking time to find the information; and (iv) unease about the research project itself.

Reasons given for not participating at all (three associations) included: (i) inability to comply without permission from the membership; (ii) unwillingness to participate in government research; and (iii) a belief that the survey was not relevant to the association concerned (an association for doctors practising herbal medicine).

The findings are grouped into four main areas:

- associations;
- membership;
- policies and procedures (including complaints); and
- current concerns of the associations.

## 6.3 Associations

### 6.3.1 Overview of participating associations

There was a proliferation of professional associations representing naturopathy and Western herbal medicine (WHM) between 1982 and 2002 (see Figure 6.1).

The 14 associations that responded to the survey were established between 1920 and 2002<sup>3</sup>, with seven emerging in the last decade of the twentieth century (Table 6.1 and Figure 6.1).

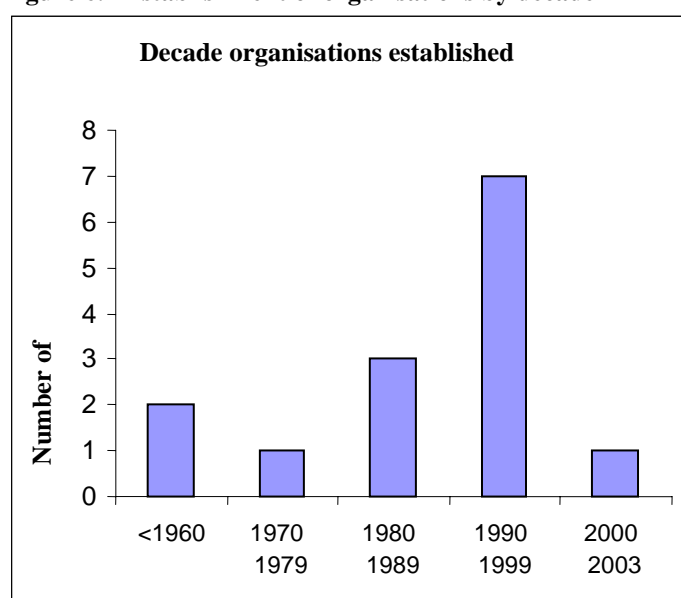
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<sup>2</sup> The Australian Natural Therapists Association is represented as ANTA<sub>sn</sub>, to distinguish it from the Australian National Training Authority (ANTA<sub>u</sub>)

<sup>3</sup> A new association, the Natural Health Care Alliance (NHCA), was established in 2003 with the aim to provide a united voice for the natural therapies industries and professions. It was not identified prior to the survey, but was approached later. However, the NHCA indicated that it was too early in its development for meaningful participation.

**Table 6.1 Eligible associations**

Participated in survey?	Association	Year established
Yes	Alumni Association of Natural Medicine Practitioners (AANMP)	1992
Yes	Australian Association of Homotoxicology (AAH)	2002
No	Australian College of Herbal Medicine (ACHM)	Unknown
Yes	Australian College of Nutritional and Environmental Medicine (ACNEM)	1982
Yes	Australian Committee of Natural Therapies (ACONT)	1990
Yes	Australian Complementary Health Association (ACHA)	1993
Yes	Australasian Federation of Natural Therapists (AFNT)	1995
Yes	Australasian Integrative Medicine Association (AIMA)	1992
Yes	Australian Naturopathic Practitioners Association (ANPA)	1975
Yes	Australian Natural Therapists Association (ANTAsn)	1955
Yes	Australian Traditional-Medicine Society (ATMS)	1984
Yes	Complementary Medicine Association (CMA)	1987
Yes	Federation of Natural and Traditional Therapists (FNTT)	1991
Yes	National Herbalists Association of Australia (NHAA)	1920
No	Naturopathic Practitioners Association (NPA)	Unknown
No	Naturopathic Physicians Association of Australia (NPAA)	Unknown
Yes	Society of Natural Therapists and Researchers (SNTR)	1990

**Figure 6.1 Establishment of organisations by decade**

Growth in the number of associations coincided with a range of factors, including:

- increasing public acceptance of CAM;
- growth in the number of private education providers and courses;
- entry of the TAFE and university sectors into the education market;
- increased scrutiny and regulation by the Therapeutic Goods Administration (TGA); and
- the advent of the goods and services tax (GST)—which necessitated dialogue with the Australian Taxation Office (ATO) to achieve recognition of practitioners for GST exemption.

These increased pressures encouraged development and activity within associations on behalf of their members and professions, such as the preparation of submissions to government on matters affecting naturopathy and WHM.

The origins of the responding associations were diverse.

- Two associations, ACNEM and AIMA, had a membership primarily made up of medical practitioners who had an interest in integrative medicine.
- ACHA was a consumer representative organisation, but approximately 50% of its membership consisted of CAM practitioners.
- FNNT was an umbrella group that was formed in response to the potential effects of TGA requirements on naturopathy and WHM.
- Seven associations had members from a range of CAM disciplines, including naturopathy and WHM.
- Two associations represented naturopaths only (CMA, ANPA).
- NHAA primarily represented WHM practitioners.

Figure 6.2 indicates the professional associations in the present study that have an interest in naturopathy and WHM. Most associations represent both naturopaths and WHM practitioners—as can be seen within the central circle. Consumers are represented by ACHA, which also has a substantial number of practitioners within its membership. Integrative medicine is represented by ACNEM and AIMA, both of which have a small number of associate members who are naturopaths.

### 6.3.2 Aims and purposes of the associations

A qualitative analysis was performed on the aims and purposes provided by the 14 participating associations. The aims and purposes of 11 associations indicated a primary role in the representation of naturopathy and/or WHM in Australia. Examples of stated aims and purposes included: ‘Develop skills and high standards of performance in naturopathy amongst members’ (ANPA), ‘to promote the pure spirituality, philosophy, art and science of traditional medicine and natural therapies ...’ (ANTAsn), and ‘promote, protect and encourage the study, practice and knowledge of medical herbalism’ (NHAA).

The major themes are summarised as follows:

- providing education and information to practitioners and the public (71%);
- promoting higher professional standards (57%);
- representing members to government and other significant bodies (43%);
- providing coordination and liaison among organisations (28%);
- promoting natural therapies (28%);
- integrating the complementary and the orthodox (21%); (the two medical organisations and one consumer organisation);
- improving the health of the Australian community through health promotion and preventive healthcare (14%);
- participating in the development of appropriate regulation (14%);
- empowering consumers (7%); (the consumer association); and
- conducting research (7%); (one medical association).

### 6.3.3 Legal status

Of the 14 responding organisations, three were incorporated companies and 11 were incorporated associations. Incorporation limits the individual liability of members. A prerequisite to be an incorporated association is that the organisation must be not-for-profit. The organisation cannot enter into trade, but it can enter into legal agreements and own or dispose of property.

Most incorporated bodies were incorporated in the eastern states. There were four in Victoria, three in Queensland, one in New South Wales (NSW), three in South Australia and

one in Western Australia (Appendix 6.2). Two associations reported that they were incorporated in all states and territories.

All 14 stated that they were national organisations with a national membership base, and 11 had their own premises.

#### **6.3.4 Association boards**

Thirteen associations provided details of a formal board structure, and seven provided copies of their constitutions. The structure and administration of the professional associations is set out in Appendix 6.2. The boards of all associations met on a regular basis, with the frequency of meetings ranging from annually to monthly.

The members of all but one of the professional associations were eligible to stand for election, hold office, and vote for office bearers. Appendix 6.3 sets out the categories of members in the associations and their rights regarding the holding of office and voting. In one organisation, ATMS, the executive consisted of members appointed by educational colleges—with one member being appointed by each educational college accredited by the association (to a maximum of 22 positions). The section on office bearers in the ATMS memorandum and articles of association (extracted from the Australian Securities and Investments Commission database, 6 December 2004) describes a process of election and appointment of office bearers by the executive. No mention is made of the participation of members in this process.

All 14 associations reported that changes to the constitution could be made only by the memberships at the annual meetings or at special general meetings. Decisions on other important issues were made by the boards in consultation with the memberships of the associations. Only ACHA, whose major role is to represent consumers and encourage improvement of standards in the CAM professions, did not include members in the consultation process.

#### **6.3.5 Staffing and consultants**

Of the 14 associations, seven reported having paid staff. The three associations with the largest staffs were ATMS, ACNEM, and ANTAsn. Seven associations relied solely on staffing via honorary positions—AANMP, AAH, ACHA, ACONT, AFNT, FNNT, and SNTR.

In 2002, seven associations employed outside expertise in the form of consultants—for periods ranging between two and 100 days.

#### **6.3.6 Affiliations**

Six associations reported no affiliations. The remaining eight reported affiliations that fell into three main categories—inter-association relationships, affiliations with education providers, and connections with a range of other health-related organisations. Some associations reported a strong network of affiliations.

##### **Education affiliations**

In the absence of occupational regulation and control of educational standards, multiple pathways have arisen for formal recognition (accreditation) of training courses. Various kinds of relationships were identified between associations and education providers.

Six associations described established mechanisms for formal recognition of courses—enabling graduates of these courses to gain automatic membership. The standards applied to course recognition varied (Appendix 6.4).

Other associations simply accepted graduates of any government-accredited course (VET or university), or dealt with applicants individually.

## Association affiliations

Professional associations have established affiliations with each other (formal and informal) in the past. One reason for these arrangements has been the need to present a united voice in order to overcome the problems government bodies have experienced in dealing with a range of organisations—each of which claims to represent the professions, but some of which state different positions. However, affiliations have a history of disintegration, making cohesive professional representation difficult to achieve. For example:

- The Natural Therapists' Forum (later known as the Federation of Natural and Traditional Therapists [FNTT]) was established in response to TGA legal requirements (see 6.3.7). The number of associations in the FNTT has declined, and the larger organisations have withdrawn.
- The Complementary Medicines Practitioner Association Council (CMPAC) was formed in response to the needs of the ATO to identify bona-fide practitioners for GST purposes. CMPAC originally consisted of four associations, but since early 2004 it has been reduced to two.

For current membership of FNTT and CMPAC see Table 6.2.

### 6.3.7 Institutional status of participating associations

The status of professional associations with the ATO, the TGA and private health insurance funds is a factor in efforts over the last two decades to develop a form of self-regulation. The need to gain formal recognition, particularly from the ATO and the TGA, was the impetus for efforts by some associations to present a united voice through federated arrangements such as CMPAC and the FNTT.

This section briefly describes arrangements with the ATO, TGA and private health insurance funds. Further information can be found in Chapter 7 (health insurance funds) and Chapter 10 (ATO and TGA). Table 6.2 sets out the status in 2003 of associations with regard to the ATO, TGA, membership of association consortiums, and recognition by private health insurance funds.

### Goods and Services Tax exemption

In 1991 the TGA began to establish regulatory requirements for the natural therapies industry. In 1999 the GST Transition Act provided GST exemption for the consultations of naturopaths, herbalists, and acupuncturists for a three year period during which it was envisaged that a suitable regulatory model to identify bona-fide practitioners would be developed. To support the implementation of the GST legislation, the Commonwealth Department of Health and Ageing (DHA) allocated \$0.5 million, which was divided among five major associations: ANTA, ATMS, FNTT, NHAA, and the Australian Acupuncture and Chinese Medicine Association (AACMA). However, a system of regulation was not able to be agreed upon. Instead, multiple associations were granted status by the Australian Taxation Office as 'recognised associations' (see 10.3.1).

The effect of the agreement with the ATO has been the recognition of multiple associations and their members without consensus between associations on educational or regulatory standards. The Expert Committee on Complementary Medicines in the Health System (hereinafter referred to as the 'Expert Committee') expressed concern that ATO acceptance 'could be interpreted as *de facto* recognition of bodies that are not representative of their professions, and militates against the development of strong, cohesive and representative professional bodies' (Expert Committee 2003, p.132).

The Expert Committee (2003 p.134) also recommended that the Australian government consider revising the definition of a professional association in order to raise the standard of self-regulatory structures.



## Therapeutic Goods Administration requirements

The legal requirements of the TGA affect the access of natural therapists to advertising of therapeutic goods. In order to receive such advertising, practitioners must either belong to an association that is listed on Schedule 1 of the Therapeutic Goods Regulations 1990, or be registered under a law of a state or territory.

Associations with Schedule 1 status issue practitioner members with a 'Certificate of Exemption', which indicates that the practitioner is exempt from restrictions on access to therapeutic goods advertising.

An association must apply to the TGA for inclusion on the Schedule. The application is processed by the FNNT and then returned to the TGA. A recommendation that an association be granted Schedule 1 status must be approved by the Parliamentary Secretary to the Minister for Health and Ageing.

Over 40 natural therapy associations have now been granted Schedule 1 status by the TGA (TGA 2004).

## Recognition of associations by health insurance funds

Most of the responding associations reported that numerous private health insurance funds offered rebates on consultations by their practitioner members. However, although associations provided lists of these funds, a survey of health insurance providers revealed that few funds would automatically accept association members as providers without requiring additional information. The health funds were aware of the variable requirements for membership of associations and, in general, expressed a preference for a more reliable regulatory model to assist them in identifying bona-fide practitioners (see Chapter 7).

**Table 6.2 Institutional status of associations**

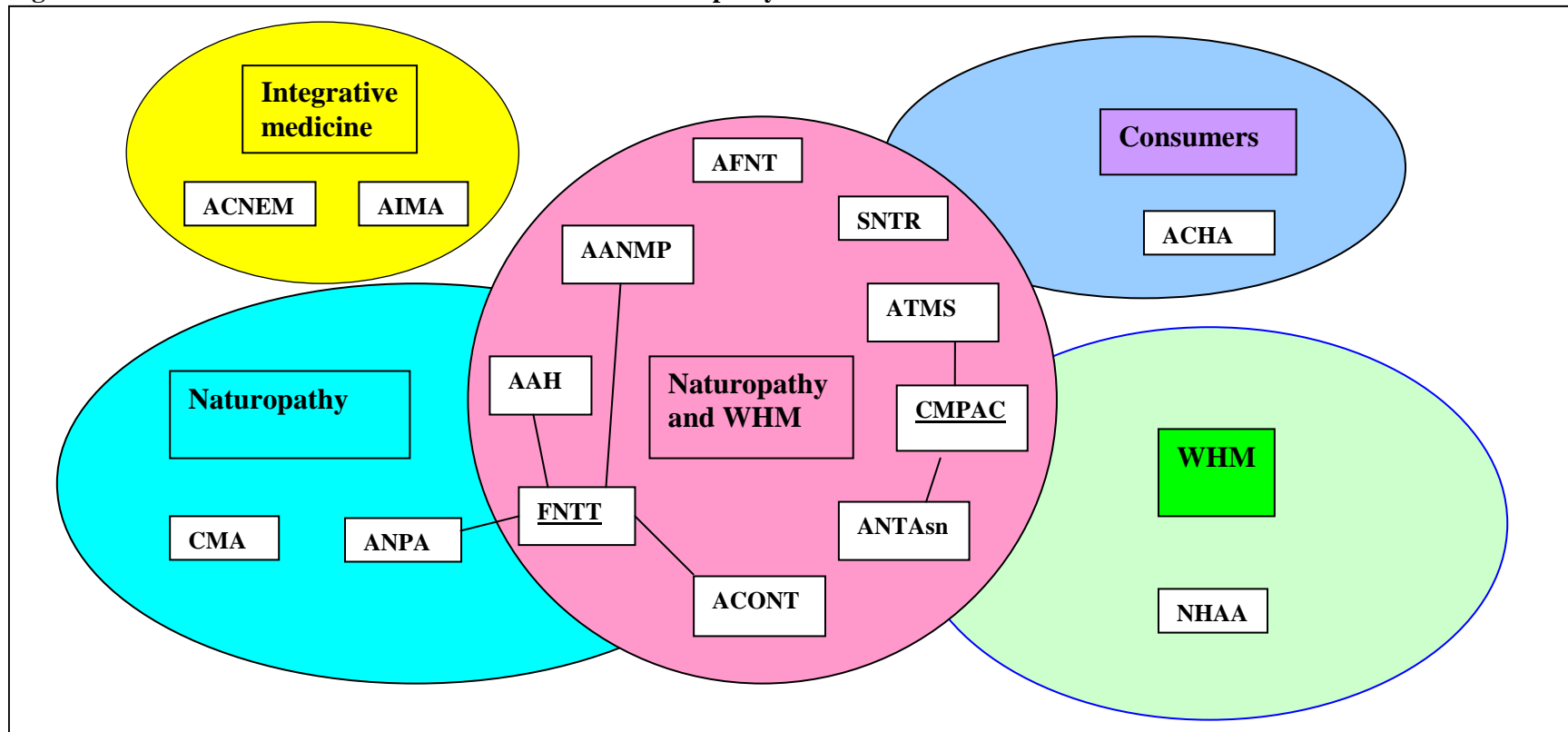
Association	ATO Recognised association	TGA Schedule 1 organisation	Member of CMPAC	Member of FNNT	Members recognised by health funds
AANMP	✓	✓	X	✓	✓
AAH	✓	✓	X	✓	In process
ACNEM	N/A	N/A	N/A	N/A	N/A
ACONT	✓	✓	X	✓	X
ACHA	N/A	N/A	N/A	N/A	N/A
AFNT	✓	✓	X	X	✓
AIMA	N/A	N/A	N/A	N/A	N/A
ANPA	✓	✓	X	✓	✓
ANTA <sub>sn</sub>	✓	✓	✓	X	✓
ATMS	✓	✓	✓	X	✓
CMA	✓	✓	X	X	✓
FNNT	✓	X*	X	N/A	X
NHAA	✓	✓	X	X	✓
SNTR	✓	✓	X	X	✓

**Notes:**

\* FNNT member associations have Schedule 1 status

N/A = not applicable

Figure 6.2 Professional associations with an interest in Naturopathy and WHM in Australia.



Note: FNTT and CMPAC are peak bodies—lines indicate member associations.

## 6.4 Membership

### 6.4.1 Number of members by practitioner type

Thirteen of the fourteen participating associations provided data on the numbers of naturopaths and WHM practitioners who were members. Efforts were made to avoid counting members twice in the present survey. These efforts included:

- instructions on the questionnaire to report members as either naturopaths or WHM practitioners, or both; and
- subtraction of FNNT members who had already been reported by the FNNT member associations (ANPA, AANMP, and ACONT).

The total numbers reported by the 13 associations were: naturopaths 4217; WHM practitioners 2469 (Table 6.3). An additional 369 practitioners were accredited to practice in both professions (Appendix 6.4).

It is difficult to ascertain the exact number of practitioners in Australia because practitioners frequently join more than one association. Bensoussan et al. (2004) found that 50% of naturopathy and WHM practitioners belonged to two associations, 15.1% belonged to three associations, and 6% belonged to four associations (Chapter 4). These data were used to re-calculate the number of members reported by associations, resulting in a finding of 1219 naturopaths and 1752 WHM practitioners (a total number of 2971 practitioners).

Researchers who carried out the workforce survey reported in Chapter 4 developed a mailing list of 1778 practising naturopaths and Western herbal medicine practitioners (see 4.2.2), substantially less than the number of memberships reported by associations to the present survey. It was also estimated that a further 16% of practitioners may not be in active practice (Bensoussan et al. 2004).

### 6.4.2 Membership categories

Common categories of membership were: fellows, full members, associate members, students, and corporate members (Appendix 6.5).

Of the 14 associations:

- five had made provision for fellows;
- all provided full membership;
- eight had an associate category;
- ten had student memberships; and
- five accepted corporate members.

The requirements for granting the various categories of membership varied from one association to another. For example, differing association requirements to become a fellow included: ‘outstanding service’, ‘associate diploma’, ‘bachelor’s degree’, or ‘a significant number of years in clinical practice’.

### 6.4.3 Number of practitioners by membership category

The largest category was that of *full membership*—with 3770 naturopaths and 2233 WHM practitioners reported. Adding the numbers of *fellows* and *full members* together for each profession produced a total of 4217 naturopathic memberships and 2469 WHM practitioner memberships (Table 6.3).

The number of members actually in practice will be substantially fewer because: (i) individuals might belong to more than one association; (ii) many of the accredited members might not be in practice (see 6.4.1). The second point raises the issue of competence related to ‘recency of practice’, particularly when an association does not require evidence of continuing professional education when renewing memberships (Appendix 6.6).

**Table 6.3 Number of members by membership category**

Association	Fellows		Full members		Associates		Students		Corporate
	Nat <sup>y</sup>	WHM	Nat <sup>y</sup>	WHM	Nat <sup>y</sup>	WHM	Nat <sup>y</sup>	WHM	
AANMP	32	0	160	0	0§	0§	420	0	N/A
AAH	0	0	300	0	30	0	20	0	0
ACNEM	N/A	N/A	0	0	24	0	N/A	N/A	N/A
ACONT	N/A	N/A	16	0	N/A	N/A	0	0	10
ACHA	N/A	N/A	N/R	N/R	N/A	N/A	N/A	N/A	70
AFNT	N/A	N/A	30	0	0	0	50	0	N/A
AIMA	N/A	N/A	0	0	8	0	0	0	N/A
ANPA	N/A	N/A	487	0	N/A	N/A	0	0	N/A
ANTAsn	361	217	845	343	0§	0§	99	7	0
ATMS	N/A	N/A	1932	1067	N/A	N/A	30	18	0
CMA	N/P	N/P	N/P	N/P	N/P	N/P	N/P	N/P	N/P
FNTT <sup>#</sup>	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
NHAA	N/A	10	0	823*	0	190	0	527	1
SNTR	54	9	N/P	N/P	N/P	N/P	N/P	N/P	N/A
<b>Totals</b>	<b>447</b>	<b>236</b>	<b>3770</b>	<b>2233</b>	<b>62</b>	<b>190</b>	<b>619</b>	<b>552</b>	<b>81</b>

**Notes:**

N/A: indicates membership category not available

N/P: indicates data not provided

N/R: indicates ACHA not able to retrieve data

§: indicates category exists, but not available to practitioners

\*: indicates members are mainly WHM practitioners (NHAA will accept naturopaths if they meet requirements for herbal medicine and nutrition education)

#: indicates that FNTT represents associations, rather than individual members

**6.4.4 Number of overseas members**

Overseas members were generally few in number, but were located in numerous countries. Four associations reported a combined total of 24 overseas naturopathy members, and two associations reported a combined total of 25 overseas WHM practitioner members.

New Zealand was the most common country in which overseas members resided—with six associations reporting members in that country. The United States of America (USA) was the next most common—with four associations reporting members in that country. Other foreign places in which members resided were the United Kingdom (UK), Ireland, Canada, Belgium, Denmark, Indonesia, Vanuatu, Hong Kong, Singapore, Austria, Greece, West Indies, Middle East, Sweden, and South Africa.

**6.4.5 Formal recognition of practitioners by associations**

A major function of professional associations is to grant professional recognition to practitioners. Associations may offer professional recognition and status to members in several ways:

1. Recognition of qualifications;
2. Eligibility to provide GST-free services;
3. Provision of a 'TGA Certificate of Exemption';
4. Provision of a certificate of membership;
5. The granting of a membership or 'provider' number.

The capacity of an association to offer these provisions to practitioner members is significant in attracting members. Associations that have been successful in gaining both formal recognition from the ATO, and inclusion on the TGA's Schedule 1 (see Table 6.2), are able to offer the highest level of recognition to practitioner members. The membership number granted by an association, also known as a 'provider number', affords a mechanism for recognition of practitioners by private health funds.

Although professional associations formally recognise practitioners through the granting of a practitioner membership, such a membership has no legal standing. Any person can practice as a naturopath or WHM practitioner in Australia as there are no legal requirements for admission to practice.

#### **6.4.6 Requirements of applicants for membership**

Minimum requirements for practitioner membership in an association varied from no minimum requirement (that is, individual assessment of each applicant's education and clinical experience) to advanced diploma (see Appendix 6.4 – Membership numbers and requirements for accreditation). Also, according to their constitutions, several associations may make individual assessments of applicants who do not have the stipulated educational requirements. At least one association did not set a minimum educational requirement for membership of naturopaths and WHM practitioners.

Six of the fourteen associations indicated that they had developed accreditation processes for assessing overseas naturopathy and/or WHM applicants. However, only one of these reported use of a gazetted education authority to assess equivalence with Australian qualifications.

#### **6.4.7 Benefits to members**

As described above, a major benefit to members is access to GST-free status for consultation fees, and Certificates of Exemption to TGA restrictions on access to advertising of therapeutic goods (see 6.3.7). Eleven of the 14 associations that participated in the current survey were recognised by the ATO, and ten were listed on Schedule 1 of the TGA Regulations 1990.

Associations also provided a range of other benefits. Information was sought on publications, dialogue with members, seminars and conferences, recognition by health funds, libraries, and other facilities. The major associations were also active in writing submissions to governments on a range of issues important to the professions.

Six associations had fewer than 500 members. The smaller associations were more likely to operate on a voluntary basis and less likely to provide a range of significant benefits for their members.

#### **Publication of periodicals**

All 14 associations published a periodical. These included newsletters (online or hardcopy), magazines, and professional peer reviewed journals.

Peer reviewed publications were the *Australian Journal of Medical Herbalism* (NHAA), *ATOMS* (ATMS), *Journal of the Australian College of Nutritional and Environmental Medicine* (ACNEM), and *The Natural Therapist* (ANTAsn). In addition, peer review of articles was undertaken as the need arose by ACHA's *Diversity: Natural and Complementary Health* and CMA's *CMA Newsletter*.

The journals and newsletters submitted to the research team by the participating associations mainly provided information to members. Only a small amount of original research and scholarly work was published in the journals provided. It was difficult to ascertain the quality or intent of peer review from some of the journals —because the policy regarding peer review was not set out in all journals that indicated use of this model of publication.

#### **Seminars and conferences**

Seminars and conferences can provide a significant vehicle for debate on professional issues, presentation of research, therapeutic approaches, and networking. The professional associations in the present survey were not very active in this area—thus limiting the opportunities for practitioners to engage in debate or to be exposed to perspectives outside their own associations.

Only five of the 14 associations provided seminars in 2002. Only two held conferences in the period 2000–02 (Appendices 6.8 and 6.9). All seminars were on health related topics such as nutrition, massage or women’s health. None included professional matters that might be of interest to practitioners, for example, regulation of naturopathy and WHM or interaction with other health professionals.

Manufacturers appear to have largely taken over the field of seminars for practitioners. An impartial ‘best practice’ approach to selection of therapeutic interventions might therefore be lacking.

### **Submissions to government bodies**

In the past five years, six associations (ACHA, ACNEM, ANPA, ANTAsn, FNNTT, NHAA) put submissions, reports, and responses to government bodies on behalf of their members. The preparation of such submissions appeared to be an activity that was restricted to the larger and better resourced associations.

### **Formal recognition of courses**

Formal recognition of a course by an association facilitates membership for graduates of such a course. Associations recognised education programs in two ways: (i) automatic recognition for government accredited courses (VET sector or university); (ii) by formally assessing the quality of courses submitted by education providers. Four associations had developed formal processes for assessing courses according to standards set individually by each association. The quality of the assessment process appeared to be strong in some associations, based on material provided to the research group. Where such material was not provided, the quality of the process could not be assessed. (See Appendix 6.4 for the process for formal recognition [accreditation] of courses).

Recognition of a course by an association is a voluntary process. The majority of education providers who participated in the current survey had had their naturopathy and WHM courses formally recognised by a professional association (see Appendix 5.9, Undergraduate programs: course details and accreditation).

### **6.4.8 Membership fees**

Appendix 6.6 sets out the membership fees. The range of annual fees for a full membership was \$55–\$300. The average fee was \$195, with a median of \$210. The lowest fee charged by a professional association was \$120 (by AIMA). The highest fee was \$300; this was charged by three associations (ANPA, ANTAsn, and SNTR).

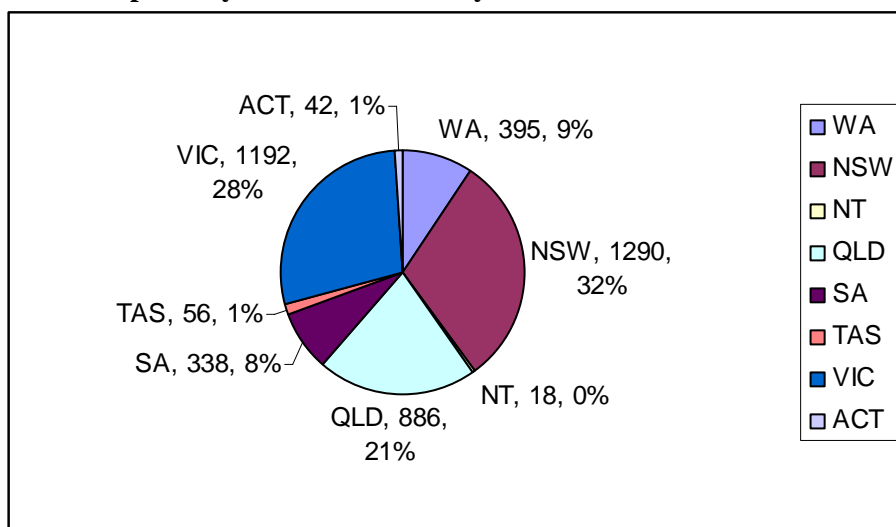
For students, the range was from nil to \$55, with an average fee of \$33. One association provided free membership for students.

### **6.4.9 Distribution of members by state and territory**

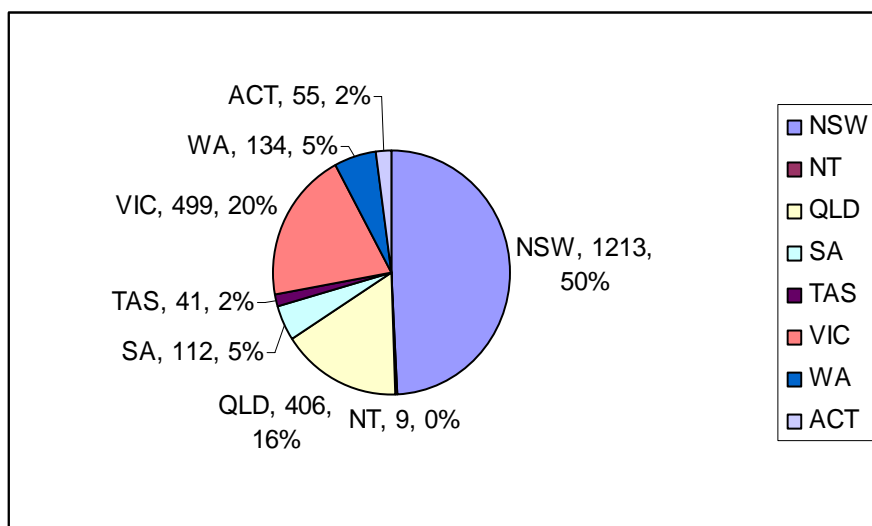
Data were provided on the distribution of naturopaths and WHM practitioners by nine of the fourteen associations, and covered 99% of WHM practitioners and 98% of naturopaths reported to the present study. Naturopaths and WHM practitioners were most likely to be located in NSW, Victoria, and Queensland (Figures 6.3 and 6.4). In most states, the reported number of naturopaths was two to three times as great as the number of herbalists.

According to the data provided by the associations, NSW had most practitioners with almost half of Australia’s herbalists, and almost one third of naturopaths. Victoria, Queensland and Western Australia followed. However, it is difficult to draw absolute conclusions about distribution of practitioners from the data because practitioners frequently belong to more than one association (see 6.4.1).

**Figure 6.3 Naturopaths by State and Territory**



**Figure 6.4 WHM Practitioners by State and Territory**



## 6.5 Practice standards

### 6.5.1 Professional requirements of members

To maintain the standards of the profession, associations imposed a range of requirements on their practitioner members. These included (see Appendix 6.6):

- *Codes of ethics*: all professional associations had developed such codes, and expected practitioners to adhere to them as a condition of membership;
- *Professional indemnity insurance*: this was a uniform requirement;
- *First aid training*: this was essential for all practitioner members;
- *Continuing professional education (CPE)*: CPE was a requirement for full membership in only eight of the eleven associations that formally recognised naturopaths and WHM practitioners for practice.

## 6.5.2 Complaints mechanisms

Of the 14 associations, 13 stated that they had a complaints mechanism. ACHA indicated that it was not part of its role to receive healthcare complaints about practitioners. Eight associations supplied information on complaints processes and disciplining of members. The approaches varied.

All dealt with the rights of practitioners and the process of expelling practitioners.

In some constitutions there was a lack of clear process regarding: (i) how complaints were to be submitted by practitioners or the public; (ii) how the nominated committee was to deal with the complaints; (iii) the rights of complainants; (iv) whether committee documents were 'blinded'; and (v) whether voting on an expulsion was conducted in the context of a general meeting or by a secret ballot.

Only six associations had insurance to indemnify them against legal costs that might be incurred during a complaints process—thus leaving the associations vulnerable to the cost of prolonged or vexatious legal processes.

Only one association stated that it had ever had a problem related to complaints. This problem had resulted from the association taking a verbal complaint, and the process had since been rectified.

Information on the nature of complaints against naturopaths and WHM practitioners is set out in Chapter 2, 'Risks Associated with the Practice of Naturopathy and Western Herbal Medicine'.

### Complaints mechanisms in Chinese medicine – a comparison

To gain an understanding of whether the establishment of a registration board might lead to an increase in the number of complaints about practitioners, enquiries were made of the Chinese Medicine Registration Board Victoria (CMRB) and the Office of the Health Services Commissioner, Victoria. The purpose was to compare the number of complaints about Chinese medicine practitioners before and after the CMRB began to accept formal complaints in 2002. The Office of the Health Services Commissioner indicated that there had been eight complaints against acupuncturists in the years 1999–2004. In the same period there were two complaints about herbalists and seven about naturopaths (Table 6.4).

**Table 6.4 Complementary Health Practitioner Complaints**

Financial Year	Acupuncturists	Herbalists	Naturopaths	Grand Total
1999-2000	1	1	2	4
2000-2001	3	0	2	5
2001-2002	1	0	0	1
2002-2003	1	0	1	2
2003-2004	2	1	2	5
<b>Total</b>	8	2	7	17

Data from the CMRB for the financial years 2002/03 and 2003/04 indicated that a total of 34 complaints was received about Chinese medicine practitioners. This is a significant increase, and suggests the effectiveness of a registration board in increasing public awareness, providing access, and providing a mechanism for receiving and handling complaints and imposing disciplinary sanctions. The number and nature of complaints about Chinese medicine practitioners are set out in Table 6.5.



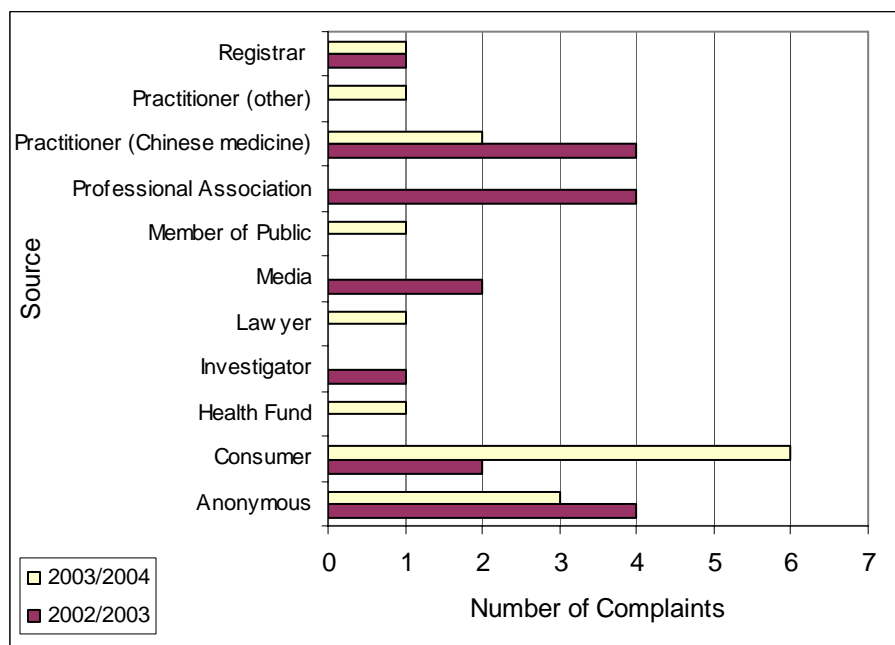
**Table 6.5 Number and nature of complaints against Chinese medicine practitioners**

Nature of complaint	2002/03	2003/04
Advertising		
Testimonials	3	2
Misleading	1	1
Breach of undertaking	1	2
Consumer general issues		
Failure to provide receipts		1
Consumer treatment issues		
Poor outcome/adverse effects		3
Other		1
Endangered species		1
Fraud		
False qualifications	3	
False statements (incl. failure to disclose)	2	3
Health funds/Medicare	5	
Infection control	3	
Incorrect title use / holding-out as		1
Character issues		1
<b>Totals</b>	<b>18</b>	<b>16</b>

Source: Chinese Medicine Registration Board, Victoria.

The source of complaints about Chinese medicine practitioners was varied—indicating that a wide cross-section of the community was aware of the CMRB’s complaints mechanism.

**Figure 6.5 Source of complaints about Chinese medicine practitioners**

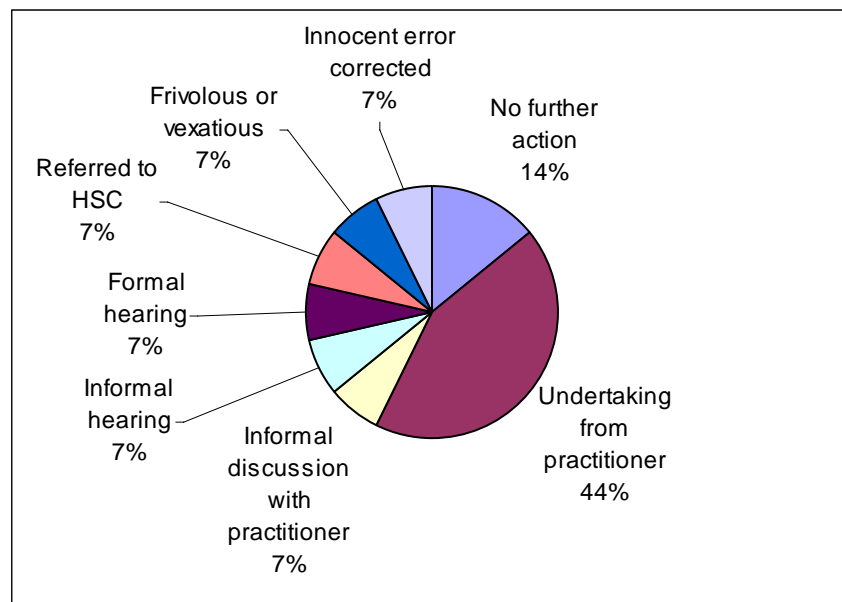


Source: Chinese Medicine Registration Board, Victoria

## Outcomes of complaints against Chinese medicine practitioners

A range of remedies is available for the resolution of complaints against Chinese medicine practitioners. Figure 6.6 shows the various outcomes from the Chinese Medicine Registration Board's investigations into complaints.

**Figure 6.6 Outcomes of preliminary investigation of complaints against Chinese medicine practitioners**



Note: HSC = Health Services Commissioner

Source: Chinese Medicine Registration Board, Victoria

### 6.5.3 Professional practice guidelines

Professional associations usually play an important role in providing informed guidelines for practitioners. Guidelines act to support the membership and clearly indicate the professional standards set by an association. Associations' knowledge of professional matters also assists registration boards in the setting of standards.

Associations were asked if they had written guidelines on a range of professional and clinical issues. These included: (i) referral to medical practitioners; (ii) accidents, injuries, and adverse events; (iii) use of scheduled or restricted herbs; (iv) medical immunisation; and (v) practice guidelines.

Most associations in this study were not very active in the development of practice guidelines (Appendix 6.7). Only six associations had developed any guidelines; however, few provided examples as requested. None of the examples was available as a discrete document, and practice guidelines had to be accessed from a range of other documents—such as codes of ethics, applications for membership, and journal articles.

#### Referral to medical practitioners

Six associations had prepared guidelines on referral to medical practitioners. In view of the fact that 72.8% of naturopaths and WHM practitioners stated that they referred patients to medical practitioners 'only occasionally' (see Chapter 4), the availability of such guidelines would assist practitioners who might otherwise be hesitant in making a formal referral.

#### Collection of data on accidents, injuries, and adverse events

Collection of data on accidents, injuries, and adverse events is important in assisting the profession to identify problems, inform other health agencies and the public of problems, support public health initiatives, and raise standards. There is a widespread belief in the

professions that, compared with adverse events caused by medical treatments, the use of natural therapies is relatively safe. However, an effective system of notification is essential to the process and to obtaining accurate data.

The present study found that:

- only four of the fourteen associations stated that they collected such data, and for three of these associations the purpose was to assist with complaints (Appendix 6.10); and
- adverse events have not been monitored effectively by the naturopathy and WHM professions, and the present system of reporting to ADRAC is not widely used by natural therapists; an improved system of reporting is needed (Expert Committee 2003).

### **Other professional guidelines**

Only three associations had prepared guidelines on the use of scheduled (restricted) herbs (Appendix 6.7). The workforce survey reported in Chapter 4 found that naturopaths and WHM practitioners still occasionally use a range of scheduled herbs in breach of the law (Table 4.13). Practitioners would benefit from easy access to informed guidelines on this matter.

Three associations had prepared guidelines on practice requirements (such as dispensing practices or manufacture of products for extemporaneous prescription), but none had prepared guidelines on immunisation (Appendix 6.7).

## **6.6 Current concerns of associations**

Participants were given an opportunity to respond to a range of open questions on regulation, access to medicines, education, and other issues relating to governmental, political, or legal activities.

### **6.6.1 Regulation**

#### **Current views of the associations on regulation**

The associations do not present a unified voice on the issue of regulation. The present study found that:

- Of the 11 associations that responded on the issue of regulation, four (36%) called for statutory regulation, three (27%) wanted stronger regulation but did not specify a model, and four (36%) supported self-regulation.
- Overall, seven (64%) of the 11 associations that responded were negative about current attempts to self-regulate.
- The need to protect the professions and practices of naturopathy and WHM was seen as a strong motivating factor by both sides of the debate.
- A key argument by some supporters of statutory regulation is that this status, and with it a raised standard of education, is essential to gain access to currently scheduled natural medicines (see 6.6.2 below).

In any regulatory system the issue of 'grandparenting'<sup>4</sup> would need to be addressed. A major association believes it is possible to draw on the collective experience of associations in developing processes and criteria that are fair, equitable, and transparent.

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<sup>4</sup> A grandparenting scheme can be established by a registration board to implement transitional provisions of a registration act. Grandparenting operates for a restricted period, for example three years, and allows a board to register persons who do not have the specified qualifications but who satisfy the board regarding other appropriate qualifications or specified experience, and professional competence.

## 6.6.2 Access to medicines

Herbs that are highly toxic, such as belladonna and aconite, have been restricted for most of the past century. In the 1970s comfrey was scheduled following the death of a young man from liver failure. The cause was unknown but comfrey was believed to be implicated.

Since the passing of the Commonwealth *Therapeutic Goods Act* in 1989, the list of herbs removed from use has steadily grown. Appendix C of the national Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) lists substances that are considered to be of sufficient danger to health that use by any practitioner (including medical doctors) is illegal. Herbs listed on Appendix C include ephedra and coltsfoot which, until recently, were used therapeutically by naturopaths and WHM practitioners. Further, herbs listed on certain Schedules under state or territory legislation are available only to practitioners with statutory registration. (See Chapter 10 for further information on scheduling of herbs). Seven associations presented a range of concerns on the issue of access to medicines. These are described below.

### State drugs and poisons regimes and the legal status of practitioners

Associations pointed out that the placing of herbs on restricted Schedules effectively means their withdrawal from use as naturopaths and WHM practitioners are unable to prescribe them, and few medical practitioners or pharmacists are trained in their use. The current regulations cannot differentiate between qualified natural therapists and lay persons.

Other concerns are (i) that some herbs that are presently available to the public should be restricted to prescription by qualified herbalists and naturopaths, and (ii) the continued illegal use of certain scheduled herbs by naturopaths and WHM practitioners (Bensoussan et al. 2004, see Chapter 4). (Almost 70% of practitioners surveyed stated that they would find it beneficial to have access to scheduled herbs, and 82.3% believed that suitably qualified practitioners should have the legal right to prescribed scheduled herbal or homeopathic medicines [Bensoussan et al. 2004, see Chapter 4]).

The current level of regulatory restraint was seen as an unacceptable restriction on the use of the profession's 'tools of trade'. This also affects consumers, who are denied access to an increasing number of therapeutic substances as potentially toxic herbs continue to come under the scrutiny of the TGA.

### Government restrictions on practice

Another issue regarding access is a perceived threat to extemporaneous supply—that is, the manufacture of their own products by naturopaths and herbalists for supply to individual patients, and mixing herbal extracts and tinctures together for individual patients. (Such products cannot be produced and sold in bulk as wholesale or retail commercial products without a manufacturing licence).

There was some concern that practitioners might, in future, be limited to pre-packaged formulae manufactured in TGA-approved facilities, or that practitioner dispensaries might be closed, thus forcing patients to have prescriptions filled in a pharmacy. The power of the pharmaceutical lobby was noted in the context of restricting the activities of herbalists.

### Education in herbal medicine

The issue of access to restricted herbs is associated with the issue of educational standards (see further discussion in 6.6.3). Concerns identified by the associations were that:

- appropriately educated practitioners should have access to restricted herbs and other natural and traditional medicines; and
- extemporaneous supply requires proper training and the oversight of an accrediting or regulating body.

## **Discrimination**

The present situation of restricted access to herbal medicines for naturopaths and WHM practitioners was seen by respondents as being anti-competitive and discriminatory. A particular issue was the right of medical doctors who usually have little or no education in herbal medicine to prescribe scheduled herbs. It was also felt that there was a ‘double standard’ in allowing many unsafe medications—such as paracetamol (an overdose of which can cause death by liver failure)—to be freely available to consumers.

### **6.6.3 Education issues**

The required level of education for naturopaths and WHM practitioners has been a matter of debate within the professions for at least three decades. Some segments of the professions have been working towards a bachelor’s degree as the minimum qualification, whereas others hold that the required educational standard should continue to be at the vocational level. The major education issues raised in this survey were as follows.

#### **Regulation and education**

- It was pointed out that with current attempts to self-regulate there is no uniform minimum standard of education.
- Because there is some risk with natural therapies there was concern about inadequately trained or incompetent practitioners. (This concern was supported by the workforce survey [see 4.6.1], where practitioners reported undertaking training courses ranging from 6 months to 6 years in duration).
- Care must be taken that regulatory effects on education do not diminish the philosophy of naturopathy and WHM.

#### **No minimum standard for entry-level training**

There was considerable criticism from the associations regarding current educational standards and the problems that arise from having professional entry courses offered at different educational levels. The following concerns were expressed.

- The diplomas and degrees available for entry to practice apply different levels of the Australian Qualifications Framework—especially with respect to critical thinking and analysis.
- Standards in the national health training package were criticised as being inadequate for professional practice.
- Universities new to education in naturopathy and WHM lack a ‘culture’ of naturopathy or herbal medicine which has adverse effects on course quality.
- Of particular concern was clinical education—in which problems were apparent in all three education sectors. These problems included: (i) reluctance to support effective clinical training; (ii) little or no time spent in clinical practicum in some courses; (iii) minimal or absent mentoring of students; (iv) clinical experience not commencing until late in a course; and (v) poor quality of clinical experience received by some students.
- There is a potential for conflicts of interest if professional associations are intimately linked with private education providers, whose commercial interests might not be served by a requirement to raise standards of education.

No association argued that diploma or advanced diploma education is the most appropriate level of education for naturopathy or WHM—even though most associations currently set this standard for full membership.

In the interests of public safety, several organisations argued that the professions must move towards a bachelor’s degree as the minimum level of education for practitioners.

In contrast, the external accreditation of courses and the monitoring for quality that occurs with VET sector and university courses was seen to have had a positive effect on education.

## **The commercialisation of education**

Associations expressed concerns that commercialisation has driven down the quality of education. Lack of regulation has allowed a greater number of providers and increasing competition—sometimes at the expense of quality.

In some locations large numbers of students graduate each year leading to market saturation, and a perception of lowered professional standards and lack of employment for graduates.

### **6.6.4 Concerns about other governmental, political, or legal issues**

The associations were invited to comment on any other areas of concern. Issues that emerged were medical and pharmaceutical dominance and relationships with government. A participating medical association also raised a number of points.

#### **Medical and pharmaceutical dominance**

Concerns about the dominance of other health groups are longstanding. Key points raised by associations are:

- the uptake of complementary therapies by medical practitioners—which reduces practice standards and may lead to limitations on the practice of naturopaths and WHM practitioners;
- access by medical practitioners to Medicare payments for complementary and alternative treatments when medical practitioners might be less qualified in the area than a CAM therapist;
- the power of the medical and pharmaceutical lobbies to influence government and regulatory bodies;
- concern that Codex (a European Economic Community system that regulates nutritional supplements and their dosages) will be introduced to Australia; and
- concern that a lack of statutory registration restricts the ability of naturopaths and WHM practitioners to lobby on issues that directly affect them.

#### **Relationships with government**

The main themes that emerged were as follows.

- The perceived cost and restrictiveness of the new Chinese Medicine registration system in Victoria should be of concern to naturopaths and WHM practitioners who, potentially, face a similar scheme.
- As a result of poor representation on relevant policy-making and regulatory bodies, both state and federal, the professions lack an effective voice on issues that directly affect their professional practice.
- There is a need to be vigilant about government proposals that are not compatible with the aspirations of the professions.

#### **General practitioner concerns**

A medical association raised the following issues:

- Reticence by GPs to refer to naturopaths and WHM practitioners because of uncertainty about their standards and qualifications, and the legal position regarding referral;
- the possibility of vicarious liability if doctors refer patients to non-medical practitioners;
- the short consultation time favoured by Medicare—which supports a pharmaceutical approach to medicine by providing a disincentive for doctors to spend the additional time with patients that CAM requires; and
- reimbursement by Medicare for complementary medicine services without specified training requirements.

### **6.6.5 Perspectives on the future of naturopathy and WHM**

Overall, the associations were very positive about prospects for the naturopathy and WHM professions. Expectations for the future included:

- continued public demand due to increasing need for primary healthcare services by naturopaths and WHM practitioners;
- a growing number of multidisciplinary practices providing comprehensive services to patients;
- increasing integration into mainstream healthcare, and interaction with the medical profession, to the benefit of patients;
- stronger regulation and improved training with more research and evidence-based care;
- acceptance of the need for increased political and regulatory scrutiny, and continued review of standards to support high quality care;
- continuing efforts to create an attitudinal change in mainstream healthcare such that it becomes a ‘healthcare system’ rather than a ‘disease care’ system; and
- more resources in mainstream healthcare for prevention, lifestyle support, and naturopathy and WHM care—such that Australians will not be penalised financially or criticised for their healthcare preferences.

Some cautions were raised about the future. These included concerns:

- about continuing domination by large associations, and the need for smaller non-political groups;
- that the increasing ‘medicalisation’ of naturopathy might be a threat to the integrity of holistic practice, and that the push for evidence-based practice needs to set in the context of ‘whole practice’, rather than single therapeutic interventions;
- that the type and character of any future legislation will determine whether public health is enhanced by the inclusion of complementary healthcare;
- that independent practice should be able to continue; and
- that there is a need to respect freedom of choice in healthcare, and that a medical monopoly in a democratic society cannot be justified.

## **6.7 Summary of results**

### **6.7.1 Organisations and membership**

- Of the 17 professional associations identified as representative of naturopathy and WHM practitioners, 14 participated in this study.
- All participant associations were legally incorporated, and all claimed a national membership.
- Approximately half of the associations were formed in the period 1990–99.
- Board members were elected by the membership in 13 of the 14 associations in this study.
- Associations reported 4217 practitioners accredited in naturopathy and 2469 in WHM; an additional 369 practitioners were accredited in both professions.

### **6.7.2 Affiliations**

- There were few affiliations among the associations in this study; four belonged to FNNT and two to CMPAC. Affiliations among associations in the professions of naturopathy and WHM have a history of instability and dissolution.
- Formal recognition of courses by associations streamlines the process of acceptance of graduates for membership of associations. However, this process could be open to abuse—for example, if a conflict of interest exists between a course provider and the recognising professional association.
- Some associations recognise courses not accredited by an independent body.

### **6.7.3 Regulation and formal recognition of practitioners**

- Efforts to self-regulate have not produced a national, consistent, and effective system of regulation for naturopathy and WHM.
- Associations were divided with respect to self-regulation or statutory registration. Some hold that the latter would protect the profession, whereas others believe it might entail damaging restrictions.
- Formal recognition (accreditation) of naturopaths and WHM practitioners was carried out by ten of the participant associations.
- Definitions of membership categories were not uniform.
- Graduates of some courses were granted automatic membership; graduates of other courses could apply for individual consideration.

### **6.7.4 Education requirements and recognition**

- There was significant variation in the minimum education standard required for practitioner accreditation.
- The education requirements for full membership ranged from ‘unspecified’ (applicants assessed individually) to advanced diploma. The range of available professional practitioner courses was from diploma to bachelor’s degree.
- There were mixed arrangements for formal recognition of education programs. Courses not accredited by the VET sector or a university could still be formally recognised by an association.
- Some associations expressed concern about poor standards of education, particularly with respect to clinical training, in an increasingly commercialised education environment.

### **6.7.5 Benefits to members**

- All associations provided a range of benefits to their members.
- Eight associations reported acceptance of members by health funds for partial rebate of client consultations.
- Most associations were not active in a range of professional areas. These included: (i) limited involvement in seminars and conferences on professional issues; (ii) inconsistent development of professional and best practice guidelines; and (iv) limited involvement in the publication of quality journals.

### **6.7.6 Requirements of members**

- Every professional association had developed a code of ethics and required practitioners to adhere to it in their practice.
- Professional indemnity insurance and first aid training were uniform requirements.
- Continuing professional education was stipulated for full members by only five associations.



### 6.7.7 Complaints and adverse events

- All the professional associations had a complaints mechanism. However, in some constitutions there was a lack of clear process regarding the handling of complaints.
- The number of complaints was small.
- Actions following upheld complaints included counselling, monitoring of practice, and withdrawal of membership.
- It was not clear who was to provide counselling or monitoring of practice. Their qualifications for so doing were also unclear.
- Associations did not appear to have a system whereby they could notify each other regarding suspended or expelled practitioners.
- There is no mechanism for professional associations to enforce disciplinary sanctions if a practitioner is uncooperative.
- Only four associations collected data on accidents, injuries, and adverse events; notification systems for such incidents were generally not well developed.

### 6.7.8 Access to medicines

- Naturopaths and WHM practitioners are denied access to herbs that are listed on Appendix C of the SUSDP, or on certain Schedules under state and territory drugs and poisons legislation.
- Naturopaths and WHM practitioners are subject to continuing restriction of access to herbal medicines because they are not recognised as legal providers under current drugs and poisons legislation.
- Statutory regulation of naturopaths and WHM practitioners would facilitate access to these herbs by providing a mechanism whereby regulators could recognise suitably qualified practitioners.

### 6.7.9 Future of naturopathy and WHM

- The associations were very positive about the future of naturopathy and WHM as primary contact professions that complement orthodox treatment by providing essential health-promoting care to the Australian public.
- Cautions raised about the future included: (i) the threat posed to holistic practice by increasing medicalisation; (ii) the need for research to investigate whole-of-practice approaches; (iii) possible adverse effects of any restrictive legislation (pertaining to naturopathy and WHM) on public health; (iv) the need to safeguard freedom of choice in healthcare; and (v) the possibility of a medical monopoly (and the view that this could not be justified in a democratic society).
- Historically, there has long been apprehension about the power of the medical and pharmaceutical lobbies; more recent concerns include the increasing use of complementary therapies by medical practitioners, and the effects on naturopathy and WHM practitioners of possible future restrictions (such as the potential imposition of the WHO Codex Alimentarium).

## 6.8 Discussion

Australia, like the UK, has traditionally supported freedom of choice in healthcare and has tolerated natural therapies. Attempts by the medical profession to ban their practice over a century ago were unsuccessful (Willis 1989), and increasing public patronage supported the growth and professionalisation of naturopathy and WHM. The absence of effective regulation has allowed standards to evolve in an *ad hoc* manner, overseen by a diverse array of associations with various positions. The growing number of associations, and disagreement among them on standards and the role of associations, weakens the voice of the profession. The recent history of the associations suggests that liaison and cooperation among organisations continues to be a problem for naturopathy and WHM.

Increasing professionalisation is a natural development (Mills 2001) and although some associations have worked diligently to improve their standards and accreditation systems, ongoing disagreements about education and occupational regulation have undermined unity on standards. The administrative arrangements with the ATO under the GST legislation have not supported effective self-regulation (Expert Committee 2003).

The mechanisms established by the ATO and TGA, and recognition by private health insurance funds, are seen by the professional associations as key aspects of the attempt to self-regulate. However, the associations vary with respect to their educational requirements for practitioner membership. Further, membership of associations by practitioners is essentially voluntary as there are no legal requirements for practice in Australia. Recognition by the ATO, TGA and private health funds is useful to practitioners, but inability to gain such recognition does not present a barrier to practice. For example, it is possible to practise using a range of therapeutic interventions that fall outside the scope of TGA regulations, such as the use of dietary regimes, raw herbs, retail products from health food stores or pharmacies, and lifestyle counselling. Consumers may not object to paying GST on consultations, and may not belong to private health insurance funds.

The need to protect the public has become stronger as a result of annual increases in the number of people accessing natural therapists (MacLennan et al. 2002). Compared with medical practice there have been few complaints but this might be due, in part, to under-reporting and the nature of the complaints mechanisms put in place by associations. The effectiveness of a registration board in creating access for complaints was demonstrated by the significant increase in complaints about Chinese medicine practitioners once a registration board was established in Victoria. In its first two years the newly established registration board received 34 complaints, compared with only four received by the Victorian Health Services Commissioner for the preceding two years.

The complaints-handling processes that had been put in place by the associations in the present study were not always transparent. Nor were they easily accessible by the public, which might contribute to under-reporting. There was also no adequate mechanism to prevent expelled members and deregistered persons from practising naturopathy and WHM.

Naturopathy and WHM have had an uneasy relationship with governments and mainstream healthcare, and the major associations have played an important role in guiding the professions. However, the lack of a clear separation between bodies that licence practitioners, and associations which advise on standards and support the professions, has confused professional boundaries. Close relationships between professional associations and education providers have raised concerns in the past (Bensoussan and Myers 1996) and continue to do so. Conflicts of interest arise when associations have strong links with particular segments of a profession, such as education providers, because the interests of the professions may conflict with the commercial interests of education providers. In particular, the issue of whether to raise the minimum required level of education to the level of a bachelor's degree has divided the associations for more than two decades, and many voices in the debate have had commercial interests in education (Jacka 1998). The inability of associations to reach agreement on a minimum standard of education for naturopathy and WHM has undermined the effectiveness of self-regulation.

It is difficult for self-regulation to be effective, transparent, and accountable while the regulatory structure is not independent of professional associations (Expert Committee 2003). The naturopathy and WHM professions need independent experts, bodies and processes to put them on a firm professional footing and to ensure the accountability and transparency that are expected in contemporary healthcare.

The establishment of effective occupational regulation will require the support of professional associations. Four of the eleven associations that responded on the issue of regulation called for statutory regulation, and another three supported stronger regulation. In addition, seven associations were negative about current attempts to self-regulate. Four supported self-regulation, with one of those preferring co-regulation—that is, government-

monitored self-regulation. Such a system would still be dependent upon the associations coming to agreement on a coordinated approach. It might also entail costs and a level of intervention by government that the associations would not find acceptable.

It is possible that the associations that support self-regulation might not wish to cooperate in occupational regulation. However, this would not be in the long-term interests of their members and would reduce the professional input of these associations to the independent accrediting body. It should be noted that the workforce survey (see Chapter 4) found that more than 70% of practitioners foresaw government regulation as having positive effects on standards of practice and education. Many of these practitioners might be taking a position contrary to that of their associations.

The small membership of some associations indicates that they lack resources for robust participation in the development of the professions. The level of resources required would best be achieved by a process of rationalisation leading to a reduction in the number of associations (Expert Committee 2003). Fewer, larger, better-resourced associations would benefit the professions and the public, for example by raising standards for professional practice. Associations should be encouraged to increase the range of practice guidelines, such as guidelines on referral to other practitioners, reporting of adverse events, infection control, drug-herb interactions, the safe use of potentially toxic herbs, and adequate standards of record-keeping and advertising.

## 6.9 Conclusion

The major current roles of the naturopathy and WHM professional associations are to: (i) set standards for the professions; (ii) accredit practitioners; (iii) protect the professions; and (iv) protect the public (through self-regulation). This study has revealed limitations in the ability of the associations to carry out important functions.

The large number of associations, and their differing standards and views on education and occupational regulation, diminishes the effectiveness of current self-regulatory regimes. The requirements for membership are not uniform, and complaints mechanisms vary in depth and quality.

The proliferation of associations and disagreement about standards has meant that the process of accrediting members is flawed and the public is not adequately protected. ATO recognition of associations for the purpose of GST exemption does not require common standards, and the attempt by the professions to self-regulate has resulted in a system that lacks transparency, accountability, and independence.

Resources to represent members adequately appear limited in smaller associations.

The responsibility of associations for both professional policy and the formal recognition (accreditation) of practitioners has led to a blurring of boundaries and the possibility of conflicts of interest.

## 6.10 Recommendations

Based upon the findings of the above survey, the following recommendations are made.

- Separation is required between regulatory bodies that accredit practitioners and professional bodies that advise on standards.
- An independent body should be established to develop, with advice from the professions: (i) uniform educational and professional standards; and (ii) effective mechanisms and sanctions relating to professional misconduct.
- All associations purporting to represent practitioners should do so through a transparent, democratic and accountable process.
- Associations should be encouraged to amalgamate.
- Government committees dealing with naturopathy and WHM issues should be constituted with adequate expert representation from these professions.

- All professional associations should be encouraged to:
  - establish continuing professional development requirements for membership;
  - hold or support conferences to provide open and independent forums for discussion and dissemination of ideas;
  - develop comprehensive guidelines for professional practice; and
  - support an effective system for reporting adverse events, accidents or injuries in the practice of naturopathy and WHM.
- To provide insight into complaints against naturopaths and WHM practitioners, further research should be undertaken on the nature of complaints, the types of action taken, and the effectiveness of such actions.

### **Acknowledgement**

Thanks to Professor Vivian Lin for constructive comments during the preparation of this chapter.

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# 7. Institutional Recognition of Naturopathy and Western Herbal Medicine in Australia

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## 7.1 Introduction

Over the past two decades, the rising popularity of complementary and alternative medicine (CAM) has stimulated responses from a range of government and private sector organisations. This has led to increasing institutional recognition of naturopathy and Western herbal medicine (WHM). Assessment of institutional support in the present study has focused on government bodies, public and professional institutions, and the insurance industry. This chapter presents the findings of enquiries made of:

- health payers;
- professional indemnity insurers;
- the Australian Taxation Office (ATO);
- statutory registration boards for the registered health professions;
- hospitals;
- higher education authorities;
- the National Health and Medical Research Council (NHMRC); and
- mainstream professional healthcare associations.

## 7.2 Methodology

Institutions were initially contacted by telephone and email. Enquiries were followed up through written communications, telephone and email as necessary to clarify information. A range of information regarding naturopathy and WHM—such as policies, plans, and committee structures—was also gathered from websites.

The Australian Health Insurance Association (AHIA) advised that there were approximately 41 health insurance companies in Australia—contact with these companies revealed a dynamic field of activity featuring changes to fund names, several funds being owned by one company, and mergers among companies.

Letters of enquiry were sent to 36 private health insurance providers and two industry bodies—(i) the AHIA, which had 29 member organisations; and (ii) the Australian Regional Health Group (ARHG), an industry representative body owned by nine health funds.

The ‘Yellow Pages’ and word-of-mouth were used to identify the insurance companies that provide professional indemnity (PI) insurance in Australia. Eleven national insurance companies were contacted and six reported that they provided PI insurance to naturopaths and WHM practitioners.

Workers’ compensation schemes are state or territory based. Reading of their websites was followed up by telephone contact with representatives in all states and territories of Australia.

Information about the policies and positions of a range of other institutions and organisations was collected through surveying the literature, accessing websites and, if necessary, clarifying information via telephone calls and email correspondence. Institutions and organisations in this group included: (i) statutory registration boards for registered health professionals; (ii) hospital authorities; (iii) mainstream professional healthcare associations; and (iv) the ATO (regarding the GST status of naturopathy and WHM practitioners).

## 7.3 Health payers

A range of organisations is involved in the reimbursement of clients or patients for costs incurred in accessing allied health services. Of these, private health insurers currently demonstrate the highest degree of engagement with the professions of naturopathy and, to a lesser extent, WHM. Bodies that are more closely regulated, or funded by government, have little or no engagement with these professions.

### 7.3.1 Private health insurance funds

Replies were received from 16 health funds and from both industry bodies. Most of the funds that responded individually also belonged to one or both of the industry groups (AHIA and ARHG). Of the 16 funds that responded to enquiries, one did not provide rebates for any form of CAM, and one had recently sold its health insurance business. There were therefore 14 (39%) valid responses from individual funds, plus responses from ARHG (representing nine funds) and the AHIA (representing 29 funds). Table 7.1 lists the funds that responded individually to the enquiry and the member funds of the two industry bodies.

**Table 7.1 Overview of responding and represented funds**

Funds that responded individually	Funds represented by AHIA*	Funds represented by ARHG**
Australian Health Management Group	Australian Health Management Group	Cessnock District Health Benefits Fund
Australian Unity Health	Australian Unity Health	Federation Health
GMHBA	BUPA Australia Health	GMHBA
Grand United Health Fund	Cessnock District Health Benefits Fund	Health Insurance Fund of WA
Healthguard	Druids Friendly Society	Latrobe Health Services
Health Insurance Fund of WA	Druids Health Benefits Fund	Mildura District Hospital Fund
HBA	Federation Health	St Luke's Health
HBF	GMHBA	Druids Friendly Society
Latrobe Health Services	GMF Health	Westfund
Medical Benefits Fund of Australia	Grand United Corporate Health	
Medibank Private	Grand United Health Fund	
Teachers Federation Health	Healthguard	
Railway & Transport Health Fund	Health Insurance Fund of WA	
St Luke's Health	Health Partners	
	HBF Health Funds	
	Hospitals Contribution Fund	
	IOR Australia	
	Latrobe Health Service	
	Manchester Unity Australia	
	Medibank Private	
	Medical Benefits Fund of Australia	
	Mildura District Hospital Fund	
	Navy Health	
	NIB Health Funds	
	NRMA Health	
	Queensland Country Health	
	St Luke's Health	
	Teachers Union Health Fund	
	Westfund	

**Notes:**

\*Australian Health Insurance Association

\*\*Australian Regional Health Group

Of the funds approached, 55% did not respond directly, therefore the total number of funds offering relevant cover could not be determined. However, every edition of the Australian Traditional-Medicine Society (ATMS) journal provides an update of approximately 40 funds that provide rebates for CAM. It can therefore be assumed that the majority do offer some form of cover for some CAM services.

Collectively, the information obtained from informal enquiries to private health funds, which included email and telephone discussions, was considered to be representative of Australian health funds' approaches to consumer needs regarding naturopathy and WHM. As a result of market forces and growing consumer demand for health insurance to cover CAM, many private health funds in Australia now offer rebates for services from CAM therapists. Table 7.1 lists the participating funds and those represented by the two industry bodies, AHIA and ARHG.

All 14 funds reported having criteria for the formal recognition of naturopaths and/or WHM practitioners as providers of services. Those funds not utilising the ARHG criteria for recognising practitioners (see below) had each developed their own criteria.

Eight funds reported that they provided health insurance cover for both naturopathy and WHM services, whereas the other six reported that they provided health insurance cover for naturopathy only.

All 14 funds reported that they provided partial rebates for consultation fees only. None provided rebates for herbal medicines or any other remedies, supplements or treatments provided by naturopathy or WHM practitioners.

### **Methods used by private health funds for the formal recognition of naturopaths and WHM practitioners as providers of health services**

The statutory registration of medical doctors provides a system whereby private health insurance funds can recognise medical doctors as authorised providers of healthcare. In the absence of statutory regulation of naturopaths and WHM practitioners, private health funds have had to develop ways to establish the credentials of CAM practitioners who are appropriately qualified to provide services. Clients of private health funds may be eligible to receive rebates (partial refunds) for the services of naturopaths and WHM practitioners formally recognised by the fund.

#### **Recognition of graduates of particular courses**

Nine funds reported that they did not automatically recognise as providers the graduates of any particular courses. Practitioners applying to these funds for recognition were required to fulfil specific criteria. Four funds automatically recognised graduates of courses provided by universities or registered training organisations (RTOs). As an interim measure, one fund recognised practitioners who held advanced diplomas from an RTO; however, in the medium to long term, the fund advised of its intention to require a bachelor's degree as the minimum qualification for recognition.

#### **Automatic acceptance of members of particular associations**

Seven funds reported automatic recognition of members of certain professional associations. These associations were: Australian Naturopathic Practitioners Association (ANPA), Australian Natural Therapists Association (ANTAsn), Australian Traditional-Medicine Society (ATMS), Complementary Medicine Association (CMA), and National Herbalists Association of Australia (NHAA). The other seven funds had set additional criteria (apart from membership of an association). Examples of these additional criteria included level of qualification, years of experience, and approval by the ARHG.

#### **Approval of practitioners on an individual basis**

Twelve funds reported that they assessed the applications of individual practitioners irrespective of association membership, and each of these funds had developed a range of criteria for this process. The criteria varied from one health fund to another. The testing of applications against these criteria was reported by some funds to be time-consuming.

Qualifications required ranged from insistence on a bachelor's degree or qualification from a course provided by an RTO (a diploma or advanced diploma), to recognition that practitioners who had trained some time ago might be acceptable (provided that they had completed some kind of formal training and had evidence of recent practice). Some funds had set a minimum number of contact hours for courses—such as 2100 hours for naturopathy. This enabled the evaluation of non-accredited courses. One fund stated that graduates of 'correspondence or short courses' were not considered for recognition.

Other criteria used to assess applications by practitioners for formal recognition as providers included: (i) professional indemnity insurance for cover of at least \$1 million; (ii) a current first aid certificate; (iii) evidence of involvement in continuing professional education; (iv) a process for ensuring practice quality; (v) a code of ethics; and (vi) a Therapeutic Goods Administration (TGA) Advertising Certificate of Exemption.

### **Review panels**

Two funds reported that they had established an independent review process to assess applications. In one instance, once a course had been approved by the panel, all future applicants who were graduates of that course were recognised as providers.

### **Overseas qualifications**

Two funds stated that applicants with overseas qualifications were referred to an independent panel to assess their qualifications.

### **Application fees**

Four funds stated that they charged for the assessment of applications for provider status. Fees ranged from \$150 to \$350.

### **Reasons for not accrediting services**

Three funds reported that they did not accept WHM practitioners as providers. The reasons cited were:

- the need to keep premiums affordable for all members;
- a perceived lack of evidence regarding the benefits of WHM;
- WHM not being recognised by the insurer as an alternative or complementary therapy;
- limited funds being available; and
- the service scope of WHM not being readily identifiable.

### **Concerns about processes for formal recognition of naturopaths and WHM practitioners within the private health insurance industry**

Of the 14 funds, eight did not express any concerns about recognition procedures. One fund reported that it did have concerns, but did not elaborate. Five other funds expressed concerns about a range of issues. Analysis of their comments revealed four major themes:

- variability of standards;
- uncertainty about practices;
- time required to assess applications; and
- 'grandparenting' provisions.

Each of these is discussed below.



### **Variability of standards**

Concern about the variability of standards was expressed with respect to all three parties involved in the accreditation of practitioners: (i) the professional CAM associations (which set varying requirements); (ii) the private health funds (which also set various requirements); and (iii) the applicants for recognition as providers (who have a wide variety of educational qualifications and backgrounds). Concerns about standards are summarised as follows:

- lack of industry regulation for naturopathy and WHM;
- difficulty in identifying bona-fide practitioners;
- variable recognition criteria developed by health funds.

The uncoordinated nature of recent attempts to develop accreditation processes had caused some frustration. One health fund stated that it was ‘... extremely concerned at the general lack of coordinated registration, regulation’.

There were difficulties in identifying bona-fide practitioners. One fund observed that:

... standards of care and ability vary greatly between practitioners. A central accreditation process is required to protect members of the public and to assist them in selecting suitably qualified practitioners.

Practitioners themselves did not seem to appreciate the difficulties perceived by some funds in an unregulated market: ‘Many providers believe that their membership of an association should provide them with automatic health fund registration’.

Concerns were also expressed about ‘... each fund having to develop [its] own recognition criteria; no regulatory control [exists] over associations, institutes, or registration’. This situation has been addressed, to some extent, by guidelines prepared by AHIA and ARHG for their member associations (see below).

### **Uncertainty about practices**

Another issue was the question of whether all treatments were actually required. One fund had applied a ‘... fund rule that all treatment and services should be medically necessary’. For this reason it had moved to enforce higher qualifications among its recognised providers. Herbal medicine was reported by several funds to be a source of concern about effectiveness and safety, and there was some interest in applying an evidence-based approach to this discipline, for example:

The decision not to pay on WHM was based on a combination of cost and benefit. That is, the need to keep our premiums affordable ... and the clinical decision that there is yet insufficient evidence as to the benefits of WHM.

### **Time and cost of administration**

The problems generated by assessing applications and maintaining records were encapsulated in the following comment:

... there is much inconsistency and difficulty with ensuring that practitioners are legitimate providers and in comparing qualifications across numerous institutions and associations. Also it is labour- and time-intensive ensuring that insurances, etc. are current and kept up to date.

These costs are likely to be passed on to the consumer through higher health insurance premiums. One fund commented that increasing use of CAM therapies will need to be:

... addressed at a government/professional level; otherwise [funds will be forced] to increase premiums so that [they] can afford to continually find ways to improve registration.

### **‘Grandparenting’ provisions**

The issue of ‘grandparenting’ was also raised by several health funds, who reported concern about practitioners with low levels of formal qualification achieving membership of professional associations. For example:

... the widespread practice of “grandfathering” where providers with little or no formal training are granted [membership] with associations—based on their history and contribution to the industry.

### **Suggestions for improvements in provider recognition**

Three funds expressed support for the industry guidelines prepared by AHIA and ARHG to assist funds to develop appropriate recognition criteria. One fund suggested that it would be much easier to deal with one regulatory authority for CAM providers, ‘As opposed to our current system of recognising 20 different associations’.

There was strong support for statutory registration from seven of the 14 responding funds. Analysis of their comments revealed that the funds believed that statutory registration would address many concerns—including education, professional standards, having to deal with multiple professional CAM associations, dubious claims, ‘grandparenting’, and costs.

A system similar to current state registration boards for other modalities (including physiotherapy, chiropractic, osteopathy, optical, dental, and psychology) would greatly assist funds in ensuring quality, consistency, and efficacy. Any legislation that would control the qualifications levels, conduct and practice of practitioners would also greatly assist, particularly where herbal remedies are concerned, to ensure the safety of our members.

In spite of the fact that half of the responding funds supported statutory registration, it was apparent that this would not necessarily guarantee formal recognition (by the funds) of registered practitioners as providers.

State legislated board registration can assist with determining eligible providers. However, as occurred with the Victorian Acupuncture and Chinese Medicine Board, many providers were granted registration under a grandfather clause. [Our fund] would ... recognise this registration [only] if all providers had to possess the appropriate qualifications, and [if] the qualifications were equivalent to a bachelor’s degree.

### **Future directions**

There appeared to be moves among the funds to have CAM providers meet higher educational standards and embrace an evidence-based approach to care. This trend was indicated by the fact that two private health insurance industry bodies have recently formulated criteria to assist member associations to identify appropriately qualified CAM providers. Both the AHIA and ARHG have developed policies that advise member associations regarding CAM therapy services (see below), but provision of cover and policy formulation have been left to individual funds to determine.

### **Australian Regional Health Group**

The ARHG provides services to the nine funds that own ARHG and has developed a process for the formal recognition of practitioners who may or may not be members of CAM professional associations. ARHG developed its current system, which became effective from 1 July 2002, because ‘... there was no effective system in the past’. ARHG reported that its system is available to non-member funds, that 17 funds currently use it, and that other funds have enquired about access to the system. The ARHG process has ‘... eliminated a number of providers in these therapies who do not meet our standards’.

The five ARHG criteria are set out below, and include the intention of each criterion as stated by ARHG:

1. That the Therapy is linked to and/or supported by educational and/or government or semi-government agencies in Australia. (This intends that recognised tertiary educational institutions are involved. [ARHG requires] an Australian University or Registered Training Organisation listed with the National Training Information Service).
2. That there is an Association or organisation which lists and accredits members with clear criteria for membership including qualifications, continuing education, ethics and quality of practice requirements. (This intends that providers have professional peer oversight).

3. That proponents of the Therapy do not make claims which cannot be substantiated. (This intends that any assertions about the therapy do not mislead subscribers/ patients).
4. That proponents of the Therapy are able to produce outcome study reports of the success of the claims made about their treatments. (This intends that the treatments given have substantial proof that they achieve what it is claimed they are said to achieve).
5. That proponents of the Therapy do not claim to cure any condition but can show that they assist, relieve, improve etc., and generally promote good health and well being. (This intends that the Therapy, as an Alternative Therapy, is not claiming to be a part of curative medicine) (ARHG 2002).

With respect to statutory regulation, the ARHG expressed concern that ‘... there is no comparable system to ours at government or non-government level to determine accreditation of providers’. The ARHG commented that a statutory regulatory authority would have difficulty meeting all the ARHG’s requirements for the formal recognition of practitioners:

‘... it is difficult for a Government agency to meet our requirements. For example, to insist upon CPE and Outcome Studies etc. as part of a registration process and to monitor these continuously is quite difficult to legislate for. These are usually the province of Professional associations’.

The ARHG suggested that:

... perhaps a combination of both government and professional association involvement would be a possible solution which would reduce the time and cost of the current processes required (ARHG 2004).

### **Australian Health Insurance Association**

AHIA is an industry association that represents 29 health funds throughout Australia. Collectively, its member associations are said to include approximately 94% of the private health insurance industry (AHIA, undated). Its role is to advance the interests of its member associations in relations with governments, the media, and other health organisations, and to provide an information and advisory service for issues affecting health financing (AHIA, undated).

The AHIA has developed guidelines that address the provision of ancillary benefits and the manner in which funds should deal with accreditation of individual providers of approved services. The guidelines were developed by a representative group of funds in response to a political initiative to produce a common accreditation system for service providers. The AHIA criteria for the recognition of ancillary providers provide that an ancillary service must facilitate an improved health outcome for a member, and must meet *one* of the following criteria (AHIA 2004):

- the provider must be registered by a state registration board (or equivalent);
- the health service must be GST-free;
- the provider must be (or must be eligible to be) a full member of a relevant association; and
- the provider must have qualifications at a tertiary level or equivalent, or the therapy must be linked to and/or supported by educational bodies and/or government or semi-government agencies in Australia.
- the provider must not make unsubstantiated claims or claim that any condition can be cured.

With regard to the last point, providers or associations:

‘can show that they assist, relieve, improve etc. and deliver health benefits to consumers. If claims are made then the providers or associations must be able to produce outcome study reports to substantiate the claim’.

The AHIA recommends that each fund should develop criteria for recognition of applicants who are not registered by a state board or who are not members of a relevant association. According to the recommendations of the AHIA, a provider must demonstrate practice safety, including the following quality features (AHIA 2004):

- infection control and hygiene procedures and protocols;
- the maintenance of confidential and secure patient records in the practice;
- production of accurate itemised accounts;
- the practice of informed financial consent;
- proof of current indemnity insurance;
- a code of practice or conduct; and
- a current first aid certificate.

The provider should also continue professional education and be able to supply updated proof of this. It is recommended that the funds be able to conduct audits on providers—both scheduled and unannounced—and that they make provision for removal of providers who fail to comply with a fund’s guidelines.

It is also recommended that the fund or industry set up a review process for recognition of individual providers. Regarding overseas qualifications, if assessment is not straightforward, the application should be referred to an independent referee or panel. All members of a panel must agree that the qualifications are equivalent to Australian standards.

The AHIA guidelines make recommendations to member associations. However each fund will be free to develop its own approach to the provision of ancillary benefits and the formal recognition of providers.

### **7.3.2 Workers’ compensation insurance**

Workers’ compensation (‘WorkCover’) in Australia is delivered according to state and territory legislation, which varies from one jurisdiction to another. Access for clients to naturopathy and WHM services is therefore also varied. The operational regulations for each Act generally restrict access to services provided by naturopaths and WHM practitioners. Table 7.2 summarises the findings with regard to WorkCover requirements in each state and territory, as reported to the research group.

WorkCover authorities take various approaches to naturopathy and WHM. In the Australian Capital Territory and Queensland, the use of these treatments by clients is specifically prohibited because they are not ‘listed occupations’ or do not have statutory regulation (such as, for example, chiropractic and osteopathy). In South Australia and New South Wales (NSW), treatment is limited to remedial physical therapies only. (Because massage is a core component of many naturopathy courses, naturopaths who have adequate massage skills, particularly remedial massage, might be eligible to become providers). In Western Australia and Tasmania, naturopathy and WHM could be deemed a ‘reasonable therapy’. Victoria has the least WorkCover restrictions on naturopaths and these practitioners can apply to become registered WorkCover providers. However, there is no provision for WHM practitioners under WorkCover in Victoria.

In jurisdictions in which treatment by a naturopath or WHM practitioner is allowed, referral or recommendation by a medical practitioner is usually required. Insurers have a role in determining whether a treatment should be given a trial period.

Data on actual usage were only available from the Victorian WorkCover Authority which has recognised naturopathy as an approved service since the late 1980s. As at 30 June 2003, 350 naturopaths were registered providers with the Victorian WorkCover Authority. In the 2002/03 financial year, 100 of these providers had provided naturopathic services to WorkCover claimants demonstrating that there is consumer interest in the use of naturopathy in rehabilitation. Reimbursement was made for naturopathic consultations, but not for medicines or any treatments provided.

**Table 7.2 Outline of WorkCover requirements in each state and territory**

Workers compensation fund	State/territory legislation	Status of naturopathy/WHM	Requirements/Comments
ACT WorkCover	Workers Compensation Act 1951, No. 2	Naturopathy/WHM not listed as occupations under legislation. Compensation not mandatory.	Must be recommended by doctor in personal injury plan. Must be agreed by insurer.
NT WorkSafe	Work Health Act 2004	All rehabilitation providers must become approved providers. Any practitioner can apply. No guidelines available re application.	Act does not require referral or recommendation from a medical practitioner. Any party can suggest naturopathy or WHM treatment; however, insurer has a role in determining acceptability of providers and treatments.
Q-Comp	Workers' Compensation and Rehabilitation Act 2003	All providers must be health professionals registered by a state board.	Services of naturopaths and WHM practitioners are not reimbursable.
Victorian WorkCover Authority	Accident Compensation (WorkCover Insurance) Act 1993	Guidelines available for naturopaths to apply to become registered providers. No provision for WHM practitioners.	Must be eligible for full membership of specified <sup>1</sup> professional associations, and have current professional indemnity insurance. Service requires referral from medical practitioner.
WorkCover Corporation of SA	Workers Rehabilitation and Compensation Act 1986	Registration as provider limited to remedial physical therapies only. Educational criteria provided.	Naturopathy specifically excluded unless practitioner has qualifications in remedial physical therapy; referral from medical practitioner required. No provision for WHM practitioners.
WorkCover NSW	Workplace Injury Management and Workers Compensation Act 1998	Accreditation as a provider limited to remedial physical therapists only.	Care by non-accredited CAM therapists is theoretically possible if recommended by a medical practitioner and if insurer approves therapy.
WorkCover Tasmania	Workers Rehabilitation and Compensation Act 1988	Act specifies only 'reasonable medical expenses' by or under the supervision of a medical practitioner.	Medical practitioner can recommend any reasonable therapy, if insurer agrees the therapy may be trialed.
WorkCover WA	Workers Compensation and Rehabilitation Act 1981	Act and regulations recognise certain forms of treatment. Naturopathy and WHM not recognised; however may be deemed as 'reasonable' therapy.	Medical practitioner can recommend any reasonable therapy; if insurer agrees, therapy may be trialed.

<sup>1</sup> Australian Natural Therapists Association, Australian Naturopathic Association, or Complementary Medicine Association.

No other WorkCover authorities in which naturopathy and WHM services are allowed could provide any data on use. Such data might be held by the numerous insurance companies who manage WorkCover cases, but the scope of this study did not support contacting every accredited insurer in Australia. Because the use of naturopathy and WHM services, where allowed, required recommendation or referral by a medical practitioner and the agreement of the insurer, actual usage may be limited.

### **7.3.3 Other payers**

Enquiries were also made of the Health Insurance Commission, the Department of Veterans' Affairs, motor accident compensation schemes, and the Commonwealth Rehabilitation Service with regard to their recognition of naturopathy and WHM. Although most of these organisations did not recognise naturopathy and WHM, most did fund part-payments for chiropractic and osteopathic services. This demonstrates acceptance by these organisations of two CAM professions (chiropractic and osteopathy) that now have statutory regulation in Australia, a uniform minimum level of education (bachelor's degree), and some evidence of effectiveness.

#### **Health Insurance Commission (Medicare)**

The Commonwealth government recently made changes to Medicare which now allow chronically ill patients access to specified allied health professionals. Naturopaths and WHM practitioners were not included in this initiative. Eligible allied health professionals are Aboriginal health workers, audiologists, chiropractors, chiropodists, diabetes educators, dietitians, mental health workers, occupational therapists, osteopaths, physiotherapists, podiatrists, psychologists and speech pathologists (Health Insurance Commission 2005). Under the new regulations, medical practitioners can refer chronically ill patients who are being managed under an 'Enhanced Primary Care Plan' to these providers, and services will be partially reimbursed by Medicare. Eligibility criteria for registration as an allied health provider with the Health Insurance Commission include either registration with a statutory board, or full membership of a national professional association specified by the Health Insurance Commission (Health Insurance Commission 2005).

#### **Department of Veterans Affairs**

The Department of Veterans' Affairs pays for medical and allied health services for eligible patients. The only allied health services approved from the CAM area are chiropractic and osteopathy.

#### **Motor accident compensation schemes**

Motor accident compensation schemes are state-based and funded by compulsory third party insurance (which is paid annually when a vehicle is registered). These schemes can broadly be categorised as either: (i) modified common-law 'fault-based' schemes; or (ii) statutory 'no-fault' schemes (Transport Accident Commission, Victoria 2005). Most states and territories rely on the former, and claimants are usually free to choose any type of therapy, including naturopathy and WHM. Whether a therapy will be funded is dependent on a range of variables—including the individual claimant, the amount of therapy required, and the level of evidence (science-based or outcomes-based).

Statutory motor accident compensation schemes apply in Victoria, Tasmania, and the Northern Territory. These 'no-fault' schemes compensate a greater number of injured people. To contain costs, benefits are more strictly defined and there is less flexibility with regard to choice of therapies by claimants. The Transport Accident Commission in Victoria includes chiropractors and osteopaths on its list of recognised providers, but does not include naturopaths or herbalists.

### **Commonwealth rehabilitation service**

The Commonwealth Rehabilitation Service (now CRS Australia) does not have a specific policy on the use of CAM by clients, but works to guidelines underpinned by the *Disability Services Act 1986*, which governs decision-making about the purchase of such services. Rehabilitation consultants develop programs to address ‘barriers’ resulting from disability, injury, or health related conditions. Any decision to purchase services (such as CAM) is based on an assessment of their potential to assist clients to reach agreed rehabilitation goals, and an evidence base to support their efficacy (CRS Australia 2005). The rehabilitation consultant works closely with the client’s medical practitioner in implementing the client’s vocational rehabilitation program, but a medical referral is not necessarily required. Services that are used to address specific barriers in a client’s program (for example, chronic pain) might include Feldenkrais, yoga, or chiropractic. However, more commonly, physiotherapy and psychology interventions are utilised (CRS Australia 2005). No data were available on the actual use of CAM therapies by clients of CRS Australia.

## **7.4 Professional indemnity insurers**

Six insurance companies reported that they provided PI insurance to naturopaths and WHM practitioners. Of these, five agreed to provide information in telephone discussions and subsequent email follow-up to clarify questions and issues.

Company representatives generally reported some difficulty in assessing the eligibility of the wide variety of qualifications held by individual applicants, and the final decision was usually at the discretion of the underwriter.

Professional indemnity insurance is readily available to naturopaths and WHM practitioners in Australia. Because access to a lower premium can be a significant benefit to members, several associations had negotiated professional indemnity insurance cover for their members. Bensoussan et al. (2004) found that 70% of naturopaths were members of group schemes arranged by their professional associations, whereas 19% had arranged individual insurance. Group schemes were provided for members through the two largest professional associations, ANTA and ATMS. Most insurers reported that they covered more practitioners in group schemes than as individuals—consistent with the findings of Bensoussan et al. (2004).

Most companies grouped CAM therapists together into one category. They were therefore unable to provide accurate numbers regarding insured naturopaths and WHM practitioners. Other companies did not wish to disclose these numbers for reasons of commercial confidence. Estimates were provided by some companies. These ranged from six CAM therapists insured by one company (which did not provide a group scheme) to approximately 5,500 for the largest group scheme.

### **Cost of professional indemnity premiums**

The annual premiums charged by companies that insured only a few individuals were significantly higher than those charged for practitioners in group schemes. The cost range of annual premiums for a minimum level of indemnity of \$1 million was \$170–\$430 for practitioners in group schemes, and \$440–\$1000 for individually insured practitioners.

### **Assessment of practitioner qualifications**

If practitioners belonged to an Australian CAM association, professional indemnity insurers accepted the level of qualification set by the association. If practitioners were not members of an association, underwriters reported that they attempted to assess their qualifications in various ways—for example, by requesting information on the course and school attended by the practitioner, and the number of years in clinical practice. School websites were also a source of information for underwriters.

A certificate level of education was the lowest reported acceptable qualification. For practitioners who did not have a formal qualification, the minimum practical experience required to gain cover was reported to be two years. If course quality was uncertain, a

practitioner could be required to prove eligibility to join an Australian association. It was reported that overseas qualifications needed to be 'effective in Australia'.

Because considerable time can be required to research the level of qualification and experience of practitioners, the majority of underwriters stated that a national standard of education would facilitate assessment of professional indemnity insurance applications for the minority of practitioners who are not members of associations. However, this sentiment was not strongly expressed because naturopaths and WHM practitioners are generally considered to be in a low risk category, as evidenced by the relatively low cost of premiums.

### **Number of claims**

Two companies who insured the smallest number of practitioners stated that they had had no claims against these practitioners. None of the other companies was willing to provide information on the number of actual claims made, or the outcomes of such claims.

## **7.5 Australian Taxation Office**

The ATO recognises certain non-medical health practitioners who either have statutory registration or are deemed to be 'recognised professionals'. These practitioners are not required to charge goods and services tax (GST) on their consultation fees, but are required to charge GST on any medicines or treatments that they provide. Because naturopathic and WHM practitioners are not registered in any state or territory, their recognition by the ATO is based on full membership of an association which has been formally assessed as meeting the ATO's definition of a 'professional association'. Over 20 associations were so recognised in 2004.

Because the associations have various standards for membership, the above arrangement has not led to the application of unified standards for entry to the professions, nor has it assisted the sector to self-regulate effectively by providing incentives for compliance with uniform standards.

For further information on the relationship between the ATO and naturopathy/WHM professional associations and practitioners, see Chapters 6 and 10.

## **7.6 Statutory registration boards**

Information was sought from a range of health practitioner registration boards to explore the extent to which they had published information for their registered practitioners on the use of CAM. Medical, nursing and pharmacy websites were accessed and a number of policies, position statements and guidelines were found.

### **7.6.1 Medical registration boards**

CAM policies were published on the websites of the state medical boards of Victoria, New South Wales, Queensland, and Western Australia.

Standards of 'Good Medical Practice' have also been adopted by various medical boards and organisations (for example, see New South Wales Medical Board below) and these may be applied to CAM practice—particularly if a board has not developed specific CAM guidelines. In applying standards of Good Medical Practice, competence would be a defining issue should a complaint be made against a medical practitioner in relation to CAM. In the assessment of competence, a fundamental distinction would be made between the application of evidence-based medicine and the application of unproven or experimental therapies.

A synopsis of CAM policies developed by the medical boards of Victoria, New South Wales, Queensland and Western Australia follows.



### **Medical Practitioners Board of Victoria (MPBV)**

The Medical Practitioners Board of Victoria's policy (*Alternative or Complementary Medicines*, undated) reminds doctors that, in practising or recommending CAM, they 'have additional ethical responsibilities' and sets out the following points:

- Special care must be taken to inform patients when therapy is unproven and to fully inform patients of any risks associated with such therapy
- Patients who are offered alternative remedies must not be denied access to standard proven therapies of a type which would be provided by medical peers
- When alternative therapies pose risks of serious side effects, the patient should be advised to seek a second independent medical opinion
- Doctors must not gain financial advantage by selling alternative therapeutic substances directly to patients (MPBV undated).

The board has also recently developed a policy for formal endorsement of doctors who practise acupuncture—provided that they have completed a course that satisfies standards developed by the Royal Australian College of General Practitioners. The board recognises that most doctors who practise herbal medicine use WHM, rather than Chinese herbal medicine, but the board states that it has no legal power to endorse doctors who practise WHM. The board has determined that medical practitioners who wish to practise Chinese herbal medicine will need to be concurrently registered by the Chinese Medicine Registration Board (Medical Practitioners Board of Victoria, undated).

### **New South Wales Medical Board (NSWMB)**

The NSW Medical Board's policy *Complementary Health Care* (undated) notes the wide range of CAM modalities and the varying approaches of medical practitioners to their use (NSWMB undated). The policy states that 'the important distinction is between proved and unproved care, rather than between conventional medicine and complementary health care', and that 'there is a paucity of scientific evidence about complementary healthcare. Some modalities can be shown to be beneficial. Others are potentially harmful'. Types of harm are identified as direct, indirect or economic.

Medical practitioners are accountable to the NSWMB for all CAM services they provide. The Board's '*Code of Conduct: Good Medical Practice*' applies to the practice of CAM and according to this code, medical practitioners must:

- have demonstrable current knowledge and skills in their area of practice
- act honestly and only in their patient's best interests
- provide patients with sufficient information to allow them to make informed choices at all stages of their [care]
- [be] honest in relation to financial and commercial matters
- keep medical records that comply with regulatory standards
- assess patients by
  - [making a] generally recognised diagnosis meeting the standard of practice generally expected of the profession
  - investigating when necessary, ensuring that patients are not denied access to generally recognised investigation modalities
  - reaching a diagnosis that reasonable medical practitioners would reach, supported by the information available
- treat the patient by advising them of any conventional treatment options, their risks, benefits and efficacy, ... [and provide] an honest account of the risks, benefits and efficacy of a recommended treatment (NSWMB undated).

Medical practitioners are also advised that:

A doctor who recommends an unproved treatment rather than one with proved effectiveness must have broad professional support in doing so, as well as the patient's fully informed consent; or must be prepared to argue, with evidence, that the treatment is safe and that the patient will not be harmed in any way by withholding conventional therapy (NSWMB undated).

#### **Medical Board of Queensland (MBQ)**

The MBQ's policy, *Unconventional Medical Practice* (undated), is similar to that of the NSW Board above, except that it advises medical practitioners to 'avoid referral of patients to unconventional health practitioners' (MBQ undated). The MBQ policy recognises that, in using CAM treatments in 'areas of uncertainty where no treatment has proven efficacy', knowledge may be advanced. However, in such a circumstance, patients must be fully informed about the degree of evaluation and the known level of efficacy and safety. Practitioners must also be prepared to support research by collecting data so that new knowledge can be 'shared with, and critically appraised by, the profession' (MBQ undated).

The MBQ policy also sets out specific questions that will be asked in the case of a complaint by a patient with regard to the use or advocacy of CAM practices. The questions address the approach to diagnosis, the level of evidence supporting the treatment (scientific or expert opinion), the cost of treatment, whether there is a reasonable expectation of a favourable outcome (greater than placebo), documented informed consent and, if the treatment is described as 'experimental', whether it is part of an approved scientific study (MBQ undated).

#### **Medical Board of Western Australia (MBWA)**

The MBWA states that its draft policy, *Complementary, Alternative & Unconventional Medicine* (2004), has been adapted 'from similar sets of guidelines issued by the Medical Board of Queensland and the Medical Council of New Zealand'. The guidelines within the MBWA policy are similar to those of the MBQ above. The MBWA expects that doctors will be competent, that is, able 'to perform a task to set standards' and that standards are generally those of relevant professional associations which 'take as their standards those treatments which are supported by scientific observation'. If such evidence is not available, standards are usually 'determined by their conformity with ethical standards, any indirect scientific support that can be adduced, and common sense'.

The MBWA points out the difficulty of defining the scope of CAM because 'orthodox medicine has been said to rely quite heavily on treatments that have not been rigorously tested'. However, the Board takes the view that 'the important distinction is between evidence-based medicine and unproved or experimental medicine, as this distinction provides the basis for assessing competence'.

Guidelines for referral differ from those of the MBQ. According to the MBWA policy, the medical practitioner should:

provide sufficient information to allow patients to make informed choices, and to refer to, or consult with, others when the patient requests it, when the practitioner requires assistance, and/or when the standard of practice requires it. (When appropriate and where there is no reason to believe such a referral would expose the patient to harm there is no barrier to making a referral to an unconventional practitioner) (MBWA 2004).

#### **Summary: medical board policies on CAM**

State medical boards recognise the increasing importance of CAM and the existence of dual usage by patients of mainstream therapies and CAM therapies. There is support for the use of CAM in medical practice providing there is sufficient high quality research evidence for any therapy used. Where this is limited or non-existent, the medical practitioner must at least be able to provide evidence that the treatment is safe and the patient will not be harmed by withholding conventional therapy. All patients should be asked about their use of CAM to

determine if such use poses any risks, particularly the risk of interaction with pharmaceutical drugs.

Patients must consent to the use of CAM and must be informed about risks and benefits. Conventional medical treatments must also be offered and patients must undergo appropriate medical assessment and diagnosis. Medical practitioners must be competent to use the CAM treatment or modality offered.

The main area of disagreement was with respect to referral to CAM therapists. Of the four medical registration board policies studied, one stated that such referral should be avoided, while another found there was no barrier provided the patient would not be exposed to harm. Two boards did not provide guidelines on the issue of referral to CAM therapists.

### **7.6.2 Other health practitioner registration boards**

Nursing and pharmacy registration board websites were accessed via the Internet. Guidelines relevant to CAM were located on the websites of four nursing boards and one pharmacy board.

Guidelines for nurses were located on the websites of the nurses' registration boards of NSW, Victoria, Tasmania, and Western Australia as follows:

- Nurses and Midwives Board NSW (1998), *Complementary Therapies in Nursing Practice*;
- Nurses Board of Victoria (1999), *Guidelines for Use of Complementary Therapies in Nursing Practice*;
- Nursing Board of Tasmania (2001), *Standards for the use of Complementary Therapies as a Nursing Intervention*;
- Nurses Board of Western Australia (2003), *Guidelines for use of Complementary Therapies in Nursing Practice*.

The nurses boards' guidelines were similar to each other in that they recognised complementary therapies (CTs) as part of the scope of nursing practice—provided that nurses:

- select appropriate levels of education for a CT, and that they practise within the limits of that education;
- inform patients, respect their choices, and obtain consent;
- practise collaboratively, incorporate CTs into care plans, and document use;
- refer as appropriate, including to experts in the CT field;
- hold professional indemnity insurance;
- take into account nursing standards, codes, competencies, and legislation; and
- apply quality assurance activities and support research.

The Pharmacy Board of Victoria's *Guidelines for Good Pharmaceutical Practice* (PBV 2004) makes reference to 'alternative therapy' only in that the 'mere supply of complementary therapy products' was not considered to imply practice. If a pharmacist does practise an alternative therapy, consultations must be carried out in a room separate from the retail area (PBV 2004).

## **7.7 Statutory education authorities**

Tertiary level courses of education may be approved or accredited by any of three educational sectors in Australia: universities, the offices of higher education in each state and territory, and the vocational education and training sector (VET). Naturopathy and WHM are recognised as healthcare disciplines in each of these sectors (see Chapter 5). Offices of higher education in Victoria, Queensland and New South Wales have formally approved a small number of naturopathy and WHM private education providers, and authorized them to award bachelor's degrees.

Responsibility for higher education (bachelor's degree and above) in Australia is shared between states, territories and the Commonwealth government. Vocational training is

the responsibility of the Commonwealth Department of Education, Science and Training (DEST).

Bachelor's degrees in naturopathy and WHM may be authorised by universities or the office of higher education in the relevant state or territory (see below). Universities are authorised by statute to internally approve (self-accredit) the courses they offer. Course proposals are rigorously assessed through a series of committees at school and faculty levels, and approved by the university council. (See Chapter 5 for a list of universities that offer approved bachelor's degree courses in naturopathy or WHM).

Advanced diplomas in naturopathy and WHM are available in the vocational education and training sector. Private providers may choose to offer a nationally accredited 'Health Training Package' in naturopathy and WHM. (See Chapter 5 for a list of education providers offering national health training packages in naturopathy and WHM). A private provider who wishes to deliver a health training package must first become a Registered Training Organisation by applying to the registering body in its state or territory (DEST 2005).

The following section describes the statutory education authorities that approve or accredit naturopathy and WHM courses in the private education sector—the state offices of higher education and DEST.

### **7.7.1 Offices of higher education**

The responsibilities of states and territories regarding the provision of higher education courses (bachelor's degree and above) include the accreditation of higher education awards offered by non-university providers. Bachelor's degrees in naturopathy and WHM have been accredited for offer by a small number of private education providers in Victoria, Queensland, and (since completion of the survey reported in Chapter 5), New South Wales (see Chapter 5).

Private provision of higher education programs is regulated by Acts of state and territory parliaments, such as Victoria's *Tertiary Education Act 1993*. Most states and territories have enacted legislation governing the recognition of higher education providers other than universities (MCEETYA 2000). Applications for both recognition and accreditation are dealt with by the offices of higher education in each state or territory. Different organisational units are assigned by state and territory governments to manage the recognition and accreditation processes.

Private providers who wish to offer a higher education course must obtain: (i) authorisation to become an approved provider; and (ii) accreditation of a course (MCEETYA 2000). Courses are subject to rigorous review conducted by expert panels who are appointed by the office of higher education. Following assessment of a course, recommendations are made to the relevant minister for education, usually through a ministerial advisory committee on education. A bachelor's degree delivered by a private provider must, like those offered by universities, demonstrate the standards for bachelor's degree courses set out in the Australian Qualifications Framework.

Applications to enrol in some privately provided bachelor degree courses are made through centralised government bodies (such as the Victorian Tertiary Admissions Centre) in the same way as is required for university places. Students are eligible to apply for government subsidies such as Austudy.

### **7.7.2 Vocational education and training**

In July 2005 the Australian National Training Authority (ANTA), an Australian government statutory authority which had provided the national and industry-led focus for vocational education and training (VET) since 1992, was abolished. The responsibilities and functions of ANTA were transferred to the Commonwealth Department of Education, Science and Training. DEST now administers the national training programs and the Australian government funding of the national VET system.

The VET sector entered naturopathy and WHM education during the late 1990s. Many colleges subsequently became Registered Training Organisations and upgraded their courses

using VET health training packages and competencies. Before the establishment of ANTAu, education packages were developed by state VET authorities and made available to private education providers and TAFE institutions. In 2003 nationally recognised health training packages began to replace the state packages, leading to re-accreditation of many naturopathy and WHM courses (see Chapter 5).

The nationally accredited health training packages are developed by the Community Services and Health Industry Skills Council Ltd in consultation with the professions. A training package is a set of national training resources consisting of: (i) core components; (ii) assessment guidelines; and (iii) national qualifications.

## 7.8 National research funding bodies

The National Health and Medical Research Council (NHMRC) and the Australian Research Council (ARC) are the two major vehicles in Australia for competitive research funding for investigator-driven research. In the United States a dedicated CAM research centre, the National Center for Complementary and Alternative Medicine (NCCAM) was established by the National Institutes for Health in 1998.

The total funding for research project grants awarded by the NHMRC to commence in 2004 was \$AUD165,616,432 (NHMRC 2005a). On average, 25% of the total research project<sup>2</sup> applications received by the NHMRC in 2004 were funded. One project grant was awarded for a CAM project in 2004—\$AUD30,014 for the development of alternatives to methadone for the management of opioid dependencies (NHMRC 2004). Fifteen CAM research proposals were submitted to the NHMRC in 2004 and 14 were not recommended for funding (NHMRC 2005c), a funding rate of 6.6%.

Total funding awarded by the ARC in the period 2003-2004 was approximately \$AU400 million across a range of disciplines (sciences and humanities). One CAM proposal was recommended for funding—\$227,967 for a project to examine the development of herbal medicines for the management of metabolic syndrome in order to prevent type 2 diabetes (Australian Research Council 2005a).

In comparison to Australian funding of CAM research, the United States Congress allocated a budget of \$USD117.7 million to the National Center for Complementary and Alternative Medicine, a dedicated CAM research institution, for the fiscal year 2004 (NCCAM 2004).

Funding allocated by government for CAM research in Australia is a negligible proportion of the total funds. One reason may be that the highly competitive nature of research funding, where experienced researchers generally receive grants, is likely to create a significant obstacle for novice researchers investigating unconventional areas of healthcare.

### 7.8.1 National Health and Medical Research Council (NHMRC)

The National Health and Medical Research Council is an independent statutory body, established under the *National Health and Medical Research Council Act 1992*, which operates within the portfolio of the Commonwealth Department of Health and Ageing. The NHMRC is a leading expert body promoting the development and maintenance of public and individual health standards in Australia (NHMRC 2005b). It also makes recommendations to the Government on its allocation of funds for health and medical research. The NHMRC has four principal committees (Research, Australian Health Ethics, Health Advisory, and Licensing) and a large number of sub-committees which oversee the Council's key areas of operation (NHMRC 2005b).

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<sup>2</sup> The Project Grant Scheme is a funding type and is the NHMRC's main avenue of support for individuals and small teams of researchers undertaking biomedical, clinical, public health or health services research in Australian universities, medical schools, hospitals or other research institutions.

The strategic plan of the NHMRC for 2003–06 includes the following objectives: (i) to create internationally competitive knowledge; (ii) to develop research capability and capacity within Australia by increasing skills in research across the spectrum of health and medical research ... and [by] working with other organisations and agencies on a broad range of research matters; (iii) to improve the utilisation of research findings in health; and (iv) to engage with the Australian community (NHMRC 2003a).

These objectives are sufficiently broad to include research into CAM, yet little funding has been made available despite the fact that more than half of the Australian population uses some form of CAM, and that its use is frequently not disclosed when being treated by medical practitioners (who often have limited training in the area, see Chapter 8).

There have been a number of calls in recent years for dedicated funding for high level clinical trials and for the development of evidence-based CAM information sources accessible by medical practitioners, CAM therapists, hospitals, health organisations and the public (For example, House of Lords Select Committee on Science and Technology 2000, World Health Organisation 2002, Expert Committee on Complementary Medicines in the Health System 2003).

The role of the NHMRC's Health Advisory Committee (HAC) is to develop evidence-based guidelines for practice (NHMRC 2003b). The HAC is authorised to establish working committees to address issues—including health promotion and illness prevention, clinical practice, development of best practice guidelines, and health service delivery (NHMRC 2003b). Given the extent of CAM usage in the Australian community, the Health Advisory Committee of the NHMRC should establish a working party to issue authoritative guidelines on evidence-based practice of CAM, and to make recommendations about improving the evidence base for CAM practices in Australia.

### **7.8.2 Australian Research Council (ARC)**

The Australian Research Council (ARC) was established under the *Australian Research Council Act 2001* as an independent statutory body which reports to the Minister for Education, Science and Training. It has a primary role in advising Government on investment in the national research effort in the fields of science, social sciences and humanities, and supports partnerships between researchers and the broader community. Its overall mission is to 'advance Australia's research excellence to be globally competitive and deliver benefits to the community' (ARC 2005b).

The ARC invested approximately \$AUD400 million in research and training in the year 2003-04 through the National Competitive Grants Program (ARC 2004). There are three types of research funding under this program:

- Discovery programs which fund individual research programs;
- Linkage programs which assist partnerships between researchers and industry, government, community organisations and the international community; and
- Centres programs which support and strengthen major research centres and networks.

The ARC received a number of proposals for CAM research (research category classification codes 321301-321399) in the period 2002-2004. The ARC does not release information on the number of applications received in particular categories of research, so the total number of submitted proposals for CAM research was not available (ARC 2005a).

### **7.8.3 CAM research in the United States**

The National Center for Complementary and Alternative Medicine (NCCAM) was established in 1998. NCCAM is one of the 27 institutes and centres that make up the National Institutes of Health (NIH). The NIH is one of eight agencies under the Public Health Service (PHS) in the Department of Health and Human Services (DHHS). NCCAM is funded by the United States Congress (NCCAM 2002).

NCCAM supports research and training at both conventional and CAM research institutions, including approximately 30 university and hospital CAM research centres. In its first five years, NCCAM funded more than 1200 projects (NCCAM 2004). Major activities include basic and clinical research, awards grants that provide training for doctoral and career researchers, the operation of an information clearinghouse for healthcare providers, consumers and researchers, conference sponsorships, a website, publications, and support for the integration of evidence-based CAM into medicine, nursing and dentistry (NCCAM 2002).

Major areas of research interest at NCCAM include:

- Anxiety and depression;
- Cardiovascular diseases;
- Indigenous health care practices;
- HIV/AIDS;
- Immune modulation/enhancement, including inflammation;
- Inflammatory bowel disease and irritable bowel syndrome;
- Insomnia;
- Liver diseases;
- Obesity/metabolic syndrome; and
- Respiratory diseases — infectious respiratory diseases and asthma (NCCAM 2005).

### **7.8.4 Australian Government response to calls for funding**

The Expert Committee (2003) made a series of recommendations relevant to research in CAM. Table 7.3 sets out these recommendations and the Government's response (Australian Government 2005).

The Australian Government's response does not reflect international concerns and trends about the need for substantial increases in research funding in order to improve the CAM evidence base (see, for example, 7.8.3). Given the extent of usage in the Australian community there is a need for additional CAM research in the areas of health services and clinical effectiveness.

**Table 7.3 Research recommendations and Government response**

	<b>Expert Committee Recommendation</b>	<b>Australian Government response and proposed implementation action</b>
33.	The National Health and Medical Research Council (NHMRC) convene an expert working group to identify the research needs (including efficacy, safety, cost-effectiveness, mechanism of action and capacity building), priorities and resources to address the use of complementary medicines consistent with the <i>National Medicines Policy</i> (NMP) and <i>The National Strategy for Quality Use of Medicines</i> (QUM).	<b>Accepted.</b> The NHMRC will consult with the Dept. of Health and Ageing and the Therapeutic Goods Administration to determine the most appropriate means of identifying and supporting any research needs consistent with the NMP and QUM.
34	Dedicated funding be made available for complementary medicine research in Australia for a minimum of five years.	<b>Noted.</b> The Government believes no decision can be made prior to consideration of research needs and priorities. However, in the interim, the Government is making available up to \$500,000 to fund a project or projects to investigate the value of the complementary medicine glucosamine in the management of osteoarthritis.
35	The amount of funding available for complementary medicine research in Australia be determined on a <i>per capita</i> basis consistent with complementary medicine research funding in the USA	<b>Not accepted.</b> The Government does not consider that funding should be tied to a specific formula, but that it should be based on research needs, which are yet to be determined (see Recommendation 33).
36	A database be established to identify researchers and centres of excellence to facilitate complementary medicine research in Australia.	<b>Accepted.</b> The Therapeutic Goods Administration will consult with the NHMRC and other stakeholders in coordinating this project.
38	Organisations involved in awarding public funds for healthcare research ensure that: (a) applications for research funding in the area of complementary medicines are assessed by fair, equitable and ethical methods (b) the methods represent the best use of community resources to meet the current and future healthcare needs of the community	<b>Noted.</b> The Government will continue to work to ensure that assessment of funding applications is based on fair, equitable and ethical grounds that make the best use of community resources.

## 7.9 Naturopathy and WHM in the hospital system

CAM offers potential benefits to hospital patients, including shortened hospital stays and improved outcomes (see Chapter 3). However, ingested complementary medicines (CMs) also pose potential risks to hospital patients—including side effects (such as altered blood coagulation and cardiovascular status) and drug interactions (with anaesthetics and other pharmaceuticals used in standard medical care (Kaye, Clarke, Sabar, Vig, Dhawan, Hofbauer et al. 2000; Norred, Zamudio & Palmer 2000; Leung, Dzankic, Manku & Yuan 2001; Silverstein & Spiegel 2001; Norred 2002).

There have been few surveys on the use of CMs in Australian hospitals. However those that were located for the present study revealed consistent problems with non-disclosure by hospital patients of use of CMs whilst in hospital, and poor documentation in medical notes and medication charts (Welch 2001, Dooley, Lee & Marriott 2004, Snape 2004). In Snape's (2004) study, most CMs were self-prescribed (47.5%), which causes concern that patients might not be aware of the possibility of drug interactions or other potential complications. More than a quarter (27.5%) was prescribed by a CAM practitioner, which demonstrates the need for communication between medical practitioners and CAM practitioners in the interests of patient safety.



The potential risks associated with use of CMs in Australian hospital patients, and the low disclosure rate, raise concerns for patient safety. However, few hospitals have well-developed policies or guidelines on use of CAM in general, or CMs in particular. In most hospitals, CMs are treated differently from pharmaceuticals—which are prescribed, dispensed, and administered by trained staff members who have statutory authority to perform these tasks. In contrast, CMs may be brought in by patients or their families, kept in drawers beside the patients' beds, and then self-administered.

### 7.9.1 Hospital guidelines on use of complementary medicines

Neither the Australian Healthcare Association (the national peak body representing publicly funded hospitals) nor the Australian Private Hospitals Association had a published position on patient use of CAM. The development of hospital policies and guidelines is largely left to individual hospitals, and is therefore somewhat haphazard.

In a number of hospitals, patients are requested to follow restrictive hospital policies with respect to the use of CMs. For example, they might be requested to: (i) declare use; (ii) sign a statement that use is with or without medical approval; (iii) store their CMs in a locked cabinet that only staff members can access; (iv) self-administer the CMs; and (v) document the use on special charts (Royal Children's Hospital 2004). Poor patient disclosure rates suggest that compliance with such policies might be problematic.

In other hospitals, patients are requested to defer their use of CMs while in hospital. Potential problems with deferral include that (Braun & Cohen 2004a, 2004b):

- the recommendation may not be based on evidence about the CM;
- it does not take into account the shared decision-making that should occur between each patient and his or her doctor, or the wishes of the patient;
- patients might indiscriminately cease their use of all CMs due to lack of knowledge, fear, or misinformation;
- new health problems may arise if the CMs are withdrawn, raising the issue of *beneficence*; and
- there is also the potential for serious adverse outcomes if hospital patients cease use of CMs. For example, withholding a CM could result in reduced activity of liver detoxification enzymes and subsequent toxicity from a pharmaceutical that was previously stable at therapeutic levels (Braun & Cohen 2004a, 2004b).

The NSW Therapeutic Advisory Group (TAG, formerly the NSW Therapeutic Assessment Group) represents experts in drug therapy from the teaching hospitals in NSW and aims to promote quality use of medicines by sharing unbiased, evidence-based information about drug therapy. TAG has prepared guidelines that: (i) recognise patients' rights to make informed decisions; (ii) acknowledge the principle of 'seamless care'; and (iii) note that it might not be in the best interests of patients to 'disallow' their use of CMs (Therapeutic Advisory Group 1999).

The Wentworth Area Health Service in NSW has developed a policy on CAM use in hospital which attempts to take into account the complex issues noted above (Wentworth Area Health Service Complementary Therapies Committee 2004). This policy outlines procedures for recording use of CAM and guidelines by which CAM practitioners may consult with hospital patients and collaborate with hospital staff. The document acknowledges the difficulties that exist in assessing the credentials of CAM practitioners (such as naturopaths and herbalists) and the possibility of conflicting views arising between these therapists and hospital staff. Appendix 7.1 outlines the main features of the WAHS policy, and appendix 7.2 provides a range of suggested approaches to the development of guidelines (Cohen and Braun 2004).

## 7.10 Mainstream professional healthcare associations

### 7.10.1 Medical bodies

#### Australian Medical Association (AMA)

The AMA's current position statement on CAM represents a change from earlier policies. A submission to Victoria's Social Development Committee in 1986 stated that:

The [AMA] maintains that a medical practitioner should at all times practise methods of treatment based on sound scientific principles and accordingly does not recognise any exclusive dogma such as homeopathy, osteopathy, chiropractic and naturopathy (Parliament of Victoria Social Development Committee 1986, p. 322).

The AMA's Code of Ethics also ruled that it was 'unethical for a member of the Victorian Branch of the [AMA] to associate professionally with or refer patients to a practitioner of any exclusive dogma such as homeopathy, osteopathy, chiropractic, hypnotherapy, etc.' (Parliament of Victoria Social Development Committee 1986 p. 322).

The current position statement, *Complementary Medicine*, recognises that 'evidence-based aspects of complementary medicine are part of the repertoire of patient care and may have a role in mainstream medical practice' (AMA 2002). The position statement includes a number of points which are summarised as follows:

- research is essential to permit scientific assessment of the evidence for CAM and the Federal Government is called upon to provide additional funding for the design and implementation of appropriate evaluative research;
- information resources for medical practitioners should be similar to those existing for mainstream medicines and therapies;
- a systematic approach is required to adverse events and alerts, and should involve both medical and CAM practitioners;
- Medical practitioners should receive adequate information about CAM in undergraduate, vocational and further education programs;
- medical colleges are encouraged to develop educational and practice standards; the AMA notes that regulation of medical practitioners in relation to the use of CAM is the responsibility of Medical Boards (AMA 2002).

#### Royal Australian College of General Practitioners (RACGP)

The RACGP 'supports approaches that build high quality, safe and systems-focused health care for all Australians' but notes that 'The current environment in relation to complementary and alternative medicines (CAM) is not necessarily consistent with this approach'. The RACGP's policy, *Complementary Medicines in the Australian Health System*, contains five recommendations which are summarised as follows:

- high level clinical trials to assess the effectiveness of complementary medicines;
- development of a practitioner-friendly information service that promotes the dissemination of high quality research results;
- active promotion of the Australian Government's health information web link for consumers (<[www.healthinsite.gov.au](http://www.healthinsite.gov.au)>) to enable their access to high quality, reliable information and resources;
- the establishment of industry-wide professional standards and monitoring processes to assure the Australian public of the safety and high quality of services provided by CAM practitioners;
- a review of CAM content in medical software prescribing systems to ensure their features meet general practice current and future requirements (RACGP 2002).

Overall, the AMA and RACGP policy documents acknowledge the growing role of CAM and support the integration of CAM into medical practice where there is sufficient high quality scientific evidence. The issue of referral to CAM practitioners was not addressed in recent policies published by the AMA and RACGP.

### **Attitudes of medical organisations to the regulation of CAM**

Both the AMA and the RACGP call for an approach to regulation that will support high professional standards and protect the public.

The AMA (2002) ‘believes that it is essential that there is appropriate regulation of complementary therapists. Such regulation should ensure that non-medical complementary therapists cannot claim expertise in medical diagnosis and treatment’.

The RACGP (2002) policy ‘expects that all health practitioners meet stringent professional standards that assure the public of their safe practice’ and addresses the need for industry-wide professional standards and monitoring processes for CAM practitioners. It recognises that ‘CAM practitioners need:

- a process that establishes industry wide standards for the practitioner and the practice setting;
- an independent process to assess practitioner competence against those standards;
- an independent process of assessment in meeting site and system standards;
- a process for ongoing monitoring of continuous skills development in CAM professionals’
- an ethical basis upon which the industry rests;
- a transparent complaints system that monitors practitioner activity and reports to the public on inappropriate action’ (RACGP 2002).

The NSW Medical Board (NSWMB 2003) made a submission against the statutory regulation of complementary health practitioners in response to the NSW Health Department’s discussion paper on ‘*Regulation of Complementary Health Practitioners*’ (2002). Regulation of herbal medicine was considered desirable by the NSWMB because it has the capacity to cause harm to patients, however, non-statutory regulation was recommended. The NSWMB opposed statutory registration on two grounds—firstly, because it would confer legitimacy on CAM practitioners; and secondly, because there was a perceived paucity of supporting scientific evidence. It should be noted that neither of these points are included as criteria in the assessment of the need for statutory regulation of a health profession.

### **7.10.2 Other health professions**

The Pharmaceutical Society of Australia’s policy *Complementary Medicine* (1997) makes three key points which are summarised as follows:

- that consumers have a right to choose and to have access to quality information and safe, efficacious products;
- that supply of CMs is at the discretion of an individual pharmacist, who is responsible for providing information and advice consistent with consumer needs; and
- PSA supports the view that a national body should be responsible for the competencies of CAM practitioners, and for professional issues such as ‘establishing educational requirements, practice standards and registration of complementary medicine practitioners; promoting safety and accurate representation of complementary medicine products to the public; monitoring the usage of complementary medicines; a reporting mechanism for any adverse effects; [and] increasing opportunities for further research in this field’ (Pharmaceutical Society of Australia 1997).

The Royal College of Nursing, Australia Position Statement *Complementary Therapies in Australian Nursing Practice* (RCNA 1999) holds that the nursing profession ‘... has the right and obligation to interpret complementary therapies within the context of nursing theory and practice’. The college recommends that policies should be developed by employers and provides a list of points that require consideration when creating guidelines. Most of these have been noted above in the summary of the policies of state nursing boards.

Complementary therapies that have been used and reported in nursing practice include improved diet and nutritional support in chronic conditions, aromatherapy and massage for problems such as stress, poor circulation, and pain relief, and stress management techniques (McCabe 2001, Nurses Handbook of Alternative and Complementary Therapies 2003).

Other guidelines were located on the websites of the Australian Nursing Federation (ANF) (*Complementary Therapies in Nursing Practice* 2005) and the Australian College of Holistic Nurses (ACHN) (*Policy Guidelines for Practice of Complementary Therapies by Nurses and Midwives in Australia* 2000). The ANF guidelines noted that various forms of healing, such as massage, relaxation and ‘environment manipulation’ (for example through colour, music and aroma) ‘have always been a part of nursing practice [and] should continue to be recognised and valued’.

Although guidelines from professional bodies such as the RCNA, ANF and ACHN support the integration of complementary therapies into nursing practice, many hospitals have been slow to respond to the call for development of policy and workplace guidelines. This has the potential to present difficulties for nursing clinicians who wish to integrate complementary therapies into their nursing care.

## **7.11 Summary of results**

### **7.11.1 Private health funds**

Fourteen private health funds, plus two industry groups representing a total of 38 funds, responded to enquiries regarding naturopathy and WHM. Where funds did recognise naturopathy and/or WHM partial rebates were paid for consultations only, not for medicines or treatments.

Criteria for approving practitioners as recognised providers varied from fund to fund, and included:

- assessment of individual practitioners using a range of criteria;
- graduation from an accredited course (university, Department of Education- authorised bachelor’s degree [private education provider], or DEST- authorised health training package);
- membership of certain professional associations (not a requirement for a significant number of funds);
- approval by ARHG (umbrella group); and
- approval by a professional assessment panel (fee charged to practitioner).

Assessment of applications from individual practitioners included:

- level of qualification and years of experience;
- required contact hours for courses;
- professional indemnity insurance;
- current first aid certificate;
- evidence of involvement in continuing professional education;
- a process for ensuring practice quality;
- a code of ethics; and
- TGA Advertising Certificate of Exemption.

The major concerns expressed by the funds were:

- variability of practitioners' qualifications and backgrounds;
- the large number of professional associations and their diverse eligibility requirements for membership;
- time and expense required for funds to assess applicants;
- lack of a coherent regulatory system; and
- need for a central registration and accreditation body.

### **7.11.2 Workers' compensation insurers**

- The services of naturopaths were allowable under some WorkCover schemes, but not under others. There were also several schemes under which such services might be allowable if interpreted as 'reasonable medical therapies' (see Table 7.2).
- South Australia and New South Wales WorkCover schemes limited the use of CAM therapies to remedial physical therapies.
- WorkCover Queensland was the only scheme that limited provision of services to practitioners who had statutory registration.
- In all other states and territories, services such as naturopathy and WHM required recommendation from (or referral by) a medical practitioner.
- WorkCover authorities reported that insurers who manage cases had considerable power to determine whether a client was reimbursed for particular services. The current enquiry did not explore insurers' attitudes to the use of CAM therapies in rehabilitation, or any guidelines that are used to assess appropriateness of therapies.
- In modified common-law schemes, clients had more freedom to choose therapists (including CAM therapists), but funding allocation depended on the evidence for the therapy (either scientific or outcomes-based) and applicability to the individual client.

### **7.11.3 Medicare, Department of Veterans' Affairs, and motor accident compensation schemes**

- In 2004 the Health Insurance Commission (Medicare) recognised CAM practitioners for the first time, when chiropractors and osteopaths registered with a statutory board were granted eligibility for registration with the Health Insurance Commission (HIC) as allied health providers. Medicare rebates are available only to patients with chronic illnesses being managed by a GP under an Enhanced Primary Care plan, and patients must be referred by their GP. Naturopaths and WHM practitioners are not recognised as allied health providers by the HIC.
- The Department of Veterans' Affairs approves only chiropractic and osteopathy as CAM services for veterans.
- Motor accident compensation schemes are state-based and are either modified common-law ('fault-based') schemes or statutory ('no-fault') schemes.
- Statutory ('no-fault') schemes apply in Victoria, Tasmania and the Northern Territory. Because 'no-fault' schemes compensate a greater number of people, access to funding is restricted and clients have less choice. The Transport Accident Commission in Victoria includes registered chiropractors and osteopaths on its list of recognised providers, but not naturopaths or WHM practitioners.
- Modified common-law schemes ('fault-based') apply in most states and territories. Under these schemes, less people are compensated but clients appear to have more freedom to choose therapists (including CAM therapists). However, funding allocation depends upon a range of variables such as the evidence for the therapy (either science-based or outcomes-based), and the amount of therapy required.

#### **7.11.4 Professional indemnity insurers**

- Membership of a recognised association was usually sufficient to gain professional indemnity (PI) insurance.
- Non-member practitioners were assessed individually by an underwriter.
- The lowest level of training accepted by a PI insurer was a ‘certificate’, or evidence of at least two years in practice.
- Naturopathy and WHM were considered low risk professions as evidenced by the relatively low premiums charged for professional indemnity.
- Annual premiums for \$1 million indemnity were \$170–\$430 (group schemes) and \$440–\$1000 (individual practitioners).
- Companies were unwilling to provide claims data.
- A national standard of education would reduce the time needed by underwriters to assess individual practitioners.

#### **7.11.5 Australian Taxation Office**

- For the purposes of GST exemption on consultations, the ATO recognised practitioners who were full members of at least one ‘recognised professional association’.
- The ATO has formally assessed over 20 professional associations as meeting the ATO’s definition of a ‘professional association’.
- Because the associations have various standards for membership, the above arrangement has not led to the application of unified standards for entry to the professions, nor has it assisted the sector to self-regulate effectively by providing incentives for compliance with standards.

#### **7.11.6 Statutory registration boards**

- Medical boards in Australia have taken similar positions on CAM, and some have produced guidelines for medical practitioners. Their approaches are generally cautious, and adequate evidence for a therapy is the primary consideration. There are differing views on referral to CAM practitioners.
- Nurses’ boards tend to support the integration of complementary therapies into nursing practice, and guidelines have been produced by several state boards.
- The Pharmacy Board of Victoria has produced brief guidelines on the practice of alternative therapy by pharmacists.

#### **7.11.7 Statutory higher education authorities**

- Universities are enabled by statute to internally approve (‘self-accredit’) the courses they offer.
- Private provision of higher education programs is regulated by Acts of state parliaments—such as Victoria’s *Tertiary Education Act 1993*. Legislation authorises offices of higher education in the states and territories to approve private education providers and the courses they offer.
- Private providers have been accredited to award bachelor’s degrees in naturopathy and WHM in Victoria, Queensland and, most recently, in New South Wales.
- The Department of Education, Science and Training has approved health training packages for advanced diplomas in naturopathy and WHM. These were widely available in Australia, either through TAFE colleges or through approved private providers.

See Chapter 5 for further information on education providers and courses in naturopathy and WHM.

### **7.11.8 National research funding bodies**

- There is very little research funding for CAM in Australia. Numerous reports have called for dedicated NHMRC funding for high level clinical trials and for the development of evidence-based CAM information sources accessible by medical and CAM practitioners, hospitals, health organisations and the public. Government response has been minimal.
- There are no independent, authoritative guidelines on evidence based practice of CAM in Australia.

### **7.11.9 Hospitals**

- Hospitals have been slow to produce policy and guidelines for staff on the use of CAM by patients or by staff. Guidelines that are available take various positions on whether patients should continue to use or stop use of complementary medicines (CMs) while in hospital, availability and accessibility of information resources, the visiting rights of complementary therapists, and the role of such personnel in extended healthcare teams.
- The level of use of CMs by hospital patients appears to be significant, but many patients do not disclose this use to clinical staff. Because many CMs are self-prescribed, patients might not be aware of the risks.

### **7.11.10 Mainstream health professional associations**

- The AMA and the RACGP have developed positions and policies supporting integrative medicine—provided that the approach is evidence-based and that doctors are appropriately qualified in the CAM therapies which they practise.
- Guidelines for the integration of complementary therapies into nursing and midwifery practice were located on the websites of the Royal College of Nursing Australia, the Australian Nursing Federation, and the Australian College of Holistic Nursing.

## **7.12 Discussion**

Naturopathy and WHM have grown significantly, both professionally and economically, in the past two to three decades. Consumer support has been a major factor in this growth and institutions have been put in the position of responding to increasing public use. Rapid and unregulated growth has resulted in an uncoordinated patchwork of policies as institutions react to public and professional needs. This chapter has considered the policies of various institutions—including a range of health payers such as private health insurance funds, statutory registration boards, professional associations and the Australian Taxation Office. The level of recognition of naturopathy and WHM by these institutions is wide ranging, but inconsistent. Another major area of institutional recognition is the federal government's Therapeutic Goods Administration (see Chapter 10).

Among major health payers in Australia, private funds have, in general, responded to community choice in healthcare more readily than have public bodies. There is widespread availability of private health insurance for consumers, and professional indemnity insurance for practitioners. However, private health funds are concerned about the variability of practitioner education and professional association standards.

The situation is less consistent with regard to workers' compensation and motor accident schemes which, in most states, do not support injured persons who might wish to utilise the services of naturopaths or WHM practitioners in their rehabilitation. The requirement in most states and territories for referral by a medical practitioner is likely to continue to restrict the use of naturopathy and WHM unless the referral patterns of medical practitioners change. However, the lack of regulatory status of the naturopathy and WHM professions, and possible repercussions of referring to an unregistered health professional, are likely to be continuing impediments to medical referral.

The ATO has developed, in conjunction with several professional associations, a system that enables recognition of members of formally recognised associations. It is a system of recognition (rather than regulation), and is not effective in ensuring consistent educational and professional standards. Nevertheless, it is significant in that it recognises the importance to the public of CAM providers and awards them a measure of equivalence with mainstream healthcare practitioners regarding non-imposition of the goods and services tax on healthcare consultations.

The statutory registration boards of medicine and nursing in a number of Australian states recognise the importance of CAM to the public and support their clinicians in the introduction of CAM therapeutic approaches consistent with the roles and values of their professions. Two medical registration boards have dealt with the issue of referral, but disagree on whether medical practitioners should refer patients to 'unconventional health practitioners'. The Queensland board stated that it should be avoided, whereas that of Western Australia advised that there is no barrier if referral is appropriate and would not be likely to expose a patient to harm. Improved regulation of naturopaths and WHM practitioners could assist medical registration boards to advise doctors on referral to appropriately qualified practitioners.

National professional associations for medical practitioners, nurses and pharmacists (such as the Australian Medical Association, Royal Australian College of General Practitioners, Royal College of Nursing Australia, and the Pharmaceutical Society of Australia) have produced policy documents and/or guidelines to assist practitioners in developing appropriate practices and workplace policies with regard to complementary healthcare.

However, at the workplace level, particularly in hospitals—there appear to have been difficulties in developing appropriate policies to support patient choice and guide staff. The development of consistent, evidence-based guidelines on the use of CAM in hospitals is not straightforward. Hospitals should, in theory, respect the autonomy of patients to make informed decisions about therapeutic interventions that they feel are in their best interests. However, hospitals also have a duty of care, and are generally reluctant to administer substances that are not part of the standard hospital formulary, that might have adverse effects, that have variable evidence of efficacy, or that require specific knowledge in their preparation or administration (Cohen & Braun 2004). Some hospitals have therefore supported a policy of requesting patients to cease use of complementary medicines while in hospital, without taking into account the possibility that such withdrawal could have negative consequences for patients. It is not unreasonable to expect that, at some time in the future, withdrawal of a complementary therapy or a failure to advise a patient against the use of a potentially harmful complementary therapy, will give rise to litigation issues (Cohen & Braun 2004). The availability of a reliable CAM information database would assist hospitals and other institutions to access high quality, current, data and information.

In recent years there has been increasing involvement of statutory education authorities in the training of naturopaths and WHM practitioners. Both VET and higher education offices have played a significant role in the formal recognition of private education providers and the accreditation of courses in naturopathy and WHM. Government-accredited courses have assisted a range of public and private institutions to identify bona-fide practitioners. However, the variety of award levels and education standards accepted for entry to the professions continues to be a problem (see Chapters 5 and 6).

Research organisations, particularly the NHMRC, have provided very little funding for CAM research. Research has been negligible in Australia despite the fact that approximately 60% of the population now uses some form of CAM, and that medical support for CAM therapies is increasing.

Enquiries of the institutions and organisations referred to in this chapter found that many recognise naturopathy and/or WHM as health professions. However, there are also misgivings. In addition to direct health concerns and disquiet about the educational standards



of practitioners, the organisations also perceive economic risks—both to the institutions' own interests and to patients—as a result of ineffective therapy or inappropriate use of effective remedies. These concerns reflect a similar dynamic occurring in other Western countries. For example, research on the role of the state in the social inclusion of CAM in Canada identified conflict within various levels of government between the need to protect the public, and the obligation to respond to consumer demands for CAM (Kelner, Wellman, Boon and Welsh 2004). Slowness to respond to consumer demand was due to uncertainty about safety, efficacy and cost-containment, and was reinforced by lack of unity among CAM groups (Kelner et al. 2004).

The failure of current attempts by naturopathy and WHM to self-regulate affects institutions in two ways: (i) difficulty in identifying appropriately qualified practitioners; and (ii) having to deal with many professional CAM associations which have not developed uniform and consistent standards. Improved regulation of naturopaths and WHM practitioners would simplify procedures for institutions that currently recognise those professions.

Numerous public and private institutions already choose to limit provision of CAM services to practitioners who have statutory registration and sufficient evidence of safe and effective practice. Improved regulation of naturopaths and WHM practitioners would benefit the public by enabling a wide range of institutions to identify practitioners who have an adequate standard of education and professional values.

### **7.13 Conclusion**

The level of institutional recognition of naturopathy and WHM has gradually increased in response to growing public and professional needs. However, the degree to which various institutions have responded to the professions, and to the consumers who seek their services, varies considerably, both within sectors and from one sector to another.

More standardisation across jurisdictions would benefit consumer interests. Institutions would benefit if the regulation of naturopathy and WHM were improved so that institutions would not have to deal with numerous professional associations with differing educational requirements for practitioners. Increased research and the availability of a reliable CAM information database would benefit healthcare institutions, professions and the public.

### **7.14 Recommendations**

Improved regulation with uniform educational requirements and professional standards would assist a range of government, public, and private institutions to recognise suitably qualified practitioners, and would support institutions in providing appropriate services to the Australian public. The following strategies are recommended.

- Institutions responsible for approval of suitably qualified practitioners (including government, public, and private institutions) should work together to develop greater standardisation across jurisdictions to benefit their own interests and those of consumers.
- Government funding should be provided to develop a high quality evidence based CAM information system—accessible to doctors, CAM therapists, education providers, health organisations, and the public.
- Institutions that make decisions about funding CAM interventions should become more acquainted with the evidence base in the interests of informed and up-to-date decision-making. Decision-making processes should be transparent.
- To protect both consumers and clinical staff, hospital associations and/or individual hospitals should design appropriate guidelines for CAM use by patients and CAM practice by staff.
- The Health Advisory Committee (HAC) of the NHMRC should establish a working party to issue authoritative guidelines on evidence-based practice of CAM, and to make recommendations about improving the evidence base for CAM in Australia.

- NHMRC and ARC should facilitate increased funding and development of additional capacity for high quality, basic and applied research in this rapidly developing area of healthcare. For example, NHMRC and ARC could fund research networks that link CAM researchers with researchers in other established disciplines as one approach to building research capacity.
- Research training within CAM educational programs also needs to be strengthened to improve the quality of novice researchers, for example through development of honours programs and the expansion of postgraduate research programs.

### Acknowledgement

Thanks to Professor Vivian Lin for constructive comments during the preparation of this chapter.

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# 8. Naturopathy, Western Herbal Medicine and Australian General Practice

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## 8.1 Introduction

A number of studies in Australia and overseas have investigated the attitudes of general practitioners (GPs) to complementary and alternative medicine. However, none of those carried out in Australia have been national studies. The present study set out to investigate Australian GPs' attitudes to a range of complementary and alternative therapies to ascertain whether their attitudes had changed in recent years.

### 8.1.1 Literature Review

As noted in previous chapters, community demand for complementary and alternative medicine (CAM) appears to have increased steadily over the past 20 years (Lloyd et al. 1993; Fisher & Ward 1994; Eisenberg, Davis, Ettner, Appel, Wilkey, Van Rompay & Kessler 1998; MacLennan, Wilson & Taylor 2002). It is of significance for medical practice that 57% of CAM users did not tell their doctors about use of these medications (MacLennan, Wilson & Taylor 2002).

The popularity of CAM in Australia suggests that many complementary therapies (CTs) can be considered 'mainstream' in general medical practice. Surveys of general practitioners have revealed that many doctors consider certain CTs to be effective and appropriate for use in general practice (Pirota et al. 2000; Hall & Giles-Corti 2000). In 2002, the Australian Medical Association (AMA) released a formal position statement on CAM that was subsequently endorsed by the Royal Australian College of General Practitioners (RACGP). It recognised: '... that evidence-based aspects of complementary medicine are part of the repertoire of patient care and may have a role in mainstream medical practice' (AMA 2002).

The increased use of CAM has been paralleled by a growing evidence base and calls for the integration of CAM therapists into mainstream healthcare. It has been suggested that most GPs have patients with chronic illness who could benefit from the services of CAM practitioners, and virtually all CAM practitioners have patients who require access to mainstream diagnosis (Cohen, 2004). It is further suggested that the dangers of not integrating CAM into mainstream medicine include: (i) delaying or depriving patients of safe and effective management; and (ii) allowing the potential for harmful interactions between drugs and herbal medicines (Cohen 2004). The prospect of integration of CAM and mainstream medicine has also led to calls for increasing regulation of CAM therapists. For example, the RACGP-endorsed AMA position statement on CAM (AMA 2002) stated that:

The AMA believes it is essential that there is appropriate regulation of complementary therapists. Such regulation should ensure that non-medical complementary therapists cannot claim expertise in medical diagnosis and treatment.

## 8.2 Survey of general practitioners

A national survey of Australian GPs was conducted to investigate their attitudes to CAM and to the increased community demand for these therapies. A self-administered postal survey was sent to a random sample of 2000 Australian GPs between May and August 2004. The survey sought GPs' opinions on: (i) the effectiveness and safety of CAM; (ii) the appropriateness of GPs' practising CAM; (iii) the appropriateness of Medicare rebates for CAM; (iv) GPs' encouragement or discouragement of patients' suggestions regarding the use of CAM; (v) the appropriateness of government regulation of CAM; (vi) the frequency of referrals to medical or non-medical complementary practitioners; (vii) the GPs' own use of CAM and willingness to practise these therapies; (viii) training and interest in training in CAM; (ix) the frequency of adverse events related to CAM; (x) the appropriateness of GPs' selling or dispensing complementary medicines; (xi) the need for undergraduate education in CAM; and (xii) changes in demand for CAM.

## 8.3 Methodology

### 8.3.1 Design of the survey

An 11-page A5-size survey booklet was designed to investigate various aspects of GPs' interactions with the following CAM systems and therapies: acupuncture, aromatherapy, Chinese herbal medicine, chiropractic, herbal medicine, homeopathy, hypnosis, massage, meditation, naturopathy, osteopathy, reflexology, spiritual healing (for example, reiki), vitamin and mineral therapy, and yoga (Appendix 8.1). This survey served as a follow-up to a survey of 488 Victorian GPs conducted in 1997 which reported opinions on, and use of, a range of CTs (Pirootta et al. 2000). By canvassing GPs nationally and asking a wider range of questions about a larger number of therapies, the present survey provided a comparison with the 1997 data, and also with a survey of Perth GPs conducted in 2000 (Hall & Giles-Corti 2000).

The survey received ethics approval from RMIT University. A financial incentive to complete the survey was offered to doctors in the form of a chance to win a \$500 book voucher.

### 8.3.2 Sample

The Health Insurance Commission (HIC), which administers the national health insurance scheme, Medicare, provided a representative sample of 2000 Australian GPs who had each seen at least 1500 patients in the previous year. The sample represented the Australian GP population in terms of gender, age, and location of practice (state and rural/urban). The representative nature of the sample was established using GP workforce data from the Commonwealth Department of Health and Ageing (DHA 2000) and classification data from the Australian Institute of Health and Welfare (AIHW 1994). On the basis of these data, the sample of 2000 doctors represented approximately 10% of Australian GPs in 2004.

### 8.3.3 Conduct and analysis of the survey

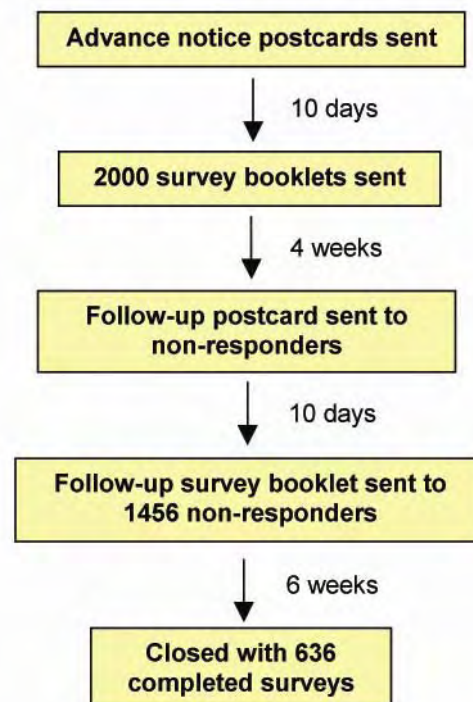
In early May 2004, a postcard was mailed to the 2000 GPs to advise that the survey would arrive in the mail shortly. About 10 days later, the survey booklet was mailed, along with a covering letter and a reply-paid envelope. This was followed up with a reminder postcard sent to those who had not responded after four weeks. After another two weeks, a second survey booklet was mailed to all non-responders. Survey booklets were accepted for another six weeks before the survey closed (see Figure 8.1).

Exclusion criteria included doctors who had left their clinic leaving no forwarding address, and those who had taken leave, retired, died, or were absent from their address for other reasons that resulted in the survey mail being returned.

The statistical analysis was performed using SPSS software (Lead Technologies 2003). Responses were analysed to search for groupings of common levels of use or acceptance.

Qualitative data (obtained from space left for handwritten comments) were classified by themes, and reported accordingly.

**Figure 8.1 Time sequence of survey**



### 8.3.4 Respondents and non respondents

After applying the exclusion criteria, 636 completed surveys were received from 1916 eligible doctors—a response rate of 33.2%. The 636 respondents represented approximately 3.4% of the Australian GP population (see Appendix 8.2).

Although the random sample accurately reflected the average age (49 years) of the GP workforce (DHA 2000), the sample differed from the GP workforce in age distribution ( $\chi^2 = 6776, p < 0.01$ ). Doctors in the younger age groups (25–34 years and 35–44 years) were underrepresented by 4% and 6% respectively, whereas doctors in the 45–54 years age group and those in the 55–64 years age group were overrepresented by 7% and 8% respectively. Doctors older than 65 years were underrepresented by 4%. The difference in age frequencies extended to the actual respondents to the survey and the sample ( $\chi^2 = 895, p < 0.01$ ).

However, there was no significant difference in the age category frequencies between the respondents and the non-respondents ( $\chi^2 = 1.65, p = 0.80$ ).

There were other minor differences among the workforce data (DHA 2000), the present sample, respondents, and non-respondents. For example, more female doctors (approximately 5%) responded to the survey than male doctors. However, because females were slightly underrepresented in the sample, the final proportion of male and female respondents was consistent with the workforce data (DHA 2000). The overrepresentation of female doctors represents a possible source of response bias.

Chi square analyses indicated a significant difference in the male and female frequencies between the workforce data (DHA 2000) and the sample ( $\chi^2 = 4.67, p = 0.031$ ). This also extended to the sample and actual respondents ( $\chi^2 = 5.18, p = 0.032$ ).

A higher response was received from doctors in Victoria (27% of respondents compared with 24% of the sample) and South Australia (12% compared with 9%).



Conversely, doctors in New South Wales responded less frequently and were underrepresented in the responses by about 3% compared with the workforce data (DHA 2000) data—31% of respondents compared with 34% of the workforce. There were no differences with respect to rural location, other than a slight overrepresentation of doctors in rural areas with a population of fewer than 10,000. Respondents were generally consistent with non-respondents in this respect.

Chi square analyses indicated that there were no significant differences in frequencies of the states in which GPs resided between the workforce data (DHA (2000) and the present sample ( $\chi^2 = 6.57, p = 0.475$ ). This extended to the sample and the respondents to the survey ( $\chi^2 = 10.3, p = 0.17$ ). In this respect the sample and the respondents reflected the DHA (2000) data in terms of the states in which doctors resided. With respect to the rural/urban mix, the sample reflected the DHA (2000) data ( $\chi^2 = 4.33, p = 0.633$ ). The respondents also reflected the sample in this respect ( $\chi^2 = 4.56, p = 0.601$ ). Similarly, the respondents did not differ significantly from non-respondents ( $\chi^2 = 9.47, p = 0.149$ ) in this respect.

Doctors were given the option to report their own demographics and, although not all respondents elected to complete this section of the survey, the results were relatively consistent with the sample demographics supplied by the Health Insurance Commission (see Appendix 8.2) as follows: male 61%, female 39%; full-time 64%, part-time 36%; group practice 82%, solo practice 18%; and urban 72%, rural 28%.

Approximately 6% of respondents reported that they saw fewer than 50 patients a week, 28% saw 51–100 patients a week, 39% saw 101–150 patients per week, and 18% saw 151–200 patients per week. The remaining 8% saw more than 200 patients per week. Using these numbers, it was estimated that, in the sample, there were 121 patient consultations on average per week per doctor.

## **8.4 Demand for CAM**

### **8.4.1 Change in demand**

Doctors were asked to indicate whether they thought that the demand from their patients for CAM was increasing, not changing, or decreasing. More than half (54%) of respondents felt that demand for CAM from their patients was increasing, 32% reported no change, and only 3% reported a decrease. Another 11% said that they did not know.

### **8.4.2 Proportion of patients asking about CAM**

GPs were asked to indicate what percentage of their patients had asked about CAM in the previous month. More than a third of respondents (38%) reported that fewer than 5% of their patients had asked. Another 31% reported 5–10%, 19% reported 11–30%, 7% reported 31–50%, and 6% reported more than 50%.

### **8.4.3 Doctors' perceptions of benefit and harm**

Doctors were asked to indicate their opinions on the potential effectiveness and potential harmfulness of 15 listed forms of CAM. See Appendix 8.3 for the table of results, and Figure 8.2.

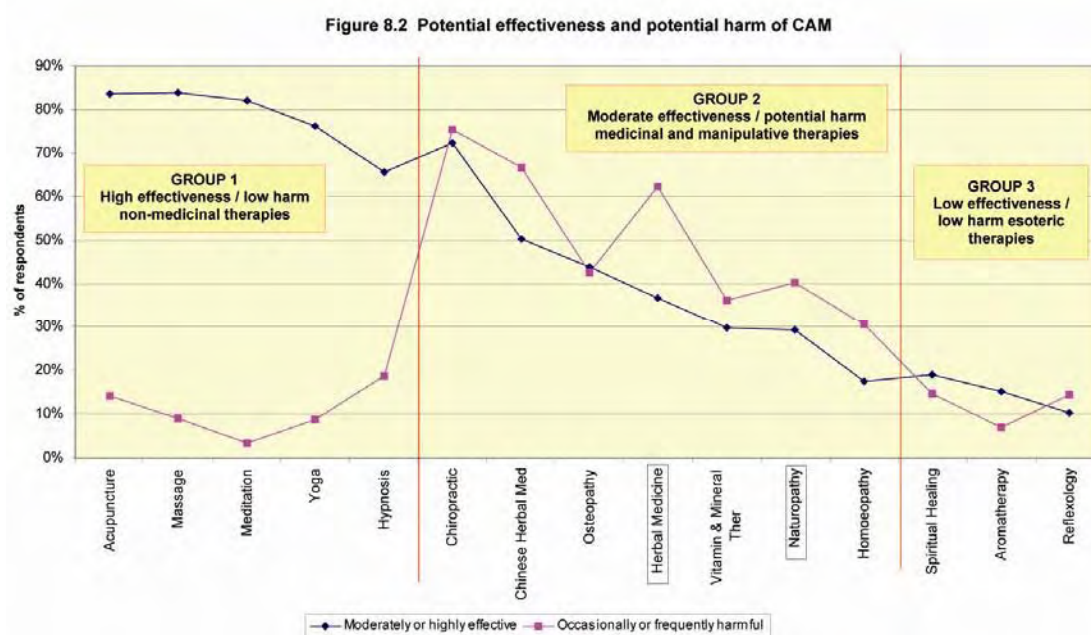
Most respondents agreed that acupuncture (84% of respondents) and massage (84%) were 'moderately effective' or 'highly effective', followed by meditation (82%), yoga (76%), chiropractic (72%), and hypnosis (66%). The least effective therapies ('not effective' or 'seldom effective') were reflexology (90% of respondents), aromatherapy (85%), homeopathy (83%), spiritual healing (81%), naturopathy (71%), and vitamin and mineral therapy (70%).

The most common theme in doctors' comments on this question (with 134 comments from 636 respondents) was that the potential 'effectiveness' of a CAM or CT depended on how the therapy was used. Another common theme was that effectiveness could be a function of a placebo effect and a therapeutic (therapist–patient) relationship, rather than a function of

the efficacy of the therapy itself. Respondents expressed a strong preference for ‘evidence-based’ therapies.

The most potentially harmful therapies (thought to be ‘occasionally harmful’ or ‘frequently harmful’) were chiropractic (76% of respondents), Chinese herbal medicine (67%), herbal medicine (62%), osteopathy (43%), naturopathy (40%), and vitamin and mineral therapy (36%). Those thought to be least harmful (‘not harmful’ or ‘seldom harmful’) were meditation (97% of respondents), aromatherapy (93%), massage (91%), yoga (91%), acupuncture (86%), reflexology (86%), spiritual healing (85%), and hypnosis (81%).

It is evident from Figure 8.2 that acupuncture, massage, meditation, yoga, and hypnosis (all non-medical therapies) were seen as being both effective and safe; whereas potential harmfulness was seen to mirror potential effectiveness with respect to the rest of the therapies.



The comments of the respondents (80 comments from 636 respondents) demonstrated that many felt that the harmfulness of CAM was more often related to incorrect, inadequate, or delayed diagnoses than to the specific risks of the therapies themselves—sometimes at considerable personal or financial cost to the patient. Others commented that CAM caused no harm in the hands of appropriately trained therapists.

## 8.5 Education

### 8.5.1 GP training in complementary therapies

GPs were asked to indicate their current level of training and their interest in pursuing further training in the listed therapies. Training included ‘self-taught’, ‘introductory workshop’, ‘certificate’, ‘diploma’, or ‘degree’. See Appendix 8.4 for the table of results, and Figure 8.3.

Respondents already had some training (any level of training) in meditation (25% of respondents), acupuncture (23%), vitamin and mineral therapy (23%), massage (17%), hypnosis (14%), herbal medicine (14%), and yoga (12%). However, much of this was self-taught or obtained by attending an introductory workshop.

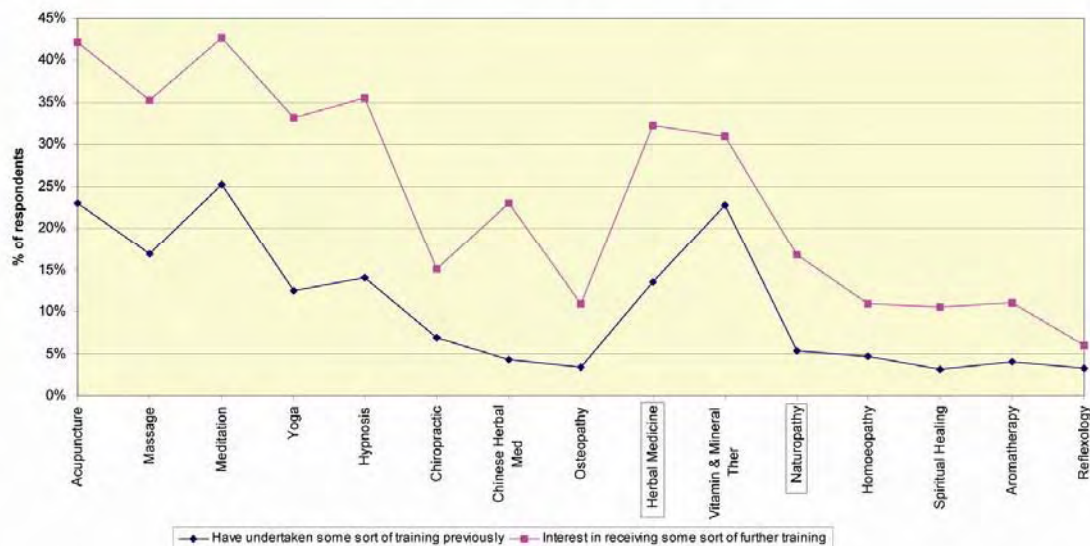
The highest levels of formal training (certificate, diploma, or degree courses) were in acupuncture (12% of respondents), hypnosis (6%), and vitamin and mineral therapy (5%).

Respondents were most interested in receiving formal training (certificate, diploma, or degree courses) in acupuncture (24% of respondents), meditation (16%), hypnosis (14%), vitamin and mineral therapy (13%), herbal medicine (11%), and yoga (11%). The highest

levels of interest in informal training (that is, workshops) were for meditation (27% of respondents), massage (22%), hypnosis (22%), yoga (22%), herbal medicine (21%), acupuncture (18%), and vitamin and mineral therapy (18%).

Many of the doctors who wrote a comment to this question (67 comments) expressed a desire to obtain further knowledge about CAM, but felt that they were already overstretched.

**Figure 8.3 Training previously undertaken and level of interest in receiving further training in CAM**



GPs were asked to rate the importance of education on CAM in the core undergraduate medical curriculum on a scale from 1 ('not important') to 5 ('extremely important'). The majority of respondents (71%) selected '3' or '4'—resulting in an average score of 3.31 (between 'moderately important' and 'very important') across all respondents.

## 8.5.2 Sources of information about CAM

Doctors were asked where they obtained information about CAM and whether they found those sources to be positive, neutral, or negative towards CAM overall.

The most commonly used sources of information by respondents about CAM were medical journals (seen as 'neutral'), the mainstream media ('positive'), and anecdotal examples from patients, family, and friends ('positive'). These sources were followed by medical conferences ('neutral') and friends or colleagues who practise complementary medicine ('positive').

## 8.6 Regulation

### 8.6.1 Regulation of CAM therapists

Doctors were asked to indicate whether they felt that these therapies should be regulated by government. More than half of the doctors surveyed felt that most of the therapies listed should be regulated, or that therapists in those disciplines should be registered. CAM systems and therapies perceived to be most in need of regulation were: chiropractic (88% of respondents), acupuncture (87%), Chinese herbal medicine (80%), hypnosis (79%), herbal medicine (77%), naturopathy (73%), osteopathy (72%), homeopathy (66%), and vitamin and mineral therapy (66%). (See Appendix 8.8).

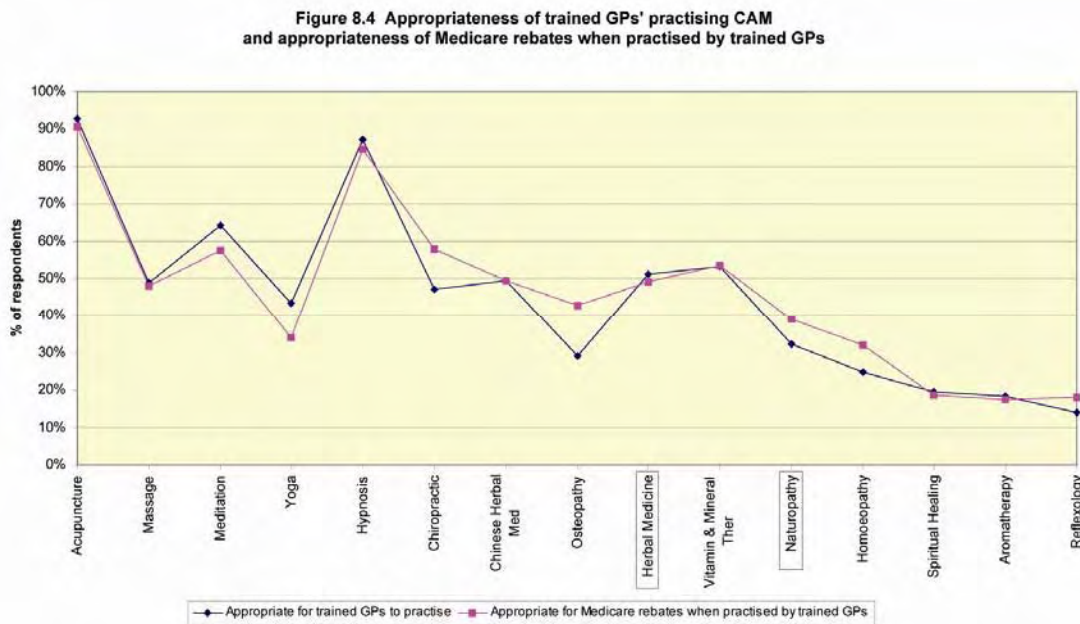
In the space for comments (76 comments), many GPs indicated that therapies that do not involve the use of medicines (such as yoga, meditation, and spiritual healing) did not

require regulation, whereas others that had potential to delay diagnosis or interact with conventional medication (such as herbal medicine or naturopathy) should be regulated. Some doctors suggested self-regulation (for example, industry accreditation) for some CAM, rather than government regulation.

### 8.6.2 Appropriateness of GPs' practising CAM

When asked how appropriate it was for suitably trained GPs to practise various complementary therapies, respondents answered that acupuncture (93% of respondents) and hypnosis (87%) were appropriate for GPs to practise if trained, followed by meditation (64%), vitamin and mineral therapy (53%), herbal medicine (51%), massage (49%), Chinese herbal medicine (49%), and chiropractic (47%). Respondents felt that the least appropriate therapies for doctors to practise were reflexology (72% of respondents), aromatherapy (67%), spiritual healing (65%), and homeopathy (63%). See Appendix 8.5 for the table of results.

GPs were also asked to indicate whether these therapies should be eligible for Medicare rebates when practised by appropriately trained GPs. As shown in Figure 8.4, there was a strong correlation between doctors' views on appropriateness to practise and appropriateness for Medicare rebates, with acupuncture (91% of respondents) and hypnosis (85%) receiving overwhelming support on both counts. The least appropriate therapies for Medicare rebates were perceived to be aromatherapy, reflexology, and spiritual healing.



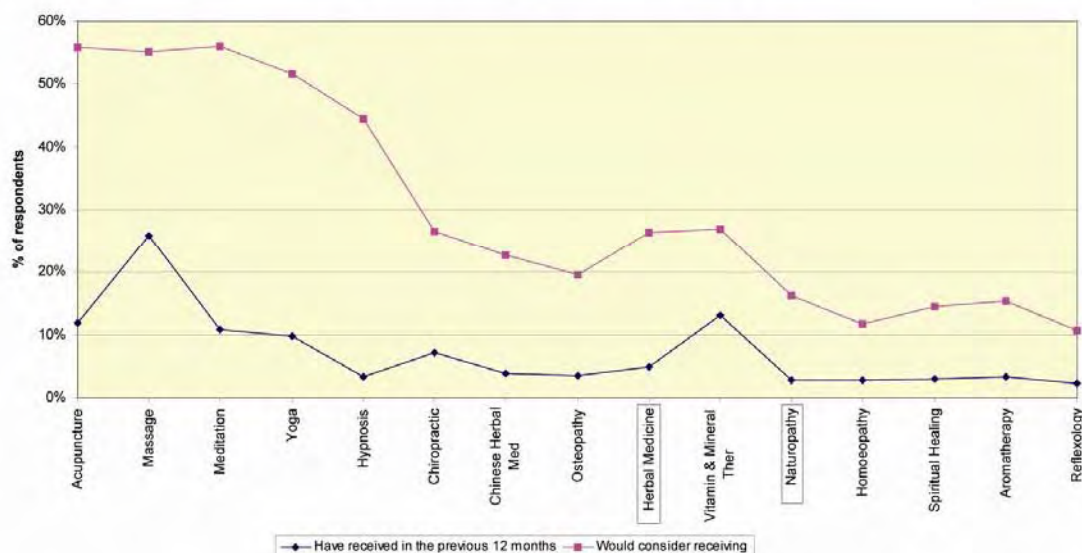
In their comments (64 comments), respondents felt strongly that Medicare rebates should be payable for CAM practised by GPs. Moreover, some indicated that rebates should be payable when practised by any appropriately trained therapist. Some doctors indicated that only those therapies with evidence-based support were appropriate for GPs to practise and that Medicare rebates should therefore be restricted to these therapies. Others maintained that none of these therapies should be eligible for rebates because this would place extra strain on the health budget. (See Appendix 8.5)

## 8.7 Use of CAM by medical practitioners

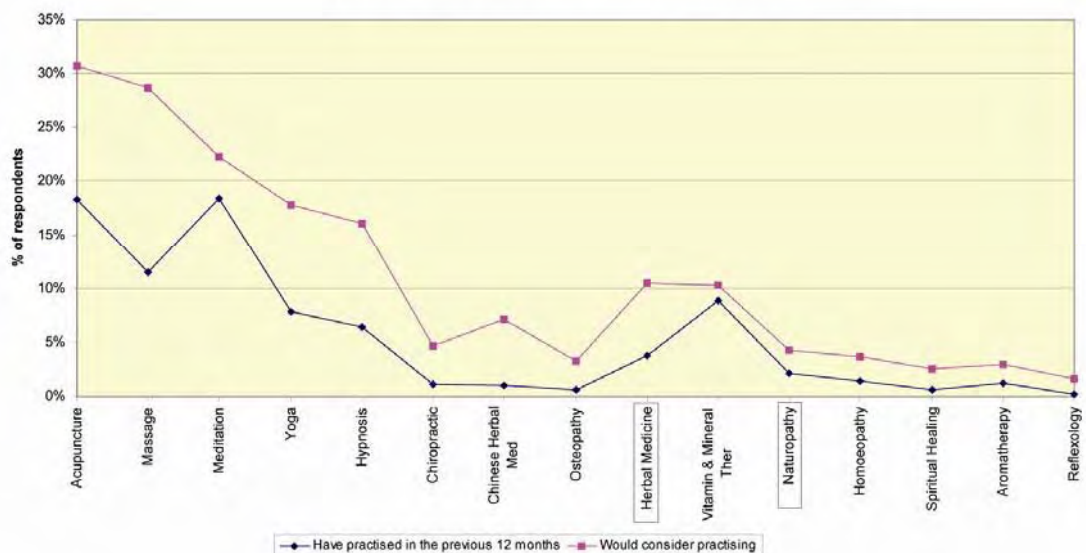
### 8.7.1 GPs' personal use of CAM

GPs were asked to indicate which therapies they had personally received or practised in the previous 12 months, and whether they would consider receiving or practising these therapies (see Figures 8.5a and 8.5b and Appendix 8.6).

**Figure 8.5a Respondents who had received CAM in the previous 12 months, or would consider receiving CAM**



**Figure 8.5b Respondents who had practised CAM in the previous 12 months, or would consider practising CAM**



More than a quarter of respondents had personally received massage in the previous 12 months, followed by vitamin and mineral therapy (13% of respondents), acupuncture (12%), meditation (11%), and yoga (10%). Furthermore, more than half of all respondents would consider personally receiving acupuncture, meditation, massage, and yoga (see Figure 8.5a).

Acupuncture (18% of respondents) and meditation (18%) were the therapies most commonly used by respondents as part of patient treatment, followed by massage (11%), vitamin and mineral therapy (9%), and yoga (8%). This was in line with doctors' willingness to consider practising these therapies. For example, 31% of respondents would consider incorporating acupuncture into their practice, followed by massage (29% of respondents), meditation (22%), and yoga (18%).

### **8.7.2 GPs' use of CAM products and technologies**

Doctors were asked to list any vitamin, mineral, herbal, or other supplement that they had taken in the previous four weeks. Of 482 respondents, 289 (60%) stated 'none'. However 40% listed a range of products that they had personally consumed. In order of frequency these were described as: 'multivitamins', 'vitamins' (C, B, and E), 'glucosamine', 'omega 3' or 'fish oil', 'zinc', 'folic acid', 'iron', 'antioxidants', 'selenium', 'garlic oil', and 'evening primrose oil'.

Doctors were also asked whether they used any CAM technologies in their practices (for example, electro-acupuncture stimulators or lasers). A majority of respondents (369 of 465, or 79%) said that they did not use such devices. However 21% reported using various therapies and complementary technologies in their practices—most commonly acupuncture devices (such as electro-acupuncture, laser, and ultrasound).

### **8.7.3 GPs' dispensing complementary medicines**

Doctors were asked if they thought that it was appropriate for GPs to sell or dispense complementary medicines (such as herbs, vitamins, and supplements) from their practices. Most GPs (66% of 623) felt that it was unethical to profit from the sales of supplements that they prescribed. Another 18% thought that it was appropriate to do this, and 16% were undecided. This question provoked many respondents to comment (309 of 636)—with the majority citing conflict of interest, potential for diminished clinical judgment, and loss of GP integrity as reasons for GPs' not selling or dispensing complementary medicines. However, others pointed out that pharmacists and other therapists did this, so why not GPs? A typical comment was: 'At least we would know what they [patients] are taking'.

## **8.8 Referral**

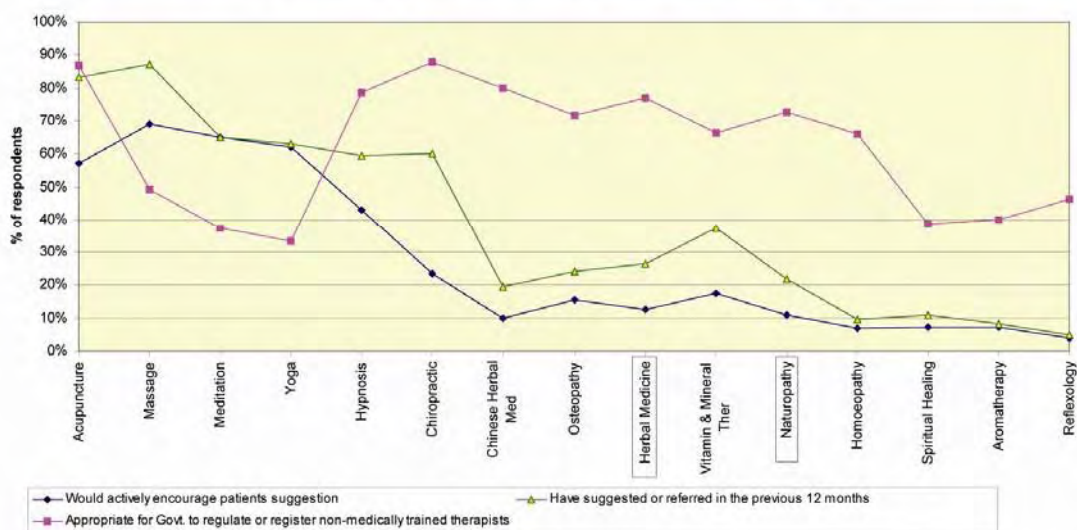
### **8.8.1 GP referrals for CAM**

Doctors were asked to indicate whether they would actively discourage or encourage (or remain neutral to) a patient's suggestion to use or consult a CAM therapist. The respondents were most likely to encourage the following therapies as a result of a suggestion from a patient: massage (69% of respondents), meditation (65%), yoga (62%), acupuncture (57%), and hypnosis (43%). Types of CAM most likely to be discouraged were: reflexology (38% of respondents), homeopathy (37%), naturopathy (26%), and aromatherapy (24%). See Appendix 8.7 for the table of results, and Figure 8.6.

Doctors were asked to indicate how often they had suggested CAM or referred a patient to a CAM therapist in the past year. The alternatives offered to respondents were: 'never', 'a few times', 'at least monthly', 'at least weekly', and 'at least daily'. Based on the frequency of all referrals, it was apparent that the respondents were most likely to refer patients for massage (87%) and acupuncture (83%), followed by meditation (65%), yoga (63%), chiropractic (60%), and hypnosis 59%. The least likely to be referred (based on the frequency of the 'never' response) were reflexology (95%), aromatherapy (92%), homeopathy (90%), and spiritual healing (89%) (Appendix 8.9).

Figure 8.6 combines the willingness of respondents to encourage a patient's suggestion to use or consult a CAM therapist with doctors' likelihood ever to refer to those therapies, and their views on appropriateness for government regulation or registration.

Figure 8.6 Responses to patients' suggestions to use CAM or consult complementary therapists, frequency of doctors' suggestions, and frequency of referrals to same; and appropriateness of government regulation of non-medically trained complementary therapists



When asked whether they distinguished between medical and non-medical practitioners of these therapies, 20% of respondents said that they referred only to medically trained practitioners, whereas 75% said that they referred to both medical and non-medical practitioners. Only 4% said that they referred to non-medical practitioners only.

There were 216 comments to this question. Most respondents said that they preferred to refer to medically trained therapists. However, because this was not usually possible (except in the case of acupuncture and hypnosis), they selected therapists who were appropriately trained and competent in their fields. Their selections were generally based on reputation, word-of-mouth recommendation, or personal knowledge. They cited difficulties in selecting appropriate practitioners—including lack of knowledge about whom to refer to, lack of availability in rural areas, and the implications for legal liability of referring to CAM therapists. These concerns are borne out by the low rate of medical referrals (5%) reported by naturopaths and Western herbal medicine practitioners (see 9.4.4).

## 8.9 Adverse events

GPs' responses to questions on adverse events involving CAM are reported in Chapter 2 (Section 2.6.2). It is clear from these responses, and from GPs' comments, that the respondents were more concerned about the possibility of delayed or missed diagnoses and treatment, rather than the risks of adverse events arising from a particular therapy. This is consistent with the finding that GPs considered chiropractic, Chinese herbal medicine, osteopathy, herbal medicine, vitamin and mineral therapy, naturopathy, and homeopathy to be the most potentially harmful—because these are the disciplines in which practitioners are more likely to take on a primary care role and potentially displace GPs.

## 8.10 General comments

Space was provided in the survey for general comments. A range of opinions was expressed (87 of 636 respondents), in line with comments received for previous questions. Some doctors requested a database of interactions between complementary medicines and pharmaceuticals. Others reiterated: (i) the need for complementary therapies to be evidence-based; (ii) the potential for harm as a result of delayed or inadequate diagnoses by CAM therapists; and (iii) the potential for harm as a result of interactions between complementary medicines and pharmaceuticals.

## 8.11 Summary of results

- Non-medicinal therapies (such as acupuncture, massage, meditation, yoga, and hypnotherapy) were the most accepted therapies in Australian general practice, and were perceived to be of low risk and high efficacy.
- Manipulative therapies (such as chiropractic and osteopathy) and medicinal therapies (such as Chinese herbal medicine, naturopathy, Western herbal medicine, vitamin and mineral therapy, and homeopathy) were perceived by GPs to have moderate efficacy and to pose moderate risks.
- GPs considered that the harmfulness of CAM was more often related to the scope of practice (and thus to incorrect, inadequate, or delayed diagnoses), rather than to the specific risks of the therapies themselves.
- There was widespread support for government regulation of CAM professions that are already regulated (such as chiropractic, acupuncture, osteopathy, and Chinese herbal medicine) and also of currently unregulated areas of CAM (such as hypnotherapy, herbal medicine, naturopathy, homeopathy, and vitamin and mineral therapy). Non-medicinal and non-manipulative therapies (such as yoga, meditation, and spiritual healing) were not perceived as requiring regulation.
- Most GPs had little formal training in CAM. Where training had been undertaken, GPs were most likely to have formal training in acupuncture, hypnosis, and vitamin and mineral therapy. The highest levels of interest in training were for meditation, massage, hypnosis, yoga, herbal medicine, acupuncture, and vitamin and mineral therapy.
- Education in CAM in the medical undergraduate curriculum was believed to be moderately important to very important.
- GPs were most likely to use acupuncture, meditation, massage, vitamin and mineral therapy, and yoga as part of their practices.
- Most GPs thought that demand for CAM was increasing, but most GPs (69%) reported that fewer than 10% of their patients had asked about CAM in the previous month.
- The attitudes of GPs towards CAM seem to have remained constant over the past seven years.

## 8.12 Discussion

### 8.12.1 Mainstream and fringe CAM

The results of this survey show that certain non-medicinal therapies (such as acupuncture, massage, meditation, yoga, and hypnosis) that address stress or other lifestyle factors have a high level of acceptance among doctors. Respondents considered them to be moderately or highly effective and were more likely to suggest or encourage their use as compared with other CAM therapies. The respondents were also more likely to receive or practise these therapies themselves.

### 8.12.2 Grouping of therapies

From the results it appears that the 15 therapies included in the survey can be classified by the responses to most questions into three distinct groups (see Figure 8.2).

#### **Group 1: Considered to be of high effectiveness and low harm**

Therapies in Group 1 included the *non-medicinal* therapies—acupuncture, massage, meditation, yoga, and hypnosis. Two thirds (or more) of respondents believed that these therapies were moderately or highly effective, and more than 80% considered them to be safe.

Respondents were more likely to encourage or refer patients to these therapies than other therapies, and were also more likely to consider personally receiving or practising them.



## **Group 2: Considered to be of moderate effectiveness and potential harm**

Forms of CAM in this group included medicinal and manipulative therapies (such as chiropractic, Chinese herbal medicine, osteopathy, herbal medicine, vitamin and mineral therapy, naturopathy and homeopathy). More respondents thought that these were potentially harmful than thought that they were potentially effective.

It is interesting to note that these forms of CAM can all be considered to offer an ‘alternative service’ to general practitioners—in that therapists in this group are all primary care practitioners who see patients from all demographics who are suffering from the full spectrum of health complaints, including potentially life threatening illnesses. It was obvious from doctors’ comments that many GPs considered that this scope of practice is potentially harmful—especially because these practitioners do not have access to the full range of diagnostic tests. Although some forms of CAM in this group (such as chiropractic, osteopathy, and, in Victoria, Chinese herbal medicine) are covered by statutory regulation, others (such as herbal medicine, naturopathy, and vitamin and mineral therapy) remain unregulated.

## **Group 3: Considered to be of low effectiveness and low harm**

Therapies in this group included spiritual healing (for example, reiki), aromatherapy, and reflexology. These therapies were seen to be relatively safe, but relatively ineffective. Fewer than 20% of respondents described them as being potentially harmful or potentially effective. Spiritual healing (for example, reiki), aromatherapy, and reflexology were considered to be the three least accepted therapies in terms of perceived efficacy, referrals, and encouragement of patients, yet these three therapies are often practiced together with massage therapy. (Massage therapy was considered to be one of the most accepted therapies based on the finding that it was personally used by most doctors, was very highly regarded by GPs with respect to efficacy and safety, and was one of the therapies GPs were most likely to encourage their patients to receive).

### **8.12.3 Evidence and acceptance**

Many respondents took the opportunity presented by the survey to express their concerns about complementary therapies that lack clinical evidence. They felt that some therapies relied mostly on placebo effect, therapeutic relationship, patient susceptibility to claims of effectiveness, and financial motive. However, other doctors indicated that the effectiveness of some therapies could not always be measured by clinical trials because the paradigms of these therapies include concepts of intangible action and benefit.

It is widely accepted that there needs to be more research into CAM (Hensley & Gibson 1998; Ezzo, Berman, Vickers & Linde 1998; Expert Committee 2003). The Cochrane Collaboration continues to conduct a range of systematic reviews of clinical trials in the field of complementary therapies (Ezzo et al. 1998). However, an ongoing concerted effort in this area is still urgently required.

### **8.12.4 Risks and regulation**

A NSW Health Department discussion paper on the regulation of CAM therapists (NSW Health Department 2002) listed the ‘generic’ risks of CTs (other than the risks specific to certain therapies) as being: (i) inappropriate withdrawal from medical therapy; (ii) failure to detect serious underlying disease; (iii) mental trauma; (iv) unsubstantiated claims of therapeutic benefit; (v) sexual misconduct; and (vi) financial exploitation. Specific risks of medicinal therapies included interactions between complementary and pharmaceutical medicines.

Respondents to the present study stated that the areas of greatest concern to them were: (i) incorrect, inadequate, or delayed diagnoses; (ii) interactions between complementary medicines and pharmaceuticals; and (iii) complications arising from patients not telling their doctors what they were taking. Previous studies have shown that more than 50% of the population use some sort of CAM and about 70% of patients do not tell their doctors about

the complementary medicines that they are taking (MacLennan, Wilson & Taylor 1996; Eisenberg et al. 1998). In the present study, 69% of respondents reported that fewer than 10% of their patients had asked about CAM in the previous month. This suggests a serious communication issue in the therapeutic relationship, and suggests that doctors do not ask for this information or that patients do not volunteer this information.

Of the forms of CAM surveyed, chiropractic and osteopathy are already regulated in all states, and acupuncture and Chinese herbal medicine are regulated in Victoria. Although most respondents thought that these forms of CAM should be regulated, the overall opinions of respondents with respect to their regulation do not appear to differ greatly from their opinion regarding the regulation of medicinal therapies (including herbal medicine, vitamin and mineral therapy, naturopathy and homeopathy). Medicinal therapies were all rated as having greater potential for harm than potential for effectiveness and (with the exception of homeopathy) featured in the serious adverse events, interactions, and delayed diagnoses reported by doctors.

The practice of naturopathy can encompass herbal medicine, vitamin and mineral therapy, and homeopathy, and more than two thirds of respondents thought that these medicinal therapies should be regulated (along with hypnosis). The comments of doctors also revealed concerns about 'medicinal' therapies and the potential for interactions with pharmaceuticals.

### **8.12.5 GP training**

The Australian Medical Council (which is responsible for standards in medical education) stated in a discussion paper (AMC 1999) that medical graduates need to have an understanding of the scope of unorthodox medical practices, the needs that these practices meet, their effectiveness and safety, the extent of their use, and their costs. Similar statements have been made in the United States of America (Whitehouse Commission 2002) and in the United Kingdom (UK) (Select Committee 2000).

Many respondents had some training (including workshop attendance or self-trained) in the non-medicinal group of therapies (acupuncture, massage, meditation, yoga, and hypnosis) and in herbal medicine and vitamin and mineral therapy from the medicinal group. The respondents' interest in further training, along with their personal use or practice, was also highest in the non-medicinal therapies. However, many respondents expressed concern at the demands placed on their time by attempting to 'stay current' with the large body of information in the field of CAM.

### **8.12.6 Comparison with other Australian and overseas studies**

Earlier studies into the attitudes of GPs to CAM in Victoria and Perth (Hall & Giles-Corti 2000; Pirota et al. 2000) showed that GPs have responded to the increased demand for CAM by training in, practice of, and referral to a range of CTs. In Victoria in 1997, 82% of GPs had referred at least a few times a year for CTs, whereas in Perth in 1998, 75% had referred to at least one of the therapies in the previous nine months. Overseas, in the UK in 1997, 25% of GPs referred patients to CTs in one week (White, Resch & Ernst 1997), and in Canada in 1995, most family doctors had at some time referred patients to CAM practitioners (Verhoef & Sutherland 1995; Goldszmidt et al. 1995).

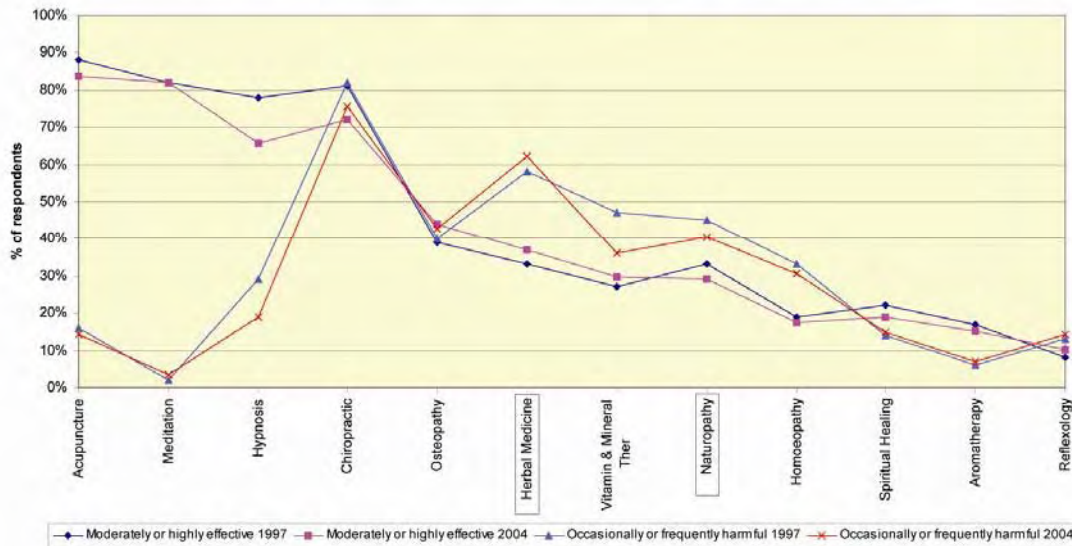
In 1997 in Victoria, between 20% and 34% of GPs already had training in four of the therapies and nearly 20% practised one of the therapies (Pirota et al. 2000). More than half of the GPs had an interest in further training in three of the therapies. In New Zealand, more than half of GPs were interested in further training in CAM (Hadley 1988) and in Israel 88% wanted training and 16% had trained (Schachter, Weingarten & Kahan 1993). Estimates of the practice of complementary therapies by GPs vary from approximately 16% in Canada (Goldszmidt et al. 1995) and the UK (Perkin, Percy & Fraser 1994; White, Resch & Ernst 1997) to 30% in New Zealand (Hadley 1988; Marshall, Gee, Israel, Neave, Edwards, Dumble, Wong, Chan, Patel & Poon 1990), 47% in Holland (mainly homeopathy) (Visser & Peters

1990), and up to 85% in Germany (mainly herbal medicine) (Himmel, Schulte & Kochen 1993).

The data from the current study are consistent with data from the 1997 survey of Victorian GPs (Pirotta et al. 2000), in which the most effective therapies were perceived to be acupuncture, chiropractic, hypnosis, and meditation. At that time, the most potentially harmful therapies were thought to be chiropractic, herbal medicine, vitamin and mineral therapy, naturopathy and osteopathy. Massage, yoga, and Chinese herbal medicine were not canvassed in the 1997 survey.

The consistency between the results of the two surveys across all questions (both surveys used similar methodology) suggests that GPs' opinions have not changed appreciably from 1997 to 2004 (see Figure 8.7). This might also indicate that therapies which were previously seen by GPs as lacking an evidence base or in need of regulation, have not progressed appreciably in those areas.

Figure 8.7 Comparison of opinions as to the potential effectiveness and potential harmfulness of CAM between the 1997 survey of Victorian GPs and the 2004 survey of Australian GPs



In the 1998 survey of Perth metropolitan GPs (Hall & Giles-Corti 2000), the most effective therapies were perceived to be acupuncture (90%), meditation (87%), massage (84%), yoga (77%), hypnosis (76%), and chiropractic (57%). Chinese herbal medicine, osteopathy, vitamin and mineral therapy, spiritual healing and reflexology were not canvassed in the Perth study.

Referral patterns of GPs and interest in training were also similar in the Perth study (Hall & Giles-Corti 2000), in that GPs were most likely to refer patients to acupuncture, massage, meditation, and yoga, and were most interested in further training in acupuncture, meditation, herbal medicine, and hypnosis.

Comparison with various studies overseas shows that Australian doctors have similar levels of interest in, training in, and referral of CAM as their counterparts in other Western countries, with the exception of Holland and Germany (Goldszmidt et al. 1995; Himmel, Schulte & Kochen 1993; Marshall et al. 1990; Perkin, Percy & Fraser 1994; Verhoef & Sutherland 1995; Visser & Peters 1990; White, Resch & Ernst 1997). However the therapies commonly practised vary by country. For example, acupuncture and meditation were the therapies most commonly practised by Australian GPs (18% of doctors), whereas only 8% of Canadian GPs (Goldszmidt et al. 1995) and 4% of UK GPs (Perkin, Percy & Fraser 1994) had training in acupuncture. In contrast, homeopathy was the therapy most practised by

British GPs (Fisher & Ward 1994; White, Resch & Ernst 1997; Perkin, Percy & Fraser 1994), but one of the least practised in Australia.

### **8.13 Limitations and strengths of this study**

The present survey canvassed GPs' attitudes and opinions, which can be assumed to reflect their real-life experience. However, the effects of self-report bias, recall bias, and response bias are unknown.

The response rate of 33.2% was low compared with the response rate of 64% in the 1997 survey of Victorian GPs (Pirotta et al. 2000) which employed the same methodology, but the results are remarkably similar. This suggests that, although GPs' attitudes towards CAM have not changed appreciably in this time, pressures on GPs' time and financial resources have increased. This was supported by many hand-written comments from respondents indicating that they were 'over-surveyed' and that they 'do not do surveys for free'.

The survey did not compare GPs' attitudes to CAM with attitudes to traditional Western medicine. Although CTs are said to be relatively safe in comparison with Western medicine, there was no attempt to make such a comparison in this study. In addition, the present survey did not define the therapies listed, and doctors might have had different interpretations of the terms used—especially with respect to such therapies as vitamin and mineral therapy, naturopathy, and spiritual healing.

This is the only national survey of GPs' attitudes to CAM to have been conducted to date. Approximately 3.4% of practising GPs responded to the survey. Although respondents were largely representative of the Australian GP workforce in average age, sex, and location of practice, it is not possible to determine whether the attitudes of respondents were significantly different from those of non-respondents. Indeed, it might be that respondents held stronger opinions (positive or negative) about CAM than non-respondents. Furthermore, the variation from the GP workforce in age distribution of actual respondents and the higher response rate from female doctors (both of which could be a source of response bias), suggest that further evaluation of the data would be appropriate—with a view to analysing respondents' opinions by age group and gender.

However, with the appropriate cautions (that the results of this study cannot necessarily be extrapolated to represent the views of all Australian GPs), some meaningful comparisons can be made among forms of CAM with respect to their relative perceived safety, effectiveness, suitability for government regulation, and the continuing education needs of GPs.

### **8.14 Conclusion**

Overall, GPs' attitudes about CAM do not appear to have changed appreciably since 1997. Some forms of CAM (such as acupuncture, massage, meditation, yoga, hypnosis, and chiropractic) can be considered 'mainstream'—with high levels of perceived effectiveness and safety among GPs. The forms of CAM that were perceived to be somewhat effective, but more potentially harmful, were the medicinal therapies—including Chinese herbal medicine, herbal medicine, vitamin and mineral therapy, naturopathy, and (to a lesser extent) homeopathy. In contrast, therapies such as spiritual healing, aromatherapy, and reflexology were generally perceived to be relatively ineffective, but safe.

Some respondents felt that the use of CAM might cause a considerable personal and financial cost to the patient. Many felt that the harmfulness of CAM was more often related to incorrect, inadequate, or delayed diagnoses than to specific risks of the therapies themselves. Respondents' concerns over interactions between complementary and pharmaceutical medicines demonstrate an urgent need for accessible databases of potential interactions among medicines, and further consideration of the issues of GP–patient communication and patient disclosure.

## 8.15 Recommendations

- Because risk to the public relates to scope of practice, as well as to the therapies practised, a regulatory mechanism is warranted and is likely to be supported by the GP profession. Appropriate regulation would also improve doctors' ability to recognise qualified CAM practitioners, thereby improving communication.
- Doctors prescribing therapies such as vitamin and mineral therapy or WHM should do an acceptable course of education.
- Medical education should expose undergraduate medical students to CAM.
- Continuing education in CAM should be available to medical practitioners.
- Medical practitioners should encourage patients to disclose consumption of complementary medications.
- More information and data should be available and accessible to medical doctors who are managing patients using both forms of medicine.

## Acknowledgments

Thanks are expressed to the doctors who responded to the survey, to Dr Marie Pirotta for assistance in the design of the questionnaire, and to Chiara Comodari for her dedication in encoding the data.

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# 9. Consumers of Naturopathy and Western Herbal Medicine

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## 9.1 Introduction

Consumers have been a driving force in the growth of complementary healthcare in Western nations. Complementary and alternative medicine (CAM), in its various modalities, is increasingly used by the Australian public (MacLennan, Wilson & Taylor 2002). International publications have revealed the extent of the rise in consumer use of natural therapies and their complementary use with mainstream healthcare (Fisher & Ward 1994; Eisenberg, Davis, Ettner, Appel, Wilkey, Van Rompay & Kessler 1998; Owen, Lewith & Stephens 2001; Barnes, Powell-Griner, McFann & Nahin 2004).

This chapter focuses on consumers of naturopathy and Western herbal medicine (WHM) to understand why people use natural therapies, what they use, and their attitudes and experiences. The information is presented in three parts: (i) a literature review of consumer perspectives on complementary healthcare, with a particular focus on naturopathy and WHM; (ii) the results of a survey that developed a profile of patients attending naturopathy and WHM practitioners in Australia; and (iii) focus group research carried out with Victorian consumers.

## 9.2 Methodology

Consumer research was carried out in three parts by the present authors: (i) a literature review (by SH); (ii) a survey of the patients of naturopathic and WHM practitioners to develop a patient profile (by AB, SM, and SMW); and (iii) four focus groups with CAM users with particular emphasis on experiences of naturopathy and WHM (by SH and JC).

### 9.2.1 Literature review methods

The literature review examined Australian and international studies on the use of, and views on, CAM (with a focus on naturopathy and WHM). The review was concerned with three major themes: (i) consumers' use of complementary and alternative healthcare; (ii) the reasons for use; and (iii) other issues related to CAM use.

Medline was searched from 1996 to 2003 using the terms 'naturopathy', 'phytotherapy', 'herbal medicine', and 'patient satisfaction'. The full text of relevant articles was retrieved.

### **9.2.2 Patient profile**

A two page patient profile was developed in consultation with the National Herbalists Association of Australia and the Federation of Natural and Traditional Therapists.

The patient profile (Appendix 9.1) was designed for practitioners to complete for up to ten consecutive patients treated on a specific clinic day. It contained 22 items and was designed to address the lack of available data on the characteristics of patients who consulted with naturopathy and WHM practitioners. The profile instrument was piloted with 13 practitioners in New South Wales, modified in response to feedback, and conducted in 2003.

The patient profile was mailed to practitioners along with the workforce survey reported in Chapter 4. Collaboration was sought with Grand United Health Fund (GUHF) to identify practitioners who would receive the patient profile and the workforce survey. (See Chapter 4, section 4.2 for explanation of the rationale for use of the GUHF national database of practitioners).

The survey required no patient or practitioner identifying data, and included an accompanying explanatory letter and a reply-paid envelope. The Human Ethics Committee, University of Western Sydney, granted ethics approval for the patient profile.

The patient profile and the workforce survey were distributed to a total of 600 randomly selected naturopathy and WHM practitioners. Practitioners were invited to provide non-identifying data on the background, diagnosis, and treatment for up to ten of their patients on a specific clinic day during a designated period. Seventy-seven packages were returned to sender. A total of 498 completed patient profiles were received from practitioners. The response rate for the patient profile was based on that for the workforce survey, which is provided in Chapter 4.

Data were collected from patients of naturopathy and WHM practitioners including:

- basic demographics;
- education and first language;
- employment status;
- health insurance coverage;
- level of inter-referral and dual patient care with other healthcare workers;
- nature of medical conditions seen;
- frequency and costs of consultations;
- specific treatments or other advice given; and
- pharmaceutical co-medication.

The survey instrument was prepared in an electronically scannable format to facilitate accuracy of data entry. All data entry was undertaken electronically with the exception of several items that required written responses. Analyses were performed using SPSS for Windows 10.0. Aggregate data only are reported.

### **9.2.3 Focus groups**

Between January and March 2004, following approval from La Trobe University Ethics Committee, 24 people who had used complementary health services, including naturopathy and WHM, were recruited to participate in four focus groups. Participants were located through the Australian Complementary Health Association, the Chronic Illness Alliance<sup>1</sup>, and the Hepatitis C Council of Victoria<sup>2</sup>. These organisations emailed members asking if they

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<sup>1</sup> The Chronic Illness Alliance of Victoria Inc. is an alliance of over 40 consumer and advocacy groups for people living with a chronic illness.

<sup>2</sup> The Hepatitis C Council of Victoria Inc. is a statewide organisation representing and catering to the



would like to volunteer for a focus group discussing consumers' views on the practice of naturopathy and WHM. Interested persons contacted an investigator who arranged the times of the focus groups. Participants were aged between 26 and 58 years. There were 13 female participants and 11 male participants.

A list of question prompts was developed by the project team following the literature review. Each focus group ran for up to 90 minutes. With the agreement of the participants, each focus group was audiotaped. A facilitator led each group and an assistant took written notes. All groups were held at the city campus of La Trobe University. Participants were told that the purpose of the focus group was to discuss consumers' views on the practice of naturopathy and WHM. All participants contributed to the discussions and provided individual opinions.

## 9.3 Literature review

### 9.3.1 Use of complementary and alternative medicine: Australian studies

Australian survey data show that use of CAM is widespread. In 2000, a large and representative survey was conducted of 3027 people aged 15 years and over, living in South Australia (MacLennan Wilson & Taylor 2002). Just over half the population used alternative<sup>3</sup> medicines, with women being slightly higher users than men. In the previous 12 months, more than one fifth (23.3%) of respondents had visited an alternative practitioner, including chiropractors. This represented a significant increase in the use of alternative medicines and therapists by women when compared to a similar survey undertaken in 1993 (MacLennan, Wilson & Taylor 1996).

Table 9.1 indicates the use of alternative therapists (excluding chiropractors and osteopaths) by people who had used at least one alternative therapist in the past year.

**Table 9.1 Percentage usage of particular alternative therapists (excluding chiropractors and osteopaths) by gender**

Alternative practitioner	Men	Women
Naturopath or natural therapist	3.3%	8.7%
Acupuncturist	2.5%	3.1%
Homeopath	0.6%	1.7%
Iridologist	0.5%	1.7%
Reflexologist	0.9%	1.6%
Aromatherapist	0.4%	2.2%
Herbal therapist	0.5%	1.4%
At least one in 2000	20.1%	26.4%

Source: MacLennan, Wilson & Taylor (2002), Table 4, p. 169

People who used alternative therapists in the survey were more likely to be female, born in Australia, employed, of higher educational level, and married (MacLennan, Wilson & Taylor 2002). People who lived in country areas were more likely to spend on medicines compared with people in metropolitan areas.

Using data combining use of medicines and practitioners, the calculated cost in 2000 was an estimated \$1671 million on alternative medicines and \$616 million on alternative practitioners (data include use of chiropractors and osteopaths) (MacLennan, Wilson & Taylor 2002). This represented a 62% increase in personal expenditure on alternative practitioners, after accounting for inflation, over the period 1993–2000 (MacLennan, Wilson & Taylor 2002).

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needs of people with hepatitis C, their carers, partners, family and friends.

<sup>3</sup> The term 'alternative' was used by MacLennan, Wilson & Taylor (2002) and was defined as 'non-medically prescribed alternative medicine (excluding calcium, iron, and prescribed vitamins)'.

Findings from another large survey present a picture of women's use in particular. Data from a national survey of Australian women, conducted as part of the Australian Longitudinal Survey of Women's Health, found that usage of CAM practitioners, by age range, were as shown in Table 9.2 (Adams et al. 2003).

**Table 9.2 Percentage usage of CAM practitioners by women, by age range**

Age range of women	Usage of CAM practitioners
18–23 years (sample 14,698)	19%
45–50 years (sample 13,972)	28%
70–75 years (sample 12,662)	15%

Source: Adams et al. (2003), p. 298

These data suggest that usage by Australian women is not confined to younger age groups; indeed higher users were of middle age. Users tended to report poorer health and have more symptoms and illness. Of particular interest was that CAM healthcare users did not necessarily use these services to replace conventional medicine; they were simultaneously high users of medical services (general practitioner and specialist) and hospital services. The authors observed that: 'These findings suggest women pragmatically select treatments from the different options to best fit particular medical and health problems' (Adams et al. 2003, p. 299).

A survey of 171 adults in Queensland found that 36% of the sample used CAM. The most common therapists were naturopaths (72% of users), followed by aromatherapists (33%), and acupuncturists (31%) (O'Callaghan & Jordan 2003). Users were more likely to be female.

Usage of complementary and alternative therapies has been found to be high among people with HIV/AIDS. De Visser Ezzy & Bartos (2000) reported on a national survey of 925 adults in which men were 94% of the sample. More than half of the sample (56%) reported using CAM. In descending order, therapies used were nutritional supplements (46% of 912); massage (24%); herbal remedies (21%); meditation or visualisation (20%); acupuncture (10%); and several other modalities, including Chinese medicine, reiki, and yoga (each fewer than 10%) (De Visser, Ezzy & Bartos 2000). The authors stated that Australian people who had HIV/AIDS were more likely than their American or British counterparts to use CAM and were also more likely to use complementary therapies and conventional medicine concurrently.

High usage of CAM has also been reported among adults and children who have cancer, and among people with chronic rheumatoid arthritis (Shenfield, Atkin & Kristoffersen 1997).

### **9.3.2 Use of complementary healthcare: selected overseas data**

Comparison of overseas studies is difficult because surveys have been conducted using different definitions of CAM, and including different CAM modalities. Despite this difficulty, selected studies are reported below.

A major American survey, which compared usage in 1990 and 1997, reported that use was increasing, with the probability of people consulting an alternative practitioner rising from 36% to 46% (Eisenberg et al. 1998). Herbal medicine was one of the therapies which had the highest growth in consumption. The highest rates of use were among people who had neck and back disorders (Eisenberg et al. 1998). People with back problems, allergies, arthritis, and digestive problems also increased their usage (Eisenberg et al. 1998). Over the survey period (1990–97), the proportion of people seeing both a medical practitioner and a CAM practitioner increased, and just under 40% discussed their use of alternative medicine with a doctor (Eisenberg et al. 1998). The authors noted that a substantial number of people used complementary therapies without input from either a medical or alternative practitioner (Eisenberg et al. 1998). This was similar to the findings of Barnes et al. (2004) who reported on the high level of self-prescribing or self-medicating in the USA.

Kelner and Wellman's (1997) survey of 300 Canadians and their use of complementary therapists found that people who used CAM were not an homogenous group. They chose particular practitioners according to their health problems and their perceptions of the capacities of practitioners to address their problems. Naturopathy users tended to be well educated with middle-range incomes (Kelner & Wellman 1997). The problems for which they consulted naturopaths were (in descending order of frequency) musculoskeletal, gynaecological, digestive, dermatological, 'colds and flu', allergic, and chronic infective (Kelner & Wellman 1997). Almost all of the study participants used conventional medicine (Kelner & Wellman 1997).

A qualitative study of use by older people in Canada (Williamson, Fletcher & Dawson 2003) reported that this group used complementary and alternative therapies to help with pain, improve quality of life, maintain health and fitness, and to assist in prevention. Chiropractic, herbal medicines, massage therapy, and acupuncture were most commonly used (Williamson, Fletcher & Dawson 2003). Poor communication between older people and general practitioners (GPs) regarding use of complementary medicine was a widespread problem.

Of people with colorectal cancer surveyed in Canada, half reported combined use of complementary and conventional medicine (Tough, Johnston, Verhoef, Arthur & Bryant 2002). The most common therapies used were psychological and spiritual therapies, vitamins, minerals, and herbs. The majority informed their doctors, but about one third did not.

Ernst (2000) reviewed seven surveys of use of complementary healthcare by dermatology patients—five conducted in Europe, one in the United States of America, and one in Mexico. His conclusion was that 'a sizeable proportion of dermatological patients try one form of complementary medicine or another' (Ernst 2000, p. 859). Extrapolating from these findings, he reported that about 40% of usage was not discussed with a doctor, raising issues of risks and safety—given the limited evidence base that exists for complementary medicines for dermatological conditions.

### **9.3.3 Concerns about CAM use**

#### **Australian studies**

Several authors have expressed concern that increased use of complementary medicines increases the potential for drug interactions with conventional medicines (Kerridge & McPhee 2004; Adams et al. 2003). In addition, many people do not tell their medical practitioners that they are using complementary treatments. Dooley, Lee & Marriott (2004) noted that 22–52% of oncology patients surveyed used at least one complementary medicine and did not readily disclose this to their doctors. About half of the samples of two other Australian studies (outpatients in a Sydney hospital and parents of children with cancer) did not tell their doctors about their use of complementary therapies (Shenfield, Atkin & Kristoffersen 1997). Respondents to the outpatient survey reported that they did not do so because they feared that their doctors might reject the therapies and because they felt that they (the patients) should be in charge of their health (Shenfield, Atkin & Kristoffersen 1997). The authors noted that doctors should discuss these issues in a 'non-judgmental manner', and that there is a '... need to acknowledge what is happening in the community' (1997, p. 517).

Kerridge and McPhee (2004, p. 165) stated that doctors should provide information about complementary and alternative treatments if:

... the burden of illness is substantial; where there is no proven conventional therapy available; where the therapy that is available is invasive or associated with minimal benefit or major toxicity; where complementary therapy may be of benefit and has few risks; and where the patient has expressed an interest in, or preference for alternative therapies.

Welsh (2001) documented inpatient use of complementary medicines at St Vincent's Hospital in Sydney. Of a sample of 511 patients, 61 were taking complementary medicines. Of these, more than a third continued to take their complementary medicines while in hospital (47 medicines in total) and half of these medicines were not recorded on their medical chart

(Welsh 2001). Welsh (2001) noted 11 patients and 20 complementary medicines in which there was a risk of interaction with medical treatment.

A survey of 234 patients in a group of hospitals and cancer care clinics in the Wentworth Area Health Service (WAHS) of NSW revealed that 123 patients (53%) had used CAM in the past five years and that 40 (17%) were currently using some form of CAM (Snape 2004). Treatments included Western and Chinese herbs, vitamins, minerals, food supplements, homeopathics, massage, meditation, and reflexology. Complementary medicines were self-prescribed by 47.5% of inpatients, prescribed by a complementary therapist for 27.5%, and prescribed by a medical doctor for 12.5%. It was of significance that 52.5% of patients did not report use of complementary medicines to clinical staff—thus increasing the risk of inadvertent drug interactions.

Several of the recommendations of the Australian Expert Committee on Complementary Medicine in the Health System (2003) were directed to this issue, and the National Medicines Policy partners were charged with finding ways of encouraging greater awareness among health professionals and health consumers of the risks associated with drug interactions and the need for better communication on these issues.

### **Overseas studies**

In the United Kingdom, a subcommittee of the House of Lords Science and Technology Committee undertook a public consultation with respect to CAM. Although it found that public satisfaction with CAM was high and that the use of CAM was increasing (Mills 2001), the subcommittee was critical of the standard of information provided to the public (Mills 2001, p. 38):

Information was often very partial, was often transmitted through uncritical channels in the media and on the Internet, and was poorly balanced by the results of good quality research.

The subcommittee saw the National Health Service (NHS) as the ‘natural home’ for ‘reliable, non-promotional information’ on all types of healthcare, including complementary and alternative medicine (Mills 2001, p. 38).

In an American survey in an outpatients department, patients and doctors alike expressed a need for more reliable information on complementary and alternative therapies because they felt they were not adequately informed (Boutin, Buchwald, Robinson & Collier 2000).

Barnes et al. (1998) surveyed 515 customers of English health food retail outlets on the theoretical actions that they would take following an adverse reaction to a herbal remedy. They found that:

- 26% would advise their GPs of a serious adverse reaction to a conventional over-the-counter medicine, but not an adverse reaction to a herbal remedy;
- 30% would report to a GP an adverse reaction to either type of medication; and
- 43% would not consult their GPs for an adverse reaction to either type.

On the basis of these findings, the authors suggested that adverse reactions to herbal remedies are underreported.

These results are similar to those of Givon et al. (2004) who found that one third of people attending family medicine practices in Israel also used complementary medicines. Half of the CAM users did not believe that the medicines caused adverse effects—because they were ‘natural’.

### 9.3.4 Consumer attitudes to regulation

In one of the few studies in which people have been asked about their views on the safety and registration of CAM practitioners, Emslie, Campbell & Walker (2002) reported on attitudes to complementary therapies in north-east Scotland. In 1999, 61% of a sample of 419 believed that a register of approved therapists was essential, and 29% thought that it was desirable (Emslie, Campbell & Walker 2002).

### 9.3.5 Reasons for use: Australian studies

To investigate the determinants of people's attitudes to alternative medicine, Siahpush (1999) conducted a telephone survey of 787 Victorians. The sample consisted of 64% women, had an average age of 40.1 years, and had an average of 13 years of education. According to the author (Siahpush 1999, p. 270):

... subscribing to the postmodern philosophy [was] associated with a positive perception of alternatives. It was shown that faith in natural remedies, subscribing to a holistic view of health, consumerism, and believing in individual responsibility were significant predictors of attitudes towards alternative medicine.

Dissatisfaction with medical encounters and dissatisfaction with medical outcomes were not significant predictors of attitudes to alternative medicine (Siahpush 1999). The author argued that a similarity between the attitudes of people and their providers in favour of CAM explained usage, rather than a rejection of medicine.

Siahpush's (1999) results were confirmed in a survey of Queensland adults by O'Callaghan and Jordan (2003). These research findings were similar to those of De Visser, Ezzy & Bartos (2000), who found that people with HIV/AIDS believed that both the complementary and conventional treatments they were using were effective. However, women were more sceptical of conventional treatments (De Visser, Ezzy & Bartos 2000).

A recent study of Wentworth Area Health Service inpatients found that their reasons for use of CAM included general wellbeing, cancer, stress management, surgery, wound healing, improved nutrition, and pain relief (Snape 2004).

## 9.4 Profile of patients who consult naturopaths and Western herbal medicine practitioners

Australian patients who utilise Chinese medicine practitioners have previously been surveyed (Bensoussan & Myers 1996), but no profile of naturopathy and WHM patients has been established. The present study sought information from naturopaths and WHM practitioners about patients who attended for treatment. (For methodology see section 9.2.2).

### 9.4.1 Patient demographics

Approximately two thirds (68%) of naturopathy and WHM patients were female. This ratio was consistent across all Australian states (ranging from 62% to 74%). The age range of patients varied from infants (less than one year old) to 86 years, with a mean age of 41 years (SD 16.7) (see Table 9.3).

**Table 9.3 Patients by age group and gender**

Age group	Female	Male	Total
0–20 years	24 (7.1%)	26 (21.1%)	54 (10.8%)
21–40 years	131 (38.6%)	36 (29.4%)	178 (35.7%)
41–60 years	146 (43.1%)	45 (36.6%)	205 (41.2%)
61–80 years	30 (8.8%)	14 (11.4%)	47 (9.4%)
>80 years	3 (0.9%)	0	4 (0.8%)
Missing	5 (1.5%)	2	10 (2.0%)
<b>Total</b>	<b>339</b>	<b>123</b>	<b>498</b>



### 9.4.2 Education, first language, and employment status

Approximately 46% of patients seeing practitioners were tertiary educated, including technical and private colleges (Table 9.4). Almost half (48%) worked as managers, administrators, or professionals (Table 9.5), and 44% were engaged in full-time work. English was the first language for 90% of patients.

**Table 9.4 Patients' highest level of education**

Education	Number (%)
Primary school	37 (7.4%)
High school (year 10)	75 (15.1%)
High school (year 12)	107 (21.5%)
Private college course	20 (4.0%)
Partial university or TAFE	15 (3.0%)
TAFE qualification	54 (10.8%)
University diploma or degree	104 (20.9%)
University postgraduate	38 (7.6%)
Subtotal	450 (90.4%)
Missing	48 (9.6%)
<b>Total</b>	<b>498 (100%)</b>

**Table 9.5 Patients' occupations**

Occupation	Number (%)
Manager or administrator	66 (19.4%)
Trade or craft person	23 (6.7%)
Sales or personal service work	49 (14.4%)
Labourer or related work	12 (3.5%)
Professional	97 (28.5%)
Clerical work	39 (11.5%)
Plant, machine operator, or driver	2 (0.6%)
Other	52 (15.3%)
<b>Total</b>	<b>340 (100%)</b>

### 9.4.3 Health insurance coverage

Health insurance covering naturopathy, herbal medicine, homeopathy, or nutritional medicine (at least in part) was held by 51% of patients. However, this varied from state to state: 47% in NSW, 58% in Victoria, 51% in Queensland, and 79% in South Australia.

### 9.4.4 Referral and shared patient care

The majority of patients who received naturopathic and herbal medicine treatment were self-referred (72.5%). Self-referral was defined as 'referral by other patients or by word of mouth'—thus excluding referral from other healthcare practitioners. A further 12% of patients were referred by advertising—including relevant telephone directories. Table 9.6 shows the frequency of referral sources. Only 5% of patients were referred by medical practitioners.

Before commencing naturopathic or WHM treatment for their conditions:

- 61% of patients had consulted other healthcare practitioners (all types, including medical practitioners) for the same conditions;
- 49% of patients had previously consulted medical practitioners (GPs or specialists) for the same conditions for which they were seeking treatment from naturopaths or Western herbalists;
- 17% of patients had consulted with medical specialists for their presenting conditions;

- 34% of these consultations with other practitioners were still continuing, and
- if treatment was continuing with another practitioner (shared care of the patient), communication between practitioners had occurred in 27% of cases.

From these data, it is apparent that a substantial proportion of patients who see naturopaths or Western herbalists are simultaneously seeing a variety of other health practitioners—most commonly conventional medical practitioners.

**Table 9.6 Sources of patient referrals**

Referral source	Number (%)
Self-referred	361 (72.6%)
Advertising	60 (12.0%)
Professional association	3 (0.6%)
Another CAM practitioner	15 (3.0%)
GP	19 (3.8%)
Specialist	5 (1.0%)
Chiropractor	8 (1.6%)
Osteopath	1 (0.2%)
Physiotherapist	0
Chinese medicine practitioner	1 (0.2%)
Pharmacist	2 (0.4%)
Counsellor or psychologist	9 (1.8%)
Health food shop worker	1 (0.2%)
Nurse	1 (0.2%)
Other	12 (2.4%)
<b>Total</b>	<b>498 (100%)</b>

#### 9.4.5 Nature of medical conditions

Patients were receiving naturopathic or WHM treatment for a wide range of conditions. These included: gynaecological disorders (12%), psychological disorders (11.6%), endocrine disorders (7%), gastrointestinal disorders (5.6%), and dermatological problems (5.2%) (see Table 9.7).

More than three quarters of patients (78%) reported that they were receiving treatment for chronic or recurrent complaints (three months or longer duration), and 71% had had their conditions for more than six months.

**Table 9.7 Principal diagnostic categories**

Diagnostic category	Number (%)
Lower respiratory	11 (2.2%)
Upper respiratory	14 (2.8%)
Gastrointestinal	28 (5.6%)
Neurological	10 (2.0%)
Rheumatological	31 (6.2%)
Dermatological	26 (5.2%)
Ophthalmological	3 (0.6%)
Endocrine	41 (8.2%)
Immunological	17 (3.4%)
Haematological	2 (0.4%)
Cardiovascular	18 (3.6%)
Psychological	58 (11.6%)
Gynaecological	60 (12.0%)
Renal	4 (0.8%)
Gerontological	2 (0.4%)
Missing	170 (34.1%)
Cancer	1 (0.2%)
Pre-menstrual tension	2 (0.4%)
<b>Total</b>	<b>498 (100%)</b>



### 9.4.6 Frequency and cost of consultations

The majority of patients (84%) consulted naturopathy or WHM practitioners twice or once per month. Approximately one third of patients saw their practitioners less than once a month during treatment periods. At the time of the survey 44% of patients had accumulated 2–5 consultations with their practitioners. Table 9.8 summarises the number of total consultations patients had had for the illnesses current at the time of the survey.

Approximately half (54%) of respondents were first-time users of naturopathic, herbal, homeopathic, or nutritional treatment. The rest were returning for further treatment for the same complaints or for other complaints.

The average monthly cost of naturopathic and WHM treatment to the patient, including any herbal medicines, was \$107. The cost of a full course of treatment, as reported by practitioners, was approximately \$392, including herbs and/or supplements.

**Table 9.8 Number of consultations for presenting illnesses**

Number of visits	Number of patients (%)
First visit	135 (27.1%)
2–5 visits	217 (43.6%)
6–10 visits	61 (12.2%)
11–15 visits	30 (6.0%)
More than 15 visits	36 (7.2%)
Missing	19 (3.8%)
<b>Total</b>	<b>498 (100%)</b>

### 9.4.7 Form of treatment administered

A wide variety of treatment techniques were administered to patients. The findings recorded here are consistent with those identified in the workforce survey (see Chapter 4 and Table 9.9).

Dietary advice was the most common treatment (78%). WHM, lifestyle advice, nutritional supplements, and exercise advice were each supplied to more than half of the patients.

**Table 9.9 Forms of treatment**

Treatment	Number (%) of patients
Western herbal medicine	309 (62.0%)
Dietary advice	386 (77.5%)
Exercise advice	261 (52.4%)
Referral to another practitioner	43 (8.6%)
Acupuncture	47 (9.4%)
Massage	143 (28.7%)
Chinese herbs	44 (8.8%)
Lifestyle advice	292 (58.6%)
Diagnostic tests recommended	77 (15.5%)
Homeopathy	88 (17.7%)
Aromatherapy	39 (7.8%)
Nutritional supplements	295 (59.2%)
Other	80 (16.1%)

Note: Multiple responses permitted

### 9.4.8 Pharmaceutical and CAM medication used concurrently

Among patients receiving naturopathic or WHM treatment, 34% were also taking pharmaceutical drugs (excluding vitamins and nutritional substances) (see Table 9.10). The combination of a variety of medicines is an area of growing concern in terms of risk to public safety (see also Chapter 2).

**Table 9.10 Patients using Western pharmaceutical drugs (excluding vitamins and nutritional supplements)**

Drugs affecting	Total cases
Nervous system	64
Endocrine system	58
Infections	13
Alimentary tract	19
Cardiovascular system	34
Blood	3
Respiratory system	15
Neoplastic disorders	3
Musculoskeletal system	4
Immune system	–
Genitourinary system	1
Skin	2
Eyes, ear, nose, and throat	6
<b>Total</b>	<b>222</b>

## 9.5 Focus group research

The objective of the focus groups was to explore consumers' views on the practice of naturopathy and WHM. The study focused on: (i) reasons for using naturopathy and WHM; (ii) satisfaction with naturopathy and WHM; (iii) use of conventional medicines in addition to naturopathy and WHM; and (iv) views on the need for consumer protection or government regulation.

### 9.5.1 Topics explored in focus groups

Discussion in the focus groups centred on participants' views about the practice of naturopathy and WHM. Participants were not asked to specify which group of therapists they were referring to for every question, but the focus of the questions was on the use of naturopaths and WHM practitioners.

The first questions encouraged participants to describe their use of different CAM practitioners in general, their motivation for using naturopathy and WHM, and their satisfaction with services. They were then invited to discuss their use of complementary services in addition to conventional medicine, and their use of pharmaceuticals and herbal medicines. The discussion moved on to questions about adverse drug reactions to herbal remedies, and to whom these would be reported. The use of over-the-counter medications and self-prescribing were discussed, including how informed decisions are made about these treatments. This led to consideration of the type of information people look for in print media and on the Internet. Finally, participants were asked their views on consumer protection and government regulation of naturopaths and WHM practitioners.

### 9.5.2 Use of CAM practitioners

The participants had consulted a range of practitioners—including naturopaths, WHM practitioners, a GP specialising in natural medicine, homeopaths, chiropractors, acupuncturists, osteopaths, masseurs, kinesiologists, Chinese herbal medicine practitioners, Buteyko practitioners, reiki healers, reflexology practitioners, an 'intuitive healer', and an 'environmental health specialist'.

Participants were not asked to state the health reasons for the visits or for information on any health condition. However, some volunteered information on their health status. Conditions mentioned by the participants included chronic fatigue syndrome, hepatitis C, HIV, cancer, insomnia, bloating and indigestion, stress, throat infection, endometriosis, eczema, and health after a stroke.

Visits were made occasionally in response to need, or on a routine basis. The latter included fortnightly or monthly visits for ‘maintenance’ consultations, or for ongoing management of chronic illnesses.

### **9.5.3 Reasons for use of naturopathy and WHM**

The reasons these consumers chose to visit a naturopath or WHM practitioner varied, but certain themes became apparent. The most common motivation was that naturopaths and WHM practitioners practise a holistic form of therapy, rather than targeting one specific area. It was said that naturopaths and WHM practitioners:

- have a lifestyle focus;
- ask why patients are sick;
- strengthen immunity;
- engage patients in the healing process; and
- use treatments that produce fewer side effects than conventional medicine.

A few people commented that herbal medicine was more ‘proactive’ than conventional medicine—which they had experienced as being ‘reactive’. A number reported failures of conventional medicine—which were contrasted with successes of naturopathic treatment.

Participants said that herbal medicine promotes health and ‘wellness’, rather than just focusing on illness. Visiting a naturopath was said to be:

... more preventative ... regular maintenance rather than fixing something.

Other participants expressed some dissatisfaction with conventional medicine. People said that GPs treat symptoms, rather than the causes of illnesses. Participants wanted practitioners to look for causes of illnesses, and it was felt that naturopaths adopted this approach:

Western medicine is mainly reactive. Herbal medicine is proactive, it looks after the wellness of a person, not just the illness.

GPs treat symptoms not [the] cause. [I] want someone to look for the cause, [and] the naturopath does that.

One participant remarked that naturopathy could not be expected to be able to cure everything. It was thought that there was a need for more research in naturopathy. One participant observed that naturopathy and WHM do not attract as much money for research as conventional medicine.

One participant was concerned about the side effects and ‘toxins’ of conventional medicine, which were said not to occur with naturopathic products. Another said that side effects were more common with medicines from GPs compared with naturopathic therapies.

### **9.5.4 Selection of practitioners**

The majority of participants said that they selected complementary medicine practitioners on the basis of word-of-mouth recommendation from friends or family members. Others chose practitioners on the basis of the locations of practitioners, referrals from GPs or naturopaths, natural health magazines or newsletters, leaflets in mailboxes, the Australian Complementary Health Association, the Australian Natural Therapies Association, schools of naturopathy, and by visiting different practitioners and assessing them.

### **9.5.5 Satisfaction with naturopathy and WHM**

Participants were asked about their satisfaction with naturopathy and WHM practitioners. The majority of participants were very satisfied, although this appeared to be dependent on finding the ‘right’ practitioner. Satisfaction was linked to the:

- quality of the relationship;
- time for discussion and being listened to;
- knowledge and skills of the practitioner; and

- opportunity to participate in healthcare.

Some practitioners were perceived as being more knowledgeable than others, and clients had to be careful whom they visited. One participant expressed dissatisfaction with a naturopath who, it was felt, had not been ‘honest’—resulting in the person feeling ‘like a guinea pig’.

A few participants commented that they were happy with their present practitioners, but that this had not previously been the case. They had needed to visit a number of practitioners before they were satisfied.

It partly depends on the practitioner. There are some practitioners [who] probably aren’t so good, and it does depend on how rigorous [their] training is, and whether [they] have a talent.

One participant commented that, notwithstanding good experiences with GPs, this person was much more satisfied with the naturopath because it was felt that the naturopath was interested and took more time. Others commented that they were satisfied because they felt that they were participating in their own healthcare.

Some participants linked satisfaction with the time available in their consultations with naturopaths—which could be quite long (1–1.5 hours). This enabled clients to talk about many things and explain what was going on in their lives. The length of consultations was contrasted with the time available with GPs, although views on this varied.

A few expressed satisfaction with both their GPs and naturopaths. These participants were using the two systems concurrently, and one noted that use of both was how this person expressed choice.

### **9.5.6 Use of naturopathy and WHM in addition to conventional medicine**

Participants were asked whether they used naturopathy and WHM services in addition to conventional medicine and, if they did, whether this was discussed with their various practitioners. Responses varied widely, but there were two main themes: systems working together and systems working separately.

A few participants said they used conventional medicine in addition to naturopathy and WHM, and that they discussed this with both sets of practitioners. Naturopathy played a role in dealing with the side effects of medications for several participants. In one instance, a GP had recommended that the participant visit a naturopath for vitamins while being treated for infected eczema with antibiotics. One participant thought that it was very important to discuss the use of other treatments with all healthcare practitioners because drug and herbal combinations can be dangerous.

For other participants, the systems worked separately or they used only complementary health services. A number of participants said that they rarely, if ever, visited GPs, and would do so only if they needed a blood test, broke a bone, needed stitches, or had a life-threatening condition. These participants said that they would first go to a naturopath for most other needs.

A number of participants said that they felt sufficiently confident and knowledgeable about their own bodies to be able to prevent illnesses. One participant did not discuss the use of naturopathy with GPs; rather, this person researched everything independently.

A number of people commented on poor communication as a result of the consumer being caught between two ‘systems’. Some said that they did not discuss use of complementary health services with their GPs because GPs did not understand or were not interested in what participants were talking about. They felt that GPs saw them as ‘weird’ if they discussed the use of complementary medicine. Others said that their naturopaths were interested in hearing what their GPs said, but that GPs were not interested in hearing what the naturopaths said. Another had informed a GP about using naturopathy simply as a ‘political statement’.

The potential danger of poor communication between the two sets of providers was raised by one participant. This person had realised only recently that there were interactions between herbs and pharmaceuticals. The reason for not talking to GPs was:

They have no idea what I am talking about if I try to talk about it.

### **9.5.7 Adverse reactions to herbal remedies**

A number of participants mentioned that they had experienced various kinds of side effects from, or adverse reactions, to naturopathic and herbal treatments. Responses to this situation varied. Two people said that they had informed their naturopaths—who altered the dose or medium for delivery. Two others had experienced adverse reactions to herbal mixtures which made them feel nauseated, but they did not mention this to the naturopaths and simply changed the doses themselves.

Other participants who had not experienced adverse reactions said that, if they did experience such reactions, they would tell whomever had prescribed the medication and stop taking it. One participant mentioned an Internet database that provided information on the side effects of various drugs, both conventional and alternative, and added that there are consumer ‘hotlines’ that provide information about some complementary medicines.

### **9.5.8 Self-prescribing and information-seeking**

The majority of participants were active in seeking information about their health, illnesses, and treatments. Most said that they self-prescribed and several had discussed this with people at health food shops whom they believed to be naturopaths. There was some concern expressed regarding whether this was a ‘full consultation’, and it was also felt that health food shop operators should be better informed.

The majority of people who self-prescribed thought that their decisions were well informed. They stated that they carried out research by reading books or seeking information on the Internet. Some checked with friends or family members who were naturopaths.

Several participants said that they did not self-prescribe because they felt their naturopaths had their interests at heart. A few had stopped self-prescribing and now consulted their naturopaths first.

The majority of participants said that they sought information about naturopathy and WHM using the Internet, books, magazines, newspapers, and leaflets. Some mentioned an interest in reading scientific studies of the research in support of treatments, whereas others were more interested in general information and people’s experiences of different treatments.

### **9.5.9 Views on the need for more consumer protection and government regulation**

There were some mixed feelings about the need for more consumer protection and government regulation. However, the majority of participants thought that there should be some form of regulation. Because consumers place a great deal of trust in practitioners, and are often vulnerable, several participants felt that practitioners should have a qualification (implying an approved qualification) and that they should be regulated.

Those who thought that there should be regulation said that it was needed to:

- raise the standard of practitioners;
- ensure consistency of care; and
- stop unethical practice.

It was also felt that regulation implied recognition of naturopathy and WHM. One person reasoned that greater awareness of naturopathy and WHM among practitioners of Western medicine would be beneficial in assisting the two systems to work together. Some participants were aware that regulation did not ensure quality care, but thought that it was important for consumers to know that a practitioner had undertaken a minimum standard of training. Comments included:

Raise the standard more and weed out any unethical practice out there.

From the perspective of the average consumer, they may not have the same level of background knowledge that we have [as experienced users].

Concerns were expressed about the ability of professional associations to investigate complaints against their members, the possibility that poor practitioners could leave (or be forced to leave) one association only to join another, and the need for a body to hear complaints:

There are people who prey on other people, so there has to be some degree of regulation.

Although some participants thought that a degree of regulation might be beneficial, they also believed that consumers needed to take responsibility for scrutinising practitioners themselves. One participant had checked qualifications and professional membership of the attending naturopath.

There were mixed responses about the benefits that regulation would confer on consumers, but the comments indicated that quality of care and continuing education were issues. One participant noted that it would be good to ensure that practitioners took part in continuing education, particularly with respect to safe prescribing.

A few participants did not think that regulation would improve the quality of practitioners, but that it might inhibit them from trying new treatments. These consumers were concerned that an intuitive approach might be lost if practitioners were required to be registered, and that registration might restrict what they could practise. It was believed that regulation would not address the critical issue of practitioners' communication skills. Furthermore, it was felt that regulation had not necessarily ensured the quality of conventional medical care:

Regulation does not result in good practitioners. Death from medical drugs is really high.

The lay or 'folk' basis of some complementary health practice was emphasised by one person who said that it was not necessary to attend college to learn how to practise CAM. This participant noted that some forms of treatment have been passed down from parents or grandparents.

## **9.6 Limitations of the studies**

In the patient profile, only a relatively small sample of patients (498) was profiled. It is difficult to assess whether this was representative of patients of naturopathy and WHM because there are little other published data on consumers of this form of treatment. Communication with naturopathy and WHM practitioners indicates that the findings fall within expectations.

There were also limitations with the focus group study. The participants were recruited through only three organisations—the Australian Complementary Health Association, the Chronic Illness Alliance, and the Hepatitis C Council of Victoria. In addition, because the participants self-selected by expressing an interest in participating, they might have had greater interest in, knowledge of, and use of naturopathy and WHM than non-participants. Moreover, the number of focus groups was small, and although participants were frequent consumers of CAM, the researchers were unable to recruit parents of children with a chronic illness who were being treated by a naturopath or WHM practitioner.

## **9.7 Summary of results**

The literature review, the patient profile, and the focus groups produced the following key results.

### **9.7.1 Choice of practitioner and care**

- The majority of patients were self-referred, following recommendation from another person.

- People believed that they had made rational and well-informed choices about using different practitioners for various health considerations. The main reasons included: (i) wanting effective treatments for health problems; (ii) maintenance of health and wellness; (iii) being treated for a chronic illness or condition; and (iv) dealing with the effects of medical treatment for a serious health condition.
- Treatment was sought for a wide range of physical and psychological problems; the majority were suffering from chronic or recurrent conditions.
- Treatments were multifaceted, with dietary advice being the most common; WHM, lifestyle advice, nutritional supplements, and exercise advice were also widely used.

### **9.7.2 Communication**

- The literature on Australian use of naturopaths and WHM therapists suggests that communication between medical and CAM practitioners can be poor—which could have adverse consequences in terms of interactions between drugs and complementary medicines.
- Approximately half of the profiled patients had consulted a medical practitioner (general or specialist) for their complaints before visiting a naturopath or WHM practitioner, but communication between practitioners occurred in only a minority of cases.

### **9.7.3 Concurrent use of conventional medicine and naturopathy or WHM**

- Concurrent use of conventional medicine and naturopathy or WHM is well established across all age ranges; employed women in higher-income brackets tend to be the largest single group of users.
- Among the profiled patients who received naturopathic or WHM treatment, 34% were also taking pharmaceutical drugs.

### **9.7.4 Quality issues**

- Research participants took an active interest in their health and wellbeing, and this was reflected in their assessments of the quality of their treatments and their practitioners (all types); this was also reflected in participants' information-seeking behaviour and self-prescribing.
- Quality of care encompassed relationships with providers, the importance of communication, and the knowledge and technical competence of providers. Participants expressed interest in the educational standards of practitioners and their ongoing professional education.

### **9.7.5 Regulation of practitioners**

- Regulation of naturopaths and WHM practitioners was favoured by the majority of focus group participants. Supporters said that regulation was needed to: (i) raise the standard of practitioners; (ii) ensure consistency of care; and (iii) stop unethical practice.
- Comments made in the focus groups suggested that consumers were of the view that regulation of naturopaths and WHM practitioners would enable consumers to navigate the two systems more easily, and would facilitate better communication between CAM and medical practitioners.

## **9.8 Discussion**

The literature revealed that people who consult naturopaths and herbal therapists do so for a range of reasons. The major reasons reported (largely confirmed by the focus group participants in the present study) were:

- wanting effective treatments for health problems;
- maintenance of health and wellness;
- strong support for the philosophy and practice of naturopathy and WHM;

- being treated for a chronic illness or condition; and
- dealing with the effects of medical treatment for a chronic or serious health condition.

The profiled patients of naturopathy and WHM were predominantly female. Approximately 77% of patients were between the ages of 21 years and 60 years. Nearly half were tertiary educated and worked in managerial and professional roles. Almost three quarters of patients were self-referred. This reflects a degree of informed decision-making by patients, rather than their being referred by other health professionals.

### 9.8.1 Risks to consumers

Three main types of risks for consumers were identified in the focus group discussions (no risk data were collected through the patient profiles). *First*, for people who use CAM practitioners exclusively, or for most of their healthcare, the minimum educational qualifications required of practitioners for clinical practice were of importance. These practitioners are responsible for the primary care of patients, and they are therefore involved in the diagnosis and treatment of a wide range of health problems using treatment modalities that entail risk.

*Secondly*, for people who use both CAM and conventional medical practitioners, there are risks associated with: (i) the treatment modalities used; and (ii) drug interactions between treatments provided by the different health practitioners. People who use both systems might be treated for serious illnesses, and communication regarding actual treatment among different providers and patients was poor. *Thirdly*, there is potential for ‘false consultations’ if consumers talk to persons they believe to be ‘naturopaths’ in health food shops. However, the present study was unable to document the extent of this risk.

Chapter 2 also summarises risks as reported in the scientific literature and by practitioners.

### 9.8.2 Use of two systems

Many people who used complementary healthcare also used conventional medical services. Although there was a smaller number who did not wish to use conventional medicine unless necessary, the literature and the present data suggest that many people navigate between the two systems.

More than half of the profiled patients were first-time users of naturopathy and WHM. It is of significance that 60% of patients had consulted other practitioners for their presenting condition before seeking naturopathic and WHM treatment, and more than 80% of these patients had consulted with a GP or medical specialist. In cases of shared care of patients, communication between practitioners occurred in only a third of cases.

Navigating between two systems has potential dangers if consumers do not feel that they can inform all practitioners about their use of particular services, or if they choose not to inform all practitioners.

### 9.8.3 Cost

The average monthly cost of treatment to the profiled patients, including herbal and nutritional medicines, was \$107. A full course of treatment cost approximately \$400.

More than half of these patients held private health insurance coverage—which is higher than the national average. In June 2004, 42.9% of the Australian population had some form of private health insurance (AGPHIAC 2004). Substantial differences existed in the use of private health insurance among states.

## 9.9 Conclusion

Use of CAM is widespread and is increasing, and concurrent use of conventional medicine with naturopathy and WHM is well established among all age groups. Consumers interviewed as part of the focus groups believed that they made rational and well-informed choices about



using different practitioners for various health reasons, including treatment of chronic conditions and maintenance of health and wellbeing. However, they were concerned that ethical and consistent standards of practice should be ensured.

Consumers of naturopathy and WHM services tend to be active in seeking health information. They expressed interest in quality of care, relationships with providers, the importance of communication, and the education of practitioners. However, there were concerns about finding a high quality practitioner. Those who favoured increased regulation said that it was necessary to raise the standard of practitioners, to ensure consistency of care, and to stop unethical practices.

Problems were identified in: (i) communication between consumers and health professionals regarding use of complementary health services and the risks associated with treatments; (ii) communication between different health professionals regarding a patient's illness and treatment (particularly with respect to treatment interactions); and (iii) accurate recording of medications. In addition, the existing system does not provide consumers with a clear, accessible, and independent system for making complaints against CAM providers and for their complaints to be handled in a fair and transparent way.

The benefits of statutory regulation of CAM practitioners to consumers included: (i) the establishment of minimum educational standards among practitioners; (ii) ongoing professional education on drug interactions; (iii) facilitation of communication between patients and doctors, and between CAM practitioners and doctors, if CAM practitioners were registered health professionals; and (iv) improvements in safe and ethical care.

The argument for statutory regulation is supported by data from this chapter in relation to three criteria of the Australian Health Ministers' Advisory Council (AHMAC) for assessing the need for statutory regulation of unregulated health occupations<sup>7</sup>—that is: (i) the risks as documented; (ii) the failure of existing safety mechanisms to overcome the problems that arise from consumers using the two systems concurrently; and (iii) the benefits from regulation identified by consumers.

## **9.10 Recommendations**

Based upon the findings of the above research, the following recommendations are made.

- Occupational regulation should be supported as a public policy measure to: (i) assist the development of communication and referral mechanisms between conventional medical providers and CAM providers; (ii) provide incentives for health services to collect accurate records of patients' medications; (iii) provide an incentive for the development of uniform educational standards; (iv) provide incentives to develop policies with respect to reporting adverse drug reactions; (v) assist in the development of transparent and independent complaints mechanisms; (vi) support improved public education in communicating risks to consumers; (vii) assist incorporation of quality assurance into the use of naturopathy and WHM; and (viii) enable the same protections to be available to consumers of naturopathy and WHM as are available to consumers of conventional medical services.
- Continuing professional education for naturopaths and WHM practitioners should be a mandatory requirement of regulation.
- Hospitals should develop policies in quality and safety that recognise the reality of consumer practices regarding concurrent use and consumption of complementary and conventional medicines.
- All centralised web-based health information providers (for example, HealthInsite, Better Health Channel) should be reviewed to ensure that up-to-date and evidence based information is provided on commonly used CAM treatments.

## **Acknowledgments**

Development of the patient profile was supported by the National Herbalists Association of Australia and the Federation of Natural and Traditional Therapists with the collaboration of Grand United Health Fund.

The focus group component was undertaken by Sophie Hill, School of Public Health, and Jo Condron and Gai Wilson of the Centre for Development and Innovation in Health, Faculty of Health Sciences, La Trobe University. Thanks are expressed to the Australian Complementary Health Association, the Chronic Illness Alliance, and the Hepatitis C Council of Victoria who assisted in recruiting participants for this study. Thanks are also expressed to the consumers who participated in the focus groups. Thanks also to Dr Pauline McCabe for constructive comments on earlier drafts of the focus group analysis.

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# 10. Existing Legislative Arrangements Affecting the Practice of Complementary and Alternative Medicine

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## 10.1 Introduction

Government regulation of health service practitioners is generally designed to safeguard quality standards and mitigate the risk of harm to consumers. For a number of health professions, such regulation occurs through statutory registration boards established under Acts of Parliament. Generally, these arrangements ensure that only suitably qualified practitioners are engaged in service delivery, and that consumers are able to give their informed consent to treatment, and be assured of confidentiality. In the event of professional misconduct or failure to adhere to acceptable standards of practice, registration boards are empowered to undertake disciplinary action.

Statutory laws are not the only means by which consumers are protected and the delivery of high quality services is maintained. In Australia, a number of health professions are subject to self-regulation. This is a process whereby practitioners voluntarily become members of a professional association that sets standards for professional conduct and service delivery, and may stipulate minimum qualification levels for membership. In the event of poor performance or unprofessional conduct by members, professional associations may initiate disciplinary processes that could, if appropriate, result in the cancellation of membership for that practitioner.

With the exception of chiropractors, osteopaths and Victorian practitioners of Chinese Medicine, for a number of complementary and alternative medicine (CAM) practitioners, including naturopaths and practitioners of Western herbal medicine (WHM), self-regulation is the primary regulatory framework available in Australia as there is no system of statutory registration of these practitioners in any jurisdiction. Under this framework there exist a number of professional associations, each of which has established its own standards and protocols. However, the standards are not always comparable or consistently applied.

Apart from legislation governing chiropractors and osteopaths, and Victoria's *Chinese Medicine Registration Act 2000*<sup>1</sup>, in every Australian jurisdiction there are various laws that directly impinge on both the practice of CAM and on the herbs and nutritional supplements that are the 'tools of trade' of these practitioners. These laws are generally similar across Australia. They have not arisen because of any systematic response by governments to address concerns about the conduct of CAM practitioners. Rather, the laws have evolved over several years in an *ad hoc* manner.

This chapter provides an overview of legislation that currently operates in Australia governing the practice of WHM and naturopathy, and the herbs and nutritional medicines

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<sup>1</sup> NSW and Western Australia are canvassing the need to regulate Chinese Medicine practitioners in response to the increase in use of Chinese herbal medicine, the increase in number of practitioners, and the level of risk to the public. NSW released a discussion paper on the regulation of complementary health practitioners to canvass public views, the results of which are yet to be announced (NSW Health 2002). In Western Australia, the Government also released a discussion paper on the regulation of practitioners of Chinese medicine in Western Australia with submissions from interested parties sought by 2 September 2005 (Department of Health Western Australia 2005).

used by these practitioners. The overview is Australia-wide but there is a particular focus on Victorian legislation.

Regulatory controls for CAM in other countries are also examined. Controls in the European Community (including the United Kingdom), Canada, the United States of America, and New Zealand are discussed. Such an examination of regulatory measures adopted in other countries can be used to inform consideration of practical models for application in Australia. Chapter 11 considers these models in greater detail in discussing the need for regulation, and options for implementing such regulation.

## **10.2 Methodology**

### **10.2.1 Legislation**

A search was undertaken for Acts and regulations relevant to the practice of CAM, especially WHM and naturopathy. This involved two phases.

The first phase involved the use of the AustLII databases <[www.austlii.edu.au](http://www.austlii.edu.au)> to search for legislation in Australia and New Zealand. The key search terms used were:

- complementary medicine;
- alternative medicine;
- naturopathy;
- Western herbal medicine;
- herbal medicine;
- herbs;
- therapeutic;
- health; and
- Chinese medicine.

The second phase involved searching for legislation in the United Kingdom (UK), Canada, United States of America (USA), and European Union (EU). The same key search terms (above) were used to search the BaLII databases for the UK and the EU <[www.bailii.org](http://www.bailii.org)>, the LII databases for the USA <[www.law.cornell.edu](http://www.law.cornell.edu)>, and the CanLII databases for Canada <[www.canlii.org](http://www.canlii.org)>.

### **10.2.2. Regulatory models**

An Internet search was also undertaken for Internet information and reports published by health and consumer affairs authorities on health practitioner registration models and legislative and policy proposals relevant to CAM practitioners. The sites searched included:

- Department of Health, Western Australia;
- South Australian Department of Human Services;
- Department of Health & Community Services, Northern Territory;
- NSW Health;
- ACT Health;
- Australian Government Department of Health & Ageing;
- Queensland Health;
- Victorian Department of Human Services;
- Department of Health & Human Services, Tasmania;
- Therapeutic Goods Administration;
- Food Standards Australia;
- Productivity Commission;
- Consumer Affairs Victoria;
- ACT Office of Fair Trading;
- NSW Office of Fair Trading;
- Department of Business, Industry & Resource Development, Northern Territory;

- Queensland Office of Fair Trading;
- Office of Consumer and Business Affairs, South Australia;
- Office of Consumer Affairs & Fair Trading, Tasmania; and
- Department of Consumer & Employment Protection, Western Australia.

### **10.3 Legislation governing CAM products and practice in Australia**

Australia's federal system of government presents CAM practitioners with a variety of laws governing both their practice and the products that they use. At the Commonwealth level, the Constitution provides the Government with various legislative powers such as the power to impose taxes and regulate corporations and trade, as well as powers with respect to quarantine and the provision of health and social welfare, including the provision of pharmaceuticals. Within this framework the Commonwealth Government has enacted a series of laws that can apply to the practice of CAM and in some instances the Commonwealth takes the lead role, such as the regulation of therapeutic products. The laws of the States and Territories often address gaps in the Commonwealth's legislative coverage of certain areas. For instance, in the case of the Commonwealth's powers over trade and commerce, the Commonwealth is unable to regulate sole traders. In addition, the laws of the States and Territories cover issues over which the Commonwealth has no constitutional power – for instance, the regulation of health practitioners.

Table 10.1 provides an overview of relevant Commonwealth laws and illustrates the range of state and territory laws that are applicable to the practice of CAM. In terms of the laws of the States and Territories, while there are many consistencies across these jurisdictions – such as the existence in all States and Territories of mechanisms to enable consumers to make complaints against providers of natural therapies, and various laws governing infection control and the regulation of dangerous substances and drugs – there are equally a number of inconsistencies. For instance, as noted earlier, Victoria is the only jurisdiction to provide for the statutory registration of Chinese medicine practitioners in that State, and only the ACT, NSW and Victoria have enacted laws to ensure that consumers can gain access to their health records held by private health practitioners practicing in those States.

As demonstrated in Table 10.1, the scope of the laws in Victoria applicable to the practice of CAM is representative of those laws that are in operation in other jurisdictions, with the addition of the Chinese Medicine Registration Act. In light of this, Victoria, along with the Commonwealth, will be used as a case study illustrating the nature of the legislation governing CAM products and practice.

#### **10.3.1 Laws governing business practice and the protection of consumers**

##### ***A New Tax System (Goods and Services Tax) Act 1999 (Commonwealth)***

To obtain GST-free status for the provision of acupuncture, naturopathy, or herbal medicine services in Australia, the goods and services taxation (GST) legislation requires individual practitioners to establish that their services are provided by a 'recognised professional' and are 'generally accepted in the relevant health profession as being necessary for the appropriate treatment of the recipient of the services'. A 'recognised professional' is a person who is subject to a state or territory law requiring permission, approval, or registration to supply those services in that State or Territory. If no such state or territory law exists, the practitioner must be a member of a professional association that has uniform national registration requirements relating to the provision of those services.

**Table 10.1: Comparable laws governing CAM products and practice in Australian jurisdictions**

	<b>C'LTH.</b>	<b>ACT</b>	<b>NSW</b>	<b>NT</b>	<b>QLD</b>	<b>SA</b>	<b>TAS</b>	<b>VIC</b>	<b>WA</b>
<b>Laws governing business practice and protection of consumers</b>	<i>A New Tax System (Goods and Services) Act 1999</i>								
	<i>Quarantine Act 1908</i>								
	<i>Trade Practices Act 1974</i>	<i>Fair Trading Act 1992</i>	<i>Fair Trading Act 1987</i>	<i>Consumer Affairs and Trading Act 1990</i>	<i>Fair Trading Act 1989</i>	<i>Fair Trading Act 1987</i>	<i>Fair Trading Act 1990</i>	<i>Fair Trading Act 1999</i>	<i>Fair Trading Act 1987</i>
		<i>Community and Health Services Complaints Act 1993</i>	<i>Health Care Complaints Act 1993</i>	<i>Health and Community Services Complaints Act 1998</i>	<i>Health Rights Commission Act 1991</i>	<i>Health and Community Services Complaints Act 2004</i>	<i>Health Care Complaints Act 1995</i>	<i>Health Services (Conciliation and Review) Act 1987</i>	<i>Health Services (Conciliation and Review) Act 1995</i>
<b>Public health protection law</b>		<i>Public Health Act 1997</i>	<i>Public Health Act 1991</i>	<i>Medical Services Act 1982</i>	<i>Health Act 1937</i>	<i>Public and Environmental Health Act 1987</i>	<i>Public Health Act 1997</i>	<i>Health Act 1958</i>	<i>Health Act 1911</i>
<b>Health information and privacy laws</b>	<i>Privacy Act 1988</i>	<i>Health Records (Privacy and Access) Act 1997</i>	<i>Health Records and Information Privacy Act 2002</i>					<i>Health Records Act 2003</i>	
<b>Laws governing products</b>	<i>Therapeutic Goods Act 1989</i>	<i>Poisons and Drugs Act 1978</i>	<i>Poisons and Therapeutic Goods Act 1966</i>	<i>Therapeutic Goods and Cosmetics Act 1986</i>		<i>Drugs Act 1908</i>	<i>Therapeutic Goods Act 2001</i>	<i>Therapeutic Goods Act 1989</i>	<i>Poisons Act 1964</i>
			<i>Drug Misuse and Trafficking Act 1985*</i>	<i>Poisons and Dangerous Drugs Act 1983</i>	<i>Drug Misuse Act 1986</i>	<i>Controlled Substances Act 1984</i>	<i>Poisons Act 1971</i>	<i>Drugs, Poisons and Controlled Substances Act 1981</i>	<i>Misuse of Drugs Act 1981</i>
<b>Statutory registration of CAM practice</b>								<i>Chinese Medicine Registration Act 200</i>	
		<i>Chiropractors and Osteopaths Act 1983</i>	<i>Chiropractors Act 2001</i>  <i>Osteopaths Act 2001</i>	<i>Health Practitioners Act 2004</i>	<i>Chiropractors Registration Act 2001</i> <i>Osteopaths Registration Act 2001</i>	<i>Chiropractic and Osteopathy Practice Act 2005</i>	<i>Chiropractors and Osteopaths Registration Act 1997</i>	<i>Chiropractors Registration Act 1996</i> <i>Osteopaths Registration Act 1996</i>	<i>Chiropractors Act 1964</i>  <i>Osteopaths Act 1997</i>

According to the Australian Taxation Office (ATO), a ‘member of a professional association’ would have voting rights with that association and be able to take part in making decisions affecting the profession (ATO 2004). A ‘professional association’ is not defined in the GST legislation. However, according to the ATO (2004) such an association would be, for example, a not-for-profit organisation with: (i) articles of association; (ii) by-laws or codes of conduct for members; (iii) the ability to set its own standards for practice and ethics; and (iv) the right to impose sanctions on members who fail to abide by its rules. The association would also set its own admission requirements, and requirements for ongoing professional development.

The interpretation of the term ‘uniform national registration requirements’ is critical to the operation of the taxation legislation in relation to practitioners of naturopathy and WHM. This term does not refer to statutory registration of a profession; rather it refers to the fact that ‘the professional association’s registration requirements must be the same in all States and Territories’ (ATO 2004). The GST legislation does not specify any criteria to be applied by professional associations in granting registration to practitioners of acupuncture, naturopathy, and herbal medicine. It is the responsibility of each professional association to ensure that only suitably qualified people gain practitioner status (ATO 2004).

Following the passage of the *Chinese Medicine Registration Act 2000*, Victoria is presently the only Australian jurisdiction that requires practitioners who supply acupuncture or Chinese herbal medicine services to be registered under a statutory registration scheme. Victorian acupuncturists and Chinese herbal medicine practitioners who are registered under the scheme are thus compliant with the requirements of Commonwealth taxation law and may provide GST-free services in Victoria. However, any person who provides acupuncture or herbal medicine services in any other part of Australia needs to be a member of a professional association that has uniform national registration requirements.

Because no Australian jurisdiction currently requires practitioners of naturopathy or WHM to have permission, approval, or registration to provide their professional services, practitioners who wish to be classed as a ‘recognised professional’ for GST purposes must be members of a professional association that has uniform national registration requirements relating to their respective disciplines.

The operation of the GST legislation would, in theory, result in industry self-regulation with nationally consistent standards of education, professional conduct and quality service delivery. However, in practice, this has not eventuated. As discussed in Chapter 6, there are a number of professional associations representing the different disciplines, each with different entry criteria and arrangements for the recognition of qualifications, and different approaches to the maintenance of ethical standards and complaints investigation. Although these disparate arrangements have not been reconciled into a single, nationally consistent body of standards for each discipline, the ATO has nonetheless recognised, for GST purposes, multiple sets of standards for multiple associations. Consequently, a practitioner found to have breached the standards of one association can join another association and maintain his or her GST free status.

### ***Quarantine Act 1908 (Commonwealth)***

Under the *Quarantine Act 1908*, all goods coming into Australia or the Cocos Islands are subject to quarantine (section 18). ‘Goods’ are defined broadly, and include any animal, plant, article, substance, or thing. This definition is sufficiently broad to include herbs used by CAM practitioners.

A quarantine officer may order into quarantine any goods that, in his or her opinion, are (or are likely to be) quarantinable pests or quarantinable diseases. A quarantine officer or other authorised person may seize any goods imported, introduced to, or brought into Australia in contravention of the Act. Penalties are imposed for those found to have breached the Act.



### **Trade Practices Act 1974 (Commonwealth)**

The *Trade Practices Act 1974* has been designed (i) to promote competition and fair trading by prohibiting anti-competitive behaviour (such as price-fixing and collusion); and (ii) to protect consumers from unfair practices (such as misleading advertising). The Act applies to professional services provided by a corporation in trade or commerce under a contract. CAM practitioners (including practitioners of naturopathy and WHM) who operate their practices through companies may be subject to various provisions of the Act.

For the purposes of this report, the key provisions of the Act are:

- section 52: which provides that a corporation shall not, in trade or commerce, engage in conduct which is misleading and deceptive or likely to mislead or deceive;
- section 53: which forbids false claims that services are of a particular standard, quality, value, or grade; and
- section 55A: which prohibits a corporation from engaging in conduct that is liable to mislead the public as to the nature, the characteristics, or the suitability for their purpose or the quantity of any services.

In addition to its powers governing the professional services provided by a corporation engaged in trade or commerce under a contract, the *Trade Practices Act 1974* is also concerned with the supply of goods. CAM practitioners who operate their practices through companies may be affected by the Act's various provisions relating to the supply of goods. Some provisions of the Act deal with product safety and product information, and require that goods comply with product standards. The Act also contains provisions regarding the compulsory and voluntary recall of goods (for example, sections 65F, 65G, and 65R).

Section 53 is a key provision of the Act in relation to goods. In part, this section provides that a corporation shall not, in connection with the supply of goods, or possible supply of goods, or the promotion of the supply or use of goods:

- falsely represent that goods are of a particular standard, quality, value, grade, or composition, or have had a particular history or previous use; or
- make false or misleading representations concerning the need for any goods.

Essentially, the Act requires that goods are fit for their purpose and of merchantable quality.

### **Fair Trading Act 1999 (Victoria)**

The Victorian *Fair Trading Act 1999* mirrors a number of the provisions of the Commonwealth's Trade Practices Act. However, unlike the Commonwealth's legislation, the Victorian Act extends to individuals, rather than being limited to regulating corporations.

CAM practitioners are subject to the *Fair Trading Act 1999* which is concerned to promote and encourage fair trading practices and competition, and to protect consumers by regulating for the safety of goods and services, and the type of information that must be provided with goods and services that are supplied in trade or commerce. Like the Commonwealth's Act, the Victorian Act implies that goods and services must be fit for their purpose and of merchantable quality.

For the purposes of this report, the key provisions of the Act are:

- section 9: which prohibits misleading or deceptive conduct;
- section 10: which provides that a person must not, in trade or commerce, engage in conduct that is liable to mislead the public as to the nature, the manufacturing process, the characteristics, the suitability for their purpose, or the quantity of any goods;
- section 11: which provides that a person must not, in trade or commerce, engage in conduct that is liable to mislead the public as to the nature, the characteristics, the suitability for their purpose of any service; and

- section 12: which forbids false claims that goods or services are of a particular standard, quality, value, or grade or that they have performance characteristics, uses, or benefits they do not have, or make a false or misleading representation concerning the need for any goods or services.

### ***Health Services (Conciliation and Review) Act 1987 (Victoria)***

The *Health Services (Conciliation and Review) Act 1987* provides users of health services in Victoria with an independent and accessible mechanism to deal with their complaints about health services and the providers of health services. The Act establishes the Health Services Review Council and the Health Services Commissioner. Section 9 of the Act empowers the Health Services Commissioner to receive, investigate, and conciliate complaints from users of health services. The Health Services Commissioner is also able to investigate any matter referred to the Commissioner by either House of Parliament or by any committee of a House of Parliament.

The types of health services that fall under the purview of the Health Services Commissioner include services provided by practitioners of naturopathy, chiropractic, osteopathy, traditional Chinese medicine, and acupuncture. Dispensers of Chinese herbs are also covered.

Under each of the Victorian health practitioner registration Acts consumers are able to lodge complaints with the relevant health practitioner registration board regarding allegations of unprofessional conduct by a health practitioner. The boards are empowered to investigate such allegations and can make determinations. The boards have a range of powers—such as the imposition of fines, the stipulation of requirements for further education, the imposition of conditions on registration, and the cancellation of a practitioner’s registration. However, in relation to unregistered practitioners such as naturopaths and herbalists, if the Health Services Commissioner receives a complaint and the practitioner is unreceptive to conciliation, there are limited avenues available.

### **10.3.2 Laws protecting public health**

#### ***Health Act 1958 (Victoria)***

If a CAM practitioner conducts a business that involves acupuncture or any other process involving the penetration of the skin in a living human being, section 366C of the *Health Act 1958* requires that the premises from which the business is conducted be registered with the local council. However, a CAM practitioner is exempted from registration of the premises if the practitioner is registered as an acupuncturist under the *Chinese Medicine Registration Act 2000* or is authorised under another Act to use the title acupuncturist. A CAM practitioner is also exempted from registration of the premises if the business is prescribed in the *Health (Infectious Diseases) Regulations 1990* as an exempt business.

However, the Health (Infectious Diseases) Regulations require acupuncturists and others undertaking skin penetration to comply with infection control standards. These regulations relate to the state of the needles and the treatment environment. They do not address the competence of the practitioner.

### **10.3.3 Laws governing access to health information and the protection of privacy**

#### ***Privacy Act 1988 (Commonwealth)***

The Commonwealth’s privacy legislation sets minimum privacy standards that must be met by all private sector entities—including individual persons, corporations, partnerships, and unincorporated associations. Most small businesses with an annual turnover of \$3 million or less are excluded from these requirements. However, regardless of annual turnover, the legislation applies to all private sector health service providers.

According to the Office of the Federal Privacy Commissioner (2001), health services include:

- assessing, recording, maintaining or improving a person's health;
- diagnosing or treating a person's illness or disability; and
- dispensing of a prescription drug or medicinal preparation by a pharmacist.

For private sector providers of health services (including providers of CAM), the National Privacy Principles enshrined in the legislation set minimum standards for the handling of health information. These principles cover such issues as the collection, storage, maintenance, security, use, and disclosure of that information. The legislation also enshrines individuals' rights to personal information held in the private sector, and choices about how that information is handled.

### **Health Records Act 2001 (Victoria)**

Victoria has enacted legislation governing the protection of an individual's health information. Like the Commonwealth's Privacy Act, the Victorian *Health Records Act 2001* establishes privacy principles for the handling of health information collected in the provision of health services, and how that information is collected, used, disclosed, and accessed. The Act applies to all private sector providers of health services—whether corporate bodies or individuals.

The Act gives consumers a legally enforceable right of access to their own health information that is held by private sector health service providers. The *Freedom of Information Act 1982* (Victoria) provides a mechanism for individuals to seek access to their own health information held in the public sector.

The Health Services Commissioner is responsible for the administration of the legislation dealing with the privacy of an individual's health information under the *Health Records Act*.

### **10.3.4 Laws governing products**

The national framework for the regulation of all medicines, including CAM products, is the National Medicines Policy, responsibility for which rests with the Commonwealth Department of Health and Ageing (DHA 2000)<sup>2</sup>. This policy is based on principles of: (i) access; (ii) standards of quality, safety, and efficacy; (iii) quality use; and (iv) a responsible and viable industry. Standards set under the National Medicines Policy are applicable to all medicines (prescription and non-prescription), including complementary medicines.

#### **Therapeutic Goods Act 1989 (Commonwealth)**

Within the Commonwealth's regulatory framework sits the *Therapeutic Goods Act 1989*. The Therapeutic Goods Administration (TGA), an authority of the Commonwealth Department of Health and Ageing, administers the Act. The Therapeutic Goods Act, whose objectives are to ensure the quality, safety, efficacy, and timely availability of therapeutic goods supplied in, or exported from, Australia, came into effect in February 1991. With the commencement of the Act came a largely uniform, national system of control over therapeutic goods—effectively replacing the inconsistent controls that applied in various state and territory jurisdictions.

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<sup>2</sup> A treaty to establish a trans-Tasman agency to regulate all medicines, medical devices, dietary supplements and complementary and alternative health care products was signed by the Australian and New Zealand governments on 10 December 2003. The intention of the agreement is to harmonise the regulation of therapeutic products in both countries in accordance with the Trans-Tasman Mutual Recognition Arrangement—an agreement that seeks to develop a more integrated trans-Tasman economy by removing impediments to trade. It is expected that this joint scheme for the regulation of all therapeutic products in Australia and New Zealand will come into operation in July 2006 subject to the passage of legislation to give effect to the treaty. The trans-Tasman agency will replace the Australian TGA and the New Zealand Medical Devices Safety Authority (Medsafe). Under the trans-Tasman agency, new legislation will specify the controls applicable to therapeutic products in both countries. For Australia, that will mean the repeal of the Therapeutic Goods Act 1989 and regulations.

The Act defines a ‘therapeutic good’ in broad terms as a good that is represented in any way to be, or is likely to be, or is taken to be, for therapeutic use. Of particular relevance to CAM practice is that the Act defines ‘complementary medicines’ as therapeutic goods that consist wholly or principally of one or more ‘designated active ingredients’. For the purposes of the Act, an ‘active ingredient’ is the therapeutically active component in a medicine’s final formulation that is responsible for its physiological or pharmacological action. A ‘designated active ingredient’ is an active ingredient, or a kind of active ingredient, mentioned in Schedule 14 of the *Therapeutic Goods Regulations 1990 (Cth)*. An active ingredient can include herbal materials (see Appendix 10.1).

Each designated active ingredient has a clearly established identity, and has a traditional use or any other use as prescribed in the regulations. In this instance, ‘traditional use’ means use of the designated active ingredient that:

- is well documented, or otherwise established, according to the accumulated experience of many traditional healthcare practitioners over an extended period of time; and
- accords with well-established procedures of preparation, application, and dosage.

The Act explains that an example of traditional use is the use in traditional Chinese medicine.

#### **(i) Key provisions of the Therapeutic Goods Act**

A number of provisions of the Therapeutic Goods Act are directly relevant to the practice of CAM (see Appendix 10.2 for a transcript of these provisions). For instance, the Act is concerned with licensing manufacturers of therapeutic goods (Part 3-3), advertising and labelling standards (Part 5-1), and post-market surveillance and monitoring, including product tampering (Part 5-3).

##### ***Australian Register of Therapeutic Goods***

The Act also provides for the inclusion of therapeutic goods on the Australian Register of Therapeutic Goods. All medicines manufactured for supply in Australia must be included in the register unless specifically exempted or excluded. The purpose of the register is to compile information about, and provide for the evaluation of, therapeutic goods for use in humans (section 9A). Complementary medicines can be included on the register either as ‘listed’ goods or as ‘registered’ goods<sup>3</sup>. For a complementary medicine to be ‘registered’, independent clinical trials must show evidence of its efficacy and safety. For a complementary medicine to be ‘listed’, evidence of quality and safety (rather than efficacy) must be provided. According to the TGA, some complementary medicines are ‘registered’ but most are ‘listed’. There are approximately 16,000 complementary medicines included on the register (TGA 2004a).

##### ***Complementary Medicines Evaluation Committee***

The Act also provides for the establishment and operation of a Complementary Medicines Evaluation Committee. This committee of the TGA is concerned with the quality, safety, and efficacy of complementary medicines. The role of the committee is prescribed in

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<sup>3</sup> To assist sponsors of complementary medicines in the process of listing or registering their therapeutic goods, the TGA, in consultation with the Australian Self-Medication Industry and the Complementary Healthcare Council of Australia, developed the *Australian Regulatory Guidelines for Complementary Medicines*. The guidelines:

- provide information to help sponsors of complementary medicines to meet their obligations under therapeutic goods legislation;
- help ensure that applications to the TGA relating to complementary medicines meet all essential regulatory requirements so that applications can be processed successfully within minimum timeframes; and
- enhance clarity and transparency of processes leading to the registration and listing of complementary medicines in the Australian Register of Therapeutic Goods.

regulation 42ZE(1) of the *Therapeutic Goods Regulations 1990*, and includes the ability to evaluate and report to the relevant minister or secretary on any of the following:

- a complementary medicine;
- an ingredient in a complementary medicine;
- a kind of ingredient in a complementary medicine; and
- a therapeutic good specified by the minister or the secretary for the purposes of regulation 42ZE(1).

#### ***National Drugs and Poisons Schedule Committee***

The National Drugs and Poisons Schedule Committee (NDPSC) also has relevance for products used in the practice of CAM. The committee is established under section 52B of the *Therapeutic Goods Act* to make decisions about the classification of drugs and poisons. The decisions of the committee are contained in the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) and its Appendices. These decisions have no force in Commonwealth law but are taken as recommendations by the states; the decisions come into effect when the Schedules are adopted into state and territory legislation (TGA 2004b). The aim is to produce a uniform, national approach to the scheduling of medicines and poisons, thereby controlling who can legally access or supply various medicines and poisons across Australia.

The inclusion of substances in the SUSDP results in some restriction of prescribing so, for example, substances in Schedules 2–4 of the SUSDP may be prescribed only by specified registered health professionals. A growing number of medicinal herbs is listed on Appendix C of the SUSDP. This Appendix contains substances that are considered to be unsafe and once listed, all therapeutic use is illegal. The information used in the NDPSC deliberations is not made public.

State and Territory drugs and poisons legislation generally adopts the SUSDP and establishes restrictions on who may legally prescribe substances in different schedules. The SUSDP also contains model provisions regarding containers and labels. These provisions apply to herbs that are considered to have toxic effects.

#### **(ii) Strengthened powers of the TGA and amendments to the Therapeutic Goods Act**

Provisions to strengthen the regulatory framework and enhance the powers of the TGA were passed in 2003 in the wake of a recall of products produced by Pan Pharmaceuticals. This involved the recall of more than 1600 complementary medicines from the Australian marketplace, and was the largest recall of medicines to have occurred in Australia. It resulted from the failure of the manufacturer to maintain appropriate manufacturing and quality control standards. The amendments made to the *Therapeutic Goods Act* included: (i) increases in maximum penalties for some offences; (ii) new penalties for falsification of documents; (iii) expansion of compulsory public notification and recall provisions; (iv) a test for ‘fit and proper’ persons to hold a licence to manufacture therapeutic goods; (v) new statutory conditions of licence; (vi) requirements regarding maintenance of records and their availability for inspection; (vii) provisions for better identification of therapeutic goods; (viii) requirements for inclusion of manufacturer details on labels; and (ix) improvements for reporting of adverse events for listed goods (DHA 2004a).

In addition to the legislative changes, the Commonwealth government responded to the concerns of consumers, health professionals, and retail business proprietors about the implications of the recall. Their concerns effectively centred on ‘the reliance consumers can place on the information available about complementary medicines when they are not assessed for efficacy by the TGA, the education and training of practitioners, and the variability of regulation across jurisdictions’ (DHA 2004b). The government’s response was to establish an Expert Committee on Complementary Medicines in the Health System (hereafter called the Expert Committee). This committee was provided with terms of reference to examine and provide advice on: (i) regulatory controls covering standards of quality, safety, and efficacy for complementary medicines; (ii) consumer information; (iii) training and education of healthcare practitioners; (iv) interactions between complementary

and prescribed medicines; (v) restrictions on advertising; and (vi) activities to promote an innovative, responsible, and viable industry.

The Expert Committee (2003 p. 20) noted that not all states have adopted legislation that mirrors the Commonwealth *Therapeutic Goods Act*. Without this, traders can manufacture therapeutic goods that are exempt from the Act, and companies operating in this manner can adopt lower standards that are inappropriate to the level of risk associated with the goods. The Expert Committee recommended nationally consistent legislation.

### **(iii) Regulation of raw herbs**

Raw herbs and some other starting materials are not subject to TGA assessment for quality, safety and efficacy (Expert Committee 2003 p.19). Some raw herbs are grown in Australia but many are imported and these are sourced from numerous countries including China, India, Europe and the USA. Bensoussan and Myers (1996) contended that the lack of regulatory coverage in this area poses a potential public health risk.

Further concern arises from that fact that because these products do not fall within the regulatory purview of the TGA, the TGA in turn is unable to give any direction to the Australian Quarantine Inspection Service (AQIS) regarding the instigation of an active surveillance program. These products therefore enter the Australian marketplace and are consumed as therapeutic substances without any quality assessment. The onus is on the practitioner who purchases and dispenses such products to ensure correct identification of the product, and to ensure that it is free from adulteration and contamination. In light of these concerns, Bensoussan and Myers (1996) recommended that the TGA and AQIS work in liaison with state authorities to resolve the question of responsibility for raw medicinal herbs used for therapeutic purposes.

The Expert Committee (2003 p.19) recommended a 'review of the controls for raw herbs and other starting materials used in dispensed and extemporaneously compounded complementary medicines to ensure that they meet appropriate standards of quality and safety'. The TGA commissioned a review in 2004 and the report has been reviewed by the Australian Health Ministers' Advisory Council, which acknowledged the concerns and endorsed continued development of appropriate regulation.

### **(iv) Relationship between the Therapeutic Goods Act and food standards legislation**

Some complementary medicines (such as herbs) can also be categorised as food. Definitions in section 3 of the Commonwealth's *Therapeutic Goods Act* (see above) determine whether a product is a food or a medicine. According to the Act, if there is no prescribed standard in the Australia New Zealand Food Standards Code, and there is no tradition of use as a food in the form presented, the goods are most likely not a food.

Products that might be classified as either a food or a medicine are referred to the External Reference Panel on Interface Matters (ERPIM) for determination. The membership of ERPIM is comprised of representatives from Food Standards Australia New Zealand (formerly the Australian New Zealand Food Authority), the TGA, state, territory, and New Zealand health authorities, AQIS, industry, and consumers (Expert Committee 2003). ERPIM recommends whether goods should be regulated as a therapeutic good or as a food. An example of a product that fits within the definition of either a food or a medicine is a clove of garlic. A clove of garlic is a food, but if it is concentrated and marketed in capsule form, with claims that it can be used to relieve the symptoms of upper respiratory tract infections, it is treated as medicine. The product's principal use is a primary consideration in determining whether it is a food or a medicine. Raw herbs are in a similar category to a clove of garlic. General guidelines published by the TGA (2004c) and Section 7 declarations (see below) made under the *Therapeutic Goods Act* also provide guidance for consumers, food and medicines industries, and regulators in determining whether a product is a food or therapeutic good.

A Section 7 declaration under the *Therapeutic Goods Act* enables the Secretary of the Commonwealth Department of Health and Ageing to declare that particular goods or classes of goods are or are not therapeutic goods. Goods or classes of goods that are declared to be

therapeutic goods must be included on the Australian Register of Therapeutic Goods. Therapeutic goods include goods declared to be therapeutic goods under section 7 of the Act, even if they are also goods for which there is a prescribed standard in the *Australian New Zealand Standards Code*.

### ***Therapeutic Goods Act 1989 (Victoria)***

The *Therapeutic Goods Act 1989* (Victoria) complements Commonwealth legislation regulating therapeutic goods. The Victorian legislation covers products and manufacturers not encompassed by Commonwealth controls—for example, unincorporated manufacturers who do not trade interstate.

The Victorian Act provides for the independent assessment of a manufacturer's data before goods are marketed, and requires compliance with good manufacturing practice and standards for therapeutic goods.

### ***Drugs, Poisons and Controlled Substances Act 1981 (Victoria)***

Amongst other matters, provisions of the *Drugs, Poisons and Controlled Substances Act 1981* enable the State of Victoria to adopt the Commonwealth's Standard for the Uniform Scheduling of Drugs and Poisons (discussed above). Under the Act, a Poisons Code has been prepared by the Minister for Health which contains a Poisons List and incorporates provisions of the Standard for the Uniform Scheduling of Drugs and Poisons governing labelling, storing, packaging and advertising of poisons and controlled substances. The Poisons List contains the nine schedules of the Standard for the Uniform Scheduling of Drugs and Poisons and a list of exemptions from these schedules as well as a list of substances that are not for general retail sale.

As noted above (see National Drugs and Poisons Schedule Committee), herbs listed on Appendix C of the national SUSDP cannot be prescribed for any therapeutic purpose. Appendix C, which is currently the listing destination for herbs deemed unsafe by the National Drugs and Poisons Schedule Committee, is also usually incorporated into state and territory drugs and poisons legislation.

State and territory legislation defines who has access to the Schedules. Substances in Schedules 2—4 can only be prescribed by specified registered health practitioners. Naturopaths and WHM practitioners are not recognised as health practitioners under this legislation. Because these professions are not subject to statutory regulation, practitioners cannot be differentiated from lay persons.

However, the Victorian Act provides a mechanism (not yet implemented) that will authorise any Chinese medicine practitioner or Chinese herbal dispenser who is registered under the *Chinese Medicine Registration Act 2000* to obtain, have in his or her possession, use, sell, or supply any Schedule 1 poison in accordance with the lawful practice of his or her profession (section 13).

The Act also provides that a registered Chinese medicine practitioner will be prohibited from selling or supplying a Schedule 1 poison, unless:

- the poison is for the therapeutic use of a person who has consulted the practitioner; and
- the practitioner has taken all reasonable steps to ensure that the person has a therapeutic need for the Schedule 1 poison.

A regulated Chinese herbal dispenser will only be able to sell or supply a Schedule 1 poison on production of, and in accordance with, an original written prescription or order of a regulated Chinese medicine practitioner, and only after he or she has taken reasonable steps to ensure that the prescription or order is in accordance with any endorsement of the registration of the registered Chinese medicine practitioner.

To assist in the implementation of the provisions of the *Drugs, Poisons and Controlled Substances Act*, the Victorian government issued the *Drugs, Poisons and Controlled Substances Regulations 1995*. The objectives of the regulations include:

- to facilitate and enhance the orderly sale, supply, prescribing, administering, dispensing, and use of drugs, poisons, and controlled substances by health professionals, authorised persons, licensed or permitted persons, and the general public; and
- to implement national recommendations regarding the advertising, sale, supply, use, packaging, and labelling of drugs and controlled substances.

The Expert Committee (2003 p.20) noted that CAM practitioners with appropriate levels of professional education should have access to some restricted substances, and that an appropriate SUSDP Schedule could be used nationally. The Committee recommended that all State and Territory governments to adopt nationally consistent therapeutic goods legislation and a nationally consistent system of access (Scheduling) to medicines (Expert Committee p.20).

### **10.3.5 Statutory registration of CAM practice**

As in other states and territories, several health practitioner registration Acts in Victoria require health professionals to be registered with a relevant professional registration board. These Acts apply to nurses, optometrists, physiotherapists, dentists, podiatrists, psychologists, pharmacists and medical practitioners. CAM providers with statutory registration in Australia are chiropractors and osteopaths (all states and territories), and Chinese medicine practitioners (Victoria only).

Registration Acts are of relevance to naturopaths or WHM practitioners if they also have another healthcare profession and are registered under the Act governing that profession.

The registration boards are statutory entities that are independent of government. Their memberships are structured such that the majority of members (all of whom are appointed by government) of each board is drawn from the relevant profession.

The primary purpose of registration under these Acts is to protect the public from significant harm, rather than protecting the interests of the profession that is regulated. The Acts allow the members of a profession to use any relevant titles, but prohibit people who are not registered practitioners from claiming to be so. In addition, the Acts require practitioners to comply with educational standards and standards of professional practice. The Acts also apply restrictions on advertising and prohibit registered health professionals from making false or misleading representations.

The *Chinese Medicine Registration Act 2000* (Victoria) applies to practitioners of traditional Chinese medicine, dispensers of Chinese herbs, and acupuncturists—who must be registered under the Act if they are to offer such services to the public in Victoria. This Act established the Chinese Medicine Registration Board with powers and functions that include: (i) the regulation of standards of practice; (ii) the registration of suitably qualified persons; and (iii) the assessment and approval of courses providing qualifications for registration purposes. If WHM practitioners or naturopaths wish to use any of the titles protected by the Victorian *Chinese Medicine Registration Act*, they must register under that Act. In doing so, they must comply with designated levels of qualification and experience, and with designated standards of practice.

In its report, the Expert Committee also considered the regulation of CAM practitioners and recommended that all States and Territories should ‘move quickly to implement statutory regulation where justified’ (2003 p.130). (See Appendix 10.3 for an excerpt from the Expert Committee’s recommendations on the regulation of practitioners).

## **10.4 International legislative controls over CAM practitioners and products**

A review of international jurisdictions reveals that there is a growing trend towards the regulation of CAM practice. This regulation is being achieved through various models which, although their nomenclature may differ across different jurisdictions, can generally be described in terms of the six general models of regulation that exist in Australia, namely:



- *Self-regulation* – Under this model a practitioner is not required by law to be registered with a statutory body. Instead, a practitioner’s voluntary membership of a professional association indicates that the practitioner is ‘...suitably qualified, safe to practise and subject to a disciplinary scheme’ (DHS 2003 p. 20).
- *Negative licensing* – Under this model a practitioner may practise ‘...in a self regulated profession unless [that practitioner is] placed on a register of persons who are ineligible to practise’ (DHS 2003 p. 20) because of prior poor practice.
- *Co-regulation* – Under this model members of a professional association are regulated by that association and government.
- *Reservation of title only* – Under this model a statutory registration board registers members of a profession by establishing ‘...qualification and character requirements for entry to the profession’ (DHS 2003 p. 20) and reserves the use of specific titles for those who are registered. If a practitioner is unregistered or is deregistered by the board, that practitioner could not use a reserved title without risking prosecution.
- *Reservation of title and core practices* – ‘Under this model certain risky and intrusive acts or procedures within the defined scope of practice of a profession are restricted via legislation only to members of the registered profession and other registered health professions identified in legislation’ (DHS 2003 p. 20). Practitioners who are either unregistered or unauthorised (but registered) risk prosecution if they use reserved titles or conduct any of the reserved core practices.
- *Reservation of title and whole practice restriction* – This model not only restricts the use of reserved titles but broadly defines the scope of practice of a profession and prohibits unregistered practitioners from practising the profession (DHS 2003 p. 20).

Some of the examples of the regulation of CAM practice that have been drawn from international jurisdictions include the following:

- In the UK, work is underway to introduce statutory regulation that would include standards being set by a registration authority and restrictions on the use of certain titles (known in Australia as the *Reservation of title only* model) for practitioners of acupuncture and herbal medicine and for the introduction of voluntary self-regulation (known as self-regulation in Australia) for practitioners of other CAM practices such as homeopathy and aromatherapy (Department of Health UK 2004b, 2005).
- In Ontario, Canada, naturopaths have been regulated under the *Drugless Practitioners Act* since 1925. The Health Professions Regulatory Advisory Council in Ontario in 1996 and again in 2001 recommended that naturopaths should be governed under the *Regulated Health Professions Act 1991* along with all other regulated health professions in that province (Health Professions Regulatory Advisory Council 2001). The *Drugless Practitioners Act* and *Regulated Health Professions Act* regulate respective practitioners under what is commonly known in Australia as the *Reservation of title and whole practice restriction* model.
- In British Columbia, Canada, naturopaths and practitioners of Traditional Chinese Medicine and acupuncture are governed under the *Health Professions Act 1996* by profession-specific colleges (licensing authorities) that have been established by the government.
- In the USA, 13 states and two territories have licensing laws for naturopaths (Appendix 10.4). There are no independent certifying bodies for herbalists in the USA, and herbal medicine is regulated as part of naturopathic medicine.

#### 10.4.1 European Union

Fundamental differences in legal structures have influenced developments in the regulation of CAM professionals in the various member states of the European Union (EU). In common law countries, such as the UK and the Republic of Ireland, a *laissez-faire* approach to CAM regulation has enabled practitioners to practise their therapies freely. This has encouraged the growth of CAM practice and education. In contrast, governments in member states that are

governed by legal codes (civil states) impose more controls on health activities (Mills 2001). This fragmented approach across the European Union is now being challenged as a result of concerns about public health, principles of free movement of workers, and goals of harmonisation in the EU (McIntyre 2001).

### **Common law states of the EU**

In common law states (such as the UK and Ireland), most CAM practitioners currently function under a system of ‘voluntary self-regulation’—with no legal protection of title or function, and no state recognition of a professional register or educational standards<sup>4</sup>. CAM practitioners can therefore practise without training, without affiliation with a registration body, and without professional indemnity insurance. The absence of practice-specific legislation has provided these practitioners with the freedom to pursue their vocations with minimal interference from the state and permitted CAM practice to flourish (Mills 2001).

In spite of the lack of statutory regulation of CAM practitioners, many professional associations are organised along conventional lines, publish formal codes of ethics and practice, and maintain registers that are open to the public (Mills 2001). However, although many practitioners have professional indemnity insurance, complaint and disciplinary procedures appear to be variable, even among the well-established CAM professions. Market forces are the main form of discipline (Mills 2001).

Private law remedies are available to the patient or consumer because the common law imposes a duty of care on CAM practitioners; a breach of the duty of care can be the basis of an action for negligence (Weir 2000). There may also be a contractual relationship between a CAM practitioner and the patient/consumer that is legally enforceable (Weir 2000).

However, even in a common law environment, practitioners have some statutory obligations to meet. They must comply with the criminal law, health and safety workplace Acts, food safety Acts, and consumer protection laws (House of Lords’ Select Committee 2000). Furthermore, the operation of a series of profession-specific statutes (discussed below) prevents CAM practitioners from:

- prescribing medicines that are classified as regulated prescription drugs;
- treating cancer, diabetes, epilepsy, glaucoma, and tuberculosis; and
- using professional titles that are regulated (for example, implying, or claiming to be, or practising as a medical practitioner or dentist).

Nevertheless, as the House of Lords’ Select Committee (2000, paragraph 5.9) noted: ‘... although statutory regulation can award a therapy protection of title, it cannot stop anyone utilising the methods of that therapy under a slightly different name’.

### **Statutory regulation of health professionals**

Of all of the CAM professions practising in the UK, only osteopathy and chiropractic are regulated by statute. Together with medicine, nursing and midwifery, dentistry, pharmacy, and optics, these professions are ‘recognised, and protected by statute, with only people registered within a statutory registration scheme enjoying professional privileges’ (Stone & Matthews 1996).

The statutory framework that applies to all mainstream health professions, as well as the alternative disciplines of osteopathy and chiropractic, is based upon a primary profession-specific statute (such as the *Medical Act 1983*). Such a primary statute establishes:

- a single register of people entitled to practise a particular profession, and
- protection of title.

Such a primary statute also delegates rule-making responsibility to a profession-specific council (such as the General Medical Council), which consists mainly of members of the particular profession. These councils govern members of the profession through education

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<sup>4</sup> In Australia, this is known as ‘self-regulation’ and is the system that applies to all CAM practitioners in Australia, with the exception of Chinese Medicine practitioners in Victoria and the practices of chiropractic and osteopathy in every Australian state and territory.

committees (which specify educational and training requirements for entry to the profession) and disciplinary committees (which investigate charges of professional misconduct and develop codes of practice and ethics). This form of regulation, whereby each profession regulates itself under a statutory scheme, is known as ‘statutory self-regulation’ (in Australia, this is more commonly known as statutory registration).

Each health profession also has a peak professional body (such as the British Medical Association) which also plays a role in setting standards and policy development.

In 2001, the Report of the Bristol Royal Infirmary Inquiry (the ‘Kennedy Report’) recommended the addition of another tier of regulation to the existing system operating in the UK for healthcare professions (Bristol Royal Infirmary Inquiry 2001). The Council for the Regulation of Healthcare Professionals (Department of Health UK 2005b) was therefore created to oversee the activities of the various regulatory bodies of the healthcare professionals (that is, the profession-specific councils such as the General Medical Council). The Council for the Regulation of Healthcare Professionals coordinates good practice guidelines and encourages regulatory bodies to act in the best interests of patients. The council also oversees the activities of each professional council and coordinates a framework for regulating health professions that prioritises the interests of patients and ensures transparency and consistency (British Medical Journal 2002).

Several health professions (such as dieticians and occupational therapists) have affiliations with their own professional bodies, but are regulated by the Health Professions Council (as opposed to profession-specific councils). (See Appendix 10.5 for a list of these health professions and their respective regulators and professional bodies.)

The Health Professions Council is an independent regulatory body in the UK which is responsible for setting and maintaining standards of professional training, performance, and conduct of the 13 healthcare professions within its jurisdiction (Health Professions Council 2005). Since July 2003 all health professionals registered with the Health Professions Council have been given title protection.

### **Recent developments in the UK**

UK legislation and policies governing health professions have been under review during the past decade. Several regulatory initiatives have been introduced that prioritise public safety, greater transparency, and accountability.

The House of Lords’ Select Committee on Science and Technology was established as a result of concern that the increasing use of CAM raised public health issues. The committee adopted the term ‘complementary and alternative medicine’—rather than ‘traditional medicine’, ‘natural medicine’, ‘non-conventional medicine’ or ‘holistic medicine’—to accommodate therapies that work alongside conventional medicine, act as a substitute to conventional medicine, and purport to offer diagnostic skills as well as therapy. However, the committee avoided the problem of formulating an exact definition of CAM, and classified these therapies and disciplines as set out in Table 10.3.

In reviewing the current regulatory regime governing the practice of CAM, the committee noted that the osteopathic and chiropractic professions are regulated by statute (see above) and recommended that a similar statutory self-regulation framework be established for herbal medicine and acupuncture. The committee suggested that similar steps might eventually be appropriate for non-medical homeopaths. This recommendation was based upon the possibility of harm that could arise in the provision of these services, their existing robust voluntary self-regulation systems (essential for the working of a regulatory body), and their credible evidence base (House of Lords 2000).

**Table 10.3 Classification of therapies and disciplines (House of Lords 2001)**

Group 1: Professionally organised alternative therapies.	Group 2: Complementary therapies	Group 3: Alternative disciplines
Osteopathy	Aromatherapy	(a) Long-established traditional disciplines: anthroposophical medicine; ayurvedic medicine; Chinese herbal medicine, naturopathy, traditional Chinese medicine
Chiropractic	Alexander technique	(b) Alternative disciplines without any credible evidence base: crystal therapy; dowsing; iridology; kinesiology; radionics
Herbal medicine Acupuncture	Bach remedies and other flower extracts Body work therapies including massage, counselling, stress therapy	
Homeopathy	Hypnotherapy Meditation Reflexology Shiatsu Healing Maharishi ayurvedic medicine Nutritional medicine Yoga	

The committee also recommended that the numerous professional associations should make strong efforts to amalgamate and develop a clear structure, and that bodies representing other healthcare providers (such as doctors and nurses) should set standards for CAM practice that are comparable to those set by relevant CAM regulatory bodies to ensure patients receive high standards of care. The committee suggested that professional associations need to develop essential clinical guidelines on such matters as how to deal with patients who do not have a medical diagnosis (Mills 2001).

The disciplines categorised as ‘professionally organised alternative therapies’ (see Table 10.3, Group 1) adopt an individual diagnostic approach, and are better organised than other CAM disciplines operating in the UK. In addition, the UK is the only country in the EU in which public sector hospitals provide CAM and in which medical practitioners work with CAM practitioners in the National Health System (NHS) (World Health Organization 2001). Therapies classed in Group 1 are those that are provided in the public sector (NHS) in addition to the private sector.

Disciplines classed as ‘complementary therapies’ (see Table 10.3, Group 2) also have NHS support, and are used as complementary therapies to conventional medicine (but without embracing diagnosis). Research and regulatory structures are not highly developed among these therapies.

‘Alternative disciplines’ (see Table 10.3, Group 3) are regarded as having no evidence base for clinical effectiveness. Naturopathy is included in this group. Although the committee recognised the long-established tradition of naturopathy and its claims to diagnostic information and treatment, the committee was not prepared to endorse statutory regulation for naturopathy. The committee believed that statutory regulation should not be offered to naturopathy and the other disciplines in Group 3 unless and until these therapies were able to produce convincing research evidence of efficacy, based on the results of well designed trials. However, the Select Committee ‘did not carry out a detailed examination’ (House of Lords 2000, paragraph.4.15) of the research available for naturopathic modalities such as nutrition (see Chapter 3 of the present report).

### **Proposed regulatory models for herbal medicine and acupuncture in the UK**

In 2003, the UK’s Herbal Medicine Regulatory Working Group (HMRWG) and the Acupuncture Regulatory Working Group (ARWG), published reports commissioned by the UK Department of Health.

The ARWG report recommended that the acupuncture profession should establish a freestanding self-regulating acupuncture body to deal with the urgent need for professional unity. The report also mooted the possibility of future collaboration with herbal medicine (Department of Health UK 2003a).

The HMRWG report (Department of Health UK 2003b) suggested two regulatory options for practitioners of herbal medicine:

- the establishment of a ‘herbal council’ that would reflect the goals of practitioners in this field and would increase the status of herbal medicine (an option viewed by the HMRWG as costly); or
- the establishment of a shared ‘CAM council’.

Details of these two options are contained in Appendix 10.6.

Subject to further research on efficacy and safety of WHM, the HMRWG favoured the second option for the following reasons (Department of Health UK 2003b).

- A register of practitioners could be maintained, and it would be possible to have separate sections of the register for the different herbal traditions (see below) and for acupuncture.
- A single regulatory framework would be more cost effective.
- A larger council would be more influential and better equipped to protect the interests of patients and practitioners.

In this context, the traditions of WHM, Chinese herbal medicine, Tibetan herbal medicine, and ayurveda are recognised in the UK as four separate groups (Department of Health UK 2003b). In 1864, UK herbalists organised themselves into the National Association of Medical Herbalists (subsequently it became an Institute) hoping that they could attain a professional status similar to medical practitioners who achieved professional unity in the mid-nineteenth century. In 1993, the European Herbal Practitioners Association (EHPA) was formed. It has been actively working towards improving the regulation of herbal medicine in the UK (EHPA 2001).

The HMRWG anticipated that the proposed 'CAM council' would perform the following functions:

- maintain a register of practitioners;
- provide advice on licensing arrangements for other health professionals using herbal products or medicines;
- determine minimum levels of education, training, and competence;
- determine a curriculum that would identify a body of knowledge and training and include a specific element for each herbal tradition; and
- control accreditation.

The HMRWG suggested organisational structures for both a 'herbal council' and a 'CAM council' that would include statutory committees paralleling other statutory healthcare councils. These committees would include an investigating committee, a professional conduct and competence committee, a health committee, and an education and training committee (Department of Health UK 2003b).

The Department of Health considered the recommendations of both the HMRWG and ARWG reports, and advised that it favoured the recommendation of the HMRWG to establish a shared 'CAM council' for herbal medicine and acupuncture (Department of Health UK 2004a). At the time of writing, work was underway in the UK to introduce statutory regulation that would include standards being set by a registration authority and restrictions on the use of certain titles (known in Australia as the *Reservation of title only* model) for practitioners of acupuncture and herbal medicine and for the introduction of voluntary self-regulation (known as self-regulation in Australia) for practitioners of other CAM practices such as homeopathy and aromatherapy (Department of Health UK 2004b, 2005b).

### **Civil states of the EU**

The individual member states of the EU have responsibility for the regulation of healthcare within their own jurisdictions. The European Commission's five year project on alternative medicine (see Appendix 10.7) identified three approaches to the regulation of CAM practitioners in the European Union:

- monopolisation system;
- tolerant system; and
- mixed system (Stepan 1985).

#### **Monopolisation system**

Under a monopolisation system, only 'the practice of modern, scientific medicine by professionals is recognised as lawful'. Sanctions are levelled against all other forms of healing practitioners (Monckton 1999). This system has been adopted in Austria, Belgium, Greece, Iceland, Italy, Latvia, Luxembourg, Malta, Poland, Portugal, Spain, Ukraine, and France.

The WHO (2001, pp 93–4) described the situation in France in the following terms.

...persons other than licensed allopathic physicians who habitually or continuously diagnose or treat illnesses, real or supposed, or who perform activities constituting medical procedures are illegally practising medicine. Persons wishing to obtain a licence to practise medicine must possess a State certificate; hold French, Tunisian, Moroccan, or European Union citizenship; and be registered by the professional society of physicians.

Despite prosecution, non-allopathic practitioners—particularly physiotherapists using complementary/alternative methods such as chiropractic and osteopathy—continue to practise, and the number of allopathic physicians using complementary/alternative medicine is increasing. Allopathic physicians providing complementary/alternative treatments either assist persons practising medicine illegally or practise complementary/alternative medicine themselves. ...Recent decisions, however, suggest that the courts are becoming more tolerant towards the practice of complementary/alternative medicine.

Acupuncture and homeopathy are the only CAM therapies to have been recognised in France, but they may be practised only by registered medical practitioners. O'Sullivan (2002) reports that medical practitioners who practise other CAM therapies, and CAM practitioners who are not medically qualified, appear to be in a legal limbo.

### **Tolerant system**

Under a 'tolerant system', only 'the system based on modern, scientific medicine is recognised, although, at least to some extent, the practitioners of various forms of complementary medicines are tolerated by law' (Monckton 1999). Germany has adopted this system and the WHO (2001, pp. 95–6) explains that

In Germany, there is no legal monopoly on the practice of medicine. Thus, licensed non-allopathic physicians may practise medicine, and all licensed medical practitioners are allowed to use complementary/alternative medicine.

There are, however, some restrictions on the performance of particular medical acts. Only allopathic physicians and dentists are allowed to practise dentistry. Only allopathic physicians are allowed to treat sexual diseases, treat communicable and epidemic diseases, deliver specific medications, give or provide anaesthetics and narcotics, practise obstetrics and gynaecology, take X-rays, perform autopsies, and deliver death certificates. In order to obtain a title as an allopathic physician, a person must have an academic degree in medicine, practical experience, a licence from public authorities, and a medical certificate confirming that there are no indications of physical or mental disability or addiction to drugs.

Licensed Heilpraktikers ('health practitioners') may practise medicine with the exclusion of these specific medical acts. To qualify for a Heilpraktiker's licence, a candidate must be at least 25 years old, have German or European Union citizenship, have completed primary school, have a good reputation in order to guarantee a normal professional practice, have a medical certificate confirming that there are no indications of physical or mental disability or addiction to drugs, and pass an examination before a health commission proving that the candidate has sufficient knowledge and ability to practise as a Heilpraktiker and that the candidate's treatments do not negatively affect public health.

### **Mixed system**

Under a mixed system, only 'health care professionals are allowed to perform specific medical acts and the violation of this limited monopoly results in an offence (monopolistic characteristic). For the remaining medical acts, persons who are not qualified as a physician are tolerated (tolerant characteristic)' (Monckton 1999). This system has been adopted in Finland, Hungary, Norway, Sweden, and Denmark.

The WHO (2001, pp. 89–90) reports that in Denmark:

...allopathic physicians holding an academic degree in medicine, having taken the Hippocratic Oath before a Faculty of Medicine, and authorized by the National Health Service are not restricted as to the medical techniques they may use. The title of "Physician" is protected and only licensed allopathic physicians may call themselves such. Public sector medical positions are reserved for authorized doctors.

Two laws regulate the practice of complementary/alternative medicine. The Medicine Act legislates the making and marketing of natural remedies and includes criteria for packaging, providing information to patients, and advertising. The Practice of Medicine Act of 1970 permits non-allopathic physicians to practise medicine regardless of their training and without previous authorization. However, non-allopathic physicians are not recognized as official health care

providers, their titles are not protected, and they are not integrated into the national health care system.

...non-physicians may not perform specific medical acts that are reserved for licensed allopathic physicians, nor are they permitted to use needles except under the supervision of an allopathic physician. The medical acts reserved for licensed physicians are the following: treating persons for venereal diseases, tuberculosis, or any other infectious disease; performing surgery; administering general or local anaesthetics; providing obstetric aid; applying medicines that may be dispensed only with a physician's prescription; using X-ray or radium treatments; or practising therapies using electric machines. Violation of this limited monopoly is punishable by up to 12 months in prison. However, non-allopathic practitioners are only prosecuted for selling harmful products, otherwise exposing patients to a provable danger, or causing the serious deterioration or death of their patients. Chiropractors are the exception to this law. Whenever patients consult a chiropractor without an allopathic physician's referral, the chiropractor must inform the patient's practitioner of the diagnosis and treatment, whether the practitioner is an allopathic physician or not.

In Switzerland, all three systems are represented—with each canton having its own regulation.

In the Netherlands, CAM practitioners are no longer considered illegal, but they are not formally regulated. The approach in the Netherlands has been based on voluntary self-regulation with a particular focus on the development of quality assurance. A quality framework has been established for CAM practitioners. This framework includes 36 criteria governing matters such as registration, education and training, practice guidelines, codes of conduct and complaints procedures (O'Sullivan 2002).

### **Recent EU developments**

In 2004 the European Parliament introduced the Traditional Herbal Medicinal Products Directive, a significant step in the harmonisation of the regulation of herbal medicines in Europe and the UK. Under this Directive regulation should address safety and quality rather than efficacy. Safety must be supported by at least 15 years use in the community (Dawson 2005). In the UK, where a system for the statutory regulation of herbalists is under development, proposed regulatory changes should 'ensure access to quality preparations prescribed and supplied by registered practitioners' (Dawson 2005).

The European Parliament has encouraged the European Union to evaluate, regulate and include CAM medicines because of high consumer interest, lack of clear regulations, and the highly divergent approaches of the member states (Ahern 2002). Because of the difficulty in developing equivalent regulatory approaches across states, professional recognition may be sought at the European level, and redress under the EU principle of the free movement of workers (Ahern 2002).

In summary, Monckton (1999) explains that in the EU member states:

... even if the free movement of physicians is relatively effective, alternative therapists/non-physicians do not have this freedom. Indeed, while they may be legally recognised in their country, they are not allowed to provide treatments throughout the European Union.

## **10.4.2 New Zealand**

### ***Health Practitioners Competence Assurance Act 2003***

The regulation of health professionals in New Zealand was completely restructured with the commencement of the *Health Practitioners Competence Assurance Act 2003* in September 2004. The Act has repealed eleven profession-specific statutes that governed 13 health professions, and has established a single overarching framework to regulate these health practitioners. In addition to legislation governing practice, all health practitioners are subject to criminal laws, various codes (such as the Code of Health and Disability Consumers' Rights), local council regulations, and civil litigation. Health practitioners are also subject to a number of other statutes—including the *Health and Disability Commissioner Act 1994*, *Medicines Act 1981*, *Fair Trading Act 1996*, *Consumer Guarantees Act 1993*, and *Food Act 1981*.



The *Health Practitioners Competence Assurance Act 2003* also provides for a process to enable health practitioners who were unregulated before its commencement (such as acupuncturists, herbal medicine practitioners, naturopaths, and traditional Chinese medicine practitioners) to make application to become registered.

The principal purpose of the Act is to protect the health and safety of the public. It is designed to ensure that regulated health practitioners are competent to practise their professions for the duration of their professional lives (section 3). The Act provides for the appointment of authorities to be responsible for the registration and regulation of specific health practitioners (section 11) and prohibits anyone from claiming to be a health practitioner if he or she is not registered (section 7). The Act also requires that registered health practitioners practise within the scope of practice of their professions unless permitted to practise outside that scope by registration, or in the event of an emergency, or for educational or assessment purposes (section 8). In addition to a health practitioner's practice being limited to the scope of practice for a profession, the Act also provides for certain activities to be restricted to particular health practitioners (section 9).

The Act enables each authority to establish a professional conduct committee to investigate complaints referred to the authority by the Health and Disability Commissioner and certain offences committed by health practitioners. The Act also provides for a single tribunal, the Health Practitioners Disciplinary Tribunal, to hear and determine charges brought against practitioners by other bodies—for example, a professional conduct committee (*Health Practitioners Competence Assurance Act 2003*, Part 4).

### **Regulation of CAM practitioners**

Before 2003, the only statute specifically regulating CAM professionals was the *Chiropractors Act 1982* (NZRBS 2005). However, with the commencement of the *Health Practitioners Competence Assurance Act 2003*, the *Chiropractors Act 1982* was repealed.

Voluntary, self-regulating associations govern other CAM therapies. These include the umbrella organisation, the New Zealand Charter of Health Practitioners Inc., which represents approximately 80% of New Zealand's CAM practitioners (NZCHP 2005), and professional associations that generally require members to hold some specific qualifications. However, membership by a practitioner is voluntary. Examples of the professional associations include: the Naturopathic College of New Zealand Inc., New Zealand Association of Medical Herbalists, New Zealand Council of Homeopaths, Society of Naturopaths, South Pacific Association of Natural Therapists Inc., and South Pacific College of Natural Therapeutics Inc.

### **Recent developments in New Zealand**

In 2001, the Ministerial Advisory Committee on Complementary and Alternative Health (MACCAH) was established to advise the Minister of Health on matters related to CAM (MACCAH 2003).

MACCAH's April 2003 discussion document (MACCAH 2003, p 2), quoting O'Connor et al. (1997), defined CAM as:

... a broad domain of healing resources that encompasses all health systems, modalities, and practices and their accompanying theories and beliefs, other than those intrinsic to the politically dominant health system of a particular society or culture in a given historical period. CAM includes all such practices and ideas self-defined by their users as preventing or treating illness or promoting health and well being.

Two key tasks that have particular relevance to CAM professionals were assigned to MACCAH (2003):

- to provide advice on the need (or otherwise) to regulate CAM practitioners in order to protect consumers who use these services; and
- to provide advice on whether, and how, specified CAM practitioners should be integrated into the mainstream health system.

The MACCAH's three year term ended with its final report being delivered to the Minister of Health in June 2004 (MACCAH 2004). The report contained eighteen recommendations, including that:

1. Practitioners of complementary and alternative health should be regulated according to the level of inherent risk involved in the modalities they practise.
2. The process of regulating practitioners of high risk CAM modalities should continue under the Health Practitioners Competence Assurance Act 2003.
3. Practitioners of lower risk CAM modalities should be encouraged to self-regulate through their professional body.
4. Practitioners (either biomedical or CAM) who practise one or more CAM modalities should undertake training and monitoring that is appropriate to the risk of each CAM modality (MACCAH 2004 p.5).

### **Therapeutic products**

Therapeutic products are categorised as medicines, dietary supplements, or foods, and are regulated under legislation. The categorisation depends on the nature of the product and the wishes of the manufacturer. Examples include:

- *Consumer Guarantees Act 1993*: which gives consumers rights of redress against suppliers and manufacturers in respect of any failure of goods or services to comply with any guarantees given. Sections 6, 7, and 8 are of particular relevance to CAM products. They deal with guarantees concerning acceptable quality (sections 6 and 7), fitness for a particular purpose (section 8), and the compliance of goods with their description.
- *Fair Trading Act 1986*: which contains provisions dealing with misleading conduct in relation to goods (section 10) and false representations (section 13).
- *Food Act 1981*: which includes provisions relating to misleading labelling and packaging (section 10) and restrictions on advertising.
- *Food Regulations 1984*: which establish general labelling requirements for food, and general standards for vitamins and minerals. The regulations also cover food additives and the protection and safety of food.
- *Dietary Supplements Regulations 1985* (made pursuant to section 42 of the *Food Act 1981*): which set out general requirements regarding daily doses and therapeutic claims. They also establish specific requirements concerning tableting aids and preservatives. Many complementary and alternative medicines are deemed to come under the definition of dietary supplements. These include any amino acids, edible substances, foodstuffs, herbs, minerals, synthetic nutrient, and vitamins sold singly or in mixtures in controlled dosage forms as cachets, capsules, liquids, lozenges, pastilles, powders, or tablets, which are intended to supplement the intake of those substances normally derived from food.
- *Food Standards Australia New Zealand Act 1991*: which regulates the delivery of safe food and is administered by the bi-national independent statutory authority (FSANZ). FSANZ operates between all levels of government in Australia and New Zealand (including the Australian TGA).
- *Medicines Act 1981* (and the *Medicines Regulations 1984*): which have broad relevance to complementary and alternative medicines or products.

### **10.4.3 Canada**

In Canada, provincial and territorial governments regulate health professions, including some CAM professions. The forms of regulation differ widely from province to province. However, all provinces have delegated some power and responsibility for governance to a core group of health professionals (medicine, dentistry, nursing, optometry, and pharmacy) giving them the imprimatur of the state for the enforcement of rules and sanctions (Gilmour, Kelner & Wellman 2002).

As in other countries, all health practitioners are subject to criminal laws, consumer protection laws, and civil litigation (De Bruyn 2001).

Currently, the profession of WHM is not regulated in any province of Canada, and any individual is allowed to set up a CAM practice. The only exception is the province of British Columbia where TCM and acupuncture practitioners are regulated under the *Health Professions Act 1996*. However, this does not prevent others from prescribing TCM herbs as long as they do not hold themselves out as TCM practitioners (Boon 2002).

Naturopaths are regulated with health professions under umbrella legislation in some provinces (such as the *Health Professions Act 1999* [Alberta] and *Health Professions Act 1996* [British Columbia]). They are regulated under occupation-specific statutes in others (such as the *Naturopathic Act 1999* [Manitoba], and *Naturopathy Act 1978* [Saskatchewan]) (Nazarali 2003). In its advice to the Ontario minister of Health and Long-Term Care, the Health Professions Regulatory Advisory Council (2001) noted that all Canadian provinces with statutes regulating naturopathy have similar scope of practice statements that emphasise natural healing processes.

The issue of whether CAM practitioners should be considered within the paradigm of conventional health regulation is being debated in Canada. However, the main problems associated with the regulation of Canadian CAM practitioners are:

- the diversity of health professional regulatory frameworks among provinces;
- a lack of cohesion within some CAM professions, which acts as an obstacle to the professionalisation of CAM groups; and
- the fact that various CAM treatment modalities are used by different CAM practitioners, as well as by regulated health practitioners (Boon 2002).

Several Canadian provinces are reviewing the regulation of healthcare professionals and various recommendations have been made to replace the exclusive scope of the practice/licensing system and the right to title/certification system with less monopolistic models of regulation (Gilmour, Kelner & Wellman 2002; Boon 2002). Traditionally, each regulated profession has had an exclusive scope of practice provision that excluded others from practising in the specified area without statutory authority. However, this approach is giving way to a system that permits shared scopes of practice. This involves legislation that describes in general terms what a profession does, and how it does it. It also involves legislation that specifies reserved, restricted, or controlled acts that present such a significant risk of harm that they warrant being reserved to a particular profession, or shared among certain professions.

## Ontario

In Ontario, WHM practitioners are not regulated, and naturopaths have been regulated under the *Drugless Practitioners Act* since 1925. When Ontario enacted the *Regulated Health Professions Act 1991*, it became the first common law jurisdiction in Canada to replace exclusive licences and to bring all health professions and some CAM practitioners under the same regime (HPRAC 2004). The Act is administered by the Health Professions Regulatory Advisory Council (HPRAC), a permanent body whose role, *inter alia*, is to administer the Act and to advise the Health Minister about which health professions should be reviewed for regulation. According to Gilmour, Kelner & Wellman (2002), the Council acts as a gatekeeper for CAM practitioners who are seeking regulation. The Health Professions Regulatory Advisory Council (2001) in Ontario has recommended that naturopaths be governed by the *Regulated Health Professions Act 1991*.

The Regulated Health Professions Act has four main goals:

- to protect the public from harm;
- to promote high quality care;
- to subject health professions to a standard form of regulation; and
- to make regulated health professions accountable to the public.

The Act provides a model of professional regulation for 23 health professions—including medicine, nursing chiropractic, midwifery and massage therapy.

The regulatory framework established by the Act consists of:

- the Act as the governing statute;
- the Health Professions Procedural Code (Schedule 2 of the Act);
- the Ministry of Health and Long-Term Care Appeal and Review Board Act;
- profession-specific statutes that specify such things as:
  - a scope of practice statement, which is a brief statement, designed for each profession;
  - a list of controlled or authorised acts of each health profession; there being a list of 13 specific procedures that only members of a regulated health profession may perform under each profession-specific statute; some regulated health professions do not have the authority to perform any of the controlled acts whereas other groups (such as medical practitioners) have the authority to perform many of the controlled acts; the authority to perform a controlled act is based on specialised knowledge, training, and the expertise necessary for public safety (Regulated Health Professions Act, section 27);
  - a harm clause—the purpose of the harm clause being to prevent health professionals from acting outside their scope of practice and to protect individuals from unqualified practitioners (Regulated Health Professions Act, section 30).
  - title protection—the title protection provision placing restrictions on the use of professional titles; each profession-specific statute contains restrictions that are relevant to that profession; this is to protect clients/patients from individuals who are not members of a regulated health profession (Regulated Health Professions Act, section 33); and
- Regulations under the Regulated Health Professions Act (Schedule 1 of the Act); (a copy of this schedule is attached at Appendix 10.8).

### **Professional colleges**

In Ontario, all regulated health professionals must be members of the professional college governing their profession<sup>5</sup>. The 22 colleges have responsibility for the following tasks:

- protecting the public interest;
- setting entry standards;
- setting and maintaining practice standards;
- developing codes of ethics; and
- enforcing compliance with laws and regulations applying to that profession.

In addition, each college council must establish and appoint members to a range of college committees that have authority to regulate and control members of the profession.

## **10.4.4 United States of America**

### **Powers of individual states**

The individual states of the USA are responsible for regulating healthcare disciplines. Few healthcare activities are permitted without state authorisation. States can regulate health practice through (Cohen 1998):

- *licensing*: whereby a licensed person is permitted to do something that is otherwise prohibited and a non-licensed person is prohibited from providing services that require a licence;
- *title licensing* : whereby practitioners claiming a particular occupational title must have achieved a demonstrable level of skill or training; other providers may offer

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<sup>5</sup> The professional colleges are registering authorities and not teaching institutions.

these services but they risk prosecution if they unlawfully use the occupational title; and/or

- *registration with an approved administrative body*: whereby non-registered providers are prohibited from practising; registration rarely imposes requirements relating to training, knowledge, or skill.

Each state has enacted licensing schemes for allied health professionals, such as nurses, physical therapists, and optometrists. For example, the Rhode Island Department of Health has a Division of Health Services Regulation which licenses, certifies, and disciplines more than 72,000 healthcare professionals in that state. Acupuncturists, chiropractors, and massage therapists are included in the regulatory scheme (Rhode Island Department of Health 2004).

### **Regulation of CAM professionals in the USA**

Historically, broad definitions of medical practice in the United States have prohibited anyone except licensed medical practitioners from engaging in any form of health care practice<sup>6</sup>. In the past, the courts have interpreted the 'medical practice Acts broadly against CAM providers where state legislatures have failed to create separate licensure or registration for such providers' (Cohen 2003, p. 80). According to Mills (2001, p. 158):

Acupuncturists, herbalists, osteopaths, and naturopaths have been prosecuted for practising without medical qualifications, and the technical illegality of much complementary practice has meant that it has been pursued informally and disparately, with less opportunity for professional organisations to develop.

Under this system, any unlicensed person who encroaches on any aspect of medical practice is at risk of prosecution. In addition, the scope of practice defined in statutes governing allied health professionals and CAM providers is narrower than the broad mandate given to medical practitioners to diagnose and treat disease. Indeed, licensed health professionals (such as medical practitioners and nurses) risk deregistration if they practise CAM modalities that are regarded as being outside their accepted scope of practice.

Nevertheless, as a result of increased usage of CAM practice, attitudes to CAM are changing. CAM providers are increasingly coming under some form of state regulation, but this varies widely from state to state. According to Cohen (2003, p. 80)

'... the four major licensed CAM professions are Chiropractic, Traditional Oriental Medicine (including Acupuncture), Naturopathy and Massage Therapy'.

Chiropractors are licensed in every state and in Washington DC, but uniformity has not been achieved throughout the USA and definitions of scope of practice vary from state to state. A similar situation exists among the 13 states and two territories that now licence naturopathy (Appendix 10.9).

The most recent legislation governing naturopathic practice is California's *Naturopathic Doctors Act 2004*, which came into effect on 1 January 2004. This Act has adopted a broad definition of naturopathy and has listed the functions that doctors of naturopathy may and may not undertake. The Act adopts a 'reservation of title' and 'whole practice restriction model'.

In general terms, the intention of the legislation is to give consumers access to a wide range of natural treatments, as well as making naturopathic doctors more accountable (Appendix 10.10). The legislation also provides for the protection of title by making it an offence for unregistered individuals to claim, or hold out, to be a licensed naturopathic doctor.

The Act is administered by the Bureau of Naturopathic Medicine created within the Californian Department of Consumer Affairs. The bureau has authority to grant licences to

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<sup>6</sup> For example, in Alaska, the term 'medical practice' means 'to diagnose, treat, operate on, prescribe for, or administer to any ... mental or physical condition' (Josefek 2000, p. 301). This definition excludes unlicensed health professionals, such as CAM practitioners, from performing these activities.

applicants who have complied with prescribed educational requirements (Article 3, *Naturopathic Doctors Act*).

The Act defines naturopathic medicine as ‘... a distinct and comprehensive system of primary health care practiced by a naturopathic doctor for the diagnosis, treatment, and prevention of human health conditions, injuries, and diseases’. The scope of naturopathic practice includes the right to examine patients, order and perform diagnostic tests (including but not limited to blood tests, speculum examinations, clinical laboratory tests, and diagnostic imaging), and to dispense defined remedies (Article 4, *Naturopathic Doctors Act*).

Acupuncture, traditional oriental medicine, and massage therapy are licensed in at least half the states, but as with chiropractic, there is lack of uniformity with regard to licensing and scope of practice provisions. Homeopathy is widely practised, but very few states license homeopaths. Those that do license homeopathy usually require the practitioner to have a medical licence (Eisenberg et al. 2002; Cooper, Stoflet & Standi 1996).

Unlike homeopathy and naturopathy, WHM is not recognised officially, and has been absorbed into the practice of naturopathic medicine. There is no independent certifying body for herbalists.

Two main associations exist for Western herbal medicine:

- Botanical Medicine Academy (BMA); and
- American Herbalist Guild (AHG).

Most members of the BMA are naturopaths, and the main purpose of the association is to enhance botanical training among this group. Membership is subject to the candidate being reviewed by a five member admissions review committee (See American Health Guild Primary Goals and Code of Ethics, Appendix 10.11).

### **Recent developments in the USA**

In addition to state-based legislation governing the practice of CAM, there have been two important developments at the federal level.

The first was the establishment in March 2003 of the White House Commission on Complementary and Alternative Medicine (WHCCAM). Although the regulation of CAM practitioners is a state matter, regulation *per se* was not a concern for WHCCAM. Rather, the commission was concerned with the right of each person to choose treatment from qualified practitioners who are accountable for their claims and responsive to the person’s needs. WHCCAM noted the need to define CAM appropriately and to distinguish between safe and unsafe health modalities, and between effective and ineffective health modalities. The commission recognised that ‘... the heterogeneous array of education, training and qualifications of CAM practitioners has made it difficult for the Commission to clearly and succinctly target its recommendations’ (WHCCAM 2002, p. xxi). Nonetheless, WHCCAM recommended that state governments should review and improve laws and policies regulating CAM professionals and that the federal government should assist states and professional associations with this task.

The second development was the replacement of the Office of Alternative Medicine by the National Centre for Complementary and Alternative Medicine (NCCAM) in 1998. The NCCAM, one of the 27 institutes that make up the National Institutes of Health, plays an important role in CAM research, research training and career development, and the dissemination of authoritative information to the public and professions.

The prohibition of health professionals, such as CAM practitioners, from performing health care practice unless licensed, has seen an increasing consumer backlash. Consumers are demanding more choice and access to any practitioner – licensed by the state or not – and are arguing that ‘health freedom is a fundamental constitutional right’ (Miller & Johnson 2004).

As a result, ‘health freedom’ legislation has now become a contentious political issue in the USA (NHF 2004; CNH 2004a). Health freedom laws have been passed in Minnesota, Rhode Island, and California. Subject to certain exceptions, these statutes exempt CAM

practitioners from prosecution under medical practice Acts. They establish a legal framework that permits CAM practitioners to provide limited healthcare services. However, CAM practitioners may not diagnose or treat disease in ways that contravene state medical practice Acts. Moreover, other states (such as Utah and New York) have ‘Freedom of Religion’ provisions that protect natural health practitioners (Upton 2002).

The Rhode Island *Unlicensed Health Care Practices Act 2002* created a right to freedom of access to health care. The Act defines ‘unlicensed healthcare practices’ as being 20 different therapies commonly used to complement conventional allopathic interventions. The Act also specifies that such unlicensed practices do not include diagnosing and treating disease, performing surgery, or prescribing, administering, or dispensing drugs.

The Act also provides for a ‘Bill of Rights’ whereby unlicensed healthcare practitioners must disclose (to each client) their education and training, the services to be provided, fees to be charged, name, address, and the telephone number of the department of health where complaints can be filed. The Act requires the department of health to handle client complaints and to invoke disciplinary measures against practitioners who fail to follow the law.

The Act also requires a client to sign a disclosure statement that all parts of the ‘Bill of Rights’ have been provided to him or her before any services begin (CNH 2004b).

## 10.5 Discussion

Arrangements for the regulation of CAM practice in Australia vary according to the type of practice, jurisdiction and the nature of the regulation. For chiropractors, osteopaths and Victorian practitioners of Traditional Chinese Medicine there exists a system of statutory registration designed to protect consumers and ensure the delivery of quality services. Other CAM practitioners are not regulated under such a system. Instead, reliance is placed on a range of different measures for the protection of consumers and delivery of quality services. These measures are either specifically related to a type of practice or they operate in a generic manner affecting a range of health professionals. The former is exemplified by self-regulation – whereby practitioners voluntarily become members of a professional association that sets standards for professional conduct and service delivery and may stipulate minimum qualification levels for membership. For practitioners of naturopathy and WHM this is a common arrangement. The latter involves a plethora of different laws that in some way impinge on both the practice of CAM and on the herbs and nutritional supplements that are the tools of trade of these practitioners. Although consideration of the need to regulate and options for such regulation will be discussed in Chapter 11 of the present report, some key observations of the arrangements that exist in Australia and in some international jurisdictions are:

- In Australia, *A New Tax System (Goods and Services Tax) Act 1999* established a regime that enables naturopaths, acupuncturists, and herbal medicine practitioners to provide GST-free services. The right to provide GST-free services is a powerful incentive for practitioners to comply with the scheme’s requirements. However, its implementation has reinforced the fragmented nature of industry representation by recognising multiple sets of standards for professional practice that are inconsistent with one another. For example, minimum educational qualifications necessary for association membership vary from unspecified (practitioners assessed individually) to advanced diploma (see Chapter 6). Membership of an ATO-recognised association cannot guarantee anything other than that the standards of that particular professional association have been met. These standards are free of any outside scrutiny, creating a system that (i) lacks consistency and transparency; (ii) is difficult to understand; (iii) is not practical; and (iv) provides only minimal protection to the public. The Expert Committee recommended that the Australian Government ‘give consideration to revising the definition of organisations whose members satisfy requirements for “recognised professionals” for the provision of GST-free services...’ (2003, p.134).

- The current legislative framework that exists in Australia to govern therapeutic goods, as it applies to the practice of naturopathy and WHM, has some deficiencies as follows.
  - (i) The legislation provides protection to the public by restricting access to some herbs with hazardous properties. However, the current scheduling system denies access to the tools of trade of competent practitioners either by listing herbs on Appendix C of the National Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) (not accessible to any health practitioner), or on Schedules 2-4 under state or territory drugs and poisons legislation (accessible only to specified registered health practitioners). This restriction of access is to be contrasted with the legislative mechanism (not yet implemented) which will enable registered Chinese medicine practitioners in Victoria (who have met the Chinese Medicine Registration Board's requirements for education in Chinese herbal medicine), to access herbs listed on Schedule 1. The Expert Committee (2003) recommended that a method be developed to allow access to restricted products by adequately qualified practitioners and noted that the legal status of practitioners could be improved by creation of a special Schedule for certain herbal and other naturopathic products. The Expert Committee (2003) also recommended that state and territory governments adopt a nationally consistent system of access (Scheduling) to medicines.
  - (ii) The current therapeutic goods framework provides no effective system for the regulation of raw herbs intended for extemporaneous dispensing. Including herbs on the SUSDP is the only mechanism currently available but this approach has a number of deficiencies when applied to herbal medicines. There is a need for a mechanism to be developed for the quality control of such herbs. Both practitioners and consumers need to be assured that the products they are purchasing are correctly identified and are of known quality. Such a system would protect consumers from potential harm as a result of incorrect identification, poor quality, or adulteration of imported herbs.
- Fair trading legislation, trade practices legislation, and the common law in Australia provide some protection to members of the public if they believe that information supplied has been false and misleading, or that goods sold were not fit for the purposes intended, or that a practitioner has been negligent. However, litigation is stressful, expensive, and unpredictable. Furthermore, these legal remedies do not allow an opportunity to challenge the professional conduct of the practitioner concerned or to subject that conduct to scrutiny that might affect the registration of the practitioner, force the practitioner to undertake further education or counselling, or restrict the scope of a practitioner's practice.
- Health complaints commissioners in Australia's States and Territories can receive complaints about the professional conduct of naturopaths and WHM practitioners. However, the avenues for disciplinary action against unregistered practitioners are few, particularly if practitioners are not receptive to conciliation.
- Reliance on self-regulation to ensure consumer protection and the provision of quality services in Australia has its shortcomings. Under such an approach, professional associations establish standards of practice. However, as already noted in terms of the goods and services legislation, numerous professional associations represent naturopaths and WHM practitioners. Several associations exist each with its own standards of practice, minimum educational qualifications for entry and disciplinary procedures. This results in overall industry standards that are piecemeal and inconsistent, and disciplinary procedures that lack transparency.
- The approach adopted in Australia to 'regulate' the practice of naturopathy and WHM is not unique. However, it is not indicative of the way in which many other developed countries have enabled practitioners of naturopathy or WHM, specifically, and CAM more generally, to practice.



- Several countries are quite restrictive in their approach to the practice of CAM with some, particularly within the EU, having declared CAM practice to be illegal (monopolistic system referred to earlier). However, various CAM practitioners in these countries operate in direct contravention of those laws.
- In some countries restricted CAM practice is permitted, but in some cases onerous scope of practice requirements serve as a *de facto* means of preventing CAM practice. This latter approach exists in parts of the EU and some states in the USA. However, in the State of Alaska (USA), the reverse occurs. Rather than specifying scope of practice for CAM, the definition of what constitutes the practice of medicine is defined broadly as ‘to diagnose, treat, operate on, prescribe for, or administer to any ... mental or physical condition’. Under such a definition, any unlicensed persons who encroach on any aspect of medical practice might be at risk of prosecution.
- In countries in which scope of practice laws and other laws do not block the practice of CAM, there are moves towards regulation. In the UK, a model under consideration is the establishment of a ‘CAM council’ which would administer a licensing scheme for multiple CAM professions.

Consideration of overseas models has yielded a number of points which may be relevant to Australian policy development.

- Public use of CAM is supported when the public has access to competent practitioners who have met minimum standards of education and professional competence.
- Public protection requires the development of a register of practitioners, standards of practice, standards of education and training and a mechanism for investigating allegations of unprofessional conduct.
- Professional associations have not been able to entirely meet these requirements because of a high number of associations and reluctance to amalgamate in order to professionalise. This has led to a plethora of inconsistent standards of practice and education and lack of expertise in developing a transparent, consistent, rigorous and fair mechanism for complaints investigation, with appropriate avenues of appeal. Further, internal divisions within the professions tend to exacerbate these issues.
- Differences and overlaps in the various CAM professions and modalities can present a challenge to the development of a clear legislative framework for statutory registration.
- Creating a legislative framework which recognises the possibility that other CAM professions or modalities may be registered in the future is a forward thinking policy initiative given the increasing public use of CAM.

## 10.6 Conclusion

Naturopathy and WHM are not regulated in Australia, however a range of legislation affects the practice of these professions. The *A New Tax System (Goods and Services Tax) Act 1999* provides a mechanism through which naturopaths and WHM practitioners, who are members of the numerous ATO-recognised professional associations that represent these practitioners, may provide GST-free services. This mechanism has not supported effective self-regulation. Naturopathy and WHM continue to be underpinned by inconsistent educational and professional standards, and disciplinary procedures that lack transparency.

The current scheduling system under state and territory drugs and poisons legislation denies access to tools of the trade to competent practitioners of naturopathy and WHM. On the other hand, there is no effective system for the regulation of raw herbs intended for extemporaneous dispensing, which are not monitored for quality, proper identification or adulteration.

Fair trading, trade practices legislation and access to the common law provide some protections to the public where information supplied is false and misleading, goods sold are

not fit for the purposes intended, or the practitioner has been negligent. However, litigation is stressful and expensive, and its outcomes can be unpredictable.

Complaints about professional conduct can be lodged with the health complaints commissioners in the various states and territories, but their ability to address poor conduct relies on the receptivity of the practitioner (except for criminal conduct which can be referred to the police).

Analysis of trends in other Western countries indicates that there are moves towards increased regulation of CAM. Some jurisdictions already regulate naturopaths. For example, they are licensed in several provinces of Canada (including, since 1925, in Ontario where the Health Professions Regulatory Advisory Council recommended in 2001 that naturopaths should be governed under the same Act as other health professionals), and in 13 states and two territories of the United States. (WHM has largely been absorbed into the practice of naturopathy in those countries).

Other jurisdictions are moving to regulate CAM professions. The UK Department of Health recently accepted a recommendation for statutory registration of herbalists and acupuncturists, and the establishment of a CAM Council with separate sections of the register for the different traditions. A Ministerial Advisory Committee in New Zealand recommended in 2004 that CAM practitioners should be regulated according to the level of risk involved in the modalities they practise.

Jurisdictions where orthodox medicine has a legal monopoly face challenges due to public demand for CAM. For example some states in the USA have introduced 'health freedom' laws which enable CAM practitioners to provide limited health services. In the EU, several countries actively prosecute CAM providers whilst in others, laws against the practice of medicine by non-physicians are not being enforced.

The absence of statutory registration for naturopaths and WHM practitioners in Australia means that there is no consistent standard which takes the protection of the public as its overarching objective.

## 10.7 Recommendations

Based upon the findings of the above review, the following recommendations are made.

- Legislation that encourages the proliferation of standards for entry to and practice of the professions should be reviewed (for example, *A New Tax System [Goods and Services] Act 1999*).
- State and Territory governments should consider mechanisms to ensure a consistent and fair approach to complaints management and unprofessional conduct.
- A uniform approach should be adopted with respect to therapeutic goods legislation.
- State, Territory, and Commonwealth governments should give consideration to the risks arising from the absence of coverage of raw herbs used as starting materials in the current legislative regime for therapeutic goods.

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# 11. Assessing the Need and Options for Regulation

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## 11.1 Introduction

Consumers are increasingly seeking the services of complementary and alternative medicine (CAM) practitioners and therapies, and government policy ought to reflect and support this preference. Recognition is being given to similar trends overseas. The use of this healthcare sector is common in many countries, but usage is often 'silent' and no comprehensive picture exists of the kind of healthcare that is actually being provided (Eisenberg et al. 2002). Against this background, the World Health Organization (WHO) Traditional Medicines Strategy 2002–2005 noted a number of challenges that require action: (i) lack of official recognition of providers and their role; (ii) inadequate or non-existent regulation; (iii) lack of access; (iv) inequitable distribution of benefits; and (v) inadequate allocation of resources for development, capacity-building, and research (WHO 2002).

This chapter summarises the policy context internationally and in Australia. The chapter then brings together the research evidence reported in Chapters 1–10 of the present report, and assesses this against the key criteria for occupational regulation. The appropriateness of various regulatory models is also considered. The chapter concludes with recommendations for the regulation of naturopathy and Western herbal medicine (WHM).

## 11.2 Policy context

### 11.2.1 International approaches

International approaches to regulation vary (see Appendix 11.1). Some countries have made CAM practice illegal; however, the laws appear to be somewhat ineffective as a result of the public demand for CAM. In most European countries and in some jurisdictions in the United States (US) and Canada, few healthcare activities are allowed without state authorisation. The US has traditionally been hostile to natural therapies, which were rendered illegal by expansive scope of practice medical acts in each state. As a consequence, legislation must now be enacted to provide choice (Josefek 2000). The White House Commission on Complementary and Alternative Medicine, established in March 2000, noted the right of each person to choose treatment from qualified practitioners who are accountable for their claims and responsive to the person's needs (WHCCAM 2002).

To gain legal standing and community acceptance in the US, a section of the naturopathic profession deemed that a level of education similar to that required for medical education was necessary. Examinations are set by licensing boards (currently established in 14 states), and candidates must have attended one of five accredited naturopathic colleges. The result is a two-tier system whereby some practitioners are said to be qualified whereas others are not (Croasdale 2002). A major national body, the American Association of Naturopathic Physicians grants full membership only to naturopaths who are eligible for state licensing (because they have qualified from accredited courses), and the White House Commission made educational recommendations only in respect of accredited courses (WHCCAM 2002).

In contrast, in the United Kingdom (UK) choice of healthcare has historically been regarded as a common-law right. The UK has therefore provided a benign legislative

environment for CAM. Some regulatory measures exist, but standards are generally set by associations. As a result, the quality of professional and educational criteria, and of complaints processes, varies widely (Mills 2001). As a consequence, the House of Lords Select Committee on Science and Technology (2000) recommended statutory regulation for herbal medicine and acupuncture in the UK. This recommendation was based on growing public use, the possibility of harm, the existence of voluntary self-regulation systems, and the credible evidence base.

The House of Lords Select Committee also recommended that the numerous associations should make strong efforts to amalgamate and develop a clear structure, and that bodies representing other healthcare providers (such as doctors and nurses) should set standards for CAM practice that are comparable to those set by relevant CAM regulatory bodies. It was also recommended that associations should develop essential clinical guidelines on certain issues—for example, on how to deal with clients who do not have a medical diagnosis (Mills 2001).

Although approaches differ from one country to another, the international trend is towards improved regulation to: (i) increase transparency and public scrutiny (which are essential to quality care); (ii) assist complementary healthcare to integrate with mainstream healthcare; and (iii) increase funding for research and capacity-building. Underlying these objectives is a need to improve educational and professional standards.

### **11.2.2 Australian developments**

As in the UK, Australian law has not impeded the practice of CAM. Where there is statutory registration of health professionals, the tendency is to protect title and not practice, or to introduce a limited scope of practice for some professions. This has protected natural therapy practice from being classified as a form of illegal medical practice. However, it has also coincided with the evolution of numerous professional bodies that disagree on a range of important standards.

Government interest in CAM in Australia has been brought about by recognition of the growing number of consumers whose preference is for access to CAM therapies and the services of CAM practitioners. If these preferences are to be supported, serious consideration needs to be given to regulation of the professions. In 2000 the Victorian parliament passed legislation to register Chinese medicine practitioners. Also in 2003, following a recall of Pan Pharmaceutical products, the Australian government established an Expert Committee on Complementary Medicines in the Health System. The Expert Committee's report (2003) expressed concern about: (i) the lack of uniform educational standards; (ii) the slowness of governments in reviewing CAM professionals (especially those practising herbal medicine modalities); and (iii) the need to implement statutory regulation (where justified).

In Australia, health practitioner regulation is typically implemented through statutory registration. Statutory registration involves a register of practitioners, standards of practice, standards of education and training, and a robust, rigorous, and fair system of investigation into allegations of professional misconduct. Such systems apply across entire jurisdictions—thus delivering a consistent approach in the jurisdiction in question. However, government has been understandably cautious about the introduction of new regulations that might create barriers to entry into professions, lessen competition, increase costs, create 'red tape', impede the smooth flow of business, and afford recognition and status to professions.

### **11.3 AHMAC criteria and regulatory models**

Occupational regulation in Australia is framed by the *Commonwealth Mutual Recognition Act* of 1992 and elaborated by the Australian Health Ministers Advisory Committee (AHMAC) 'Criteria for Health Occupations', consisting of six criteria that must be satisfied if a profession is to be regulated. In 1995 AHMAC adopted a general position of limited government involvement in professional regulation and legislation was passed enshrining National Competition Policy (NCP) in all Australian jurisdictions. This legislation requires that the costs and benefits of regulation be weighed, that a competition test be applied, and



that there be a net public benefit from regulation. Consideration must also be given to potential problems in implementing competition policy—such as the creation of barriers to entry and/or an increase in the burden related to regulation. The sixth AHMAC criterion reflects the NCP principle and addresses the question of whether other means exist (apart from regulation) for achieving the desired net benefits.

The criteria are:

- Is it appropriate for Health ministers to exercise responsibility for regulating the occupation in question, or does the occupation more appropriately fall within the domain of another ministry?
- Do the activities of the occupation pose a significant risk of harm to the health and safety of the public?
- Do existing regulatory or other mechanisms fail to address health and safety issues?
- Is regulation possible to implement for the occupation in question?
- Is regulation practical to implement for the occupation in question?
- Do the benefits to the public of regulation clearly outweigh the potential negative impact of such regulation?

The six general models for regulation of the health professions (DHS 2003) are:

- self-regulation;
- negative licensing;
- co-regulation;
- reservation of title only;
- reservation of title and core practices; and
- reservation of title and whole of practice.

In what follows, the evidence from the present study is assessed against the AHMAC criteria. The models noted above are then assessed.

## 11.4 Assessment against the AHMAC criteria

### 11.4.1 Criterion 1

Is it appropriate for Health ministers to exercise responsibility for regulating the occupation in question, or does the occupation fall more appropriately within the domain of another ministry?

The findings of the present study indicate that:

- naturopaths and WHM practitioners are healthcare practitioners;
- naturopaths and WHM practitioners are primary contact practitioners delivering healthcare services to the Australian public; and
- there is widespread use of the services and treatments of naturopaths and WHM practitioners.

Naturopathy and WHM practitioners are primary contact healthcare providers delivering healthcare services to the Australian community. The present study has shown that consumers' parallel use of the two systems—conventional medicine and naturopathy/WHM—is well established in all age groups. Furthermore, such dual usage often continues over a prolonged time because users are often being treated for chronic illnesses or conditions, or are using complementary healthcare products to deal with the effects of medical treatments for serious health conditions.

Complementary healthcare products are governed by a number of Acts within the health portfolio. These include the *Therapeutic Goods Act*, food standards legislation, and hygiene standards under public health legislation. Although the advertising and sale of complementary healthcare products are covered under fair trading and trade practices legislation, and although some CAM practitioners do function in a predominantly commercial context, this is not the dominant setting for the provision of CAM services in Australia. By

and large consumers seek the services of naturopaths and WHM practitioners as primary contact practitioners for health advice—both for therapeutic purposes and for the maintenance of health and well-being.

Consumer complaints about CAM practitioners have been handled by the Health Services Commissioner in Victoria (and equivalents in other states and territories), and by the various professional associations.

### **Conclusion regarding criterion 1**

It is clearly appropriate for Health ministers to exercise responsibility for regulating naturopathy and WHM.

#### **11.4.2 Criterion 2**

Do the activities of the occupation pose a significant risk of harm to the health and safety of the public?

The present study has revealed that the practice of naturopathy and WHM presents a range of risks of varying significance.

The occupations of naturopathy and WHM differ from registered health professions with respect to the nature of practice, the scope of practice, the variety of education available for practitioners, and how consumers access practitioners (including how they integrate their use of these practitioners and therapies with their use of other health practitioners and therapies). The risks posed by the practice of naturopathy and WHM are therefore different from those posed by other professions. In addition, there are risks presented by the ‘tools of the trade’ of these professions (the herbs and nutritional supplements used in the practice of these occupations).

The risks posed by naturopathy and WHM can be categorised as follows:

- risks associated with the specific modalities
- risks associated with the scope of practice; and
- risks associated with the practice context.

The risks associated with the *specific modalities* are perhaps more apparent in the practice of WHM (see Chapter 2), whereas the risks associated with the *scope of practice* and the *practice context* are more closely associated with naturopathy because of the more diverse nature of its practice. However, any delineation between naturopathy and WHM is blurred by the fact that many naturopaths practise WHM, and WHM practitioners can use additional modalities and practise in a manner that gives rise to concerns regarding their practice context. The three categories of risk (specific modalities, scope of practice and practice context) are described below.

#### **Risks associated with the specific modalities**

As reported in Chapter 2, the risks associated with the *specific modalities* fall into two categories. The first is risks associated with the clinical judgment of the naturopath or WHM practitioner. The second is risks related directly to the consumption of nutritional and herbal medicines. More specifically, the following problems were identified:

- Cases of adverse events related to acts of commission (such as recommending cessation of medical treatment and failure to avoid known interactions with pharmaceuticals), and acts of omission (such as misdiagnosis and failure to refer to an appropriate practitioner) have been reported in the literature. Although they do not appear to represent widespread malpractice, concerns exist among consumers and healthcare practitioners about the nature and extent of such risks.
- Like Western medicines, herbal medicines can produce predictable and unpredictable effects. Cases were identified in both of these areas. Predictable effects included direct toxicity, toxicity related to overdose of a preparation, and interaction with Western pharmaceuticals. Unpredictable effects included allergic and anaphylactic reactions to herbal medications, and idiosyncratic reactions.

- A number of herbs have been well documented as causing toxic reactions. Severely toxic substances are restricted by current legislation. However, a number of potentially toxic substances continue to be available to practitioners for use in prescriptions.
- Herbal medicines have potential to interact with pharmaceutical drugs, and numerous cases of such herb-drug interactions have been reported.

The profile of risks to the consumer is changing as a result of: (i) concurrent use of pharmaceutical medicines; (ii) the development of manufacturing techniques that alter potency of products; and (iii) the application of naturopathic and herbal medicines to a wider range of illnesses.

The number of recorded adverse events associated with the practice of naturopathy and WHM in Australia is substantial, and the types of events reported are considered significant. Australian workforce data suggest that, on average, naturopathic and WHM practitioners experience one adverse event every eleven months of full-time practice, or 2.3 adverse events every 1,000 consultations. The general practitioner (GP) survey data suggest that one adverse event associated with complementary healthcare practices can be expected in every 125 consultations, or about one per week. GPs believe that the risks related to naturopathy and WHM are comparable to other regulated professions—chiropractic and Chinese medicine (including acupuncture). It is difficult to determine whether the adverse events associated with herbal medicines and nutritional supplements are a result of poor practice (including inappropriate prescribing) or directly attributable to the products themselves.

It is likely that the level of risk identified in this report is underestimated because:

- there appears to be significant under-reporting to government agencies of adverse events associated with nutritional and herbal medicines—possibly due in part to practitioners' lack of awareness of the appropriate avenues for such reporting;
- practitioners may be suspicious that if adverse events are reported, access to medicines may be withdrawn;
- the current Adverse Drug Reaction Reporting System (ADRS) database administered by the Therapeutic Goods Administration (TGA) appears to be limited in its usefulness and applicability to complementary medicines; the reporting system is not sufficiently utilised by unregistered practitioners; and
- the complaints data held by professional associations are largely about professional issues (such as communication and sexual harassment).

Some differentiation of the nature of risks posed by the practice of naturopathy and WHM is possible. The possible toxicity posed by herbal medicines and their interaction with pharmaceutical products, compared with the use of nutritional supplements and homeopathic products, clearly points to certain risks associated with the practice of WHM. However, the aggregate of risks linked to the various modalities used in naturopathy is also of concern. Naturopaths use herbal medicines, nutritional products, and homeopathic products. This diversity, the changing scope of practice, and the variability of training might explain the slightly higher rate of adverse events (see Table 2.13) in naturopathic practice compared with that among WHM practitioners.

Data reported in Chapter 4 indicate that practitioners occasionally use scheduled herbs. This suggests a lack of awareness of the legal restrictions that apply or a lack of willingness

to comply with the law. Such practice also presents a risk to the public—especially in the context of the varied education and training of CAM practitioners.

Further research needs to be undertaken to provide a more accurate assessment of the risks associated with specific products and interventions.

In summary, regulation of naturopathy and WHM is warranted due to the identification of significant risks inherent in their practice. These risks are:

- the number of adverse events associated with Western herbal medicines and nutritional medicines
- the toxicity of some herbs and their interactions with pharmaceutical drugs
- the occasional prescription of scheduled herbs by naturopaths and WHM practitioners
- acts of commission including two deaths linked to naturopathic practice which have been investigated by the Coroner in recent years
- professional misdemeanours resulting in complaints to health complaints services and professional associations.

### **Risks associated with the scope of practice**

Naturopathy and WHM can be considered to offer an ‘alternative’ service to that offered by GPs—in that naturopaths and WHM practitioners are primary care practitioners who see consumers from all demographics who are suffering from a wide range of health complaints, including potentially life-threatening illnesses. The scope of practice is therefore wide. As primary care practitioners, naturopaths and WHM practitioners are involved with diagnosis and treatment, but within a paradigm that is different to conventional medicine. However, naturopaths and WHM practitioners also have an important role in determining when to refer consumers for medical diagnosis.

Risks to the public can arise from the exercise of clinical judgment by practitioners. These risks can arise from acts of commission or acts of omission and exist in all healthcare practices.

GP survey respondents (see Table 2.15) expressed concerns about herbal medicine practice in relation to specific herbal products and interactions. However, they considered the risks of harm of CAM to be related more to the scope of practice (incorrect, inadequate, or delayed diagnoses) than to the specific risks of the therapies themselves. There is clearly, *prima facie*, risk associated with a workforce of clinicians who consult directly with consumers who present with a full range of health conditions.

It is also important to note the *expanding* scope of practice. New therapies, new manufacturing methods that increase the potency of herbal and nutritional medicines, use of new pharmaceutical drugs by consumers, and the likelihood that consumers will attend CAM practitioners for an increasingly wide range of illnesses, all contribute to an expanding scope of practice.

### **Risks associated with the practice context**

In relation to the *practice context* of naturopathy and WHM, three categories of risk were identified. These were: (i) the lack of barriers to entry to the professions, particularly the lack of a minimum standard of education required to qualify for the professions; (ii) the use of naturopathy/WHM as an additional primary care system alongside conventional medicine and the challenges for consumers in negotiating these two systems of medicine; and (iii) difficulty in recognising appropriately qualified practitioners. These three categories of risk are further described below.

First, for people who largely or exclusively use naturopaths or WHM practitioners, the most important issue is the lack of barriers to entry to the professions. In the current setting, any person can set up practice as a naturopath or WHM practitioner. Coupled with the lack of minimum educational standards required to qualify for clinical practice, this represents a risk to consumers because:

- there are risks associated with the treatment modalities used;
- the range of herbal and nutritional medicines in use continues to expand;
- these practitioners are responsible for the primary care of people, and therefore participate in the diagnosis and treatment of their health problems;
- the scope of practice is broad, embracing a wide range of health problems;
- these practitioners do not have access to a range of diagnostic tools of conventional medicine and need to be sufficiently educated to know when to refer;
- the risk of misdiagnosis is greater if clinical training hours are inadequate and there is inadequate exposure to a range of health conditions, settings, and demographics; and
- there is a low incidence of guidelines in school clinics on the clinical management of patients taking pharmaceutical drugs (see Table 5.10).

Secondly, for people who use both naturopathy/WHM and conventional medical practitioners, there are risks associated with: (i) the treatment modalities used; and (ii) potential drug interactions among treatments provided by different health practitioners. The latter risk is exacerbated by a lack of communication regarding treatment among various providers and patients. Chapter 9 of the present report showed that 34% of patients consuming herbal medicine were concurrently taking pharmaceutical medications (excluding vitamin and mineral supplements).

Thirdly, it can be difficult for consumers to recognise appropriately qualified practitioners. For example, false or inadequate consultations might occur when people talk to naturopaths (or so-called ‘naturopaths’) in health food shops. Chapter 9 reported that this does occur, but the extent, frequency or impact of such a risk was unable to be documented.

The fact that naturopathy and WHM practitioners are primary care providers is clearly an important issue. Many consumers are not consulting GPs or other primary care practitioners to seek diagnosis and treatment of their conditions. The following findings from Chapter 9 (Consumers’ Use) are relevant.

- The majority of patients self-refer following recommendation from another person.
- Treatment is sought for a wide range of physical and psychological problems, and management is multifaceted (including lifestyle advice, nutritional supplements, herbal medicines, and exercise).
- Approximately half of the profiled patients had previously consulted a medical practitioner (general or specialist) for their complaints before visiting a naturopath or WHM practitioner, but communication between practitioners occurred in only a minority of cases.
- Among the profiled patients receiving naturopathic or WHM treatment, 34% were also taking pharmaceutical drugs.
- Poor communication between medical and CAM practitioners can have dangerous consequences in terms of drug interactions and delayed diagnosis.
- Consumers are seeking care from naturopaths and WHM practitioners for chronic conditions—which indicates that they are likely to be frequent and routine users.

The use of complementary and alternative medicines and services in conjunction with the use of conventional services increases the potential for drug interactions. In addition,

many people do not tell their medical practitioners of their use of CAM treatments. Participants in the focus group (Chapter 9) reported that they did not do so because the doctor might reject the therapy or because they felt that they should be in charge of their health. The lack of communication between consumers and practitioners is a particular cause for concern.

Although some degree of misdiagnosis and delayed treatment can occur in any healthcare profession (regulated or unregulated), the fact that naturopathy and WHM are unregulated, with no barriers to entry and variable standards of training, causes concern when conventional medicine and CAM are used simultaneously. There is: (i) limited communication between practitioners; (ii) limited disclosure by consumers; and (iii) routine and continuous use of CAM practitioners who have variable educational standards and limited access to diagnostic tools. The GP survey undertaken for this study revealed that GPs consider the harmfulness of CAM to be related more to the scope of practice (and thus to incorrect, inadequate, or delayed diagnoses), than the specific risks of the therapies themselves.

While some degree of misdiagnosis and delayed treatment may be found in any regulated or unregulated healthcare profession, the concern is that there exists simultaneously: (i) routine and continuous use of both conventional and complementary healthcare, (ii) limited communication between the practitioners and limited disclosure by the consumer, and (iii) variability of educational standards, and (iv) limited access to diagnostic tools on the part of CAM practitioners.

Several of the recommendations of the Australian Expert Committee on Complementary Medicine in the Health System (2003) were directed to the issue of misdiagnosis and delayed treatment, and the National Medicines Policy partners were charged with finding ways to encourage greater awareness among health professionals and health consumers of the risks associated with drug interactions and a lack of communication. This is clearly an important recommendation, and its acceptance and implementation would ameliorate the risks. However, at present, little has been done in this regard, and the current situation (as described above) constitutes a serious risk to the health and safety of the public.

All of these risks are compounded by the significant variation that exists in the education and training of naturopathy and WHM practitioners. In addition, the relatively low level of training that is required overall for admission to these professions suggests that practitioners might not have the capacity to keep up with the exponential growth in the available research evidence related to their practices.

Regulation of naturopaths and WHM therapists was generally favoured by a range of stakeholders surveyed in this study. Consumers who favoured regulation said it was needed to raise the standard of practitioners, ensure consistency of care, and prevent unethical practice. GPs who favoured regulation believed that it would help them with communication and referrals.

## **Conclusion regarding criterion 2**

The activities, scope of practice, and practice context of naturopathy and WHM pose significant risks of harm to the health and safety of the public. Minimisation of such risks should be a priority of both government and the professions.

### **11.4.3 Criterion 3**

Do existing regulatory or other mechanisms fail to address health and safety issues?

Existing attempts at self-regulation have not succeeded. They have been hampered by a fragmented regulatory framework and disagreement on standards and regulatory models amongst professional associations. There are no effective barriers to entry to the professions. Therefore, expelled members and deregistered persons cannot be prevented from practising naturopathy and WHM—which cannot be effectively policed in the current self-regulatory setting.

The main problems associated with the current situation are the failure of self-regulation, the fragmented regulatory framework, inadequate complaints mechanisms for consumers, and lack of access for naturopaths and WHM practitioners to some of the tools of their trade. These problems are described in the following sections.

### **Fragmented regulatory framework**

The practice of naturopathy and Western herbal medicine is framed by a myriad of legislation and regulations at state and federal levels. Taken together, this amounts to a complex and confusing array of regulatory mechanisms. These legislative and regulatory measures represent disparate responses to various legislative or policy imperatives from time to time, and they do not therefore form a coherent legislative framework for the regulation of naturopathy and WHM practice.

### **Failure of self-regulation**

Current arrangements with the TGA and the Australian Taxation Office (ATO) have not provided effective self-regulation (Expert Committee 2003). The present model—a mixture of self-regulation and statutory requirements—does not serve the public, the profession, or the industry well. The *A New Tax System (Goods and Services) Act 1999* established a regime that enables naturopaths, acupuncturists, and herbal medicine practitioners who are members of recognised professional associations to provide GST-free services. The right to provide GST-free services is a powerful incentive for practitioners to comply with the scheme's requirements, and it is relatively simple for naturopaths, acupuncturists, and WHM practitioners to acquire GST-status by joining a recognised association. However the legislation allows the co-existence of sets of professional practice standards created by the different associations. The standards are inconsistent with one another and do not need to have regard to standards set by other bodies.

The legislative scheme does not actually require professional associations to have standards of practice, a complaints mechanism, infection control guidelines, or requirements for education and qualification for practitioners. Although many professional associations have attempted to establish appropriate standards in such areas, these are not developed consistently and sometimes lack the degree of professionalism required to achieve the desired outcome of public protection. The result is confusion for both practitioners and the public. Accreditation by a particular professional association means only that the standards of that particular professional association must be met.

The better resourced professional associations in naturopathy and WHM have made considerable, but ultimately unsuccessful, attempts to develop a uniform and effective model of regulation. The large number of associations, and the politics involved, has worked against such an outcome.

Nevertheless, if statutory regulation were to be established, the professional associations would have important roles to play in: (i) continuing to represent practitioners; (ii) supporting them through allegations of misconduct; (iii) providing advice on educational matters (such as course accreditation and the structure of continuing education programs); and (iv) advising government on the development and future needs of the professions (HMRWG 2003).

Given the large number of professional associations and, the relatively small number of practitioners involved, the level of resources required to carry out this role effectively would be facilitated by rationalising the number of associations—preferably to one national organisation each for naturopathy and WHM. Special focus groups catering for particular interests can be established within a major association. Once minimum standards are defined by a future regulatory body, associations would also need to reach consensus on the criteria for member eligibility (HMRWG 2003).

The current model of self-regulation has produced variable standards of training and a multiplicity of professional associations. This has led to a number of problems.

- Educational standards vary widely, with courses being available at diploma, advanced diploma, and bachelor's degree level. Not all courses are accredited by an independent professional or educational body. Courses not accredited by the VET sector or a university can be formally recognised by an association.
- Practitioners have widely differing qualifications that are accepted by the various associations. Definitions of membership categories are not uniform, and there is significant variation in the minimum educational standard required for practitioner accreditation.
- Associations are divided in their preferences for either continued self-regulation or statutory registration, and there is a history of unsuccessful or short-lived affiliations between associations that has hindered the development of consensus and the stability required to implement industry self-regulation.
- Private health insurance funds do not apply consistent standards or educational requirements, although one industry body (Australian Regional Health Group) has approved guidelines recommending that education should be at tertiary level (university or registered training organisation). Not all private funds provide rebates for naturopathy and WHM services. Of those that do, some rely on the standards set by professional associations, which are inconsistent. Others, recognising the variation in standards, insist on individual applications from practitioners.
- GPs do not know to whom to make referrals or where to obtain guidance, and hospitals are uncertain about who to accredit and on what basis.
- Problems arise when professional associations take on the role of accreditation of practitioners in a context of disagreement over educational standards, practice standards, and modes of regulation.
- Currently, associations accredit practitioners and also advise on professional standards. Associations are therefore open to charges of conflict of interest if they have strong links with particular segments of the profession such as education providers.

The confusing situation that has arisen out of attempts at self-regulation has made it difficult for the public and other healthcare professionals to identify practitioners who have been adequately prepared for safe and competent practice.

### **Poor complaints mechanisms**

Although there have been few complaints regarding professional practice, this might be due to: (i) a lack of public awareness of the appropriate avenues for complaint; and (ii) the inadequate nature of complaints mechanisms put in place by associations, some of which demonstrate a lack of clear process.

There are multiple channels for complaints management—including associations and health complaints commissioners—but these mechanisms vary in quality and ease of access. Given the level of harm that is reported formally and informally, these complaints mechanisms appear to be underutilised. The complaints mechanisms that have been established by some associations are likely to be fundamentally flawed because association members and office bearers may lack experience in matters of fairness and the application of natural justice. The processes differ from one professional association to another. They might: (i) not be transparent to the public; (ii) have limited avenues of appeal, and (iii) lack the power to impose sanctions to prevent a practitioner simply joining another professional body. Those who are charged with the responsibility of hearing a complaint might be personal acquaintances of the practitioner who is the subject of a complaint. Given these limitations, even if the processes were scrupulously fair, the public and the complainant might perceive the process as lacking in fairness and transparency.



In general, respondents to the various surveys and consumers in the focus groups perceived that regulation would improve public access to a complaints pathway and would improve quality and transparency in decision-making. It would also help to prevent expelled members and deregistered persons from retaining their GST-free status and practising naturopathy and WHM—which cannot be effectively policed in the current self-regulatory setting.

Nor is there an adequate mechanism for addressing professional misconduct—including the imposition of sanctions, conditions on the right to practise, and (ultimately) the withdrawal of the right to practise if the misconduct is sufficiently serious. Current regulation therefore does not provide the level of protection the public is entitled to expect, given the identified risks of harm.

### **Lack of access to tools of the trade**

The current system of limiting access to toxic herbs via the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) causes competent naturopaths and WHM practitioners to be denied access to some important tools of their trade—the herbs they might wish to use in treatment.

Problems with access to scheduled herbal preparations exist because the SUSDP places a range of products out of reach of practitioners who are trained to use them. Following the implementation of occupational regulation it would become possible to identify qualified, registered practitioners. Access for these practitioners to scheduled herbal preparations would then be possible under state government drugs and poisons legislation.

### **The registration of Chinese medicine practitioners: an example**

The implementation of statutory registration for Chinese medicine practitioners in Victoria, under the *Chinese Medicine Registration Act 2000*, illustrates how standards can be set and applied (through ‘grandparenting’ and course approvals), and how professional associations and the public have made use of the disciplinary powers of the Chinese Medicine Registration Board (CMRB). Of the 1002 applicants for registration since 2001 (up to October 2004), 10% have been refused registration on the basis of insufficient qualification or inability to demonstrate competence to practise safely. The 34 complaints investigated have covered a range of professional practice issues, as well as public health and safety concerns—including advertising, fraud, illegal use of title, infection control, adverse events, and communication (CMRB 2003–04). The number and types of complaints handled by the CMRB illustrate the value of a comprehensive statutory regime. The register, course approval status, and outcomes of formal hearings are publicly available on the CMRB website—providing a level of transparency not found through professional associations.

In summary, there is a need for legislation to ensure protection of public health and safety by establishing and enforcing minimum qualifications for entry to and practice of naturopathy and WHM, providing a framework for handling consumer concerns, and ensuring appropriate access to the tools of the trade. The present regulatory framework inhibits best practice by the professions.

### **Conclusion regarding criterion 3**

Given that (i) the risks identified; (ii) evidence that the existing regulatory mechanisms—by government and within the professions—are inadequate in safeguarding and protecting members of the public as consumers of naturopathy and WHM; and (iii) the lack of an enforceable minimum standard of education for naturopaths and WHM practitioners, occupational regulation is warranted. Under statutory regulation, the accreditation and representation of practitioners would be separated—thereby reducing the possibility of conflicts of interest. Moreover, professional associations would be able to focus their resources on support of their members, professional issues, and development of the professions. Statutory regulation would also provide a higher standard of complaints process

with regard to access, transparency, and equity, and disciplinary actions would be upheld by statute and an appeals process.

#### **11.4.4 Criterion 4**

Is regulation possible to implement for the occupation in question?

The AHMAC criteria seek to clarify whether an occupation is well defined by its body of knowledge and practices. The scope of this study is confined to consideration of the professions of WHM and naturopathy. WHM is well established throughout Western history and can be readily understood to be the practice of herbal medicine from the traditions of Britain, Europe and North America. Herbal medicine practised in the Chinese medicine tradition is already regulated under the *Chinese Medicine Registration Act 2000* in Victoria. Other traditions such as ayurveda are not covered in this study. WHM is one of the modalities used by naturopaths and these professions have overlapping identities and modalities. Naturopathy is an established body of knowledge and the boundaries of its practice are defined in the health training package, but because no barriers to entry exist, naturopaths can practice any modality and still use the title. The boundaries of practice have not been enforced. Naturopathy's modalities are also practiced as single modalities by other practitioners—WHM practitioners, homeopaths, massage therapists, nutritionists, and lifestyle counsellors. However, under protection of title legislation, definitions of practice are not required.

Education for naturopaths has been offered at tertiary level for four decades in Australia. There is broad professional agreement on core competencies and curriculum requirements through the adoption of the National Health Training Package (the minimum requirements set by the Vocational Education and Training sector) which has the support of professional associations. Naturopathy and WHM curricula have also been developed to bachelor's degree level by a number of universities and private education providers. It is therefore possible to define the professions sufficiently for the purposes of regulation.

#### **Conclusion regarding criterion 4**

Naturopathy and WHM are defined professions, with defined modalities, for which it is possible to implement regulation. There are complexities in relation to naturopathy—because of the diversity of practices adopted by the profession and the fact that practitioners can specialise in some modalities while not practising others. These practical issues pertain to Criterion 5 (below).

#### **11.4.5 Criterion 5**

Is regulation practical to implement for the occupation in question?

Practitioners of naturopathy are recognised and regulated in some other jurisdictions—notably in various states of the United States and provinces of Canada. Chinese medicine (including herbal medicine and acupuncture) has been successfully regulated in Victoria since 2000, despite not all modalities within Chinese medicine being covered by statutory registration. These examples demonstrate the practicality of implementing occupational regulation for CAM.

In the case of Chinese medicine, the title of 'Chinese medicine practitioner' was restricted when the term 'Chinese medicine' was also used by practitioners to cover a range of modalities—including acupuncture, Chinese herbal medicine, massage, qi gong, dietary therapy, and others. Although only the modalities considered to be sufficiently 'risky' (acupuncture and Chinese herbal medicine) were regulated (via restricted use of professional titles), practitioners who practise the 'non-risky' modalities are now unable to use the title of 'Chinese medicine practitioner' in Victoria unless they are registered with the Victorian board.

For the Chinese Medicine Registration Board of Victoria (CMRB), there have been practical challenges in:

- setting the registration fee—given that the actual number of practitioners (and the number likely to be granted registration) were unknown;
- ‘grandparenting’—particularly in assessing the competence of existing practitioners who had a low level of qualification but who had undertaken additional multiple short courses, and those whose clinical training was limited;
- setting appropriate standards for education—by defining learning outcomes (rather than specifying curricular design) and by allowing institutions time to upgrade their courses;
- educating the profession, private health funds, and the public about the role of the board, and distinguishing it from professional associations; and
- aligning standards for practice with other registration boards—given their legislated role to endorse their practitioners for acupuncture.

It is likely that similar practical issues will emerge for naturopathy and WHM should statutory regulation be undertaken, but the problems are not insurmountable. Indeed, for naturopathy and WHM, the numbers of potential registrants could be expected to be higher than for Chinese medicine. The financial viability and fee levels should therefore be of less concern than for Chinese medicine practitioners.

The experiences of the CMRB would be beneficial if naturopathy and WHM were to be regulated, and sharing the resources and systems already developed could be usefully explored. Given the possibility of a policy shift towards national registration of medical practitioners, consideration could also be given to commencing registration for naturopathy and WHM practitioners through cross-jurisdictional cooperation—thus reducing the cost and time required in each jurisdiction.

As described above, the GST legislation—*A New Tax System (Goods and Services Tax) Act (1999)*—established a mechanism for naturopaths, acupuncturists, and herbal medicine practitioners to provide GST-free services. However, the creation of this system is a complicating factor in considering registration of the professions of naturopathy and WHM, insofar as it has created a perception of occupational recognition, if not regulation. Statutory regulation would set in place a system of standards of practice and standards of education and training for practitioner registration. It is quite likely that such standards would differ from the many different sets of standards currently set by professional associations. Some practitioners who currently meet standards set by some professional associations might fail to meet those set by a statutory registration board, causing consternation for the affected practitioners and professional associations. However, the current system of recognition by the ATO was set up as a taxation mechanism—without regard to the adequacy or consistency of the standards that have proliferated under it. The development of a system that has protection of the public as its principal criterion for professional standards and levels of education and training is to be preferred to a taxation mechanism that does not incorporate standards for protection of the public.

The major practical issue is the question of how to define the professions. It is clear that WHM is a definable practice and a definable profession. The question is whether naturopathy can be similarly defined—given that it involves a more eclectic range of practices. Herbal medicine is, however, a core practice for naturopaths (as defined by the National Health Training Package), and nutritional medicine is a second core practice.

Another practical difficulty occurs due to the multiplicity of titles used by practitioners. At present, practitioners can refer to themselves in terms of generic professional titles or in terms of the individual modalities that they offer. If titles do become protected for naturopathy and WHM, a new restriction to entry (insofar as use of titles is concerned) will be imposed. The protected titles might conflict with some of the titles currently being used by

education providers, associations, private health funds, or taxation authorities (under the GST legislation).

Although the practice of WHM is easy to define as a modality (with some specific risks associated with the tools of the trade), the title of ‘naturopathy’ includes a complex range of ‘risky’ and ‘non-risky’ practices. It is common for those who call themselves ‘naturopaths’ to be practising one or more of the following modalities: herbal medicine, nutritional medicine, homeopathy, tactile therapies, and lifestyle counselling. At present, practitioners can adopt the title of ‘naturopath’ if they are practising only one of these or if they are practising several of them. If title protection were mandated only for WHM practitioners, it is possible that naturopaths practising herbal medicine would escape the statutory mechanism for protecting public health and safety. On the other hand, the protection of the title ‘naturopath’ would mean that naturopaths using only ‘lower risk’ practices (such as nutritional medicine and homeopathy) would be forced to choose between registration and not using the title.

Some practitioners might attempt to escape the regulatory net by adopting terms such as ‘natural therapist’, ‘complementary therapist’, ‘homeopath’, ‘clinical nutritionist’, and ‘nutritional medicine’. For example, some practitioners might be refused registration (or not seek registration) because they have lower standards of training. They might continue to practise under alternative titles—including the potentially confusing title of ‘natural therapist’. If so, consideration will have to be given to the identification of unregistered practitioners who are holding out to be registered naturopaths or WHM practitioners. The use of such status or title by private health funds or the ATO may provide means for identifying practitioners who are holding out to be naturopaths or WHM practitioners.

Consideration also needs to be given to the extent of support for (or opposition to) occupational regulation. The data collected in this study indicate strong support for statutory registration among a range of stakeholders.

- The consumer focus group participants concurred with overseas research in terms of supporting registration.
- The GP survey participants indicated support for government regulation of herbal medicine and naturopathy, as well as of homeopathy and vitamin and mineral therapy.
- The majority of naturopaths and WHM practitioners in the workforce survey viewed government regulation positively and supported more substantial practitioner regulation than currently exists.
- The views of the educational institutions were more mixed. Of the 14 private educational providers that responded, more than a third supported statutory registration and more than a quarter supported co-regulation. Only one institution supported continued self-regulation. Of the university providers who responded, all indicated informal support for statutory registration (although this was not a formally adopted position of any institution).
- The views of the professional associations were also mixed. Of the 11 associations that responded, seven were negative about current attempts to self-regulate and wanted stronger regulation (and four of these called for statutory registration); only four supported continued self-regulation.
- The practitioners in the workforce survey reported in Chapter 4 were generally in favour of regulation. It can be assumed that most practitioners would be likely to comply with statutory requirements.

Nevertheless, concerns have been expressed in the literature that statutory regulation would result in the ‘medicalisation’ of naturopathy and WHM (Stone 1996; Eisenberg et al. 2002). These concerns include: (i) subordination to medical doctors; (ii) the effect on practice of a highly regulated environment; (iii) increased patient volume; (iv) less time with patients; (v) less individualised care; and (vi) violation of practice philosophy (Eisenberg et al. 2002). Stronger regulation is likely to introduce a degree of standardisation. Cooper, Laud & Dietrich (1998) have noted that, in a future pluralistic healthcare system, regulation will need

to ensure that primary care clinicians can provide uniform high quality care. Naturopathy and WHM will need to have a voice in determining the nature of quality standards that are consistent with Australia's traditions of naturopathy, WHM, and the law. However, statutory registration will not, in itself, ensure high standards. Its primary purpose is to protect the public and provide a statutory complaints mechanism, and also a mechanism for enforcement of minimum standards for entry to the profession. The demonstration of competence, commitment to research, ethical conduct, and accessible and effective complaints processes are necessary to earn professional respect (Stone 1996).

Two approaches would help to alleviate concerns about stronger regulation—(i) registration boards consisting of a majority of practitioners who are well qualified in the non-medical traditions of naturopathy and WHM; and (ii) increased research into the holistic frameworks applied in naturopathy and WHM. With respect to the second of these, it is the different philosophies and approaches to health which support the co-existence of two systems of health care—conventional and non-conventional—(Josefek 2000), therefore research into the naturopathic and WHM paradigms is essential.

Given the increasing number of consumers who use CAM therapies and consult CAM practitioners, other CAM therapies might have to be considered for registration in future, particularly those that use ingestive therapies. Consideration should therefore be given to a 'complementary and alternative medicine registration board'—rather than a more narrowly focused 'Western herbal medicine and naturopathy registration board'. This would allow protection of the titles of WHM and naturopathy and make it quite clear that some modalities are to be brought under the regulatory net whereas others are not—based on a thorough risk assessment and the other AHMAC criteria.

### **Conclusion regarding criterion 5**

Occupational regulation is not without some practical difficulties. However, experiences in other jurisdictions and the registration of Chinese medicine practitioners in Victoria can be drawn upon in implementing appropriate occupational regulation for currently unregulated naturopathy and WHM practitioners

#### **11.4.6 Criterion 6**

Do the benefits to the public of regulation clearly outweigh the potential negative impact of such regulation?

A wide range of positive social effects is likely to be promoted by the regulation of naturopathy and WHM. The advantages and disadvantages of occupational regulation are summarised in Table 11.1. A strong case exists for the public benefit to be gained from registration, whereas the adverse effects are largely limited to some elements of the professions.

### **Conclusion regarding criterion 6**

The benefits of promoting public safety clearly outweigh the potential negative impacts of occupational regulation.

**Table 11.1 Benefits and negative impacts of regulation**

Benefits	Negative Impacts
Equitable access to a transparent and accountable system for managing complaints and professional misconduct (including access to an appeals process)	Potential increase in fees for practitioners (registration plus membership of professional associations), which might be passed on to consumers
Improved quality and safety in healthcare as a result of better communication and referral among qualified practitioners	Increased restrictions to entry to practice of the professions
Better information and protection for consumers	Potential loss (or diminution) of livelihood for some practitioners who are refused registration
Improved and consistent standards of education (including better quality assurance processes and greater fostering of research)	Increased cost for some educational institutions to upgrade their courses which may be passed on to students
Assurance for insurers and employers of appropriate standards of training of practitioners	Potential loss of GST-free status for practitioners who are refused registration.
Increased community confidence in the professions and enhanced status of practitioners	Increased costs for practitioners who may have to upgrade their qualifications to achieve registration
Greater focus by professional associations on continuing professional development and providing other benefits to members	Loss of market share for those educational institutions unable to upgrade to meet higher standards
Further mainstreaming of complementary and alternative healthcare practices into the health system	
Potentially better access to tools of the trade for the professions with therapeutic benefit to the community	
Increased partnerships between public and private sectors, in both health and education sectors	
Decreased administrative burden for funds and insurers.	
Compulsory professional indemnity insurance to protect patients from financial harm when injuries occur.	

## 11.5 Overall assessment against the AHMAC criteria

Australian survey data show that the use of CAM is widespread. Chapter 9 of this report demonstrated that use has increased since 1993, and that there was a 62% increase in personal expenditure on CAM practitioners (after accounting for inflation) from 1993 to 2000.

Using data on the cost of consultation fees (Chapter 4), naturopaths and WHM practitioners turned over approximately \$85 million in 2003 based on an estimated 1.9 million consultations.

Governments should note the clear consumer preference that emerges from these data, and the risks (both actual and potential) that the data present. As an increasing number of consumers use CAM therapies and consult CAM practitioners, an increasing number of citizens will be exposed to any risks associated with these therapies.

In reviewing the current situation against the criteria proposed by AHMAC and NCP, the research group concludes that:

- naturopathy and WHM are within the appropriate responsibility of health ministers;
- some naturopathy and WHM practices pose a significant risk of harm, and the risks are compounded by the primary healthcare context and the broad scope of practice;
- existing regulatory mechanisms are inadequate for safeguarding and protecting consumers;
- there are definable modalities within naturopathy and WHM for which it would be possible to implement regulation;
- there are some practical challenges for occupational regulation, but implementation lessons can be drawn from overseas experience and the experience of regulating Chinese medicine practitioners in Victoria since 2000 (although some practitioners are likely to escape the regulatory net by using non-regulated titles, particularly ‘umbrella’ titles such as ‘natural therapist’ and ‘complementary therapist’); and
- the benefits of protecting public safety through occupational regulation outweigh the potential adverse effects.

## 11.6 Options for regulatory models

As noted in Chapter 10 (see 10.4), six general models exist for regulation of the health workforce (DHS 2003 p.20):

- *Self-regulation* – A practitioner’s voluntary membership of a professional association indicates that the practitioner is suitably qualified, safe to practise and subject to a disciplinary scheme.
- *Negative licensing* – A practitioner may practise in a self-regulated profession unless listed on a register of persons who are ineligible to practise because of a finding of poor practice.
- *Co-regulation* – Members of a professional association are regulated by that association and government.
- *Reservation of title only* – A statutory registration board registers members of a profession and reserves the use of specific titles for those who are registered.
- *Reservation of title and core practices* – Certain risky procedures within the defined scope of practice of a profession are restricted via legislation to members of the registered profession and other specified registered health professions.
- *Reservation of title and whole practice restriction* – This model restricts the use of reserved titles, broadly defines the scope of practice of a profession, and prohibits unregistered practitioners from practising the profession.

### 11.6.1 Self-regulation

The model of *self-regulation* presumes that the industry has an appropriate mechanism and capacity to monitor members of the profession and to effect disciplinary procedures as required. Naturopathy and WHM are purportedly self-regulated at present. However, in effect the professions are presently unregulated (rather than self-regulated) because neither profession has enforceable standards of training for entry, nor a transparent, credible, and fair mechanism of self-regulation across its whole industry.

This study has found that the continuing model of ineffective self-regulation is not practical for the following reasons: (i) ongoing proliferation of professional associations with different standards; (ii) concerns about wide variation in educational levels among practitioners; (iii) tolerance of low grade qualifications by some associations; and (iv) some evidence that courses are becoming shorter (especially in the VET sector).

### 11.6.2 Co-regulation

*Co-regulation*, a form of government monitored self-regulation, has been proposed by some professional associations within the sector. Under such a model, the government would have oversight of mechanisms and procedures.

Given the current state of the professions, it would be necessary for government either to monitor numerous bodies or to take the lead in facilitating the establishment of a single regulatory authority that is separate from the current professional associations, and also to establish incentives for compliance. This is likely to be intrusive and would also have high transaction costs. This is potentially a more costly model of regulation, and the costs would necessarily be borne by taxpayers.

### 11.6.3 Negative licensing

This study found no evidence that *negative licensing* has been applied in Australia in relation to regulation of the professions. It would limit regulation to those identified as failing to meet certain standards of professional conduct or education. In this context, there have been instances of deregistered health practitioners continuing to practise, using the title of naturopathy or WHM. A system of negative licensing could offer protection to the community against such behaviour.

This mechanism could co-exist with other forms of health practitioner regulation. However, issues of civil liberty do arise in any such system.

### 11.6.4 Statutory regulation

The following models are all forms of statutory regulation:

- *Reservation of title only* ;
- *Reservation of title and core practices*;
- *Reservation of title and whole practice restriction*.

Statutory regulation with reservation of title only was considered by the research group to be the most practical option.

Statutory regulation is a well established model for health professions across Australia. The legislative frameworks and operational arrangements used in other health professions can be readily adapted and applied to naturopathy and WHM—as has already been done in the case of Chinese medicine. The current framework also represents a form of co-regulation in that it is a co-operative arrangement between government and profession.

A naturopathy and WHM board could be integrated with existing boards (for example, the Chinese Medicine Registration Board) to improve efficiency of operation and reduce cost to practitioners.

## 11.7 Conclusion and recommendations

In considering the application of the AHMAC criteria for health workforce regulation to the current state of naturopathy and WHM practice within Victoria and Australia, the research group concluded that:

- a negative licensing model is a minimum requirement to prevent those practitioners who engage in seriously unethical or illegal conduct from continuing to practice or practising without scrutiny; and
- that statutory regulation is desirable and warranted.

Statutory regulation is warranted for the following reasons:

- there is a level of risk in naturopathy and WHM comparable to other regulated professions;
- there is a particular risk related to interaction of herbal medicine and pharmaceutical drugs, and the need for appropriate prescribing frameworks;
- existing regulatory frameworks are insufficient to protect against professional misconduct;



- variable arrangements currently exist for professional practice standards among professional associations, and professional associations have been unable to come to common arrangement; and
- variable standards exist among education and training institutions, with no evidence of movement towards common standards (including the failure of current regulatory frameworks to ensure basic standards for education).

To protect public health and safety, it is recommended that occupational regulation be applied to naturopathy and WHM, with the following titles to be protected:

- herbal medicine practitioner;
- Western herbal medicine practitioner;
- phytotherapy practitioner;
- phytotherapist;
- medical herbalist;
- herbalist;
- Western herbalist;
- naturopath;
- naturopathic medicine practitioner;
- naturopathic physician; and
- ND (naturopathic doctor/doctorate; naturopathic diploma).

The following titles would not be protected:

- natural therapist, complementary therapist, and similar ‘umbrella’ titles;
- nutritional medicine practitioner;
- clinical nutritionist;
- homeopath;
- massage therapist;
- body work therapist; and
- relaxation therapist.

Protection of title might have unintended consequences for practitioners of herbal medicine in other traditions—such as ayurvedic medicine. It will be important for such professions to receive exemptions from the offence provisions, as long as practitioners make clear the tradition within which they practise and ensure that the title they use does not suggest that they are practising WHM or naturopathy.

Protection of title might also have adverse consequences for those naturopaths who have limited training, but who have been in practice for many years. It will be important to have a fair and reasonable ‘grandparenting’ provision in the legislation that allows for recognition of this category of practitioners.

A significant implication of occupational regulation will be the requirement for change in some educational institutions. Sufficient time must be allowed for an appropriate transition to occur in the nature of their courses.

Although this study examined some aspects of the practice of multiple modalities (that is, the naturopathic modalities of herbal medicine, nutritional medicine, and massage or homeopathy, as defined by the National Health Training Package), the question of whether some of these single modalities should be subjected to occupational regulation has not been considered. The review of risks suggested that nutritional medicine and homeopathy also carry some risks. It is therefore recommended that a future study be commissioned in relation to these two practices, as well as ayurvedic medicine.

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# Research Group

## **Professor Alan Bensoussan, PhD, MSc**

Professor Alan Bensoussan is the director of the Centre for Complementary Medicine Research at the University of Western Sydney. Professor Bensoussan has been in clinical practice for 20 years and is an active researcher who has attracted funds from industry, state health departments, and the National Health and Medical Research Council. He works in an advisory capacity for both government and industry, including as an expert panel member to the Complementary Medicines Evaluation Committee of the Australian Therapeutic Goods Administration, and frequently serves as a short-term consultant to the World Health Organization. He sits on several journal editorial committees, has published two books—including a review of acupuncture research (1990) and a major government report on the practice of traditional Chinese medicine in Australia (1996). The latter contributed to the passage of the Victorian *Chinese Medicine (Practitioner) Registration Act*. Professor Bensoussan's research contributions, particularly his clinical trials and public health research in Chinese medicine, have been widely reported and recognised. In 2003 Professor Bensoussan was appointed by the Hon. Trish Worth to the Expert Committee on Complementary Medicines in the Health System.

## **Professor Marc Cohen, MB,BS (Hons), PhD (TCM), PhD (ELEC ENG), BMedSci (Hons), FAMAC**

Professor Marc Cohen is the founding head of the Department of Complementary Medicine at RMIT University, president of the Australasian Integrative Medicine Association, and the past founding director of the Centre for Complementary Medicine at Monash University. In addition to his medical qualifications, he has undertaken extensive studies in traditional Chinese medicine and received his PhD in 1994. He also received a second PhD which investigated the electromagnetic basis of acupuncture in the Department of Electrical and Computer Systems Engineering at Monash University. Professor Cohen plays an active role in the teaching and research of complementary medicine. He has been involved in many clinical trials and basic science research projects, as well as teaching at undergraduate and postgraduate levels to both doctors and other health practitioners.

## **Ms Susan Dean, Dip App Sc (Naturopathy), NHAA**

Ms Susan Dean is an Executive Director on the board of the National Herbalists Association of Australia (NHAA), and was president of the association for four years to May 2005. In 2000-2001 Ms Dean represented the NHAA on the Australian National Training Authority's Industry Reference Group for Complementary and Alternative Health Care, advising on the development of the Health Training Packages for Western herbal medicine and naturopathy. She was a contributor to the NHAA's successful application for funding under the Federal Government's GST registration project, and subsequently was a member of the small teams responsible for completing various components of this project, including: the development of a model for the self-regulation of the natural and complementary medicine disciplines; the revision and upgrading of the education standards for herbalists; and, in collaboration with the University of Western Sydney, the first independent workforce study of Western herbalists and naturopaths. Ms Dean has been in clinical practice for eight years and operates a clinic in the Victorian regional centre of Ballarat. She has presented numerous seminars to her peers as part of the NHAA's continuing education program.

## **Dr Sophie Hill, BA (Hons), MA, PhD**

Dr Sophie Hill is the coordinating editor of the Cochrane Consumers and Communication Review Group, based in the School of Public Health at La Trobe University. This group coordinates the production of systematic reviews of the effectiveness of interventions to improve interactions with the health system. In her capacity as senior research fellow, she is

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### **Ms Genevieve Howse, BA, LLB**

Genevieve Howse is a public health lawyer who has worked as a solicitor, barrister, government lawyer, and academic. She is currently director (programs) of the Centre for Public Health Law in Australia, which is funded by the Commonwealth Department of Health and Ageing and is the first centre of its kind in Australia. In this capacity she undertakes research, teaching, and consultancies in the area of public health law. More recently, she has undertaken several large projects in the development of legislation policy in the Pacific region. She is also a member of the Global Population Health Law Exchange, an international body funded to further the use of law as a tool in health protection.

### **Professor Vivian Lin, MPH, DrPH**

Vivian Lin took up the Chair of Public Health and Head of the School of Public Health at La Trobe University in mid-2000. From 1997 until 2000, she was the executive officer for the National Public Health Partnership. She has previously held senior positions within the NSW Health Department, the National Occupational Health and Safety Commission, and the Victorian Health Department (and its successors). Over the years, she has had responsibility for policy, planning, and program development across a wide range of health issues—including health promotion, ethnic health, Aboriginal health, aged care, health technology, pharmaceuticals, intergovernmental relations, regional planning, and health export. She has been the honorary policy convenor for the Public Health Association, and currently serves on the public health committee of the Australian Medical Association. She was a founding board member of the Chinese Health Foundation, and was appointed as the inaugural president of the Chinese Medicine Registration Board of Victoria in late 2000. Professor Lin consults for the World Bank, the UK Dept for International Development, World Health Organization, and AusAID, as well as various Australian governments. Her recent books include the co-authored *Health Planning: Australian Perspectives* (with K. Eagar and P. Garrett), and the co-edited *Evidence-based Health Policy: Problems and Possibilities* (with Brendan Gibson). Before coming to Australia, she worked in the US health planning program and tutored at UC Berkeley in public health and in ethnic studies. Her qualifications include BA (Yale) in biology and political science, and MPH and DrPH from UC Berkeley, where she concentrated on social epidemiology, occupational health, and health policy.

### **Dr Pauline McCabe, PhD, MHSc(PHC), ND, RN, Midwife**

Dr Pauline McCabe has practised as a nurse, midwife, naturopath, academic, and researcher in various phases of her career in complementary healthcare. Her PhD thesis identified the natural phenomena underlying the theories of traditional Chinese medicine, naturopathy, and ayurveda. In recent years she has had a leading role in developing complementary therapies policy for the nursing profession, and she designed and coordinated a double degree in nursing and naturopathy at La Trobe University. She has had numerous publications related to complementary healthcare, including an edited text entitled *Complementary Therapies in Nursing and Midwifery: from vision to practice* (Ausmed, 2001). Dr McCabe has had significant experience in the design and evaluation of tertiary courses for natural therapies, and has participated in course approval panels for the Chinese Medicine Registration Board of Victoria and the NSW Office of Higher Education. She was employed as a Research Fellow

in the School of Public Health at La Trobe University from 2003-2005, and operates an education consultancy called 'Complementary Care Education'.

### **Professor Stephen P Myers, PhD, BMed, ND**

Professor Stephen P Myers is the foundation director of the Australian Centre for Complementary Medicine Education and Research. Before the establishment of this centre in 2001, Stephen was the foundation head of the School of Natural and Complementary Medicine at Southern Cross University, where he still plays an active role. Professor Myers initially qualified as a naturopathic practitioner, and later qualified in Western medicine. He has a PhD in basic and clinical pharmacology and has been extensively involved with naturopathic medicine education at an undergraduate and postgraduate level in Australia for the past 20 years. He is actively engaged in research in herbal medicine, nutraceuticals, therapeutic foods, and public health issues in complementary medicine. He has acted as a consultant to industry, government, and educational institutions on a broad range of issues involving natural medicine. In conjunction with Professor Alan Bensoussan, he co-authored the report 'Towards a Safer Choice' in 1995, which reviewed the practice and regulatory requirements of Traditional Chinese Medicine in Australia. In 1997 he was appointed by the Commonwealth government to the Complementary Medicine Evaluation Committee, a statutory expert advisory committee to the Therapeutic Goods Administration. In 2003 he was appointed to the Commonwealth government's Expert Committee on Complementary Medicine in the Health System, which reviewed complementary medicines and practices in Australia. In 2004 he received the prestigious Lady Cilento Award by the Complementary Healthcare Council, which is awarded to individuals who have made a significant and sustained contribution to the field of complementary medicine over many years.

# Glossary

## Acupuncture

Acupuncture originated from China. It involves inserting small needles into various points in the body to stimulate nerve impulses. Traditional Chinese acupuncture is based on the idea of *qi* ('vital energy'). This is said to travel around the body along 'meridians', which are affected by the acupuncture points. Western acupuncture uses the same needling technique, but is based on affecting nerve impulses and the central nervous system. Acupuncture can be used in the West as an anaesthetic and analgesic modality (House of Lords Select Committee 2000).

## Aromatherapy

Aromatherapy is a specialised branch of herbal medicine that is based on the therapeutic use of aromatic oils derived from flowers and plants. The complex chemical constituents of the oils are believed to affect the mind, emotions, and physiology. In Australia, oils are mainly used topically (via massage) or by inhalation. However, in Europe (especially in France), aromatic oils are prescribed by some medical doctors, and are taken orally.

## Ayurveda

Ayurveda ('science of life') is the traditional form of medical practice in India. It is claimed to be the oldest extant system of medicine. It is concerned with physical, mental, and emotional aspects of wellbeing, and with the interaction of people and their environments. Ayurveda includes dietary and lifestyle advice, physical therapies, yoga, meditation, Indian herbal medicine, and mineral therapies (Expert Committee 2003). Ayurveda is a recognised part of the Indian healthcare system.

## Bach and other flower remedies

Flowers are believed to contain the 'life force' of a plant, and this method was developed by Dr Edward Bach using English wildflowers. The 'life force' is diffused into water by immersion under sunlight, and flower remedies are believed to help a person release the emotions that might underlie a disease process (House of Lords 2000). Flower remedies are also made from the native flowers of other countries, including Australia.

## Chinese medicine

Chinese medicine (CM) (also known as traditional Chinese medicine) is diverse and is used to treat both acute and chronic illness. Modalities used in practice include: Chinese herbal medicine (which uses plant, animal, and mineral substances); acupuncture; Chinese massage; dietary and lifestyle advice; and other specific techniques (such as moxibustion, cupping, breathing, movement, meditation, orthopaedic manipulations, and surgery). CM employs a variety of theoretical frameworks to analyse health problems, but the main diagnostic methods are identification of the patterns of dysfunction, and tongue and pulse diagnosis (Expert Committee 2003). CM is an accepted part of the Chinese healthcare system, and numerous state hospitals and universities provide care and tuition.

## Chiropractic

Chiropractic perceives the body to be a self-regulating, self-healing organism. These functions are controlled by the brain, spinal cord, and nerves of the body. Chiropractic involves the location of subluxations of spinal structures, reducing their impact on the nervous system, and a philosophy of natural healthcare based on a person's inborn potential to be healthy (Australian Chiropractors' Association 2005)

## Complementary and alternative medicine

Complementary and alternative medicine is a group of diverse medical and healthcare systems and therapies that are based on theories or explanatory mechanisms that are not in keeping with the orthodox biomedical model (Bensoussan 1999). CAM systems generally

hold medicine to be a science of the human person, and understand disease as involving a systemic dislocation of the whole person (Foss, in Robson 2003, p.2). Major CAM systems include naturopathy, Western herbal medicine (WHM), Chinese medicine, ayurveda and homeopathy.

### **Complementary therapies**

Complementary therapies (CTs) are non-conventional therapies that are used together with conventional healthcare. The list of what are considered by conventional medicine practitioners to be complementary therapies changes continually, as those therapies that are proven to be safe and effective become adopted into conventional health care and as new approaches to health care emerge (National Center for Complementary and Alternative Medicine 2002). Examples of therapies used to complement conventional healthcare are nutritional medicine, meditation and massage. Also, consumers may choose to complement conventional healthcare with a wide range of non-conventional therapies, sometimes independently of medical advice.

### **Feldenkrais**

The Feldenkrais method is a form of somatic education that uses gentle movement and directed attention to improve movement and enhance human functioning. Its aim is to increase ease and range of motion, improve flexibility and coordination, and rediscover the innate capacity for graceful, efficient movement. The method is based on principles of physics, biomechanics, and an empirical understanding of learning and human development. By expanding the self-image through movement sequences that bring attention to the parts of the self that are 'out of awareness', the method enables increased awareness of habitual neuromuscular patterns and rigidities, and expands options for new ways of moving (Feldenkrais Educational Foundation of North America 2005).

### **Homeopathy**

Homeopathy is a system of treating patients using very low doses of preparations according to the principle that 'like should be cured by like'. The effects of the preparations, when administered to healthy subjects, correspond to the manifestations of the disorder in an unwell patient. Homeopathy teaches that minute doses of a substance can stimulate a specific reaction against a disease with similar symptoms. The theory holds that, if an overdose of a substance causes a particular set of symptoms, a dilute but 'potentised' dose of the same substance will stimulate a healing response (Expert Committee 2003).

### **Integrative medicine**

Integrative medicine combines mainstream medical therapies and CAM therapies for which there is some high quality scientific evidence of safety and effectiveness (National Center for Complementary and Alternative Medicine 2002).

### **Iridology**

Iridology is the study of patterns in the iris to determine potential health problems. Iridologists believe that changing patterns and markings in the iris can be used to reveal emerging conditions and to identify inherited weaknesses that might lead to physical and emotional disorders. Iridology cannot detect a specific disease. Rather, it is a preventive practice that helps people to understand their basic health issues so that they can seek treatment, if necessary, from an appropriate specialist (International Iridology Practitioners Association 2005).

### **Kampo**

Kampo (also known as Kanpo) is the Japanese version of Chinese medicine, and is the most popular form of complementary healthcare in Japan. Kampo is well integrated into the Japanese healthcare system and is widely available from hospitals, physicians, and pharmacies. Kampo practitioners might also administer acupuncture, moxibustion, and

manipulative therapies. Japan has the highest per capita consumption of herbal medicine in the world (Expert Committee 2003).

### **Massage therapy**

Massage therapy is the manipulation of the soft tissue of body areas to bring about generalised improvements in health. These include relaxation or improved sleep, or specific physical benefits (such as relief of muscular pain) (Expert Committee 2003).

### **Meditation and relaxation**

Meditation involves techniques to relax a patient to facilitate deep reflection and a clearing of the mind (House of Lords Select Committee 2000).

### **Moxibustion**

Moxibustion is a technique used to treat and prevent diseases through the application of heat via a smouldering herb positioned just above an acupuncture point (Robson 2003 p. 90).

### **Muscle testing**

Also known as ‘applied kinesiology’ or ‘touch for health’, muscle testing is a form of diagnosis in which muscles are used as primary feedback mechanisms to examine how a person’s body is functioning. In general, if an applied kinesiologist finds a muscle that tests under- or overactive, the kinesiologist then attempts to determine why that muscle is not functioning properly. Depending on the cause, treatment might include various myofascial therapies, meridian therapy, or clinical nutrition (for dietary sensitivities) (International College of Applied Kinesiology 2005).

### **Naturopath**

For this study, a naturopath was taken to be a practitioner whose practice and modalities have been defined by the National Training Package (introduced in 2002, see Appendix 1.1)—that is, a practitioner having core training in naturopathic principles and philosophy, and in at least three of four practice modalities: (i) herbal medicine; (ii) nutritional medicine; and (iii) either massage or homeopathy. It is recognised that the modalities encompassed by naturopathy might be practised as single modalities, that is, either naturopaths or other practitioners may have a practice consisting of only one modality. However, this report does not address those practitioners whose training and practice are in the single modalities of massage, nutritional medicine (sometimes called ‘clinical nutrition’), or homeopathy.

### **Naturopathy**

Naturopathic medicine is a distinct system of primary health care—an art, science, philosophy, and practice of diagnosis, treatment, and prevention of illness. Naturopathic medicine is distinguished by the principles that underlie and determine its practice (see Chapter 1). These principles are based upon the objective observation of the nature of health and disease, and are continually re-examined in the light of scientific advances. The methods used are consistent with these principles and are chosen on the basis of patient individuality. Naturopathic physicians are primary healthcare practitioners whose diverse techniques include modern and traditional, scientific, and empirical methods. (American Association of Naturopathic Physicians definition of naturopathic medicine; prepared for the House of Lords Select Committee 2003.)

### **Nutritional medicine**

Nutritional medicine, as practised by naturopaths, occurs in the context of naturopathic medicine. It integrates scientific nutrition and the principles of naturopathic medicine into a distinct approach whereby diet and nutritional supplements are used to address and prevent disease. The core components are: respect for the traditional and empirical naturopathic approach to nutritional knowledge; recognition of the value of food as medicine; an understanding that whole foods are greater than the sums of their parts; and recognition that



individuals have unique interactions with their nutritional environments (Naturopathic Nutrition Forum, Southern Cross University, 2003).

### **Osteopathy**

Osteopathy recognises that all parts of the body are interrelated, with structure being closely related to function. Osteopaths help maintain optimal function of the internal organs which, in turn, promotes and maintains the body's balanced production of natural chemicals. The aim of osteopathic treatment is to restore the individual's natural abilities to heal by using a combination of biomechanics, lifestyle improvements, and healthy nutrition. Manual techniques that might be used include soft-tissue massage, muscle stretching, passive range of motion, and gentle joint manipulation (Australian Osteopathic Association 2005).

### **Reiki**

Reiki is a form of energy medicine used for stress reduction and relaxation. It aims to access an unlimited supply of 'life force energy' to improve health and enhance the quality of life. Reiki treats the whole person including body, emotions, mind, and spirit, and is said to create many beneficial effects including relaxation and feelings of peace, security, and wellbeing. Reiki is described as a simple, natural, and safe method of spiritual healing and self-improvement that everyone can use (International Centre for Reiki Training 2005).

### **Western herbal medicine**

Herbal medicine, in general, refers to the therapeutic use of relatively crude (and therefore chemically complex) plant extracts, or simply herbs in their dried forms. WHM comes from a European tradition that has evolved from Egyptian, Greek, and Roman medical systems. Over time other herbal traditions have had significant influences—most notably traditions from North America and Asia. Plant materials are used fresh, dried, or as liquid or solid plant extracts. They are used for both internal and external treatments (Expert Committee 2003).

### **Western herbal medicine practitioner**

For the purposes of the present study, a 'Western herbal medicine practitioner' was understood to be a health practitioner who engages in extemporaneous<sup>1</sup> compounding of herbal medicines for therapeutic purposes for individuals under his or her care. Such a WHM practitioner will have satisfied core training in the principles, philosophy, and practice of herbal medicine, as defined by the National Health Training Package for WHM (introduced in 2002, see Appendix 1.1).

### **Whole practice research**

Whole practice (or whole systems) research is an emerging research field within complementary medicine which assesses the way that practitioners actually practice. In clinical practice, naturopaths and Western herbalists use multiple therapeutic tools accompanied by dietary and lifestyle assessment and advice, patient education, and counselling. Researching a single herb or nutrient does not reflect the whole of practice (Myers 2005).

### **Yoga**

Yoga is a system of adopting postures (with related exercises) designed to promote spiritual and physical wellbeing (House of Lords Select Committee 2000).

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<sup>1</sup> Extemporaneous preparations are those prescribed as part of a consultation for an individual patient.

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## Abbreviations

AANMP	Alumni Association of Natural Medicine Practitioners
AAH	Australian Association of Homotoxicology
ABN	Australian Business Number
ACNEM	Australasian College of Nutritional and Environmental Medicine
ACONT	Australian Committee of Natural Therapies
ACHA	Australian Complementary Health Association
ADRAC	Adverse Drug Reactions Advisory Committee
ADRS	Adverse Drug Reaction Reporting System
AFNT	Australasian Federation of Natural Therapists
AHMAC	Australian Health Ministers' Advisory Committee
AIMA	Australasian Integrative Medicine Association
AMA	Australian Medical Association
ANPA	Australian Naturopathic Practitioners Association
ANTAsn	Australian Natural Therapists Association
ANTAu	Australian National Training Authority
ATMS	Australian Traditional-Medicine Society
ATO	Australian Taxation Office
CAM	Complementary and alternative medicine
CM	Chinese medicine
CMA	Complementary Medicine Association
CMPAC	Complementary Medicine Professional Associations Council
CMRB	Chinese Medicine Registration Board, Victoria
CNME	Council for Naturopathic Medical Education (US)
CT	Complementary therapy
DE	Distance education
DHS	Department of Human Services, Victoria
DVA	Department of Veterans' Affairs
FNTT	Federation of Natural and Traditional Therapists
GP	General practitioner
GST	Goods and services tax
NCP	National Competition Policy
NHAA	National Herbalists Association of Australia
NHMRC	National Health and Medical Research Council
RACGP	Royal Australian College of General Practitioners
SNTR	Society of Natural Therapists and Researchers
SUSDP	Standard for the Uniform Scheduling of Drugs and Poisons
TAC	Transport Accident Commission
TAFE	Technical and Further Education
TCM	Traditional Chinese medicine
TGA	Therapeutic Goods Administration
UK	United Kingdom
US	United States of America
VET	Vocational and Educational Training
WHM	Western herbal medicine
WHO	World Health Organization

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# Appendix 1.1 Outline of Health Training Packages for Naturopathy and Western Herbal Medicine

Australian National Training Authority 2002

## HLT60502 Advanced Diploma of Naturopathy

This qualification covers the skills needed to practise as a naturopath. Besides compulsory common and specialisation units, a choice of four elective streams is offered. Students must select two of the four streams. The streams are: homeopathy, herbal medicine, massage therapy, or a general 'other' category, which includes nutrition as well as other endorsed training package units.

### PACKAGING RULES

A minimum of 21 units must be selected for this qualification including:

- All **common** units
- All **specialisation** units
- All units from two streams of **electives** required

### Common

BSBFLM303A	Contribute to effective workplace relationships
HLTCOM2A	Develop professional expertise
HLTCOM3A	Manage a practice
HLTCOM4A	Communicate effectively with clients/patients
HLTCOM6A	Make referrals to other health care professionals when appropriate
HLTFA2A	Apply advanced first aid * or HLTFA 1A Apply basic first aid
HLTHIR2A	Contribute to organisational effectiveness in the health industry
HLTIN4A	Manage control of infection
HLTHSE2A	Implement and monitor occupational health and safety policies, procedures, and programs

### Specialisation

HLTNAT 1A	Provide naturopathic treatment
HLTNAT2A	Provide Western herbal medicine treatment
HLTNAT3A	Provide naturopathic nutritional treatment
HLTNAT5A	Plan naturopathic treatment strategy
HLTNAT6A	Perform naturopathic health assessment
HLTNAT7A	Manage work within a naturopathic framework
HLTNAT8A	Apply naturopathic diagnostic framework
HLTNAT9A	Work within a naturopathic framework

\* *HLTFA1A Apply basic first aid is a prerequisite for this unit*

## Electives [naturopathy]

All units from two streams are required. Selection must include either massage or homeopathy. Elective choices can be determined by individual training providers.

Homeopathy	Herbs	Massage	Nutrition	Other
HLTHOM 12A Work within a homeopathic framework	HLTHER8A Provide specialised Western herbal medicine treatment	HLTREM 1A Work within a massage framework	HLTNUT 1A Apply literature research findings to clinical nutritional practice	Other units which may be selected as elective choices include: Endorsed units which may be developed at a later stage and which are consistent with the practice of naturopathy (e.g. aromatherapy)
HLTNAT4A Provide acute homeopathic treatment	HLTHER3A Operate a Western herbal medicine dispensary	HLTREM9A Perform massage health assessment	HLTNUT2A Provide specialised nutritional care	
		HLTREM8A Apply massage assessment framework		
		HLTREM7A Plan massage treatment		
		HLTREM6A Provide massage treatment		
Selection of these units would result in a statement of attainment to be credited towards further studies in homeopathy	Articulation from naturopathy to advanced diploma of Western herbal medicine will be on the basis of credit for common units and RPL assessments by RTO's for other units.	Selection of these units would result in an additional qualification: Certificate IV in massage	Selection of these units would result in a statement of attainment to be credited towards further studies in nutrition when developed	

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## HLT60102 Advanced Diploma of Western Herbal Medicine

This qualification covers the skills needed to work at practitioner level in Western herbal medicine. A substantial range of herbal medicine is included (a minimum of 130 herbs) as well as the skills required to operate a herbal dispensary.

### PACKAGING RULES

18 units must be selected for this qualification including:

- All **common** units
- All **specialisation** units

### Common

BSBFLM303A	Contribute to effective workplace relationships
HLTCOM2A	Develop professional expertise
HLTCOM3A	Manage a practice
HLTCOM4A	Communicate effectively with clients/patients
HLTCOM6A	Make referrals to other healthcare professionals when appropriate
HLTFA2A	Apply advanced first aid * or HLTFA1A Apply basic first aid
HLTHIR2A	Contribute to organisational effectiveness in the health industry
HLTIN4A	Manage the control of infection
HLTHSE2A and programs	Implement and monitor occupational health and safety policies, procedures,

### Specialisation

HLTHER 1A	Apply Western herbal medicine diagnostic framework
HLTHER2A	Manage work within a Western herbal medicine framework
HLTHER3A	Operate a Western herbal dispensary
HLTHER4A	Perform Western herbal medicine health assessment
HLTHER5A	Plan a Western herbal medicine treatment strategy
HLTHER6A	Prepare and dispense Western herbal medicine
HLTHER7A	Provide dietary advice
HLTHER8A	Provide specialised Western herbal medicine treatment
HLTHER9A	Provide Western herbal medicine treatment

\* *HLTFA1A Apply basic First Aid is a prerequisite for this unit*

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## Appendix 2.I Medline and Embase Search Strategies

### Medline search terms

toxicity  
adverse reaction  
side-effect  
adverse event  
adverse effect  
herbal  
medicine, herbal (MeSH term)  
plants, medicinal (MeSH term, subheading of adverse effects)  
plant, preparations (MeSH term, subheading of adverse effects)  
plant, extracts (MeSH term, subheading of adverse effects)  
phytotherapy (MeSH term, subheading of adverse effects)  
homeopathy (MeSH term)  
vitamins (MeSH term, subheadings of adverse effects, contraindications, poisoning, toxicity)  
minerals (MeSH term, subheadings of adverse effects, contraindications, poisoning, toxicity)  
calcium, dietary (MeSH term, subheadings of adverse effects, contraindications, poisoning, toxicity)  
dietary, supplements (MeSH term, subheadings of adverse effects, contraindications, poisoning, toxicity)  
iron, dietary (MeSH term, subheadings of adverse effects, contraindications, poisoning, toxicity)  
potassium, dietary (MeSH term, subheadings of adverse effects, contraindications, poisoning, toxicity)  
antioxidants (MeSH term, subheadings of adverse effects, contraindications, poisoning, toxicity)  
flavonoids (MeSH term, subheadings of adverse effects, contraindications, poisoning, toxicity)  
foods, specialised (MeSH term, subheadings of adverse effects, poisoning, toxicity)  
trace, elements (MeSH term, subheadings of adverse effects, contraindications, poisoning, toxicity)  
sodium, dietary (MeSH term, subheadings of adverse effects, contraindications, poisoning, toxicity)  
phosphorus, dietary (MeSH term, subheadings of adverse effects, contraindications, poisoning, toxicity)  
dietary, fibre (MeSH term, subheadings of adverse effects, poisoning, toxicity)

### Embase search terms

toxicity  
adverse reaction  
side-effect  
adverse event  
adverse effect  
herbal  
medicine, herbal (MeSH term)  
medicinal plant (MeSH term)  
phytotherapy (MeSH term)  
homeopathy (MeSH term)  
vitamin (MeSH term, subheadings of adverse drug reaction, side-effect, drug toxicity)  
mineral (MeSH term, subheadings of adverse drug reaction, side-effect, drug toxicity)  
calcium (MeSH term, subheadings of adverse drug reaction, side-effect, drug toxicity)

iron intake (MeSH term, subheadings of adverse drug reaction, side-effect, drug toxicity)  
dietary fibre (MeSH term, subheadings of adverse drug reaction, side-effect, drug toxicity)  
phosphate intake (MeSH term, subheadings of adverse drug reaction, side-effect, drug toxicity)  
potassium intake (MeSH term, subheadings of adverse drug reaction, side-effect, drug toxicity)  
diet supplementation (MeSH term, subheadings of adverse drug reaction, side-effect, drug toxicity)  
trace element  
antioxidant (MeSH term, subheadings of adverse drug reaction, side-effect, drug toxicity)  
health food (MeSH term, subheadings of adverse drug reaction, side-effect, drug toxicity)  
flavonoid (MeSH term, subheadings of adverse drug reaction, side-effect, drug toxicity)

*Note: Similar search strategies were utilised with Medscape.*

## Appendix 2.2 Litigation Search Strategy

### Court decisions

#### Databases

Various litigation websites were searched, with particular reference to court cases or general prosecutions that have stemmed from Western herbal medicine (WHM), naturopathy, homeopathy, and alternative medical practices in general. Legal database systems such as LexisNexis, Casebase, Austlii, and Wordlii allow worldwide searches of particular cases and subject matter.

#### Austlii and Wordlii

The Austlii and Wordlii websites provide free access to a full range of Australian and international legal material. The Austlii database includes all courts in all jurisdictions throughout Australia. International court searches were undertaken through Worldlii.

Austlii and Worldlii cover primary legal materials including legislation, decisions of courts and tribunals, and treaties. Searches can be made of all courts within Australia and internationally, from 1903 onwards.

Searches were conducted using titles of cases and the general search terms noted below. No timeline restrictions were placed upon any of the searches.

#### CaseBase

Casebase is a case annotator that covers cases, library publications, and unreported judgments as part of Butterworths online. Casebase includes unreported judgments from registries of various courts around Australia. It also allows unlimited searches for cases internationally. There are no restrictions on timelines.

#### Search terms

Search terms included 'alternative medicine', 'WHM', 'naturopathy', 'naturopaths', 'homeopathy', and 'risk'. In addition, searches were conducted using combinations of 'naturopaths' and 'herbal medicine' with 'prosecution', 'death', 'fatalities', 'standards', 'coronial inquest', 'adverse effects', and 'negligence'.

The term 'naturopathy' produced a huge number of reference citations. This was therefore narrowed down into subsections by combining the terms, as listed above. For the same reason, the term 'medicine' was not used as a lone search item.

#### Courts searched

The following searches were conducted within the Latrobe Library database research system and within particular courts.

##### Commonwealth of Australia

- High Court of Australia
- Federal Magistrates Court

##### Victoria

- Supreme Court
- Court of Criminal Appeal
- Appeal decisions

##### New South Wales

- Supreme Court
- Court of Criminal Appeal
- Court of Appeal
- District Court

### **South Australia**

- Supreme Court
- Court of Criminal Appeal
- District Court

### **Western Australia**

- Supreme Court
- Court of Criminal Appeal
- Court of Appeal
- District Court

### **Queensland**

- Supreme Court
- Court of Appeal
- District Court

### **Tasmania**

- Supreme Court

### **Australian Capital Territory**

- Supreme Court

Dates for the above searches were unlimited; however, searches were closed at December 2003.

## **Legislation**

### **SCALEplus**

This database allows searches of the legislation regarding the Commonwealth and its territories.

### **Digests, citators, and law reports**

The following databases were utilised:

- Medical Laws and Legislation Australia Periodicals
- Australian Health & Medical Law Reporter (1998–2003)
- *Australian Health Law Bulletin* 1992 vol. 1–2004 vol. 12
- *Journal of Law and Medicine* 1993/94 vol. 1–2003 vol. 11
- OVID–AMED (allied and complementary medicine) 1995 to January 2004
- OVID–MEDLINE 1989 to January 2004

### **Other**

LexisNexis is an academic database service that allows searches of any news content. It has a two year search restriction but produces relevant material on any topic worldwide.

The searches conducted on LexisNexis included the search items noted above, including the various combinations. This database produced a vast amount of the international information on cases supplied by newspaper articles. It also allowed searches of legal articles and reviews.

General internet searches were also used. These included:

- Google, legal: <[www.google.com](http://www.google.com)>
- Bailii: <[www.bailii.org](http://www.bailii.org)>
- Canlii: <[www.canlii.org](http://www.canlii.org)>
- Skeptic Friends: <[www.skepticfriends.org](http://www.skepticfriends.org)>

## Appendix 2.3 Enquiries through Government Surveillance and Complaints Bodies

The websites of numerous government bodies and surveillance bodies were searched. These included:

- Health Services Commissioner (Victoria): <[www.health.vic.gov.au](http://www.health.vic.gov.au)>
- Health Care Complaints Commission (NSW): <[www.hccc.nsw.gov.au](http://www.hccc.nsw.gov.au)>
- Health and Disability Commissioner (NZ): <[www.hdc.org.nz](http://www.hdc.org.nz)>
- Health Rights Commission (Qld): <[www.hrc.qld.gov.au](http://www.hrc.qld.gov.au)>
- Tasmanian Health Complaints Commission: <[www.justice.tas.gov.au](http://www.justice.tas.gov.au)>
- Western Australian Ombudsman: <[www.ombudsman.wa.au](http://www.ombudsman.wa.au)>
- Therapeutic Goods Administration: <[www.tga.health.gov.au](http://www.tga.health.gov.au)>
- South Australian Ombudsman: <[www.ombudsman.sa.gov.au](http://www.ombudsman.sa.gov.au)>
- Commissioner of Western Australian Health: <[www.healthreview.wa.gov.au](http://www.healthreview.wa.gov.au)>
- Health Insurance Commission: <[www.hic.gov.au](http://www.hic.gov.au)>
- Western Australian Health Consumers Council: <[www.hccc-wa.asn.au](http://www.hccc-wa.asn.au)>
- Medical Practitioners Board of Victoria: <[www.medicalboardvic.org.au](http://www.medicalboardvic.org.au)>
- ACT Health and Community Services: Commissioner:  
<[www.canberraconnect.act.gov.au](http://www.canberraconnect.act.gov.au)>

Direct follow-up contact was made with many of the agencies for further clarification and confirmation of data.

The Australian Council for Safety and Quality in Health Care was unable to assist.

## Appendix 3.1 Methodology for General Citation Review Searches

Searches were performed on both Medline and EMBASE Drugs and Pharmacology using the search terms in the table below. The searches were saved as text files and imported into Endnote libraries so that duplicates could be removed. Yearly searches were then performed using the Endnote libraries. Medline incorporates citations from 1966 and EMBASE incorporates citations from 1990. Searches were performed on 18 June 2004.

	<b>Medline terms</b>	<b>EMBASE terms</b>
Homeopathy	Homeopath* Homoeopath* Homeopathy (MeSH term)	Homeopath* Homoeopath* Homeopathy (MeSH term)
Echinacea	Echinacea Echinacea (MeSH term)	Echinacea Echinacea (MeSH term)
Ginkgo	Ginkgo biloba Ginkgo biloba (MeSH term)	Ginkgo biloba Ginkgo biloba (MeSH term)
St John's wort	Hypericum (MeSH term) Hypericum perforatum St Johns wort	Hypericum perforatum (MeSH term) Hypericum perforatum St Johns wort
Evening primrose oil	Oenothera biennis (MeSH term) Evening primrose oil	Evening primrose oil Evening primrose oil (MeSH term)
Garlic	Garlic Garlic (MeSH term)	Garlic Garlic (MeSH term)
Valerian	Valerian Valerian (MeSH term)	Valerian Valerian (MeSH term)
Saw palmetto	Saw palmetto Serenoa (MeSH term)	Saw palmetto Sabal (MeSH term)
Ginseng	Ginseng Eleutherococcus (MeSH term) Panax (MeSH term)	Ginseng Ginseng (MeSH term)
Peppermint oil	Peppermint oil Mentha piperita (MeSH term)	Peppermint oil Peppermint oil (MeSH term)
Tea-tree oil	Melaleuca oil Tea tree oil Tea tree oil (MeSH term)	Melaleuca oil Tea tree oil Tea tree oil (MeSH term)
Fish oils	Fish oil* Fish oils (MeSH term)	Fish oil* Fish oil (MeSH term)
Glucosamine	Glucosamine Glucosamine (MeSH term)	Glucosamine Glucosamine (MeSH term)
Chondroitin	Chondroitin Chondroitin (MeSH term)	Chondroitin Chondroitin (MeSH term)
Vitamin E	Vitamin E Vitamin E (MeSH term)	Vitamin E Alpha-tocopherol (MeSH term)
Vitamin C	Vitamin C Ascorbic acid (MeSH term)	Vitamin C Ascorbic acid (MeSH term)
Folic Acid	Folic acid (MeSH term) Folic acid	Folic acid Folic acid (MeSH term)
Calcium	Diet* calcium Calcium supplement* Calcium dietary (MeSH term)	Calcium intake (MeSH term) Diet* calcium Calcium supplement*
Iron	Diet* iron Iron supplement* Iron dietary (MeSH term)	Iron intake (MeSH term) Iron therapy (MeSH term) Diet* iron Iron supplement*
Magnesium	Diet* magnesium Magnesium supplement*	Diet* magnesium Magnesium supplement*
Zinc	Zinc supplement* Diet* zinc	Zinc supplement* Diet* zinc

## Appendix 3.2 Methodology for Pharmacology Literature Survey

### Sample 1

The Complementary Healthcare Council, one of the peak bodies representing the complementary-medicines industry in Australia, was approached to provide a list of the 10 most-utilised herbal medicines in the 2004 Australian market.

The following list was provided: *Echinacea* species, *Ginkgo biloba*, *Hypericum perforatum* (St John's wort), *Oenothera biennis* (evening primrose oil), *Allium sativa* (garlic), *Valeriana officinalis* (valerian), *Serenoa repens* (saw palmetto), *Panax ginseng*, *Mentha piperita* (peppermint oil), and *Melaleuca alternifolia* (tea-tree oil).

### Sample 2

Ten herbs were randomly selected from the *Materia Medica* A-list of the National Herbalists Association of Australia's *Herbal Medicine Curriculum and Course Accreditation Guidelines*. This list identifies herbal medicines that must be taught as part of an NHAA-accredited course and contains 98 herbs. The herbs in this list were numbered 1 to 98, and an on-line random-number generator was used to generate the sample.

Herbs randomly chosen for inclusion in the review were: albizia (*Albizia lebbbeck*), black cohosh (*Cimicifuga racemosa*), myrrh (*Commiphora molmol* spp.), clivers (*Galium aparine*), greater plantain (*Plantago major*), rhubarb (*Rheum officinale*, *R. palmatum*), danshen (*Salvia miltiorrhiza*), sage (*Salvia officinalis*), stinging nettle (*Urtica dioica*), and bilberry (*Vaccinium myrtillus*).

### Medline

PubMed was searched online on 14 October 2004.

*In vitro* studies were identified by using each of the search terms followed by 'and in vitro'—for example: (saw palmetto or serenoa repens) and in vitro.

Animal studies were identified by using each of the search terms followed by 'and animal'—for example: (saw palmetto or serenoa repens) and animal.

Clinical trials were identified by using the search terms while limiting the results to 'Clinical trials'.

MEDLINE search terms used were:

- echinacea
- ginkgo
- hypericum [or] st john's wort
- evening primrose oil
- garlic [or] allium sativum
- valerian [or] valeriana officinalis
- saw palmetto [or] serenoa repens
- panax ginseng [or] Korean ginseng
- peppermint oil
- tea tree oil
- albizia lebbbeck [or] albizzia lebbbeck
- black cohosh [or] cimicifuga racemosa
- myrrh [or] commiphora molmol
- clivers [or] galium aparine
- plantago major
- rheum palmatum [or] rheum officinale [or] rhubarb root
- salvia miltiorrhiza [or] danshen or dan shen
- salvia officinalis

- urtica dioica [or] stinging nettle
- vaccinium myrtillus [or] bilberry.

## **EMBASE**

EMBASE Drugs and Pharmacology was searched online on 14 October 2004.

If a herb had several subject headings, they were used. The EMCLAS classification limits 'Pharmacology' and 'Toxicology' were used to identify studies in the areas of pharmacology and toxicology.

Herbs with one or more relevant subject headings were: echinacea, ginkgo, St John's wort, evening primrose oil, garlic, valerian, saw palmetto, Korean ginseng, *Albizia lebbek*, black cohosh, danshen, stinging nettle, and bilberry.

If a herb did not have a subject heading, the following search terms were searched in the fields 'Title' and 'Major drug descriptors':

- peppermint oil
- tea tree oil
- myrrh [or] commiphora molmol
- clivers [or] galium aparine
- plantago major
- rheum palmatum [or] rheum officinale
- salvia officinalis.



## Appendix 3.3 Methodology for Nutrition Literature Searches

### Medline

The limits used to screen references were as follows:

Articles on randomised controlled trials:

- publication years: 2001–2003
- language: English
- publication type: randomised [randomized] controlled trial
- check tags: human.

Articles on systematic reviews:

- publication year: 1993–2003
- language: English
- check tags: human
- publication type: meta-analysis, review literature.

Term entered	Relevant mesh term	Number of references		
		Total	RCTs	Reviews
vitamin	vitamins growth substances, pigments, vitamins	~350,000	1076	477
mineral	Mineral	55,985	207	69
dietary supplement	calcium—dietary dietary fibre iron—dietary phosphorus—dietary potassium—dietary sodium—dietary dietary supplements	25,200	668	143
trace element	trace elements	158,821	271	117
antioxidant	antioxidants	24,974	263	70
bioflavonoid	bioflavonoid	2,995	11	0
food	food—fortified health food food—specialised [specialized]	15,921	185	37

Keywords	Number of references	
	RCTs	Reviews
acidophilus pepsin nutrient vitamin trace element mineral dietary*	1777	633
lecithin psyllium pigment dietary fibre antioxidant health food bioflavonoid	346	126

## EMBASE

The limits used to screen references were as follows:

Articles on randomised controlled trials:

- publication year: 2001–2003
- language of article: English
- Emclas classification: human medicine
- keywords: randomised [randomized] controlled trial.

Articles on systematic reviews:

- publication year: 1993 to 2003
- language of article: English
- document type: review
- Emclas classification: human medicine.

Term entered	Relevant mesh term	Number of references		
		Total	RCTs	Reviews
vitamin	vitamin	86,677	852	55
mineral	mineral	1,968	101	16
dietary supplement	calcium intake dietary fibre iron intake phosphorus intake potassium intake sodium intake diet supplementation	21,832	819	489
trace element	trace elements	2,271	30	97
antioxidant	antioxidants	25,911	192	639
bioflavonoid	bioflavonoid	234	3	15
food	health food	108	1	

Keyword	Number of references	
	RCTs	Reviews
acidophilus nutrient vitamin mineral	719	1,407
dietary* lecithin psyllium	416	1142
pigment dietary fibre antioxidant health food bioflavonoid	256	831

### **RCT Papers**

Total number of articles on randomised controlled trials (EMBASE and Medline): 4,118 (with duplicates removed).

The articles on randomised controlled trials (RCTs) were screened for papers that did not fall within the practice of naturopathy or Western herbal medicine (for example, compounds that were administered intravenously). This reduced the number of papers on RCTs (2001–2003) to 1,401. The number was further reduced to 420 by admitting articles only from 2003. It was then decided that the number of articles was still too great to be reviewed successfully in this context.

### **Review Papers**

Total number of review papers (EMBASE and Medline): 4,018 (with duplicates removed).

The review papers were screened for papers that did not fall within the practice of naturopathy or Western herbal medicine (for example, compounds that were administered intravenously). Only meta-analyses and systematic reviews were included (using the search terms: meta-analysis [and] systematic). This reduced the number of papers on reviews (1993–2003) to 136. This number was further reduced to 84 articles by admitting articles published only between 2001 and 2003.

On 24 February 2004, another search was performed repeating the search strategies of the 3 December search; this identified an additional 30 articles. All 114 articles were ordered, and then reviewed for appropriateness and quality using a prearranged questionnaire. Papers were excluded from the final review if they were reviews of the literature (not systematic), historical reviews, reviews of CAM treatments other than nutritional, reviews published in a foreign-language journal, evidence-based reviews, reviews of orthodox medical treatment, or reviews of the safety of nutrition. A final total of 38 meta-analyses and systematic reviews was included in this summary.

## Appendix 3.4 Methodology for Herbal Medicine Literature Searches

### Medline

The limits used to screen references were as follows:

Articles on randomised controlled trials (RCTs):

- publication year: 2001 to 2003
- language: English
- publication type: randomised [randomized] controlled trial.

Articles on systematic reviews:

- publication year: 1993 to 2003
- language: English
- publication type: meta-analysis; review; review-literature; review-academic; review-multicase; review of reported cases; review-tutorial.

Term entered	Relevant mesh term	Number of references
herbal medicine	medicine, herbal plant preparations phytotherapy	62,075

Keywords	Number of references
plant extract	23,116
phytotherapy	8,939
plant preparation	750
medicinal plants	36,860
herbal medicine	1,484
herbal*	12,996

### EMBASE

The limits used to screen references were as follows:

Articles on randomised controlled trials:

- publication year: 2001 to 2003
- language of article: English
- keyword: randomised [randomized] controlled trial.

Articles on systematic reviews:

- language of article: English
- document type: review.

Term entered	Relevant mesh term	Number of references
herbal medicine	herbal medicine herbaceous agent	5,765

<b>Keywords</b>	<b>Number of references</b>
Plant extract	964
phytotherapy	2,837
Plant preparation	27
medicinal plants	1,485
herbal medicine	4,305
herbal*	5,930

### **RCT Papers**

Total number of RCT papers: EMBASE plus Medline: 585 (with duplicates removed).

The papers on randomised controlled trials were screened for papers that did not fall within the practice of naturopathy or Western herbal medicine (for example, compounds that were administered intravenously). This reduced the number of papers on RCTs (2001–2003) to 470. This number was further reduced to 128 by admitting articles only from 2003. It was then decided, in view of the large number of RCT articles found overall (420 for nutrition and 128 for herbal medicine), that RCT papers would be excluded from this review.

### **Review Papers**

Total number of review papers (EMBASE plus Medline): 4,406 (with duplicates removed).

The review papers were screened for articles that did not fall within the practice of naturopathy or Western herbal medicine (for example, compounds that were administered intravenously). Only meta-analyses and systematic reviews (using the search terms: meta-analysis, review, systematic) were included. This reduced the number of review papers (1993–2003) to 147. The number was further reduced to 74 by admitting articles published only between 2001 and 2003.

On 24 February 2004, another search was performed (repeating earlier search strategies) that identified 26 herbal medicine review articles in addition to the 74 already located. All 100 articles were ordered, and reviewed for quality using a prearranged questionnaire. Other exclusion criteria included reviews of the literature (not systematic), historical reviews, reviews of CAM treatments other than herbal medicine, reviews published in a foreign journal, evidence-based reviews, reviews of orthodox medical treatment, repeat papers published in different journals, or reviews of the safety of herbal medicines. A final total of 34 meta-analyses and systematic reviews was included in the summary.

## Appendix 3.5 Summary of Nutrition and Herbal Literature

### 1. Cardiovascular system

#### 1.1 Nutritional supplements

##### 1.1.1 Coronary heart disease and fish oil

The effect of the intake of N-3 polyunsaturated fatty acids on coronary heart disease was investigated by Bucher et al. (2002) using a meta-analysis of 11 randomised controlled trials (RCTs) ( $n^{\text{treatment}} = 7951$  and  $n^{\text{placebo}} = 7855$ ) published between 1966 and 1999. The authors found that the risk ratio of fatal myocardial infarction was 0.7 (95% CI: 0.65–0.8,  $p < 0.001$ ), the risk ratio of sudden death was 0.7 (95% CI: 0.6–0.9,  $p < 0.01$ ), and the risk ratio of overall mortality was 0.8 (95% CI: 0.7–0.9,  $p < 0.001$ ) (all with non-significant heterogeneity and with the overall study quality being good). Some publication bias might have been present.

Geleijnse et al. (2002) investigated the response of blood pressure to fish oil supplementation using a meta-regression analysis of 36 randomised studies, dating from 1990 to March 2001. Fish oil (predominantly eicosapentaenoic acid and docosahexaenoic acid) was found to reduce systolic blood pressure by 2.1 mm Hg [95% CI: 1.0–3.2;  $p < 0.01$ ] and diastolic blood pressure by 1.6 mm Hg [95% CI: 1.0–2.2;  $p < 0.01$ ]. The anti-hypertensive effect of fish oil tended to be greater in older and hypertensive populations. Funnel plots showed possible publication bias with relatively small studies in which large changes in blood pressure were slightly overrepresented.

##### 1.1.3 Cardiovascular mortality and antioxidants

A meta-analysis using 12 RCTs was conducted by Vivekananthan et al. (2003) to elucidate the role of antioxidant vitamins in preventing death from cardiovascular disease. The authors reviewed eight trials of  $\beta$ -carotene ( $n = 138,113$ ) and seven trials of vitamin E ( $n = 81,788$ ) which showed no significant heterogeneity. Vitamin E was found to have no significant benefit for all-cause mortality, cardiovascular death, and cerebrovascular death.  $\beta$ -carotene had a small but significant benefit for all-cause mortality versus placebo (7.0% vs 7.4%); odds ratio = 1.07 (95% CI: 1.02–1.11,  $p = 0.003$ ); and for cardiovascular death (3.1% vs 3.4%); odds ratio = 1.1 (95% CI: 1.03–1.07,  $p = 0.003$ ).

Using a literature review, Hermansen et al. (2003) studied the evidence for the effect of soy and other natural products on LDL:HDL cholesterol ratio and other lipid parameters. A meta-analysis of 38 controlled trials showed that a daily intake of 47 g of soy protein decreased levels of total cholesterol, LDL, and triglycerides by 9%, 13%, and 11% respectively. Seven clinical trials had been performed on soy products that contained high levels of isoflavones, soy cotyledon fibres, and soy lecithin. These trials reported significant reductions in LDL cholesterol (4–21%) and LDL:HDL ratio (3–27%) compared with control (+6 to –19%). Three meta-analyses of the effect of psyllium on cholesterol parameters showed a 6–7% reduction in LDL cholesterol following daily consumption of 9.1–10.2 g of psyllium. Results from seven trials of beta glucan containing oat bran showed that high levels of beta glucan (~3.0–8.7 g per day) reduced total cholesterol by 2–17% and LDL cholesterol by 2–26%. A meta-analysis of 67 RCTs showed a small reduction in LDL cholesterol (0.057 mmol/L per gram of dietary fibre). Twelve studies of plant stanol and sterol esters reported significant reductions in total cholesterol (4–16%) and LDL cholesterol (4–18%). Three meta-analyses on the effect of garlic on blood lipids were reviewed—revealing a significant reduction of total cholesterol of 6–12%. However, later RCTs did not support these conclusions, due to methodological differences (such as dietary control).

## 1.2 Herbal medicines

### 1.2.1 Hypercholesterolaemia and extract of *Cynara scolymus* leaf

Pittler, Thompson and Ernst (2002) systematically reviewed the effects of artichoke leaf extract (ALE) (*Cynara scolymus*) on total cholesterol levels and included RCTs of oral preparations of artichoke leaf extract administered to patients with cholesterol levels  $\leq 5.17$  mmol/L. Two studies (n=167) were identified as fulfilling the inclusion criteria. In one trial ALE reduced cholesterol from 7.74 mmol/L to 6.31 mmol/L after 42 days $\pm$ 3 days, whereas placebo results showed a reduction from 7.69 mmol/L to 7.03 mmol/L. The second trial showed a significant reduction compared with placebo in a subgroup of patients with baseline total cholesterol of greater than 230 mg/dl. Both studies reported mild, transient, infrequent adverse events during short term use. It was concluded that few data existed on the effect of ALE on cholesterol levels and that further research was required to establish and verify the effects of the herb and the safety profile.

### 1.2.2 Chronic heart failure and *Crataegus oxycanthoides*

A meta analysis by Pittler, Schmidt and Ernst (2003) presented data from a search of six databases for RCTs on mono-preparations of hawthorn extract (*Crataegus oxycanthoides*) in patients with chronic heart failure, together with information from 10 manufacturers and 9 experts and subsequent hand searches of retrieved data. Eight trials (n=632) were assessed as moderate in quality. These showed a primary outcome of mean change in maximal workload using bicycle ergometry (increase of 25 watt every 2 minutes) compared with base line. Results showed that the study treatment was more beneficial than placebo (weighted mean difference, 7 watt, 95% CI 3–11 watt,  $p < 0.01$ , n=310). The treatment group showed a beneficial decrease in pressure–heart rate product (weighted mean difference –20, 95% CI: –32 to –8, n=264). Dyspnoea and fatigue improved significantly in the treatment group compared with placebo. Adverse events were mild and transient, and included gastrointestinal tract (GIT) symptoms, dizziness, and some cardiac complaints. It was suggested that hawthorn was a safe and effective adjunctive treatment in chronic heart failure.

### 1.2.3 Hypercholesterolaemia and herbs

After a search of six databases, 25 randomised trials met the inclusion criteria for a review by Thompson Coon and Ernst (2003) of trials investigating the effects of mono-preparations of herbal medicines (given as supplements) on serum cholesterol levels. Quality was assessed using the Jadad scale, and the hypercholesterolaemic properties of 11 herbs were reviewed. These included Gum Guggul (*Commiphora mukul*) (n=388), artichoke (*Cynara scolymus*) (n=187), garlic (*Allium sativum*) (reviewed elsewhere), fenugreek *Trigonella foenum-graecum* (n=140), red yeast rice (n=695), *Panax ginseng* (n=36), yarrow (*Achillea millefolium*) (60), eggplant (*Solanum melongena*) (n=52), holy basil (*Occimum sanctum*) (n=40), milk thistle (*Silybum marianum*) (n=20), and arjun (*Terminalia arjuna*) (n=105). The results showed reductions of 10%–33% in studies using *Commiphora mukul*, fenugreek, red yeast rice, and *Cynara scolymus*. The reviewers indicated that the methodological quality of 13 of 25 trials was below 3 on the Jadad scale. Adverse events included GIT symptoms, headache, rash, and anxiety/restlessness; however, there were few reports of these events in the trials reviewed. The authors pointed out that *Panax ginseng* and *Commiphora mukul* had potential to interact with pharmaceutical preparations. Due to the paucity of research into the safety of the herbs, further studies were recommended to estimate the effectiveness of the herbs in reducing cholesterol.

### 1.2.4 Chronic venous insufficiency and *Aesculus hippocastanum*

Three databases were searched by Siebert et al. (2002), and information was obtained from manufacturers and hand searches of the bibliographies of selected studies, for RCTs on patients with chronic venous insufficiency (CVI) who had been treated with horse chestnut seed extract (*Aesculus hippocastanum*) (HCSE) for at least 20 days. These methods identified 13 RCTs (n=1051) and three observational studies (n=10,725). The average study quality was 5 on the Jadad scale (range 3.5–6) for the RCTs and 3 (range 2.5–4) for the observational studies. The main outcome measurements were the clinical signs and symptoms of CVI (leg volume, ankle and calf circumference, oedema, calf cramps, itching, and so on). The meta-analysis used random and fixed-effects models to pool outcomes. There was significant heterogeneity in the results for leg volume, leg fatigue/heaviness, and calf cramps. The

observational studies were heterogeneous in the same outcomes ( $p < 0.001$ ). Results showed that HCSE reduced leg volume by 46.4 mL (95% CI: 11.3–81.4 ml), increased the likelihood of improvement in leg pain 4.1-fold (95% CI: 0.98–16.8), increased the probability of improvement in oedema 1.5-fold (95% CI: 1.2–1.9), and increased the probability of improvement in itching 1.7-fold (95% CI: 0.01–3.0). All of these improvements were as compared with placebo. The evidence was not sufficient to show improvements in leg fatigue or calf cramps. Significant improvement in symptoms was noted in the observational studies. Adverse events were mild, and the reviewers concluded that further long term observational studies were required to assess the safety and efficacy for prolonged treatment.

Pittler and Ernst (2004) assessed the efficacy and safety of HCSE versus placebo or reference therapy in the treatment of chronic venous insufficiency (CVI). Six databases were explored, and information was gathered from manufacturers and experts in the field. The reviewers identified 14 RCTs on the acute effects of oral HCSE mono-preparations for patients with CVI. Quality was assessed using the Jadad scale (average score 3.4). Overall results suggested an improvement in signs and symptoms. Six trials (n=552) reported a significant reduction in leg pain; four trials (n=461) reported a significant reduction in oedema; 6 trials (n=542) reported a significant reduction in pruritus; five trials (n=420) assessed leg volume; and meta-analysis of four trials (n=239) suggested a weighted mean difference of 58.57 in favour of HCSE over placebo. Circumference at calf and ankle was assessed in six trials (n=240): four suggested a significant reduction at the ankle (n=120) and two (n=60) at the calf. Adverse events were mild and transient, and included GIT symptoms, dizziness, nausea, headache, and pruritus. The researchers concluded that HCSE appeared to be a safe and effective short term treatment for CVI; however, further research was required.

## 2. Endocrinology

### 2.1 Nutritional supplements

#### 2.1.1 Type 2 diabetes and chromium

A meta-analysis investigating the effects of chromium on glucose and insulin responses in glucose-intolerant and type 2 diabetic subjects was conducted by Althuis et al. (2002). A total of 15 trials was reviewed (n=618), involving 193 subjects with type 2 diabetes and 425 subjects who were in good health or had impaired glucose tolerance. Chromium was found to have no significant effect on glucose or insulin levels in healthy subjects. No clear result could be ascertained for the effect of chromium on diabetic subjects because the major study with diabetic subjects (Anderson et al. 1997 with n=155), was excluded. [This study was excluded because it studied Chinese subjects (who might have represented a chromium-deficient population) and because its inclusion in the meta-analysis significantly increased heterogeneity (which was otherwise good). (Anderson et al. (1997) actually showed a positive effect for chromium supplementation on fasting glucose and insulin, non-fasting glucose and insulin, and glycated haemoglobin concentrations.] No investigation of publication bias was undertaken.

The types of dietary supplements used for glycemic control in diabetic patients were examined by Yeh et al. (2003) using a systematic review.

### 2.2 Herbal medicines

#### 2.2.1 Diabetes and herbs

Yeh et al. (2003) also conducted a systematic review of the role of herbs and dietary supplements in glycemic control in diabetes. They sought information from four databases (1960–2002) and hand searched bibliographies of selected studies. They also requested input by experts and manufacturers in the field. Quality was assessed using the Jadad scale (average score 2.2, range 1–4). In all, 108 trials were retrieved. These examined the effects of 36 herbs (alone or in combination) and dietary supplements on 4565 patients who had diabetes or impaired glucose tolerance. Of these, 26 trials (n=729) investigated single herbs. (garlic n=1 trial, *Aloe vera* n=2, jackfruit (*Artocarpus heterophyllus*) n=2, *Bauhinia forficata* n=1, *Coccinia indica* n=2, common fig (*Ficus carica*) n=1, ginseng n=4, Small Indian Ipecac (*Gymnema sylvestre*) n=2, *Momordica charantia* n=2, *Myrcia uniflora* n=1, Sacred basil (*Ocimum sanctum*) n=1, *Opuntia streptacantha* n=2, silymarin n=1,



fenugreek (*Trigonella foenum-graecum*) =4) and five trials (n=616) explored the effects of combination herbs (TCM combination n=1 trial, xiaoke n=1, SPDA n=1, Native American combination n=1, Tibetan combination n=1). The results showed that 88% of the trials examining single herbs and 60% of the trials examining combination herbs reported statistically significant treatment effects. Efficacy was reported for *Coccinia indica* and American ginseng (*Panax quinquefolium*). The researchers concluded that there is not sufficient evidence to make recommendations regarding the efficacy of herbs in the control of diabetic conditions, but the researchers emphasised their safety.

### 3. Gastrointestinal system

#### 3.1 Nutritional supplements

##### 3.1.1 Diarrhoea and probiotics

The efficacy of probiotics in preventing antibiotic-associated diarrhoea was studied using two meta-analyses by Cremonini et al (2002). The authors reviewed seven homogeneous RCTs (n = 881) and found that the relative risk of diarrhoea was 0.397 (95% CI: 0.27–0.57) (a beneficial effect being shown with a RR and CI of less than 1). However, due to the lack of placebo control and a peculiar study population, the authors felt that the result was not definitive. The results of the study were plotted on a funnel plot and found to be symmetrical—indicating no publication bias.

D'Souza et al. (2002) used a meta-analysis to investigate the prevention of antibiotic-associated diarrhoea with probiotics. The odds ratio pooled data for the nine placebo-controlled randomised trials was 0.37 (95% CI: 0.26–0.53,  $p < 0.001$ ) in favour of probiotics.

Huang et al. (2002) reviewed 18 RCTs in a meta-analysis to study the use of probiotics in the management of acute diarrhoea in a paediatric population. Using a random effects pooled estimate, the use of probiotics reduced the duration of diarrhoea by 0.8 days ( $p < 0.001$ ). Significant heterogeneity was present in this analysis, and a number of sub-analyses were therefore performed. These included analyses for hospitalised patients, double blinded studies, and trials that used lactobacilli and *Lactobacillus GG* as the study treatment (which produced a similar result to the overall estimate, with a range of –0.6 to –1.2 days).

The efficacy of lactobacilli in treating acute infectious diarrhoea in children was studied using a meta-analysis by Van Niel et al. (2002). Eight randomised, double blind, placebo- controlled trials were selected from a search of ten databases. It was found that lactobacillus supplementation reduced diarrhoea duration [summary point estimate = 0.7 days (95% CI: 0.3–1.2) and diarrhoea frequency on day 2 of 1.6 stools per day (95% CI: 0.7–2.6 less stools)]. Significant reductions in days of diarrhoea were found for sub-analyses conducted for studies that: (i) contained subjects from developed countries [0.8 days (95% CI: 0.1–1.5 days)]; (ii) used live *lactobacillus* preparations [0.8 days (95% CI: 0.3–1.3 days)]; and (iii) contained subjects with diarrhoea from multiple causal agents [0.5 days (95% CI: 0.1–1.0 days)].

#### 3.2 Herbal medicines

##### 3.2.1 Irritable bowel syndrome and herbs

Spanier, Howden and Jones (2003) systematically reviewed the literature for RCTs on adults with IBS using herbal treatments. The review also identified a range of alternative therapies in the treatment of irritable bowel syndrome (IBS); however, only herbal medicines are assessed in this summary. The quality of the trials was assessed by the Jadad scale, and was generally found to be low (average score 1.8). The review identified one trial using Chinese medicinal herbs (n=106), one trial using an ayurvedic preparation (*Aegle marmelos correa* and *Bacopa monniera*) (no study numbers provided), and five trials of peppermint oil (*Mentha piperita*) (n=153). There were sufficient data in four of these trials to attempt a meta-analysis, and this showed a slight improvement in outcomes for peppermint oil compared with placebo. However, the analysis found significant heterogeneity in outcomes, and this limited the interpretation of results. A rigorous study using Chinese medicinal herbs significantly improved digestive symptoms compared with placebo after 16 weeks of treatment; however, no therapy was considered to be supported by the literature. The authors concluded that further research was required in all aspects of IBS treatment.

### 3.2.2 Dyspepsia and Iberogast<sup>1</sup>

A meta-analysis by Gundermann, Godehardt and Ulbrich (2003) included four RCTs (n=592) of patients with functional dyspepsia lasting at least four weeks. The study treatment was Iberogast compared with placebo or control (cisapride). The primary outcome measure was the GIS sum score. No details on quality assessment were reported and meta-analysis scores were not combined. The reviewers reported that the study treatment showed substantial improvements in symptoms compared with placebo, and that: 'Meta-analysis of all studies, demonstrated a clear, highly significant overall therapeutic effect of Iberogast'. Adverse events (n=23) were mild and few in number, and five were judged to be related to the study medication. No conclusions were drawn.

### 3.2.3 Dyspepsia and herbs

A systematic review by Thompson Coon and Ernst (2002) examined the evidence for the use of herbal medicinal products in the treatment of non-ulcer dyspepsia. They sought RCTs of herbal preparations administered as supplements to patients diagnosed with non-ulcer dyspepsia. Included trials were placebo-controlled or equivalent. All retrieved data were reviewed for safety information and possible mechanisms of action. Quality was judged on the Jadad scale (average score 2.4, range 1–5) in 17 trials (n=1808), of which four used monopreparations (turmeric (*Curcuma longa*), greater celandine (*Chelidonium majus*), banana powder, *Emblica officinalis*) and 13 used a combination of herbs (nine of which contained peppermint and caraway (*Carum carvi*)). There was an improvement in symptom scores ranging from 60% to 95% compared with baseline and/or placebo or the comparator drug. There were few reports of adverse events; however, safety data were not well reported in individual studies. It was concluded that several herbs had anti-dyspeptic properties and an encouraging safety profile; however, further research was recommended.

## 4. Neurological system

### 4.1 Nutritional supplements

#### 4.1.1 Cognitive impairment and lecithin

In a Cochrane library meta-analysis, Higgins and Flicker (2003) investigated the clinical efficacy of lecithin in the treatment of dementia and cognitive impairment. Twelve RCTs were reviewed (Alzheimer's disease, n = 265; Parkinsonian dementia, n = 21; subjects with memory problems, n = 90). No clear benefit of lecithin for Alzheimer's dementia or Parkinsonian dementia was found. However, in the one study that examined subjects with subjective memory problems, the mean difference between lecithin and placebo was 10.3 (95% CI: 6.3–14.3)—a highly significant result.

#### 4.1.2 Cognitive impairment and acetyl-L-carnitine

Montgomery, Thal and Amrein (2003) reviewed 21 randomised, placebo-controlled, double blind trials (n = 1479) using meta-analysis to study the efficacy of acetyl-L-carnitine in the treatment of mild cognitive impairment and mild Alzheimer's disease. The authors combined all the clinical and psychometric tests to produce an 'All Scales Effect Size' of 0.201 (95% CI: 0.107–0.295). This showed a significant positive effect for acetyl-L-carnitine compared with placebo. The 'Clinical Global Impression of Change' was pooled separately to give an ES of 0.32 (95% CI: 0.18–0.47), which was significantly in favour of acetyl-L-carnitine. The authors concluded that acetyl-L-carnitine showed beneficial effects, first seen at three months and increasing over time, for mild cognitive impairment and mild Alzheimer's disease in both clinical and psychometric tests.

#### 4.1.3 Autism and vitamin B<sub>6</sub> and magnesium

The effect of a combination of vitamin B<sub>6</sub> and magnesium on the social, communication, and behavioural responses of children and adults with autism was studied using a Cochrane meta-analysis by Nye and Brice (2002). Five databases were searched for RCTs. Only two small clinical trials

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<sup>1</sup> 'Iberogast' is a proprietary herbal mixture used in Germany for the treatment of gut dysfunctions in association with dyspeptic diseases and irritable colon. It contains the following herbal extracts: German chamomile (*Matricaria recutita*) flower, Clown's mustard (*Iberis amara*) plant, Angelica (*Angelica archangelica*) root and rhizome, Caraway (*Carum carvi*) fruit, Milk thistle (*Silybum marianum*) fruit, Lemon balm (*Melissa officinalis*) leaf, Celandine (*Chelidonium majus*) aerial part, Licorice (*Glycyrrhiza glabra*) root, Peppermint (*Menthae x piperita*) leaf.

(n=20) were found, one of which contained data that were unsuitable for inclusion in the analysis. This single study found that there was no significant difference between treatment and placebo.

#### **4.1.4 ADHD and vitamins**

Arnold (2001) performed a systematic review of the alternative treatments for adults suffering from attention deficit hyperactivity disorder (ADHD). There has been little or no research done on ADHD in adults, so most of the studies in this review were child-based. Megadose multi-vitamins were found to have been largely ineffective and might have caused adverse reactions. Supplementation with essential fatty acids, iron, magnesium, and zinc all had promising pilot data, but required well controlled randomised clinical trials to elucidate their efficacy.

#### **4.1.5 Intellectual development and micronutrient supplementation**

The role of micronutrient supplementation in the development of intelligence in children was investigated with a systematic review of 13 clinical trials (Benton 2001). Ten of these found a positive benefit in non-verbal intelligence from the use of mineral and vitamin supplementation. The study suggested that improvement in non-verbal intelligence might be restricted to groups of children whose dietary intake is deficient in nutrients.

#### **4.1.6 Insomnia and melatonin**

The efficacy of melatonin in the treatment of insomnia in elderly subjects was studied by Olde Rikkert and Rigaud (2001) using a systematic review. Six RCTs (n=95) were reviewed. Sleep latency (time between subject's self-appointed sleep time and sleep onset) decreased significantly in four studies. Sleep efficiency (the percentage of time that the subject was in bed following sleep onset that was spent asleep) increased in three of the studies. However, the populations used in these studies were very select, and larger generalised studies were required to elucidate melatonin's efficacy in the broader community.

### **4.2 Herbal medicines**

#### **4.2.1 Age-related macular degeneration and *Ginkgo biloba***

Evans (2000) searched four databases and performed a hand search on retrieved papers to identify one RCT (n=20) on the use of *Ginkgo biloba* in age related macular degeneration. Quality was assessed as poor. The trial medication was 80 mg of *Ginkgo biloba* given twice daily, compared with a placebo. Treatment was provided for six months. Primary parameters that were assessed included distance and near visual acuity, visual field, and clinical assessment of disease progression—measured at base line and end of treatment. Results showed that, although both the treatment group and the placebo group reported improvement in visual acuity, the improvements for subjects using *Ginkgo biloba* were higher. Clinical assessment of macular degeneration progression showed improvement in nine of ten subjects in the treatment group compared with two in the placebo group. There were no significant changes in the remaining outcome measurements. Poor quality study methodology might have reduced the validity of the trial outcomes. The review concluded that further research was necessary.

#### **4.2.2 Depression and St John's wort**

After a search of Medline and EMBASE, and product information from manufacturers, Whiskey, Werneke and Taylor (2001) identified 22 RCTs on the use of St John's wort (*Hypericum perforatum*) in depression. No indication of quality analysis was provided; however, data were extracted with a standardised template. A two stage meta-analysis was conducted. In stage 1, all data from studies using the Hamilton Depression Scale (HAM-D) were included (n=23). In the second stage, a sub-analysis of studies that fulfilled the intention-to-treat analysis and adhered to predefined inclusion criteria (age, diagnosis, HAM-D scores) were analysed (six RCTs and four active comparator trials). Trials comparing St John's wort versus antidepressants (n=9) and St John's wort versus placebo (n=14) were analysed separately. In the analysis of St John's wort versus antidepressants, only trials administering an effective dose of St John's wort and sufficiently powered to show a difference were included. Adverse events were mild and transient, with fewer reports than for standard antidepressants. Adverse events included GIT symptoms, dry mouth, dizziness, fatigue/sedation, and restlessness. Results of the meta-analysis using the Hamilton Depression Scale as the outcome showed St John's wort to be significantly more effective than the verum group [relative risk 1.98 (95% CI: 1.49–2.62)],

but not significantly better than the active antidepressant [relative risk 1.98 (95% CI: 0.90–1.11)]. The sub-analysis demonstrated that St John's wort was more effective than placebo [relative risk 1.77 (1.16–2.70)] and of similar efficacy as standard antidepressants [relative risk 1.04 (0.94–1.15)]. The authors concluded that further research was required using appropriately powered, large scale trials.

Kasper and Dienel (2002) conducted a meta-analysis on the data from three RCTs (n=544) conducted between 1998 and 2001 on antidepressant treatment with Hypericum extract in mildly to moderately depressed outpatients. The analysis was performed to answer criticisms of earlier studies. To be included, the trials had to use subjects diagnosed with depression according to DSM-IV criteria, use the Hamilton rating scale for depression as a primary outcome measurement, and be a double blind study of at least 6 weeks' duration in which synthetic antidepressants were also included. Trial investigators had pre-trial training in the use of both the Hamilton rating scale and DSM-IV criteria. A cluster analysis of the data showed two clusters of items from the Hamilton Rating Scale. The first cluster was interpreted as an indicator of the core symptoms of depression (including most somatic symptoms) whereas the second cluster included other symptoms of depression (such as insomnia and anxiety). Hypericum reduced both clusters of symptoms more effectively than placebo, but was specifically effective in reducing the core symptoms of depression and improving recovery from depression. No definite conclusion was drawn, but the authors indicated that the therapeutic action of Hypericum might have been similar to the actions of selective serotonin-reuptake inhibitors.

#### **4.2.3 Cognitive impairment and *Gingko biloba***

Fifteen databases were screened by Birks et al. (2002), along with information from experts and manufacturers, to obtain 33 RCTs of patients (n=3278) with dementia of any severity or acquired cognitive impairment treated with *Gingko biloba* compared with placebo. Primary outcomes that were assessed included cognitive function, functional performance, behavioural disturbance, global impression, quality of life, dependency, acceptability of treatment, and safety. Two reviewers assessed quality; however, no assessment scale was mentioned. The data for meta-analysis were based on the summary statistics for each study. There were insufficient data to perform an intention-to-treat analysis. Results showed benefits associated with Gingko (dose less than 200 mg daily) compared with placebo at less than 12 weeks when measuring clinical global improvement (15.32, 95% CI: 5.9–39.8,  $p < 0.0001$ ). Benefits were also noted when the dose was higher than 200 mg/day measured at 24 weeks (2.16, 95% CI: 1.11–4.20,  $p = 2$ ). Because of the number of different assessment tests used, there was wide heterogeneity in outcomes relating to cognition, and this might have reduced the validity of the results. Cognition improved with Gingko (dose less than 200 mg/day measured at 12 weeks) (SMD –0.56, 95% CI: –1.12–0.0,  $p = 0.05$ ) and improvements were shown for any dose measured at 24 weeks (SMD –0.17, 95% CI: –0.32 to –0.02,  $p = 0.03$ ) and 52 weeks (SMD –0.41, 95% CI: –0.71 to –0.11,  $p = 0.01$ ). Activities of daily living improved for doses less than 200 mg/day measured at 12 weeks (SMD –1.10, 95% CI: –1.79 to –0.41,  $p < 0.01$ ), at 24 weeks (SMD –0.25, 95% CI: –0.49 to –0.00,  $p = 0.05$ ) and at 52 weeks (SMD –0.41, 95% CI: –0.71 to –0.11,  $p < 0.01$ ). Mood and emotional function improved on doses less than 200 mg/day compared with placebo measured at less than 12 weeks (SMD –0.51, 95% CI: –0.99 to –0.33,  $p = 0.04$ ) and measured at 12 weeks (SMD –1.94, 95% CI: –2.73 to –1.15,  $p < 0.0001$ ). No significant differences were found in the number of patients experiencing adverse events in the treatment and placebo groups. The authors were unable to exclude the possibility of publication bias affecting earlier results. It was concluded that Gingko appears to be clinically safe, with encouraging evidence regarding efficacy (especially in improving cognition and function). Early trials demonstrated poor study methodology and three later trials showed inconsistent results. Further rigorous research was required in larger trials that allow for an intention-to-treat analysis.

#### **4.2.4 Anxiety and Kava**

Six databases and hand searches of the bibliographies of retrieved data and relevant medical journals, along with information from experts, manufacturers, and conference proceedings, were screened by Pittler and Ernst (2003) for RCTs using oral, mono-preparations of kava extract (*Piper methysticum*) in the treatment of anxiety. The quality of 11 trials (n=645) was assessed with a Jadad scale (average score 4). The outcome measure was the Hamilton Anxiety Scale, and this showed a significant reduction in scores among subjects receiving the study treatment compared with placebo (weighted

mean difference 5.0, 95% CI: 1.1–8.8,  $p=0.01$ ,  $n=345$ ). One trial was responsible for heterogeneity. Subjects in this trial were women with anxiety due to climacteric syndrome, and other sources of heterogeneity could not be identified. Adverse events were mild and transient, and it was concluded that kava was a safe and effective short term treatment for anxiety. Further research was required.

## **5. Respiratory system**

### **5.1 Herbal medicines**

#### **5.1.1 Obstructive airways disease and Ivy leaf extract**

Hofmann, Hecker and Volp (2003) sought RCTs from two databases and hand searched the bibliographies of retrieved studies as well as searching papers obtained from lay sources and German publications not available through the databases on the efficacy of dry extract of ivy leaves in children with bronchial asthma. The authors independently assessed the trials to ensure that the methodological quality was high. Objective outcome measurements included spirometry and body plethysmographic tests. The subjects were children with obstructive airways disease, and diagnosis of bronchial asthma was confirmed by Ventolin challenge. The treatment intervention was any form of ivy leaf extract. Three trials were identified ( $n=75$ ). Only one trial included a placebo control. Results showed that ivy leaf extract administered as drops significantly reduced airways resistance compared with placebo. It was concluded that ivy leaf extract had some efficacy in improving the respiratory function of children with obstructive airways disease, and had few reported adverse events over short term treatment. Further research evidence was needed—especially on long term use.

## **6. Musculoskeletal system**

### **6.1 Nutritional supplements**

#### **6.1.1 Bone density and Vitamin D**

Papadimitropoulos et al. (2002) studied the effect of vitamin D on mineral bone density and fractures in postmenopausal women by performing a meta-analysis of 25 RCTs ( $n=4017$ ). The authors found that vitamin D reduced the incidence of vertebral fractures with a relative risk of 0.63 [95% CI: 0.45–0.88,  $p<0.01$ ] and reduced the number of non-vertebral fractures [RR = 0.77 (95% CI: 0.57–1.04,  $p=0.09$ )]. It was also found that hydroxylated vitamin D had a greater effect on bone density than did standard vitamin D. Both hydroxylated vitamin D and standard vitamin D did, however, increase the risk of subjects discontinuing medication due to symptomatic adverse events or abnormal laboratory results [RR = 1.37 (95% CI: 1.01–1.88,  $p=0.05$ )].

#### **6.1.2 Osteoarthritis of the knee and Glucosamine sulphate**

Richy et al. (2003) performed a meta-analysis of 15 randomised, placebo-controlled trials to determine the efficacy of glucosamine sulphate and/or chondroitin sulphate in treating osteoarthritis of the knee joint. The 15 trials ( $n=1020/755$ ; glucosamine/chondroitin) had an average quality of 78.4% (according to Jadad et al. 1996) and good homogeneity. A significant positive effect was found for glucosamine in radiological evolution of osteoarthritis measured by joint space narrowing (JSN) when compared with placebo—with an effect size of 0.41 (95% CI: 0.21–0.6) which is equivalent to 27 mm (95% CI: 0.13–0.41) over three years. No corresponding high quality data were available for chondroitin. For outcomes of measures of pain and physical function, the results for glucosamine and chondroitin were combined—because there was no significant difference between them. The effect of glucosamine and chondroitin on symptomatic relief (measured using the Lequesne Index) was found to have an effect size of 0.43 (95% CI: 0.32–0.54,  $p<0.001$ ), using WOMAC (measures pain, stiffness, and physical dysfunction on 24 visual analogue scales) ES=0.30 (95% CI: 0.11–0.49,  $p=0.001$ ) and using VAS (visual analogue scale for pain) ES = 0.49 (95% CI: 0.31–0.67,  $p<0.001$ ). The authors also found the relative risk of being a responder to glucosamine and/or chondroitin was 1.60 (95% CI: 1.38–1.82)—a highly significant result.

#### **6.1.3 Postmenopausal osteoporosis and calcium**

The prevention of postmenopausal osteoporosis by calcium supplementation was examined in a meta-analysis by Shea et al. (2002). A total of 15 RCTs was selected from a search of two databases between 1966 and April 1998. The pooled difference for the change from baseline was significant

after two years. For total bone density (BD) it was 2.05% (95% CI: 0.24–3.86), for lumbar spine BD it was 1.66% (95% CI: 0.92–2.39), for hip BD it was 1.64% (95% CI: 0.70–2.57), and for distal radius BD it was 1.91% (95% CI: 0.33–3.50). The relative risk of fractures between placebo and calcium was not significant.

#### **6.1.4 Osteoarthritis and SAME**

Soeken et al. (2002) conducted a meta-analysis on the safety and efficacy of S-adenomethionine (SAME) for the treatment of osteoarthritis, combining 11 RCTs (n=1442). Eight databases were searched and the average quality of the studies was 87.5% (according to Jadad). It was determined that SAME produced an improvement in physical function [ES=0.309 (95% CI: 0.098–0.19)] but produced no significant change in pain [ES=0.223 (95% CI: –0.247 to 0.693)] compared with placebo. When SAME was compared with non-steroidal anti-inflammatory drugs (NSAIDs), they were found to be equivalent—with pain ES=0.122 (95% CI: –0.029 to 0.273) and physical function ES=–0.25 (95% CI: –0.127 to 0.176). When reviewing the safety markers, the authors found that subjects treated with SAME were 58% less likely to experience side effects compared with subjects taking NSAIDs.

#### **6.1.5 Osteoarthritis and nutraceuticals**

A systematic review of the nutraceuticals used for the treatment of osteoarthritis was conducted by Häuselmann (2001). They found that glucosamine sulphate and chondroitin sulphate had beneficial effects on cartilage and provided pain relief equivalent to NSAIDs, but without gastrointestinal side effects. Avocado/soybean unsaponifiable residues, studied in one well designed study, showed modest reductions in pain, with only 1% of subjects suffering side effects. There was some information suggesting that vitamins C and D and fish oils were beneficial in the treatment of osteoarthritis; however, more research was required.

#### **6.1.6 Fibromyalgia and complementary medicines**

Holdcraft, Assefi and Buchwald (2003) reviewed the use of complementary or alternative medicines in fibromyalgia (pain and stiffness in the muscles or joints that is diffuse or has multiple trigger points) and related syndromes. Two small RCTS had been conducted on the effect of magnesium in treating fibromyalgia, with one of the studies showing significant positive results for tender point index scores between control and active. The use of SAME in the treatment of fibromyalgia was reviewed using seven clinical trials, and SAME was found to reduce the number of tender points in five of the seven studies; depression rating dropped in six of the seven trials. However, in one of the larger, well designed studies, SAME did not improve pain ratings on VAS, the number of tender points, self-reported depression, and physical rating global assessment. Two clinical trials looked at the supplementation of *Chlorella pyrenoidosa* (a unicellular green alga) in fibromyalgia. Both studies showed a reduction in number of tender points and an increase in functioning.

### **6.2 Herbal medicines**

#### **6.2.1 Osteoarthritis and avocado/soybean extract, tipi tea, capsaicin and Reumalex<sup>2</sup>**

Little and Parsons (2001) searched ten databases and hand searched retrieved papers, and identified five RCTs of generally high quality that assessed herbal medication compared with placebo in the treatment of osteoarthritis. The data from two studies (avocado/soybean unsaponifiables n=327) were pooled and assessed separately. The remaining studies were single studies of herbs and included tipi tea (n=20), capsaicin (n=70), and Reumalex (n=52). The methodological quality of the studies was reported as variable—ranging from 2 out of 5 (tipi tea) to 5 out of 5 (avocado/soybean unsaponifiables). No clear conclusions could be drawn from the single studies, but the combined data showed positive results in the outcome measures of use of NSAIDs, VAS pain scores, and functional index. A global evaluation of the treatment in both studies on avocado/soybean unsaponifiables rated improvements as ‘good’ to ‘very good’ on a 5-point evaluation scale. There were minimal side effects in both studies. The reviewers concluded that there was strong evidence for the use of avocado/soybean unsaponifiables in arthritis, but that interventions on the basis of single studies could not be recommended.

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<sup>2</sup> ‘Reumalex’ is a traditional herbal remedy for rheumatic disorders which contains guaiacum resin, black cohosh, white willow, sarsaparilla and poplar bark.

## 6.2.2 Rheumatoid arthritis and herbs

Soeken, Miller and Ernst (2003) assessed the evidence for and against the use of herbal medicine in the treatment of rheumatoid arthritis through searches of six databases and subsequent hand searches of bibliographies of retrieved data. The Jadad scale was used to assess the quality of 14 RCTs that fulfilled the inclusion criteria (n=18–182 with an average of 47). Average quality score was 3.9, with a range of 3–5. The trials reviewed the following herbs: gamma-linolenic acid (n=2 studies), evening primrose oil (n=3), blackcurrant seed oil (n=1), capsaicin (n=1), curcumin (n=1), feverfew (*Tanacetum parthenium*) (n=1), flaxseed oil (n=1), extract of *Boswellia serrata* (n=1), olibanum (n=1), a standardised ayurvedic formulation (Reumalex) (n=1), and *Tripterygium wilfordii* Hook F (n=1). A meta-analysis of single and pooled effect sizes for gamma-linolenic acid showed significant improvements in pain, tender joint count, swollen joint count, and stiffness compared with placebo. Only the swollen joint count failed to reach significance. The remaining single studies resulted in weak evidence. Adverse events included GIT symptoms, light-headedness, and skin rash. The review concluded that gamma-linolenic acid had moderate support in the treatment of rheumatoid arthritis. Moreover, although all the herbs were safe to use, further research was required to explore safety and efficacy.

## 6.2.3 Osteoarthritis and herbs

Long, Soeken and Ernst (2001) systematically reviewed RCTs linking osteoarthritis with herbal medicine. Other information was sought from experts and manufacturers in the field, authors' personal files, and hand searches of retrieved studies from the databases. Twelve trials and two systematic reviews fulfilled the inclusion criteria, and methodological quality was assessed with the scale designed by Jadad (average 4.2, range 1–5). The efficacy of herbal medicine in osteoarthritis was reviewed in: (i) single trials on Articulín-F<sup>3</sup> (n=42), Eazmov<sup>4</sup> (n=60), ginger (*Zingiber officinalis*) (n=56), Gitadyl<sup>5</sup> herbal medicine (n=35), Reumalex herbal preparation (n=51), stinging nettle (*Urtica dioica*) (n=27), and willow bark (*Salix alba*) (n=78); (ii) two trials on avocado/soybean unsaponifiables (ASU) extract of avocado and soya (n=327), and devil's claw (*Harpogophytum procumbens*) (n=139); and (iii) four trials on capsaicin (n=248).

The results showed promising evidence for the efficacy of Articulín-F, capsaicin, devil's claw, Reumalex, and willow bark in the treatment of osteoarthritis. There was a reduction in the consumption of NSAIDs when using ASU extract of avocado and soya. Adverse events were mild and transient—including GIT symptoms, pruritus, and headache. Capsaicin caused temporary burning pain on application in some patients. It was concluded that the herbal remedies reviewed could offer a viable alternative in the treatment of osteoarthritis.

# 7. Reproductive system

## 7.1 Nutritional supplements

### 7.1.1 Pre-eclampsia and calcium

Eleven randomised, placebo-controlled studies were reviewed in a meta-analysis by Hofmeyr et al. (2003) to define the effect of calcium supplementation in preventing pre-eclampsia. The authors studied the effect of calcium supplementation during pregnancy on the risk of high blood pressure and other related maternal and fetal/neonatal adverse outcomes. It was found that calcium significantly reduced the risk of high blood pressure with the relative risk being 0.81 (95% CI: 0.74–0.89). This effect was higher in women with a high risk of hypertension and those with low baseline calcium levels [RR = 0.45 (95% CI: 0.31–0.66) and RR = 0.49 (95% CI: 0.38–0.62] respectively). Calcium also significantly decreased the risk of pre-eclampsia with a RR of 0.68 (95% CI: 0.57–0.81], again with a higher effect in subjects with high risk of hypertension and low calcium levels. A smaller

<sup>3</sup> 'Articulín-F' is a herbal and mineral formulation containing *Withania somnifera*, *Boswellia serrata*, *Curcuma longa* and a zinc complex.

<sup>4</sup> 'Eazmov' is an Ayurvedic herbal preparation containing *Cyperus rotundus*, *Tinospora cordifolia*, *Saussurea lappa*, *Picrorrhiza kurroa*, and *Zingiber officinale* (ginger).

<sup>5</sup> 'Gitadyl' is a herbal preparation containing *Tanacetum parthenium*, *Populus tremuloides*, and *Achillea millefolium*.

number of babies with a birth weight less than 2.5 kg were born to subjects who were supplemented with calcium [RR = 0.83 (95% CI: 0.71–0.98)].

### **7.1.2 Complications of pregnancy and nutritional supplementation**

Villar et al. (2003) investigated the role of nutritional interventions during pregnancy in reducing maternal morbidity, mortality, and preterm labour by conducting a review of RCTs and systematic reviews. The authors investigated a number of complications associated with pregnancy—including pre-eclampsia, hypertension, anaemia and haemorrhage-related outcomes, maternal infection, and obstructed labour/caesarean section. They also studied a number of supplements—including calcium, magnesium, fish oil, vitamins E, A, and C, iron, folate,  $\beta$ -carotene, and zinc. It was determined that vitamin A and  $\beta$ -carotene reduced maternal mortality, that calcium supplementation was beneficial for women with low calcium intake and a high risk of pre-eclampsia, that fish oil and magnesium might have prevented preterm labour, and that iron and folate were effective for preventing and treating severe anaemia (even postpartum).

### **7.1.3 Premenstrual syndrome and mineral and vitamin supplementation**

Stevinson and Ernst (2001) examined various complementary and alternative therapies in the treatment of premenstrual syndrome using a systematic review. Thirteen RCTs were examined. These tested nutritional supplements such as calcium (n=2), magnesium (n=3), vitamin E (n=2), and multivitamin supplement (n=5). There was also one study with a carbohydrate drink. The majority of these studies reported a positive benefit for the various supplements. However, due to the relatively small sample size and other methodological problems, the authors were unable to recommend any of these treatments.

## **7.2 Herbal medicines**

### **7.2.1 Menopause and *Cimicifuga racemosa***

After a search of seven databases, papers in the reviewer's personal files, and information supplied by manufacturers, a total of four RCTs (n=226) met the inclusion criteria for a review of the clinical efficacy of *Cimicifuga racemosa* in the treatment of menopause symptoms by Borelli and Ernst (2002). Three of the trials scored between 2 and 3 using the Jadad scale, and 1 scored a maximum of 5 points. All trials used a commercial presentation of *C. racemosa* called 'Remifemin', in either tablet or liquid form. Outcome measurements included the Kupperman menopausal index, Hamilton anxiety scale, serum hormone levels, and vaginal epithelium status. The results showed some beneficial effects that the reviewers postulated as being due to central dopaminergic-2 receptors. They concluded that insufficient evidence was available on the clinical efficacy of *C. racemosa* and that further more rigorous trials were required.

### **7.2.2 Premenstrual syndrome and herbs**

Stevinson and Ernst (2001) conducted a systematic review to determine whether the use of complementary and alternative medicine (CAM) is effective for pre menstrual syndrome (PMS). A search of six databases produced seven trials relating to herbal medicine (two on *Vitex agnus castus*, one on *Ginkgo biloba*, and four on evening primrose oil). The authors did not perform a quantitative assessment of quality—due to the heterogeneity of the trial outcomes. Mild transient adverse events were reported. The trials assessed in this study had poor methodological quality, and presented no convincing evidence of efficacy in the treatment of PMS.

### **7.2.3 Menopause and herbal medicines**

Kronenberg and Fugh-Berman (2002) reviewed the literature from two databases and their personal files and retrieved 29 studies on CAM therapies for obstetrical and gynecologic conditions likely to be used by women of reproductive age and by pregnant women. Ten of these studies related to the use of herbal medicine in menopause. Four of the RCTs investigated the effects of black cohosh (n=285), two assessed the effects of red clover (*Trifolium pratense*) (n=88), and the remainder were single studies—of dong quai (*Angelika sinensis*) (n=71), evening primrose oil (n=56), ginseng (n=384), and Chinese herb mixture (n=78). Outcome measures included serum hormone levels, frequency and intensity of hot flashes, and psychological well being as measured by the Kupperman index score. Results showed some efficacy for black cohosh in the relief of hot flashes, but the remaining herbs had



no significant effects. The study concluded that black cohosh had potential in relieving menopausal symptoms, but pointed out that further research was required into the long term safety of using the herb.

Huntley and Ernst (2003) sought RCTs on the use of herbal medicine in menopause. Four databases were screened, together with information from manufacturers, the authors' personal files, and bibliographies of retrieved studies. Primary outcomes assessed were the physical or psychological symptoms of menopause. Herbs used in the trials included black cohosh (n=4), red clover (n=4), kava (n=3), and single studies on dong quai, evening primrose oil, and ginseng. Four trials investigated 'combination products'. The quality of the studies was described as 'good', with most scoring three points on the Jadad scale (n=16 trials). The review concluded that black cohosh had potential in the treatment of symptoms of menopause, but trial methodology was described as 'poor'—a statement that appeared to be in conflict with the earlier appraisal regarding quality. Red clover and kava showed some promise, but the remaining herbs demonstrated inconclusive evidence for use. Further research was recommended.

#### **7.2.4 Induction of labour and Castor oil**

The objective of a review by Kelly, Kavanagh and Thomas (2004) was to determine the efficacy of castor oil in cervical 'ripening' or induction of labour in the third trimester of pregnancy. Five databases were searched and hand searches were made of retrieved studies. Only one trial (n=100) met the inclusion criteria, and this was of poor methodological quality. The reviewers indicate that the study numbers were small and only large differences in outcomes could have been detected. All participants complained of the taste of the oil. It was concluded that further research was necessary.

#### **7.2.5 Benign prostatic hypertrophy and *Serenoa repens***

In a study of benign prostatic hypertrophy (BPH), Wilt, Ishani and MacDonald (2002) searched four databases, hand searched bibliographies of retrieved studies, and obtained information from experts in the field and manufacturers. A total of 21 trials (n=3139) met the inclusion criteria. Quality was seen as 'adequate' in 52% of studies for treatment allocation concealment. Inclusion criteria were patients with BPH treated with *Serenoa repens* as mono-therapy or combination therapy compared with placebo, with treatment duration of at least 30 days. Primary trial outcomes were assessed on clinical measurements of urinary symptoms or urodynamics. Results showed that treatment with *Serenoa repens* improved urinary symptoms and flow measures compared with placebo. The weighted mean difference for the urinary symptom score was -1.41 points (scale range 0-19) (95% CI: -2.52 to -0.30, n=1 study) with a risk ratio for self-rated improvement of 1.76 (95% CI: 1.21 to 2.54, n=6 studies). The weighted mean difference for nocturia was -0.76 times per evening (95% CI: -1.22 to -0.32, n=10 studies), and for peak urine flow was 1.86ml/sec (95% CI: 0.60 to 3.12, n=9 studies). Adverse events were mild, transient, and infrequent. The reviewers concluded that the study medication provided mild to moderate improvements in urinary symptoms and flow measures. However the long term safety and efficacy of *Serenoa repens* had not been demonstrated and further research was required.

#### **7.2.6 Benign prostatic hypertrophy and *Pygeum africanum***

In another study of BPH, three databases were screened by Wilt et al. (2004), along with information obtained from manufacturers and experts and subsequent hand searches of the bibliographies of retrieved papers. The search identified 18 RCTs (n=1562) on men with symptomatic BPH that compared the effects of the study medication *Pygeum africanum* with placebo or medical treatment. Study quality as assessed by the method of Schultz et al. (1995) was generally poor. The primary outcome assessed was a change in urological symptoms scale scores; secondary outcomes were changes in urological symptoms (peak and mean urine flow (mL/sec) prostate size, frequency, urgency, dysuria, and nocturia). Effect size was defined by the difference of the mean change for each outcome divided by the pooled standard deviation for each outcome [-0.8SD (CI: -1.4 to -0.3 (n=6 studies))]. Subjects taking *Pygeum africanum* were twice as likely to report an improvement in urological symptoms (RR=2.1, 95% CI: 1.4-3.1). The analysis reported a 19% reduction in nocturia, 24% reduction in residual urine volume, and a 23% increase in peak urine flow for individuals taking *Pygeum africanum* compared with placebo. There were insufficient studies to produce clear evidence

for or against publication bias. The most frequently reported adverse events were mild GIT symptoms. The review concluded that *Pygeum africanum* might be of use in the treatment of BPH. However, the preparation would need to be standardised. Further research was required in larger trials of longer duration than those reviewed in this paper. These trials should employ active controls with proven efficacy and use standardised symptom scores.

## **8. Urinary tract**

### **8.1 Herbal medicines**

#### **8.1.1 Urinary tract infections and cranberry juice**

Jepson, Mihaljevic and Craig (2001) searched nine databases and approached manufacturers of cranberry products for information on the use of this product in the management of urinary tract infections (UTIs). Seven trials fulfilled the inclusion criteria (n=604) and were assessed for quality by two authors with discrepancies resolved by a third. The overall quality of the studies was described as 'good'. The RCTs assessed the effects of cranberry juice (*Vaccinium oxycoccos*) (5 trials), cranberry tablets (1 trial), and both juice and tablets (1 trial). Only two RCTs were assessed as 'high quality'. These were included in the meta-analysis and the results showed a significant reduction in the incidence of UTIs at the end of 12 months. The reviewers concluded that cranberry products might have reduced the number of symptomatic UTIs in women over a 12 month period. However, the evidence was not clear in other groups—such as elderly men, elderly women, and children. The authors speculated that the large number of dropouts reported in the studies might indicate that cranberry juice was not tolerated over long periods of time. Further research to determine an effective dose and concentration of cranberry products needed to be carried out, with emphasis placed on studies using cranberry tablets or capsules.

## **9. Systemic effects**

### **9.1 Nutritional supplements**

#### **9.1.1 Body strength, composition and performance and creatine supplementation**

Dempsey, Mazzone and Meurer (2002) conducted a meta-analysis of whether oral creatine supplementation increased maximal strength and power in healthy adults. Sixteen, generally low quality studies were included (n = 414). No significant heterogeneity or publication bias was found. The difference in maximum bench-press lifted weight and maximum squat-lifted weight between creatine-supplemented subjects and placebo-controlled subjects was 6.85 kg (95% CI: 5.24–8.47) and 9.76 kg (95% CI: 3.37–16.15) respectively. Seven of the ten studies that reported maximal strength included young men engaged in resistance training; the benefit might therefore have applied in only this population.

The effect of creatine supplementation on body composition and performance was explored by Branch (2003) using a meta-analysis. One hundred randomised studies of unknown quality with a placebo control were reviewed (n = 1847). The effects of all body composition and performance variables were found to be normally distributed (as the measure of heterogeneity), and all studies were therefore included in the final analysis. The only measure of publication bias was a comparison of the effect size of studies that received financial support and those that received no support. No bias was found. Creatine was found to improve measurements in a small but significant way: 'repetitions accomplished, mass lifted, force and power generated and work accomplished during high intensity, short duration isotonic, isometric, isokinetic and leg ergometer exercise'. No evidence of differences between gender and training status was found.

#### **9.1.2 Child growth and zinc supplementation**

Brown et al. (2002) investigated the effect of zinc supplementation on the growth and serum zinc concentration of prepuberal children with a meta-analysis of 37 RCTs (n = 2637). A highly significant increase in the height and weight of prepuberal children from both developed and developing countries was achieved: effect size = 0.35 (95% CI: 0.189–0.511) and effect size = 0.309 (95% CI: 0.178–0.439) respectively. There was also a significant increase in serum zinc concentration: weighted mean effect size = 0.82 (95% CI: 0.499–1.14). Publication bias was not directly estimated; however, it was

calculated that more than 500 studies with a zero effect would be required to invalidate the reported findings.

### **9.1.3 Physical function in the elderly and vitamin D**

A meta-analysis examining the effectiveness of vitamin D supplementation in preventing falls and improving the physical function of elderly people was completed by Latham, Anderson and Reid (2003). Thirteen randomised placebo-controlled trials ( $n = 2496$ ) were selected after a search of four databases (from 1966 to May 2002). The methodological quality of many of the trials was found to be poor, so only the four highest quality trials ( $n = 1317$ ) were pooled to give a relative risk of falling of 0.99 (95% CI: 0.89–1.11). This result indicated that vitamin D did not decrease the risk of falling in elderly people. There was evidence that the combination of vitamin D and calcium did improve physical function—thereby reducing the risk of falls in the elderly. However, a large, well designed study was required to substantiate this conclusion.

### **9.1.4 Resistance training and creatine supplementation**

Nissen and Sharp (2003) studied the ability of various dietary supplements to augment lean mass and strength gains with resistance training. In all, 48 studies with an overall quality score of 33.7% (according to Chalmers et al. 1981) were chosen as RCTs studying creatine (18 trials), beta-hydroxy-beta-methylbutyrate (HMB) (9 trials), chromium (12 trials), androstenedione (3 trials), and dehydroepiandrosterone–DHEA (2 trials). Chromium, androstenedione, and DHEA produced no significant change in lean mass or strength gains with resistance training. Creatine produced a gain of 0.36% in lean body mass per week (95% CI: 0.25–0.48%,  $p < 0.001$ ) and a 1.09% gain in strength per week (95% CI: 0.65–1.52%,  $p < 0.001$ ). HMB produced a significant gain of 0.28% in lean body mass per week (95% CI: 0.13–0.42%,  $p < 0.001$ ) and increase in strength of 1.40% per week (95% CI: 0.41–2.39%,  $p < 0.01$ ). No significant publication bias was found.

### **9.1.5 Weight loss and guar gum**

The efficacy of guar gum in reducing body weight was studied by Pittler and Ernst (2001) using a meta-analysis containing 11 randomised, double blind, placebo-controlled trials. The authors found that there was no difference between placebo and guar gum for weight reduction, that the studies were homogeneous, and that there was little publication bias present.

### **9.1.6 Weight loss and chromium picolinate**

Six databases were searched by Pittler, Stevinson and Ernst (2003) to collect randomised, double blind, placebo-controlled trials for a meta-analysis to assess whether chromium picolinate is efficacious in the reduction of body weight. The authors located a total of 10 clinical trials ( $n = 489$ ) that were found to be homogeneous. The authors concluded the chromium picolinate produced a significant difference in the amount of weight loss when compared with placebo—weighted mean difference:  $-1.11$  kg (95% CI:  $-1.8$  to  $-0.4$ ). It was suggested that this effect was largely based on a large single study—weighted mean difference:  $-0.9$  kg (95% CI:  $-2.0$  to  $0.2$ ),  $n = 335$ .

Gorsky and Epstein (2002) performed a systematic review of the effect of topical retinoids on leukoplakia of the oral mucosa. Four non-randomised controlled trials were found that tested the effect of topical vitamin A compounds in the form of gel or lozenges. Complete resolution of lesions was achieved in 10–27% of patients and partial response (50% reduction in size of lesions) was achieved in 54–90%. Although there was a 50% rate of recurrence, the side effects were minimal.

### **9.1.7 Systemic oxidative stress and antioxidants**

The clinical pharmacokinetics of a number of antioxidants and their effect on systemic oxidative stress were examined by Schwedhelm et al. (2003) with a systematic review. Supplements that were shown to have some anti-oxidative stress activity included vitamin C, vitamin E, and carotenoids (such as  $\beta$ -carotene, lycopene, and lutein).

## **9.2 Herbal medicines**

### **9.2.1 Liver disease and *Silybum marianum***

Jacobs et al. (2002) searched ten databases and examined material supplied by manufacturers and experts in the field for RCTs using human subjects administered milk thistle (*Silybum marianum*)

compared with placebo in the treatment of liver disease. Fourteen trials (n=1209) were identified and were assessed for quality on the Jadad scale; the average score for the trials was 3.0 ±1.3. Measurements were histology of liver biopsy (n=237) and biochemical markers (n=840). The review also analysed mortality data. Results showed that four trials (n=433) reported outcomes for mortality; the overall summary odds ratio was 0.8 (95% CI: 0.5–1.5,  $p=0.6$ ) compared with placebo. Quality assessment was performed only for histology outcomes (due to the variable samples and limited data). Histology outcomes were inversely related to study quality (Jadad 5: no treatment effect; Jadad 1: substantially improved clinical effect). There were no significant differences in biochemical markers between the treatment group and the verum group. Adverse events were mild and equal to placebo. It was concluded that the treatment appears to be safe; however, no reduction in biochemical markers was noted in the three study outcomes. The data were too limited to allow the reviewers to recommend milk thistle as a beneficial and safe treatment in liver disease.

### 9.2.2 Hepatitis B and Chinese herbs

In studying the effects of Chinese herbal medicines on hepatitis B, McCulloch, Gao and Colford (2002) searched six databases and supplemented the information with hand searches of bibliographies, journals from non-indexed medical and professional journals, papers from personal files, and Chinese language and English language journals. These procedures identified 27 RCTs (number of patients not given) that compared the effects of Chinese herbal medicine alone versus Interferon alfa or Chinese herbal medicine combined with Interferon alfa versus Interferon alfa alone in the treatment of hepatitis B. Outcomes of interest were biochemical markers (HbsAg, HbeAg, HBV DNA). Data were abstracted with a standardised form by two reviewers and quality assessed with a modified Jadad scale (low score 0; high score 3). All trials scored between 0 and 1. Trials using Chinese herbal medicine alone versus Interferon alfa (n=15) were significantly more likely to achieve sero-reversion of HbsAg (RR=1.20, 95% CI: 0.99–1.49) and HBV DNA (RR=0.94, 95% CI: 0.80–1.11). All three biochemical markers improved in studies using Chinese herbal medicine combined with Interferon alfa opposed to Interferon alfa alone [HbsAg (RR=2.08, 95% CI: 1.45–2.96); HbeAg (RR=1.64, 95% CI: 1.39–1.94); HBV DNA (RR=1.58, 95% CI: 1.35–1.85)]. Significant improvements were also found in patients receiving a combination of Chinese herbal medicines and Interferon alfa with an active component of Bufotoxin [HbeAg (RR=1.50, 95% CI: 1.09–2.08); HBV DNA (RR=1.75, 95% CI: 1.24–2.47)]. Chinese herbal medicine with an active component of Kurorinone alone had an equivalent effect to Interferon alfa on the sero-reversion of HbeAg (RR=0.93, 95% CI: 0.68–1.27) and HBV DNA (RR=0.88, 95% CI: 0.66–1.16). The study concluded that, even though the RCTs had poor study methodology, there appeared to have been evidence of the efficacy of Chinese herbal medicine in the treatment of hepatitis B. Further more rigorous research was required.

### 9.2.3 Cancer and *Viscum album*

Eight databases were searched by Ernst, Schmidt and Steuer Vogt (2003) for RCTs that had explored the effects of mistletoe on any type of cancer. The reference lists of retrieved studies and papers from the reviewer's personal files were hand searched. Ten studies met the inclusion criteria. These were described in narrative form and summarised in a table. One study was not summarised—due to poor methodology. The Jadad scale was used to assess the quality of the RCTs. However, due to the heterogeneity of outcomes, data could not be pooled for statistical analysis. The methodological quality of the studies ranged from 1 to 3 with an average of 2.2. The review itself was poorly reported. It covered a variety of cancers—including colorectal cancer (n=139), bronchial cancer (n=626), glioma (n=35), melanoma (n=830), breast cancer (n=279), and bladder cancer (n=45). The review concluded that rigorous trials were required to determine the efficacy of mistletoe. The results of the studies had to be considered as equivocal in view of the poor study methodology of the trials. The methodology of the review itself must also be questioned in view of the poor quality of the report.

Kienle and Berrino (2003) searched 11 databases and made hand searches of the bibliographies of retrieved studies, as well as consulting with experts in the use of mistletoe (*Viscum album*) in the treatment of cancer. Twenty-three trials were identified—16 randomised (n=2495); 2 quasi-randomised (n=155), and 5 non-randomised (n=1896). Quality was assessed as 'adequately filled' to 'not fulfilled'. Cancer sites included breast (four studies), colon/rectum (three studies), skin (melanoma) (two studies), female reproductive tract (three studies), stomach (one study), head and

neck (one study), kidney (one study), bladder (one study), and brain (glioma) (one study). There was substantial heterogeneity of interventions and outcomes, poor quality within the study methodologies, and potential bias in outcomes. The review identified positive outcomes for survival (n=8), remission (n=1), and improvements in quality of life (n=3). No major side effects were reported, and the reviewers concluded that there were encouraging reports for the use of mistletoe in cancer; however, further rigorous research was required.

## 10. Infection

### 10.1 Nutritional supplements

#### 10.1.1 Infectious disease, immune status and iron supplementation

The relationship between iron and immunity and infectious diseases was examined by Oppenheimer (2001). The author found that studies since 1980 had shown that iron supplementation increased the risk of certain infectious diseases—probably because iron therapy stimulated organisms (such as plasmodia, mycobacteria and salmonella) that spent part of their life cycle intracellularly. In malarious areas, the risk of infection (odds ratio) associated with iron supplementation ranged from 1.5 to 6.5, with most being greater than 2. There was also some evidence that there was a detrimental relationship between iron and HIV infection. Iron supplementation conferred many benefits on populations with iron deficiency; however, in malarious areas, the increased risk of malarial infection outweighed these benefits.

#### 9.2.4 Viral infections and herbal medicines

Martin and Ernst (2003) searched five databases and personal files, and made hand searches of the bibliographies of retrieved papers for trials on the use of a single herb extract in the treatment of viral infections. In all, 41 trials (33 randomised, 8 non-randomised) met the inclusion criteria and were assessed for quality using the Jadad scale. The quality of the trials ranged from 5 (n=8) to 1 (n=1), with an average score of 3. The randomised studies investigated *Phyllanthus* (n=1033), *Melissa officinalis* (n=182), *Sambucus nigra* (n=100), *Andrographis paniculate* (n=258), *Clinacanthus nutans* (n=180), Aloe vera (n=80), *Glycyrrhiza glabra* (n=652), *Melaleuca alternifolia* (n=20), *Buxus sempervirens* (n=145), *Salvia officinalis* (n=149), and *Allium sativum* (n=146). Non-randomised trials covered *Phyllanthus* (n=28), *Andrographis paniculata* (n=79), *Clinacanthus nutans* (n=77), *Melissa officinalis* (n=115), and *Glycyrrhiza glabra* (n=62). Of the 14 RCTs investigating *Phyllanthus*, only seven produced positive results. The remaining trials showed positive results for all herbs except for *Salvia officinalis*, *Melaleuca alternifolia*, *Buxus sempervirens*, and *Glycyrrhiza glabra*. The results of the non-randomised trials showed mild to moderate improvements following treatment with all herbs, apart from a study of the effects of *Andrographis paniculata* in HIV-positive patients which had to be terminated due to adverse reactions. There was no report of adverse events from other herbs in the review. The reviewers concluded that, overall, the herbs showed positive results; however, they speculated that negative trials might not have been published and stated that further more rigorous research was required.

### 10.2 Herbal medicines

#### 10.2.1 Hepatitis B and Chinese herbal treatment

Liu, McIntosh and Lin (2001) sought RCTs or quasi-RCTs of patients who were asymptomatic carriers of hepatitis B virus infection. They searched five databases and made hand searches of five Chinese herbal journals and conference proceedings. In all, 22 trials of poor quality met the inclusion criteria with an average size of 88 patients (range 10-13). Patients in the studies had to be HbsAg positive and/or HbeAg positive, with no symptoms or signs of hepatitis for more than six months. A total of 11 RCTs (n=932) was found that randomised subjects into treatment with a Chinese medicinal herb versus placebo, no treatment, or treatment with Interferon. Jadad scale assessment demonstrated poor methodological quality in all trials. Only three of these trials (n=307) met the inclusion criteria of a minimum 3 month follow-up after the end of treatment. These three trials tested Jianpi Wenshen formula and showed significant effects (compared with Interferon) in clearing viral markers. The results of the eight trials with less than three months follow-up were pooled separately. These showed no significant effects compared with placebo. No major adverse event was reported, but there were

instances of GIT symptoms, sore mouth, tiredness, flu-like symptoms, dizziness, and headache (and one case of a truncal rash in a trial assessing the effects of *Phyllanthus amarus*). The reviewers concluded that Jianpi Wenshen recipe might have been of benefit in treating hepatitis B carriers, whereas *Phyllanthus amarus* and *Astragalus membranaceus* showed no significant effect compared with placebo. Further rigorous research was required.

### 10.2.2 Hepatitis B and genus *Phyllanthus* herbs

Studies on hepatitis B and genus *Phyllanthus* herbs were obtained by Liu, Lin and McIntosh (2001) through searches of five databases and hand searches of published and unpublished Chinese literature. In all, 22 trials met the inclusion criteria with an average size of 88 patients (range 10–213). Thirteen trials studied a single herb and nine studied a compound of *Genus phyllanthus*. Outcome measures were clearance of serum HbsAg, HbeAg, and HBV DNA. Length of treatment ranged from 4 weeks to 26 weeks. No serious adverse events were reported, and minor adverse events were GIT-related. The methodological quality was high in five double blind trials and low in the 17 remaining trials. Results showed that the study medication had a positive effect on the clearance of serum HbsAg compared with placebo or no intervention. No significant difference was found in the clearance of biological markers compared with Interferon alone. However, *Phyllanthus* used in combination with Interferon resulted in a better clearance effect. The reviewers concluded that the evidence of the trials was not conclusive due to poor trial methodology and variations in the herbs itself. They recommended further research.

### 10.2.3 Hepatitis C and herbs

Liu et al. (2003) searched four databases and made hand searches of five Chinese journals and one Japanese journal. They identified 13 RCTs (n=818) that studied 14 medicinal herbs in the treatment of hepatitis C and assessed the quality of the trials by using the Jadad scale. The overall quality of the trials was poor. Herbs assessed included CH-100 (n=40), silybin (n=20), glycyrrhizin (n=54), complete thymic formula (n=38), oxymatrine (n=43), bing gan ling (n=324), gansu (n=59), bing gan capsule + IFN (n=56), yi zhu decoction (n=40), qinggan and bushen granule (n=66), and yi er gan tang (n=78). Only silybin showed a significant reduction in liver enzymes in one trial. Some of the herbs were associated with adverse events, but these were not described. It was concluded that further more rigorous research was required to determine the efficacy and safety of the herbs.

## Nutrition references

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## Appendix 3.6 Homeopathic Research

### 1. Introduction

Homeopathic research has had a short, but chequered, history—covering laboratory research, animal research, and human studies. Laboratory research has generally focused on two areas: (i) to demonstrate differences between potentised and non-potentised homeopathic preparations; and (ii) to discover the (as yet unexplained) mechanism by which homeopathic preparations exert an effect. Animal research is interesting, and it can be useful in refuting the accusation that homeopathic action is mainly due to placebo effect, but it has little external validity. If the main purpose of medical research is to drive clinical practice, the most valuable area for homeopathy is human research. Accordingly, this appendix focuses on human research into homeopathy and, in particular, on recent controlled clinical studies.

Because homeopathy is based on individualised preparations, many homeopaths are concerned that the methodology of randomised, placebo-controlled, clinical trials is incompatible with homeopathy. These homeopaths prefer to prove the efficacy of homeopathy with epidemiological evidence and case studies. However, some believe that non-experimental epidemiology ‘cannot reliably distinguish between false or true negative (or positive) conclusions’ (Van Haselen 1998). In an attempt to prove that homeopathy is an effective therapy, clinical trials have been undertaken with increasing frequency. Such clinical trials are the nexus between two discrete paradigms—homeopathy and orthodox medicine. De Lange de Klerk et al. (1994) observed that ‘trials of homeopathy have to meet the criteria of both disciplines’. To be accepted by both the scientific and homeopathic communities, trial protocols need to be designed to incorporate a framework in which high-quality methodology and homeopathic procedures are integrated.

### 2. Historical overview

In the literature from 1975 to February 2004, 97 published controlled clinical trials have been identified. Before 1975, only four published papers (Kennedy 1971; Paterson 1943; Ritter 1966; Ustianowski 1974) have been identified. Compared with research in conventional medicine, this is a small body of research. Systematic reviews have been used to compare the results of these identified studies—usually with the objective of ascertaining whether homeopathy has an effect greater than placebo. An extension of this is a meta-analysis—which is a technique that compares the results from a number of clinical trials that have common objectives and methodology such that a statistical combination and joint analysis of the trial results can be undertaken (Swayne & Mau 1996). Several important meta-analyses of controlled homeopathic trials have been conducted since 1990. Wilson and Henry (1992) were of the view that meta-analyses have assumed a greater role and might even replace traditional narrative reviews as primary subject overviews.

Kleijnan, Knipschild & ter Riet (1991) published an assessment of 107 controlled studies on the efficacy of homeopathic interventions. When assessed according to guidelines formulated by Wilson and Henry (1992), this meta-analysis demonstrated high quality. Of the 107 studies, two were found to have uninterpretable results, 24 demonstrated no positive effect of homeopathy, and the remaining 81 indicated a positive effect. Trials were allocated points to a maximum total of 100 for the following seven methodological criteria: (i) patient characteristics adequately described; (ii) number of patients analysed; (iii) randomisation; (iv) intervention well-described; (v) double blinding; (vi) effect measurement relevant and well-discussed; and (vii) presentation of results in such a manner that the analysis can be checked by the reader. Twenty-one studies scored greater than 55%. Of these, eight scored 80% or above. The mean score of the 107 trials was 42.3% (ranging from 0% to 90%). In 42 of the trials, insufficient data were provided to enable the verification authors to interpret the results. The results could not be pooled statistically because there was wide variation in the trials. Publication bias was evident in the small number of trials published with non-significant or negative results. Despite the shortcomings of the research methods of individual trials, the meta-analysis demonstrated evidence for the efficacy of homeopathy. The authors emphasised a need for greater rigour when designing trials in homeopathy, and the provision of a clear description of the methodology.

A meta-analysis by Linde et al. (1997) examined 89 of 186 identified trials. The selected trials covered a total of more than 10,500 patients. Trials included low-potency homeopathic preparations (1X-8X, 1C-4C), medium-potency preparations (9X-23X, 5C-11C), and high-potency preparations (>23X, >11C) potencies. This analysis included all published reports of controlled clinical trials of homeopathy in all languages. Selection criteria specified that: (i) all trials had to be on people being treated for illness or entered into a preventative trial; (ii) trials had to be placebo-controlled; (iii) trials had to be randomised or double-blinded; (iv) there had to be a written report on the trial; and (v) sufficient data for outcome-rate calculations had to be provided. Homeopathic ‘provings’, single-case experiments, trials on healthy subjects, trials without placebo controls, and trials with insufficient data were all excluded. Trials were assessed qualitatively using the Jadad scale (Jadad, Moher & Klassen 1998). Of the trials, 29% met the criteria for ‘high quality’. This meta-analysis by Linde et al. (1997) was of a higher quality than the review by Kleijnen, Knipschild and ter Riet (1991). Quantitative analysis indicated an overall odds ratio of 2.45 in favour of homeopathy (95% CI: 2.05–2.93), although this was reduced to 1.66 (95% CI: 1.33–2.08) when only the 26 ‘high-quality’ studies were included. Correction for publication bias decreased the odds ratio by about 27%, but statistical significance was maintained. Pooling of effect sizes is an analytical method that is used in conventional meta-analyses. Linde et al. (1997) followed this protocol, and made the assumption that the treatment effect sizes for the different treatments in different disease conditions were comparable. Given the heterogeneity of the eligible trials, this was unlikely and the pooling of effect sizes might have been an inappropriate analytical method for this study (Cucherat et al. 2000). A lack of independent replication of any of the trials was noted. Indeed, this remains a feature of homeopathic research. Linde et al. (1997) suggested that there were few, if any, implications for clinical practice—because ‘... there was insufficient evidence that homeopathy is clearly efficacious for any single clinical condition’. Nevertheless, the authors concluded that the results of the meta-analysis were ‘... not compatible with the hypothesis that the clinical effects of homeopathy are completely due to placebo’.

A meta-analysis by Cucherat et al. (2000) broadened the body of evaluated homeopathic evidence. A wide-ranging literature review identified all published and unpublished randomised controlled trials of homeopathy up to June 1998. Of 118 trials, only 16 satisfied the inclusion criteria. These included: (i) a comparison of homeopathic efficacy with placebo or a treatment without an active constituent; (ii) a dilution greater than one part in a million; and (iii) a clearly defined primary outcome. This represented 17 comparisons. Blinded and unblinded trials were both included. The aim of this review was to demonstrate evidence of efficacy of homeopathic treatment in patients with any condition. The broad nature of this question meant that the conventional statistical analytical methods of meta-analysis were difficult to apply. To overcome this, significance levels ( $p$  values) were combined. Using this approach, the null hypothesis tested was that homeopathic efficacy was not demonstrated in any of the included trials. The combined  $p$  value for the 17 comparisons was 0.000036, but this was reduced to 0.082 when only the five highest-quality trials were included. As Linde et al. (1997) had previously observed, Cucherat et al. (2000) found an inverse relationship between trial quality and significance. This relationship is not limited to homeopathy; a similar effect has been reported by Moher et al. (1998) in trials in other areas of medicine. In testing the null hypothesis, Cucherat et al. (2000) noted that the results of their meta-analysis provided evidence that, in *at least one* trial, homeopathic treatment was more efficacious than placebo; the authors did not assert that efficacy was demonstrated in all trials. The authors concluded that the strength of the evidence supporting homeopathic efficacy was low due to the overall low quality of the trial designs and reporting. The method of meta-analysis might also contribute to this. The lack of robust evidence was insufficient to conclude that homeopathic treatments were clinically effective.

### 3. Clinical trials

The use of clinical trials in homeopathic research is an attempt to establish the scientific plausibility of homeopathy. In conducting such clinical trials, protocols that can withstand close scrutiny are obviously necessary. Hornung (1991) formulated a set of guidelines to ensure higher-quality clinical trials. In 1994, the Directorate General XII of the European Commission, under the aegis of the European Parliament, created the Homeopathic Medicine Research Group to investigate all aspects of

homeopathic practice. The findings of this group, including a detailed set of recommendations for protocols of clinical trials in homeopathy (Dangouman 1996), were published in a report to the commission in 1996.

Research shortcomings are not restricted to homeopathic research. Kleijnen, Knipschild and ter Riet (1991) concluded that ‘... there is no reason to believe that the influence of publication bias, data massage, bad methodology, and so on, is much less in conventional medicine’. Towheed and Anastassiades (2000) provided evidence for this observation when they demonstrated a mean quality score for trials published in mainstream medical journals of only 38.5%.

### **3.1 Quality measurement of randomised clinical trials**

There are several reasons to support quality assessment of clinical trials. First, the results of any clinical trial are dependent on the quality of the trial method. It has been shown that inadequate concealment of allocation yields exaggerated estimates of treatment effects (Schulz et al. 1995). Secondly, assessment of the efficacy of medical interventions relies upon randomised controlled clinical trials, and it is not uncommon to have conflicting results from separate trials of the same medical intervention. Resolution of this situation requires an assessment of trial quality. Thirdly, trial quality is assessed before any trial can be included in any meta-analysis or systematic review.

Jadad et al. (1996) outlined three basic methods by which the quality of clinical trials can be assessed. First, for a peer-review process, the use of individual markers is appropriate. The second method, also appropriate for peer review, is the use of checklists. Both of these methods are also suitable for use in differentiating between trials of conflicting results. A third method is the use of scales to give a quantitative score. This last method is particularly suited for establishing entry criteria for inclusion of trials into meta-analyses and systematic reviews. Jadad et al. (1996) reported the existence of 25 such scales—only one of which ‘... had been developed following established methodological procedures’.

A reviewer’s definition of ‘quality’ will determine which of many aspects of a clinical trial are used in an assessment. These include the literary style of the report, the clinical relevance of the research question, the likelihood of producing biased results, the precision and extent to which it is possible to generalise the results (external validity), the appropriateness of the statistical analysis, the presentation of the data, and the ethical implications of the intervention evaluation (Jadad, Moher & Klassen 1998).

Assessment of individual components of quality can be achieved easily and quickly, but this provides little information about the overall quality of a trial (Jadad, Moher & Klassen 1998). Such a narrow focus can be widened by grouping individual components and incorporating them into checklists or scales. In addition to assessing individual components of quality, checklists can also incorporate groupings of items (but without providing a numerical score). Such a score can be achieved by using scales that incorporate groups of components—which can be used to provide an overall quality score. The first such scale was developed by Chalmers et al. (1981). By 1993, an additional 24 scales had been published (Moher et al. 1995). The first checklist was published in 1961, and a further nine had been published by 1993 (Moher et al. 1995). Since then, further instruments have been developed. Notable among these are the scale published by Jadad et al. (1996) and a more recent checklist published by the Consolidated Standards of Reporting Trials (CONSORT) group (Altman et al., 2001).

A comprehensive scale developed by Chalmers et al. (1981) presented a systematic and rigorous approach to the assessment process. Of four aspects proposed as necessary for the assessment of trial quality, the protocol section and the statistical analysis were regarded as the two most important contributors to quality. In their instrument, sectional raw scores were weighted and a final score was provided to three decimal places. The instrument was designed to be used by specialist personnel who were well versed in statistics and clinical trials. Its use by less-experienced personnel increases the potential for variation in quality assessment of trials, depending on the knowledge and background of individual assessors. Although this instrument (accompanied by the recommended procedures for application) was comprehensive and rigorous, it is probably better suited to use as a systematic review tool, rather than for general quality assessment of trials—because the numerical score can be used as an entry criterion for acceptance into such a review. The drawback to the use of a single numerical

score to report general trial quality is that such a global score does not enable identification of areas of strength or deficiency.

A modified version of the Chalmers et al. (1981) scale has been designed to allow a quick assessment of trial quality. Coupled with a method formulated by Bensoussan and Myers (1996), the instrument combines qualitative and quantitative assessment of trials. One component of the modified version is adapted from Chalmers et al. (1981). This allocates points to a total of 81 (or 84 if posterior  $\beta$  estimates are conducted). These are then converted to a percentage to provide a mean quality score. The component adapted from Bensoussan and Myers (1996) involves the use of a checklist of ten items that are considered essential for high-quality trial design.

In an attempt to minimise selection bias being introduced into systematic reviews and meta-analyses, Jadad et al. (1996) developed methodological procedures to examine the effect of the blinding of assessors to certain aspects of reports of pain research. The instrument, which initially had 49 items, has undergone several revisions and now contains only three questions directly related to bias reduction:

- Was the study described as randomised?
- Was the study described as double-blind?
- Was there a description of withdrawals and drop-outs?

Although this scale was originally developed for a specific purpose—to test the effect of blinding in assessment of reports of pain research—its application has been wider. Its ease of administration has facilitated its use as a general assessment of quality of trials in any area. Indeed, the authors suggested that the instrument could be used by trained and untrained personnel in a variety of situations for various purposes: to assess study protocols; to identify scientifically sound journal reports; to monitor the likelihood of bias in research reports; to perform differential analysis of meta-analyses on the basis of the quality of the individual primary studies; and to evaluate the validity of the evidence presented to patients by health professionals (Jadad et al. 1996).

In general, the instrument focuses on internal validity as a measure of quality assessment. Internal validity is defined as ‘confidence that the trial design, conduct, analysis, and presentation have minimised or avoided biased comparisons of the interventions under evaluation’ (Jadad, Moher & Klassen, 1998). However, it is limited to specific questions regarding bias, and an understanding of these limitations is essential. The scale does not take into account other methodological features—such as statistical analysis, sample size, interventions, outcome measures, sample selection, and adverse effects. When a more comprehensive assessment of quality is required, supplementation with another instrument that reports a wider range of assessment items might be appropriate.

For the majority of trials, quality is usually inferred from the quality of the published report. In response to the inadequate reporting of clinical trials, the CONSORT statement was developed in the mid 1990s as a set of guidelines for authors (Moher, Schulz & Altman 2001). Revised in 1999, this instrument now consists of a checklist of 22 items (Altman et al. , 2001). The CONSORT guidelines enable the reader to comprehend the results of randomised controlled trials more readily through an improved understanding of the design, conduct, analysis, and interpretation of the trial.

Quality assessment is essential for: (i) differentiating between clinical trials that have conflicting results; (ii) the peer-review process; and (iii) consideration of trials for inclusion in systematic reviews and meta-analyses. Checklists can be useful for all three purposes; however, they are most appropriate for the first two. A numerical score elicited from an assessment scale, although not appropriate as a single reporting mechanism, is more appropriate for use in conjunction with systematic reviews and meta-analyses. The assessment of quality is dependent upon the limited information that is presented in the published report. Due to publishing constraints, authors need to be selective in their presentation. Because various assessment instruments emphasise different criteria, trial quality varies according to the degree of overlap of the report and the components of the instrument. However, authors cannot know, in advance, which criteria will be used to evaluate their published report.

In summary, the main criticism of homeopathic research is a lack of high-quality clinical trials—although this criticism can also be applied to clinical trials in general. Trial quality is

influenced by several factors, including the assessment instrument itself. The adherence to suggested guidelines for clinical trials might assist in improving the general quality of homeopathic trials.

### 3.2 Homeopathic clinical trials

Some homeopaths argue that clinical trials do not reflect the ‘real world’ of homeopathic clinical practice in which treatment is rarely aimed at any single clinical condition. Rather, it is aimed at the complete ‘symptom picture’ of the individual. Clinical trials on homeopathy usually fall into one of two categories—(i) evaluation of the effect of a single preparation against placebo; and (ii) treatment of a single medical condition. Neither of these two trial designs corresponds to homeopathic practice.

Homeopathy rarely involves the prescription of a single remedy for a group of people—the possible exception being in the event of an epidemic. Homeopathic prescription is conducted on an holistic basis whereby a patient is treated as an individual and receives the homeopathic preparation that best suits the ‘symptom picture’. Testing a single condition in a clinical trial usually requires a prior diagnosis, typically from a non-homeopathic perspective, whereas homeopathic practice requires no such diagnosis. The patient is treated on the basis of the ‘symptom picture’ alone. For these reasons, clinical trials of homeopathy are often unpopular with many supporters of homeopathy—causing them to opt for research alternatives (such as case reports and observational studies) (HMRA 1996). However, rigorous research evidence is necessary if homeopathy is to refute the sceptics and achieve a wider level of respect and acceptance.

Reports of 28 controlled clinical trials of homeopathy have been identified since 2000. Of these, 25 trials have assessed the efficacy of homeopathic intervention in various medical conditions (23 conditions); one trial assessed the use of a homeopathic preparation in improving athletic performance (Zambrano 2000); and three trials evaluated aspects of homeopathic method (McCarney et al. 2002; Vickers, van Haselen & Heger 2001; Walach et al. 2000). Apart from three trials, all compared homeopathic treatment with placebo. Two used a known proven therapeutic control (Stam, Bonnet & van Haselen 2001; van Haselen & Fisher 2000) and one compared homeopathic treatment with a non-treatment control group (Zambrano 2000). For the purposes of this appendix, each trial has been assessed according to the modified Chalmers/Myers–Bensoussan instrument. The trials so assessed were: (Aabel (2000), Aabel et al. (2000), Baker et al. (2003), Balzarini et al. (2000), Bonne et al. (2003), Clark & Percivall (2000), Fisher & Scott (2001), Friese et al. (2001), Jacobs et al. (2000), Jacobs, Springer & Crothers (2001), Lewith et al. (2002), Oberbaum et al. (2001), Ramelat et al. (2000), Schmidt & Ostermayr (2002), Shackelton et al. (2000), Smith, Baker & Williams (2002), Stevinson et al. (2003), Straumsheim et al. (2000), Strauss (2000), Reilly et al. (2000), White et al. (2003), Yakir et al. (2001).

Of the trials evaluating efficacy of homeopathy in medical conditions, nine trials reported a statistically significant difference between the homeopathic intervention and placebo. The two trials using a positive control reported no difference between it and the homeopathic intervention—a result in favour of homeopathy. The inclusion of a placebo arm would have enhanced the rigour of these trials.

#### 3.2.1 Trials of medical conditions

Trials were classified into groups according to the assessed quality score as follows:

- ‘high quality’: score of 80% or greater;
- ‘medium quality’: score of 60–79%;
- ‘low-quality’: score of 50–59%; and
- ‘poor quality’: score less than 50%.

#### High quality

Five double-blind placebo-controlled trials have evaluated homeopathic intervention in respiratory conditions—four of which evaluated allergen-induced conditions and one of which evaluated individualised treatment of undifferentiated asthma. The immunotherapy trials used a form of homeopathy known as ‘isopathy’, in which the homeopathic preparation is manufactured from the stimulating allergen. All five trials were of high methodological quality with scores ranging from 82% to 90%.

Aabel et al. (2000) conducted two randomised placebo-controlled trials examining the effect of *Betula alba 30C* (manufactured from birch extract) for patients with birch pollen allergy. The first trial administered the preparation to 66 allergy sufferers for four weeks during the birch-pollen season of 1995. Following an initial rise in symptom score for both groups, the active homeopathic group demonstrated a significant improvement in symptoms for the next ten days. This was not matched in the last ten days, and total symptoms scores therefore demonstrated a non-significant difference between groups. *Post hoc* calculations showed that the sample size was insufficient to demonstrate the 90% power as originally calculated. However, results were sufficiently encouraging for the authors to repeat the trial in the following year.

Some protocol variations were instituted to improve the likelihood of success in the second trial by Aabel et al. (2000). A VAS was substituted for the previous symptom score and prophylactic treatment was administered for four weeks before the ten-day study period. The study period was to commence with the onset of symptoms or (for asymptomatic patients) on the day that the first pollen count was announced in the media. Power calculations revealed that a sample size of 80 was required to demonstrate a power of 90%; however, only 73 patients completed the study. This second trial also demonstrated non-significant differences between groups, but with a trend towards the placebo group. The lack of success in this trial might be attributed to unusually low pollen counts for 1996 (when pollen counts were high enough to provoke an allergic response on only three days).

Reilly et al. (2000) evaluated the effectiveness of homeopathic treatment for allergic rhinitis—the fourth in a series of trials designed to test whether a homeopathic response is a placebo response. A total of 51 patients was recruited, but this total was below the 50 per group shown to be required by the power calculation. Patients were treated with homeopathically prepared allergen at 30C potency or a placebo. Two outcome measures were described. A significant difference between groups was demonstrated for nasal inspiratory peak flow ( $p=0.0001$ )—a result that was demonstrated across all five study centres. Analysis of a 100-millimetre VAS of symptom severity (completed on a daily basis) revealed no significant difference between the active group and the placebo group. Although of high quality, this trial would have been improved if nasal inspiratory peak flow had been nominated as the single primary outcome measure. When these results were pooled with the three earlier trials in the series, the VAS results demonstrated a significant homeopathic treatment effect over placebo ( $p<0.001$ ).

Lewith et al. (2002) evaluated the use of homeopathically prepared allergen to treat asthmatic people who were allergic to house-dust mite. After a four-week baseline period, 242 patients were administered homeopathic immunotherapy (manufactured from house-dust mite at 30C potency) three times within a 24-hour period. Their responses were assessed over the following 16 weeks. Primary outcome measures of forced expiratory volume in one second (FEV<sub>1</sub>) and a quality-of-life score ('asthma bother score') demonstrated significant improvements in both groups, but no significant difference between the groups.

White et al. (2003) assessed the effect of individualised homeopathic prescriptions or placebo as an adjunct treatment for asthma. The trial assessed 93 children over a 12-month period and used a quality-of-life instrument (the 'Childhood Asthma Questionnaire') as the primary outcome measure. This was administered at baseline and at completion of the study. Various secondary measures were used to monitor progress during the study period. A total of 74 children completed pre- and post-treatment questionnaires. Despite the very high methodological quality of this study, some weaknesses were evident. With an intention-to-treat analysis, the higher drop-out rate of 20% might have had an effect on the significance level. The main outcome measure was limited—in that the questions asked were not applicable to all age groups and the pooling of results might have been inappropriate. Pre-randomisation bias might also have had an effect because only patients with mild asthma were enrolled (the severe cases being excluded for ethical reasons). No pilot study was conducted upon which a sample size could be calculated.

Baker et al. (2003) evaluated the use of *Argentum nitricum* in reducing test anxiety in an attempt to replicate a previous (1982) study. A total of 62 test-anxious university students completed the trial. After pre-trial administration of the main outcome measure (the 'Revised Test Anxiety Scale', or 'RTA'), *Argentum nitricum 12X* or placebo was self-administered twice daily for four consecutive days, and the RTA was re-administered. No significant difference was demonstrated between the



groups. This trial based its protocols on the measurement of trait test anxiety and did not challenge subjects with any form of stress. However, the short treatment period suggests that the anxiety state being measured was acute. This is a situation suggestive of state anxiety, and the homeopathic effect might therefore have been better measured using state-anxiety scales. The incorporation of some form of stress stimulus would have ensured an elevation of state-anxiety levels. Without this, it is possible that a homeopathic effect was present but not measured.

A study by Jacobs et al. (2000) examined the effect of individualised homeopathic treatment of acute childhood diarrhoea in a sample of children in Nepal. This study was a replication of a previous study conducted in Nicaragua by the principal investigators. A total of 126 children was administered an individualised homeopathic preparation or placebo after each unformed stool for five days. In all, 116 children completed the study. Outcome measures were duration of diarrhoea (defined as the period of time until there were fewer than three unformed stools per day for two consecutive days), and the average number of stools per day for each group. Both outcome measures demonstrated significant differences in favour of the active treatment group ( $p=0.023$  and  $p=0.036$  respectively). Withdrawals were included in the intention-to-treat analysis. No power calculation was reported, and the lack of blocking in the randomisation procedure led to disproportionate numbers being present in the groups, and it was necessary to adjust for this in the regression analysis. Despite these shortcomings, the study quality was high. Although this study was not, strictly, an independent replication, it demonstrated comparable results for individualised homeopathy in two different samples by two different study teams.

Numerous studies have been conducted to evaluate the effect of *Arnica montana* in pain and bruising in various situations. Stevinson et al. (2003) examined the effect of *Arnica 6C*, *Arnica 30C*, or placebo in the reduction of bruising and pain after surgery for carpal tunnel syndrome. Subjective and objective measures were used. Pain was measured using the 'McGill Pain Questionnaire' and bruising was assessed using a technique that allowed digital colour separation to be analysed. Patients self-administered the preparations three times daily for seven days preoperatively and for 14 days postoperatively. Pain was assessed at recruitment and on days 4, 9, and 14 after surgery. The bruising was photographed on days 4, 9, and 14, and digitally analysed to calculate red and blue pixels within each frame. The study was of very high methodological quality. However, it failed to take into account the many characteristics upon which a homeopathic prescription is based. This trial is typical of the 'one-size-fits-all' approach that has been adopted by other studies in evaluating the use of *Arnica* for pain and bruising—an approach that does not reflect traditional homeopathic practice.

Oberbaum et al. (2001) investigated the efficacy of a patented homeopathic preparation, Traumeel S<sup>®</sup>, in the treatment of stomatitis following chemotherapy in a group of 25 patients undergoing stem-cell transplantation. Treatment with either placebo or Traumeel S began on day 2 following stem-cell infusion. Patients were required to rinse their mouths vigorously with the fluid five times daily for thirty seconds before swallowing. This continued until symptoms were scored as a grade 0 for two consecutive days, or (in the case of asymptomatic patients) until a minimum of 14 days after the start of treatment. Two main outcome measures were employed—the area under the curve (AUC) and the time to first worsening of symptoms. Despite the intention-to-treat protocol, data from two withdrawals (one from each group) were not included in the analysis—each having received only one dose of the preparation. A statistically significant difference between groups was demonstrated for the AUC scores ( $p<0.01$ ), but no difference was noted for time to worsening of symptoms. This trial was the first to evaluate homeopathic treatment in this condition. It is likely that this explains why sample-size calculations were not reported—a factor that certainly lowered trial quality. In this case, only 30 patients were enrolled. This is about half the number that might be expected for a properly powered trial.

Jacobs, Springer and Crothers (2001) designed a rigorous preliminary study that compared individualised homeopathic treatment with placebo in 75 children suffering from otitis media. Following a homeopathic interview, parents were instructed to administer a 30C preparation three times daily for five days, or until improvement occurred. Apart from analgesics, no other medication was permitted. Outcome measures included: (i) daily symptom diaries; and (ii) the proportion of cases within each group with treatment failure after five days, two weeks, and six weeks of treatment. A statistically significant improvement was noted in diary scores among the group receiving the

homeopathic preparation after 24 and 64 hours of treatment ( $p < 0.05$ ). No significant differences were demonstrated in other outcome measures. A *post hoc* power calculation based on the treatment failure rates showed that a sample size of 243 patients and a power of 80% were needed to show a significant difference ( $\alpha = 0.05$ ). Even with a small dropout rate (4%), this trial was significantly underpowered. During the interview process, each child saw only one of the four homeopaths involved in the trial. No assessment of inter-rater reliability was performed to ensure uniformity of prescribing methods. This trial, like several others, demonstrated a trend in favour of homeopathic treatment that could not be supported in view of small sample size. In this case, the study was designed to be a preliminary study for the collection of data to conduct a larger study that will be powered to demonstrate a significant difference (if one exists).

Van Haselen and Fisher (2000) compared the application of topical Spiroflor SRL<sup>®</sup> gel with a piroxicam gel in reducing pain associated with osteoarthritis of the knee. On the basis of the largest of the piroxicam gel trials, a projected sample size of 225 was estimated. Due to local problems, recruitment ceased after 184 patients had been enrolled. After baseline assessment, patients were instructed to apply approximately one gram of the gel three times daily for four weeks, after which they were reassessed. Primary outcome measures were pain on walking and pain on palpation—both recorded on 100-mm VASs. Mean pain reduction was greater in the piroxicam group. The mean difference between groups was 8.4 mm. After adjustment for pain at baseline, analysis of covariance revealed a difference between groups of 6.8 mm (95% CI: -0.3 to 13.8). This did not lie within the equivalence range of -5 to 5. The authors therefore concluded that a clinically relevant difference in favour of the SRL gel might have been present. The trial design did not allow this conclusion to be drawn.

### Medium quality

Bonne et al. (2003) evaluated the effect of individualised homeopathic treatment in 39 patients with generalised anxiety disorder. Five weeks after an initial single dose of a prescribed homeopathic preparation, patients were re-examined by the same clinical team, consisting of the same psychiatrist and same homeopath. The procedure was repeated, although at this stage, the homeopathic prescription could be changed according to the opinion of the interviewing homeopath. Post-treatment evaluation was conducted five weeks later. The Hamilton Rating Scale for Anxiety was the main outcome measure, and was administered at each clinical visit. Both groups improved on the primary outcome measure, and no statistical difference between groups was demonstrated. Several issues can be identified that might have affected the outcome. Generalised anxiety disorder is recognised as a 'placebo-responsive' disorder (Bonne et al. 2003), and a combination of placebo effect and the Hawthorne effect (improvement in some clinical trial subjects is purportedly due to their inclusion in the trial and not to treatment) could therefore have played a major role. The addition of a non-treatment arm would have assisted in separating these factors. The dependence on a single homeopathic practitioner might also have been a factor. The authors identified the need for a longer follow-up period in which to test for the possibility of a higher tendency to relapse in the placebo group. Given that power calculations suggested that 30 subjects were required in each group (60 in total), it is possible that this trial was underpowered to demonstrate the desired 5% significance and 80% power.

A study by Balzarini et al. (2000) evaluated the use of *Belladonna 7CH* and a novel preparation, *X-ray 15CH*, in reducing symptoms associated with acute dermatitis as a result of radiotherapy for breast cancer. A total of 61 patients was assessed for skin colour, heat to the touch, cutaneous and/or subcutaneous oedema, and cutaneous hyperpigmentation. They were assessed on a weekly basis during six weeks of radiotherapy, and again at day 15 and day 30 after completion of radiotherapy. A statistically significant difference between placebo and the active groups was demonstrated on a one-way analysis of variance ( $p = 0.05$ ) for the average of the total scores during the recovery period. When each outcome measure was assessed individually, results varied during the study period. Without a power calculation, the significance of the results is questionable.

Clark and Percivall (2000) reported a significant benefit from the use of *Ruta graveolens 30C* in reducing pain from plantar fasciitis. A total of 18 patients was studied. Each patient was administered two tablets three times daily for two weeks in conjunction with the wearing of orthotics to raise their affected heels. The main outcome measure was a daily self-reported 100-mm VAS for pain. Data from

14 patients were included in the analysis. Although both groups experienced a significant reduction in pain, linear regression analysis demonstrated a significant difference in the speed of reduction in favour of the active homeopathic group ( $p < 0.05$ ). Although this study was of reasonable quality, it contained some serious methodological and statistical flaws. No power calculations were performed and data from withdrawals were left out of the analysis—which might have affected the significance level. The level of activity of patients was not controlled. Some became more active as they felt better, thereby exacerbating the pain. The effect of the interventions might therefore have been compromised. The addition of a non-treatment arm would have facilitated differentiation of the placebo effect.

A study by Ramelat et al. (2000) demonstrated no preventative effect of *Arnica montana* in post-operative bruising. A single dose of *Arnica 5CH* was administered the night before surgery and immediately after surgery to 130 patients undergoing unilateral or bilateral venous stripping of the lower limbs. Although the report was very brief and omitted descriptions of certain features (such as power calculations, how withdrawals were handled, and randomisation procedures), enough detail was included to show medium-level quality. The research question was very narrow and it is difficult to argue with the authors' conclusions that *Arnica 5CH* was ineffective. From a homeopathic perspective, the trial took into account only one of many characteristics of *Arnica* upon which a prescription would usually be based.

Conflicting results were demonstrated by Straumsheim et al. (2000) in a trial evaluating the prophylactic effect of individualised homeopathic treatment for migraine. Power calculations demonstrated that the sample size of 73 patients was greater than required. Patients assessed pain intensity, attack frequency, attack duration, and the need for medicine in each attack, and recorded these data in a diary. A month after recruitment, homeopathic prescriptions were selected following assessment by a homeopath, who reassessed patients on a monthly basis for the remainder of the four-month treatment period. Assessment by a neurologist occurred five months after commencement. No difference between groups was demonstrated when diaries were analysed. From the neurologist's assessment, only the attack frequency showed a significant difference in favour of the active group ( $p = 0.04$ ). The discontinuance of conventional medication and the inclusion of a 'washout period' would have raised the methodological quality. The trial report lacked detail, and this contributed to a reduced quality assessment.

Over a period of eight years, Fisher and Scott (2001) investigated the effect of homeopathic intervention on inflammation in rheumatoid arthritis. Patients who were stabilised on non-steroidal anti-inflammatory drugs or disease-modifying anti-rheumatic drugs were randomised to receive individualised homeopathic preparation for three months and placebo for three months (on a crossover basis). Outcome measures were a 100-mm VAS of pain, Ritchie articular index, and duration of morning stiffness. Blood samples were taken at 0, 3, and 6 months for measurement of erythrocyte sedimentation rate and haemoglobin. The report of this trial lacked structure and clarity, and this contributed to a lower quality assessment. Statistical analysis was limited to the 58 patients who completed the trial, and it appears that withdrawals were simply replaced and their data not included. The report did not indicate any sample-size calculation to support this protocol. Nor was a *post hoc* calculation performed to assess the power of the trial. No significant change from baseline was demonstrated for either homeopathic treatment or placebo—except for pain, in which both treatments were found to produce a significant reduction. No significant difference was noted between treatments.

A trial by Friese et al. (2001) compared the use of homeopathic preparations with placebo in the treatment of adenoid vegetations. A feature of the trial protocols was that treatment was limited to only five possible homeopathic preparations (*Nux vomica 200X*, *Okoubaka 3X*, *Tuberculinum 200X*, *Barium iodatum 4X*, and *Barium iodatum 6X*) or placebo over the treatment period of three months. The main outcome measure was the assessed need for surgery at the end of the treatment period. No significant benefit was demonstrated for the homeopathic treatment. Of the 97 enrolled patients, only 74 were included in the analysis—well below the assessed sample size. Post-treatment calculations demonstrated that the study was vastly underpowered to confirm a 60% homeopathic effect. A sample size of 1000 was required for this purpose.

The efficacy of homeopathic treatment for the symptoms of premenstrual syndrome was studied in a five-month trial conducted in Israel by Yakir et al. (2001). The 'Menstrual Distress Questionnaire'

was the main outcome measure. This was administered daily for five months—two months baseline and three months post-treatment. Homeopathic preparations were selected from a group of five according to patient symptom clusters. These were administered as a single one-gram dose at 200C potency on the seventh day after the start of each menstrual period. Of 23 women, 19 completed the trial. There was a significant reduction in mean pre- and post-treatment scores for the active homeopathic group ( $p=0.0013$  Wilcoxon) whereas the difference in pre- and post-treatment scores for the placebo group was non-significant. A small sample size and a failure to provide a power calculation were apparent. The use of the symptom clusters was proposed as a method of overcoming the problem of incorporating individualisation of prescriptions into clinical trials. The validation of such a method is doubtful because it does not reflect whole practice.

An interesting set of protocols was formulated by Smith, Baker and Williams (2002) to evaluate the effect of a bromide-based homeopathic preparation in the treatment of seborrheic dermatitis. The preparation consisted of potassium bromide (1X0), sodium bromide (2X), nickel sulphate (3X), and sodium chloride (6X). The preparations were of low dilution, with only the last of the four constituents being diluted beyond one part in a thousand. This trial was double-blinded for ten weeks, after which it continued for a further ten weeks as an open trial. The open period enabled the original placebo group to be administered the active medication, and also served to confirm the significant results demonstrated by the active treatment group in the blinded period. The 'Seborrhoea Area and Severity Index' was used as the main outcome measure to evaluate progress at weeks 0, 5, and 10. Of the 53 patients enrolled, 29 completed the 10-week blinded section and 21 completed the full 20-week study period. Analysis demonstrated a significant improvement in the active treatment group during the blinded period as compared with the placebo group ( $p<0.04$ ). However, despite a good quality score, closer examination of the trial methodology revealed some serious shortcomings. The 45% withdrawal rate, the lack of sample-size calculation, and the non-inclusion of data from the withdrawal group suggest that the results might not be as robust as first thought. The brief discussion section of the report did not include any mention of possible errors or weaknesses.

Schmidt and Ostermayr (2002) investigated the effect of *Thyroidinum 30CH* on the rate of weight reduction in fasting patients who had either reached a weight-loss plateau or experienced a weight gain. Patients were administered a single dose of five pilules of the active homeopathic preparation or placebo, and their weights were monitored for the ensuing three days. The primary outcome measure was to be the amount of weight loss on Day 1. However, the protocol was altered after a semi-deblinded interim analysis had demonstrated a greater difference between the groups for day 2. After three years, data from 208 patients were analysed—despite only 194 patients having fulfilled the requirements of the protocol. A sample size of 300 had originally been calculated. Initial analysis demonstrated significant weight reduction in the active treatment group ( $p=0.034$ ), but this became non-significant after adjustment for baseline differences. It is possible that the smaller-than-calculated sample size also contributed to the lack of significance. This trial was important because it attempted to measure the efficacy of homeopathic intervention using only objective measures of outcome. Unfortunately, it seems that the outcome measures were not sufficiently sophisticated. The use of body mass index (rather than body weight) and percentage weight reduction (rather than absolute weight reduction) would have returned a significant result ( $p=0.034$ ). The authors demonstrated how the overall results of a trial can depend on the initial definition of the outcome measures. In this case, the result would have shown a greater reduction on day 1 in the active group if the main outcome measure had been defined as 'the change (on day 1) from the mean baseline difference in weight reduction on days -3 to 0' (rather than 'absolute weight reduction').

A study by Stam, Bonnet and van Haselen (2001) compared a topical homeopathic preparation (Spiroflor SRL<sup>®</sup> gel) with a capsaicin rubefacient (Cremor Capsici Compositus FNA) in reducing acute lower-back pain. Patients were instructed to apply a dose of approximately three grams of the gel three times daily to the affected area for seven days. The primary outcome measure was a 100-mm VAS (of pain) which was administered at days 0 and 7. An intention-to-treat analysis of the data from 154 patients demonstrated a significant reduction in VAS scores from day 0 to day 7 for both groups ( $p<0.001$ ). Poor treatment compliance and protocol violations reduced the number of patients who met all protocol criteria to only 21 (13 SRL and 8 CCC). For this reason, further statistical analysis was not reported. Without a sample-size calculation, the reliability of the results is uncertain.

### Low quality

A study by Strauss (2000) used a patented homeopathic preparation, Selenium-Homacord<sup>®</sup>, in the management of attention-deficit hyperactivity disorder. Twenty patients were included in the trial—ten of whom were on methylphenidate hydrochloride (Ritalin) and ten of whom formed the non-Ritalin group. Each of the groups was subdivided and randomised to receive either placebo or active treatment—making subgroups of five patients. The ‘Conners Parents Symptom Questionnaire’ (PSQ) and the ‘Children’s Checking Task’ (CCT) were administered at days 0, 30, and 60. Significant improvement was reported for the active treatment group ( $p=0.0134$ ) on the PSQ. A similar result was described for the CCT, but no  $p$  value was reported. The study report was inadequate in not fully describing patient-selection criteria, treatment protocols, blinding and randomisation procedures, sample-size calculation, and handling of withdrawals—thus making replication difficult.

### Poor quality

A non-randomised, single-blind study by Shackelton et al. (2000) evaluated the effect of homeopathic *Coca 200C* on high-altitude mountain sickness. It reported significant reductions in nausea, headache, and difficulty in breathing during the night at altitudes of 12,672–17,600 feet, but examination of the data shows these to be on individual days, rather than being calculated on a means basis. Oxygen-saturation levels were similarly reported, and it can be assumed that a non-significant result would have been returned if means had been calculated. The lack of randomisation and double-blinding reduced the quality of this study, making the findings questionable. The experimental group travelled as a group whereas the control group was a disparate set of individuals trekking to the Mt Everest base camp. Protocols for data collection for the control group were different from those for the experimental group. Given the nature of the study setting and the unmatched groups, this study was subject to many uncontrolled variables.

Zambrano (2000) attempted to evaluate the effectiveness of Rendimax<sup>®</sup> in improving athletic performance. This trial differed from most in that it was not designed to measure efficacy of a homeopathic preparation in unwell people. A total of 50 healthy subjects undertook a 20-week training program. Of these, 25 were allocated to the study group and were administered the trial medication as an adjunct before and after training. The remaining 25 subjects were allocated to the non-treatment control group. Ten subjects were withdrawn from the study due to illness or muscular problems—four from the study group and six from the control group. Maximal oxygen consumption, serum lactate, and measures of body composition were measured every 14 days. A statistically significant increase in lactate in the treatment group was demonstrated ( $p<0.05$ )—an indication that anaerobic capacity had increased. No other differences were noted. Several factors are evident that weaken the methodology of this study. No blinding or randomisation protocols were reported, sample size was not calculated, and no indication was given of whether data from withdrawals were to be included in the analysis. There was little discussion of possible errors and their effects on results.

## 3.2.2 Trials of homeopathic concepts

Three studies used double-blind randomised controlled trial methodology to test homeopathic principles. Homeopathic ‘proving’ is a process whereby a substance is administered to healthy subjects and the observed effects recorded as characteristics attributable to the substance. ‘Proving’ are the basis of the homeopathic *materia medica*.

### High quality

Vickers, van Haselen and Heger (2001) designed a trial to assess the feasibility of a quantitative ‘proving’. A total of 118 subjects undertook a one-week single-blind placebo run-in, followed by the administration of either placebo or homeopathic *Mercurus solubilis 12C*. This was followed by another week of placebo run-out. Subjects checked symptoms on a daily basis against a novel checklist of ten symptoms—five ‘true’ symptoms and five ‘false’ symptoms for mercury (taken from the *materia medica*). A score was calculated from the daily checklists. The primary outcome measure was the mean difference score for weeks 2 and 3, minus the difference score for week 1. Several other scores were calculated as secondary outcomes. No statistical significance was demonstrated for any outcome measure. *Post hoc* power calculations using this methodology and primary outcome measures

indicated that the sample size would need to be nearly 50,000. Redefinition of the outcome measure did not reduce the sample size to a practical level.

### Medium quality

Walach et al. (2000) also used a double-blind placebo-controlled design to test the concept of homeopathic ‘proving’—in this case for *Belladonna 30CH*. This design used a two-week baseline period followed by a week of placebo run-in. Trial medications were administered in week 3, followed by an observation week. Week 5 was a ‘wash-out week’, after which subjects were crossed-over to the other medication with protocols as per weeks 3 and 4. Analysis of daily diary data demonstrated no significant difference between the placebo and active groups for reported symptoms. The two trials were clearly supportive of the null hypothesis. The observed effects were described as probably ‘chance fluctuations of a baseline status’.

McCarney et al. (2002) tested ‘dowsing’ by hypothesising that homeopaths can detect homeopathic medicines by dowsing—in this case, by using a pendulum. Six medically qualified homeopaths who used dowsing in clinical practice participated. They were asked to identify by dowsing which of a bottle pair contained active *Bryonia 12C* and also to indicate a level of confidence in their choice. Each volunteer assessed 26 pairs. Of responses given with ‘high confidence’, 45% were correct ( $p=421$ ). The sample is small and this might have led to the non-detection of any actual effect.

## 4. Future research

The measurable quality of clinical trials of homeopathy has increased—perhaps as a result of the detailed focus of systematic reviews and meta-analyses. This has not necessarily translated into increased levels of evidence in support of the efficacy of homeopathy. In fact, an inverse trend is becoming more evident. It might be time to reassess the appropriateness of the protocols of many of the trials.

The demand for *whole practice* research that more closely reflects clinical practice is increasing. The use of a ‘one-size-fits-all’ homeopathic prescription, the investigation of efficacy in single medical conditions, and the use of isopathy (whereby homeopathic medicines are manufactured from the substance stimulating the disease) are contrary to traditional homeopathic principles. Clinical trial protocols need to be designed that take into account the individualisation of prescriptions for patients—notwithstanding any medical condition that might be manifested. Unfortunately, the incorporation of such protocols into conventional clinical trial design introduces an unacceptable level of variability. As can be seen from the reported trials, sample sizes need to be immense to account for this.

It might be necessary to reassess trial designs that were hitherto thought to be less than desirable in terms of scientific rigour and quality. Single-subject research, in which the sample is comprised of one subject who acts as his or her own control, is a design that is appropriate to clinical practice. Such an ‘n-of-1’ clinical trial allows the practitioner to design an optimal treatment regimen for each individual patient. An adaptation of this design might enable whole-practice research in homeopathy.

Recent research in statistical analysis (Johannessen, Fosstvedt & Petersen 1991) has suggested that the pooling of results from multiple single-subject trials enables a level of external validity that is not available in an individual ‘n-of-1’ trial—that is, the results can be generalised to a wider population. Assuming that this is valid, a single-subject design is well-suited to whole-practice homeopathic research—with the incorporation of individualised prescriptions into a trial and no requirement for an homogenous sample.

The increasing quality of clinical trials and the interest in whole practice research augur well for homeopathy. To offer real choice for the consumer and to widen the acceptance of homeopathy, a solid foundation of evidence is needed to support the use of homeopathy. To achieve this, clinical research must be a priority.

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## Appendix 3.7 Controlled Clinical Homeopathic Trials since 2000

Reference citation <sup>1</sup>	Title	Significance <sup>2</sup>	Quality score <sup>3</sup>
Aabel et al. 2000	Is homeopathic immunotherapy effective? A double-blind, placebo controlled trial with the isopathic remedy Betula 30C for patients with birch pollen allergy	No	82.7%
Aabel 2000	No beneficial effect of isopathic prophylactic treatment for birch pollen allergy during a low-pollen season: a double-blind, placebo-controlled clinical trial of homeopathic Betula 30C	No	86.3%
Balzarini et al, 2000	Efficacy of homeopathic treatment of skin reactions during radiotherapy for breast cancer: a randomised, double-blind clinical trial	No	67.9%
Clark & Percivall 2000	A preliminary investigation into the effectiveness of the homeopathic remedy, Ruta graveolens, in the treatment of pain in plantar fasciitis	Yes ( $p<0.05$ )	66.1%
Jacobs et al. 2000	Homeopathic treatment of acute childhood diarrhoea: results from a clinical trial in Nepal	Yes ( $p=0.036$ )	81.5%
Ramelat et al. 2000	Homeopathic Arnica in post-operative haematomas: a double-blind study	No	71.4%
Shackelton et al. 2000	The effect of homeopathic Coca on high altitude mountain sickness: Mt Everest base camp	Yes ( $p=0.003$ )	27.8%
Straumsheim et al. 2000	Homeopathic treatment of migraine: a double-blind placebo-controlled trial of 68 patients	No	67.3%
Strauss 2000	The efficacy of a homeopathic preparation in the management of attention deficit hyperactivity disorder	Yes ( $p=0.0134$ )	50.6%
Taylor et al. 2000	Randomised controlled trial of homeopathy versus placebo in perennial allergic rhinitis with overview of four trial series	Yes ( $p=0.0001$ )	88.9%
van Haselen & Fisher 2000	A randomised controlled trial comparing topical piroxicam gel with a homeopathic gel in osteoarthritis of the knee	No	82.7%
Walach et al. 2000	The effects of homeopathic Belladonna 30CH in healthy volunteers: a randomised, double-blind experiment	No	67.3%
Zambrano 2000	The effects of a complex homeopathic preparation on aerobic resistance, anaerobic the capacity, strength, and flexibility	No	32.1%
Fisher & Scott 2001	A randomised controlled trial of homeopathy in rheumatoid arthritis	No	66.7%
Friese et al. 2001	Results of a randomised prospective double blind clinical trial on the homeopathic treatment of adenoid vegetations	No <sup>c</sup>	78.6%
Jacobs, Springer & Crothers 2001	Homeopathic treatment of acute otitis media in children: a preliminary randomised placebo-controlled trial	Yes ( $p<0.05$ )	86.9%
Oberbaum et al. 2001	A randomised, controlled clinical trial of the homeopathic medication TRAUMEEL S <sup>®</sup> in the treatment of chemotherapy-induced stomatitis in children undergoing stem cell transplantation	Yes ( $p<0.01$ )	81.5%

Stam, Bonnet & van Haselen 2001	The efficacy and safety of a homeopathic gel in the treatment of acute low back pain: a multi-centre, randomised, double blind comparative clinical trial	No	75.0%
Vickers, van Haselen & Heger 2001	Can homeopathically prepared mercury cause symptoms in healthy volunteers? A randomised controlled trial	No	84.5%
Yakir et al. 2001	Effects of homeopathic treatment in women with premenstrual syndrome: a pilot study	Yes ( $p<0.05$ )	69.6%
Lewith et al. 2002	Use of ultramolecular potencies of allergen to treat asthmatic people allergic to house dust mite: double blind randomised controlled clinical trial	No	90.5%
McCarney et al. 2002	Can homeopaths detect homeopathic medicines by dowsing? A randomized, double-blind, placebo-controlled trial	No	63.1%
Schmidt & Ostermayr 2002	Does a homeopathic ultramolecular dilution of Thyroidinum 30cH affect the rate of body weight reduction in fasting patients? A randomised placebo-controlled double-blind clinical trial	No	78.6%
Smith, Baker & Williams 2002	Effective treatment of seborrheic dermatitis using a low dose, oral homeopathic medication consisting of potassium bromide, sodium bromide, nickel sulfate, and Sodium chloride in a double blind, placebo-controlled study	Yes ( $p=0.0035$ )	74.1%
Baker et al. 2003	The effects of homeopathic Argentum nitricum on test anxiety	No	88.1%
Bonne et al. 2003	A randomised, double-blind, placebo-controlled study of classical homeopathy in generalised anxiety disorder	No	70.8%
Stevinson et al. 2003	Homeopathic arnica for prevention of pain and bruising: randomised placebo-controlled trial in hand surgery	No	90.5%
White et al. 2003	Individualised homeopathy as an adjunct in the treatment of childhood asthma: a randomised placebo-controlled trial	No	82.1%

1. Full list of names available in Appendix 3.6 (References).
2. Significance is based on single primary outcome measure. Studies demonstrating partial significance (i.e. those with more than one primary outcome measure) have been classified as having non-significant results.
- 3 Quality score based on modified Chalmers scale.


## Appendix 3.8 Modified Chalmers Score Sheet for Quality Assessment of Clinical Trials

Author/Total scores		/81 or 84	%
Design			
Main outcome meas.			
Study population			
Preparation			
Results			


Qualitative analysis of the study methods			
Specification of the hypothesis		Randomised design with full specification ★	
Single primary outcome variable		Consideration of pre-randomisation bias	
Detailed definitions of all study variables		Double-blind ★	
Justification of sample size		Appropriate statistical analysis	
Specification of the study population		Consideration of possible errors	
<b>Specific methodological issues:</b>			
<b>Key: X=not described or performed; ✓=described or performed; P= poorly described or performed</b>			

Chalmers method of evaluating clinical trials	Total points	Total possible
Selection description		3
Number of patients seen or reject log		3
Withdrawals		3
Therapeutic regimens definition		3
Control regimen appearance		1.5
Control regimen smell		1.5
Randomisation blinding		4
Blinding of patients		10
Blinding of physicians re therapy		12
Blinding of physicians re results		4
Prior estimate of numbers		3
Testing randomisation		3
Testing blinding		3
Testing compliance		3
On major endpoints		3
Posterior $\beta$ -estimates		3/NA
Statistical inference: confidence limits		2
Statistical inference: regression correlation		2
Appropriate statistical analysis		4
Handling of withdrawals		4
Side effects, statistical discussion		3
Proper retrospective analysis		2
Blinding of statistician or analyst re results		2
Tabulation of events employed as endpoints		2
<b>Total</b>		<b>81/84</b>


# Appendix 4.1 Naturopathy and WHM Practitioners Workforce Survey



**GRAND UNITED**  
YOUR ALTERNATIVE HEALTH FUND



Complementary Health Research Centre



UNIVERSITY OF WESTERN SYDNEY  
HEALTHCARE & HUMAN SERVICES

## NATIONAL WORKFORCE SURVEY of NATUROPATHS & WESTERN HERBALISTS

*This project aims to compile comprehensive and detailed information about the naturopathic and herbal professions in Australia. This survey is in part response to the request by the Commonwealth Department of Health and Aging that Complementary Medicine practitioners establish a uniform national accreditation system.*

*Your participation in this survey is voluntary. We do, however, strongly encourage you to respond as information gathered will be used to provide a realistic and complete view of our professions to inform any accreditation process. Any information you provide will be completely anonymous. When completing the questionnaire, please **do not write your name on it**. Outcomes of the survey will be published and made available to all practitioners at a later date.*

*If you have any questions regarding the survey please contact **Kate O'Connor** at the Centre for Complementary Medicine Research at the University of Western Sydney on (02) 9772 6622.*


*Please return the questionnaire **as soon as possible** and preferably **no later than the 12th of December** in the reply paid envelope to:*

**Centre for Complementary Medicine Research**  
**Reply Paid 70475**  
**University of Western Sydney**  
**Locked Bag 6189**  
**Penrith South DC NSW 2750**

### INSTRUCTIONS


- Use a blue/black ballpoint pen or 2B pencil
- Do not use red or felt tip pens
- Do not fold or bend
- Erase mistakes fully
- Make no stray marks
- Cross out pen errors

Please  
**MARK LIKE THIS**  
ONLY:



Where the answer requires a number, first write the number in the area provided then mark the corresponding oval below.

If the number of patients seen was 2:




PLEASE FILL IN THE APPROPRIATE RESPONSE AND WRITE DETAILS WHERE REQUIRED.


**1.** Please write, and then mark, the postcode of the suburb or town in which your main practice is located.

E.g.:  
Postcode  
2021

POSTCODE



POSTCODE



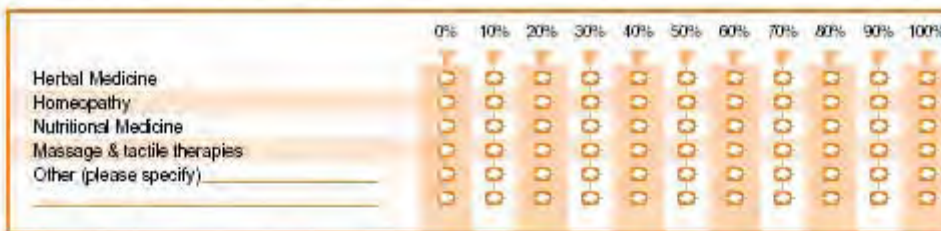
**2.** In how many locations do you practise any aspect of naturopathy or herbal medicine?

1     2     3     4 or more

**3.** Which of the following titles best describes the nature of your practice? *(You may select more than one)*

<input type="checkbox"/> Herbalist	<input type="checkbox"/> Chiropractor
<input type="checkbox"/> Naturopath	<input type="checkbox"/> Osteopath
<input type="checkbox"/> Homeopath	<input type="checkbox"/> Physiotherapist
<input type="checkbox"/> Nutritionist	<input type="checkbox"/> Nurse
<input type="checkbox"/> Massage therapist	<input type="checkbox"/> Counsellor
<input type="checkbox"/> Aromatherapist	<input type="checkbox"/> Psychologist
<input type="checkbox"/> Bach flowers practitioner	<input type="checkbox"/> Traditional Chinese Medicine Practitioner
<input type="checkbox"/> Meditation/relaxation (including yoga, qi gong)	<input type="checkbox"/> Acupuncturist
<input type="checkbox"/> Medical specialist	<input type="checkbox"/> Other (please specify)
<input type="checkbox"/> General medical practitioner	
<input type="checkbox"/> Pharmacist	

4 Please indicate the proportion of your practice that is devoted to each of the following modalities.



5 If you practise herbal medicine, which tradition/s have you been educated in and which practises do you use regularly? (You may select more than one)

Not applicable

	Educated in	Practise
Western herbal medicine	<input type="checkbox"/>	<input type="checkbox"/>
Ayurvedic herbal medicine	<input type="checkbox"/>	<input type="checkbox"/>
Chinese herbal medicine	<input type="checkbox"/>	<input type="checkbox"/>
Kampo (Japanese herbal medicine)	<input type="checkbox"/>	<input type="checkbox"/>
Tibetan herbal medicine	<input type="checkbox"/>	<input type="checkbox"/>
Other (please specify)	<input type="checkbox"/>	<input type="checkbox"/>

6 Describe your use of manual / tactile therapies in your practice: (You may select more than one)

None at all       Spinal manipulation  
 Massage       Other (please specify)  
 Soft Tissue manipulation

7 On average how many hours per week do you spend in clinical practice?

0-4 hours       16-24 hours       More than 40 hours  
 4-8 hours       24-32 hours  
 8-16 hours       32-40 hours

8 On average how many consultations do you perform in your practice each week?



9 How long, on average, is your face-to-face contact time with your patient in the initial and follow-up consultations?

	Initial	Follow-up
Less than 15 minutes	<input type="checkbox"/>	<input type="checkbox"/>
Between 15 and 30 minutes	<input type="checkbox"/>	<input type="checkbox"/>
Between 31 and 45 minutes	<input type="checkbox"/>	<input type="checkbox"/>
Between 46 and 60 minutes	<input type="checkbox"/>	<input type="checkbox"/>
Longer than 60 minutes	<input type="checkbox"/>	<input type="checkbox"/>

10 How frequently do you use Western medical diagnostic tests in your naturopathic or herbal medicine treatments?

*(Includes tests such as pathology, radiology, etc., either self-ordered or ordered by patients or colleagues)*

Never / almost never       Frequently  
 Occasionally       Always / almost always  
 In about half of the cases

11 How frequently do you utilise Western medical diagnoses to guide your naturopathic or herbal medicine treatments?

Never / almost never       Frequently  
 Occasionally       Always / almost always  
 In about half of the cases

12 Which diagnostic tools or methods do you utilise in your practice? (You may select more than one)

Iris diagnosis  
 Tongue diagnosis  
 Electro-dermal screening (eg LISTEN, Vega)  
 Muscle testing  
 Hair testing  
 Haemaview / Live Blood Analysis  
 Functional Pathology (salivary test, stool analysis, clot retraction test, etc)  
 Physical examination (B.P. auscultation, palpation, etc)  
 Oriental diagnosis  
 Face diagnosis  
 Other (please specify) \_\_\_\_\_

13 Do you keep records of each new patient consultation?

Yes       No

14 Do you make notes on every subsequent visit?

Yes       No

15 In what form are your records and notes kept?

On paper or cards  
 Computerised notes  
 Combination of computer and paper or cards  
 Other (please specify) \_\_\_\_\_

16 What is the average fee you charge for an **initial** consultation (before GST)?



17 What is the average fee you charge for a **follow-up** consultation (before GST)?



18. If you practise **herbal medicine**, have you ever caused any significant adverse reaction in a patient due to the consumption or application of herbal medicines? Please identify the adverse reaction and the number of times you estimate it to have occurred in all your years of practice. Please also indicate in the "0" column, if you have never had an adverse reaction of this kind.

Not applicable

No. of times:	0	1	2	3	4	5	>5 (specify)
Mild gastrointestinal symptoms (nausea, discomfort)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Severe gastrointestinal symptoms (vomiting, diarrhoea or pain)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Significant skin reaction	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Severe fatigue	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Jaundice	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Fainting or dizziness	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Headaches	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Menstrual irregularities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Palpitations	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
High blood pressure	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Psychiatric disturbance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Hepatotoxicity (as identified by blood tests)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Renal toxicity (as identified by blood tests)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Significant respiratory disturbance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
CNS effects (eg numbness, palsy)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Referral to medical practitioner / hospital	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Death	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____

Other (please specify adverse effect and frequency of each)

19. If you practise **nutritional medicine**, have you ever caused an adverse reaction in a patient due to the consumption of nutritional supplements? Please identify the adverse reaction/s and number of times it has occurred. Please also indicate in the "0" column, if you have never had an adverse reaction of this kind.

Not applicable

No. of times:	0	1	2	3	4	5	>5 (specify)
Mild gastrointestinal symptoms (nausea, discomfort)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Severe gastrointestinal symptoms (vomiting, diarrhoea or pain)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Significant skin reaction	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Severe fatigue	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Jaundice	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Fainting or dizziness	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Headaches	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Menstrual irregularities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Palpitations	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
High blood pressure	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Psychiatric disturbance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Hepatotoxicity (as identified by blood tests)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Renal toxicity (as identified by blood tests)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Significant respiratory disturbance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
CNS effects (eg numbness, palsy)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Referral to medical practitioner / hospital	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Death	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____

Other (please specify adverse effect and frequency of each)

20. If you practise **homeopathic medicine**, have you ever caused any significant adverse reaction in a patient due to the consumption or application of homeopathic remedies? Please identify the adverse reaction and the number of times you estimate it to have occurred in all your years of practice. Please also indicate in the "0" column, if you have never had an adverse reaction of this kind.

Not applicable

No. of times:	0	1	2	3	4	5	>5 (specify)
Mild gastrointestinal symptoms (nausea, discomfort)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Severe gastrointestinal symptoms (vomiting, diarrhoea or pain)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Significant skin reaction	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Severe fatigue	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Jaundice	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Fainting or dizziness	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Headaches	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Menstrual irregularities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Palpitations	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
High blood pressure	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Psychiatric disturbance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Hepatotoxicity (as identified by blood tests)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Renal toxicity (as identified by blood tests)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Significant respiratory disturbance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
CNS effects (eg numbness, palsy)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Referral to medical practitioner / hospital	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Death	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____

Other (please specify adverse effect and frequency of each)

21. Do you **usually** report any adverse reactions?  
 Yes  No

22. If yes, who do you usually report adverse reactions to?

- Therapeutic Goods Administration
- Manufacturer
- Supplier
- Professional association
- Australian Drug Reaction Advisory Committee
- Other (please specify) \_\_\_\_\_

23. Please indicate whether you prescribe any of the following substances as herbal preparations:

	Yes external	Yes oral	No	Unsure
<i>Aconitum</i> spp (Aconite, Monks hood, Wolfs bane)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<i>Acorus calamus</i> (Sweet flag or Sweet sedge)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<i>Aristolochia</i> spp (Chinese fairy vine)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<i>Atropa belladonna</i> (Deadly nightshade)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<i>Borago officinalis</i> (Borage)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<i>Colchicum autumnale</i> (Autumn Crocus or Meadow saffron)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<i>Convallaria</i> spp (Lily of the Valley)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<i>Datura</i> spp (Jimson weed or Thorn apple)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<i>Digitalis</i> (Foxglove)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<i>Ephedra</i> spp (Ma huang)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<i>Gelsemium</i> spp (Yellow jasmine)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<i>Hyoscyamus niger</i> (Henbane)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<i>Piper Methysticum</i> (Kava)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<i>Lobelia inflata</i> (Indian tobacco)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<i>Mandragora officinalis</i> (Mandrake)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<i>Medicago officinalis</i> (Sweet clover)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<i>Pulmonaria</i> spp (includes Lungwort)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<i>Rauwolfia</i> spp (Indian snake root)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<i>Senecio</i> spp	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<i>Symphytum</i> spp (Comfrey)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<i>Tanacetum vulgare</i> (Tansy)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<i>Tussilago farfara</i> (Coltsfoot)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

24. Are there herbs, homeopathics or supplements that are currently restricted from use, which you would find beneficial to prescribe in your practice?

Yes  No

If yes, please identify 2 or 3 \_\_\_\_\_

25. Do you believe that suitably qualified practitioners should be granted prescribing rights for scheduled herbs or homeopathics?

Yes  No

26. If you practise herbal medicine or homeopathy, which of the following forms do you usually prescribe?

	Herbal Medicine	Homeopathics
Tablets / capsules / pills	<input type="radio"/>	<input type="radio"/>
Pillules	<input type="radio"/>	<input type="radio"/>
Tea infusions	<input type="radio"/>	<input type="radio"/>
Extracts / tinctures	<input type="radio"/>	<input type="radio"/>
Creams	<input type="radio"/>	<input type="radio"/>
Pessaries	<input type="radio"/>	<input type="radio"/>
Granules / powders	<input type="radio"/>	<input type="radio"/>
Raw herb decoctions	<input type="radio"/>	<input type="radio"/>
Glycerol preparations	<input type="radio"/>	<input type="radio"/>
Liquid single homeopathics	<input type="radio"/>	<input type="radio"/>
Liquid homeopathic complexes (Brauers, Reckeweg)	<input type="radio"/>	<input type="radio"/>
Radionically prepared homeopathics	<input type="radio"/>	<input type="radio"/>
<input type="radio"/> Other (Please specify) _____		

27. Of the herbal medicines or homeopathics you prescribe, what proportion do you mix or combine on site at your clinic using standardised source material purchased from a supplier?



28. Do you prepare the following medicines from raw materials as part of your practice?

	Never	Occasionally	Half the time	Frequently	Always
Herbal extract/tinctures	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Infused oils	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Pessaries	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Creams / ointments	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Tablets	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Homeopathics	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Other (Please specify) \_\_\_\_\_

29. For the herbal medicine and homeopathics you mix or prepare in your clinic, what details do you have on the dispensing labels?

	Herbal Medicine	Homeopathics
No label	<input type="radio"/>	<input type="radio"/>
Clinic name	<input type="radio"/>	<input type="radio"/>
Your name	<input type="radio"/>	<input type="radio"/>
Patient name	<input type="radio"/>	<input type="radio"/>
Date	<input type="radio"/>	<input type="radio"/>
Formula name	<input type="radio"/>	<input type="radio"/>
Part list of ingredients	<input type="radio"/>	<input type="radio"/>
Full list of ingredients	<input type="radio"/>	<input type="radio"/>
Proportions of ingredients	<input type="radio"/>	<input type="radio"/>
Exact amount of ingredients	<input type="radio"/>	<input type="radio"/>
Potency	<input type="radio"/>	<input type="radio"/>
Dosage regimen	<input type="radio"/>	<input type="radio"/>
Storage details	<input type="radio"/>	<input type="radio"/>
Expiry date	<input type="radio"/>	<input type="radio"/>
Batch number	<input type="radio"/>	<input type="radio"/>
Clinic contact details	<input type="radio"/>	<input type="radio"/>
ABN	<input type="radio"/>	<input type="radio"/>
<input type="radio"/> Other _____		



## REFERRALS

Please use this scale to indicate your answers to the following questions by filling in the appropriate number

- |   |  |  |
|---|--|--|
| <input type="radio"/> Never or almost never | <input type="radio"/> Referral in about half the cases | <input type="radio"/> Frequent referral                |
| <input type="radio"/> Occasional referral   |  | <input type="radio"/> Always or almost always referred |

Please indicate how frequently your clients are referred to you from the following sources:

	1. Never or almost never	2. Occasional referral	3. Referral in about half the cases	4. Frequent referral	5. Always or almost always referred
30 Self referred (including friends, other patients)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
31 Advertising (including Yellow Pages)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
32 Professional association	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
33 Another Complementary Medicine Practitioner	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
34 Traditional Chinese Medical Practitioner (including herbs and acupuncture)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
35 Chiropractor	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
36 Osteopath	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
37 General medical practitioner	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
38 Medical specialist	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
39 Physiotherapist	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
40 Pharmacist	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
41 Counsellor or psychologist	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
42 Health food store worker	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
43 Nurse	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
44 Other (Please specify)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please indicate how frequently you refer your clients to the following types of practitioners, using the scale as above. If some of your work is in a multi-disciplinary practice, also identify the other therapists available by shading the oval marked .

		1. Never or almost never	2. Occasional referral	3. Referral in about half the cases	4. Frequent referral	5. Always or almost always referred
45 Another Complementary Medicine Practitioner	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
46 Traditional Chinese Medicine Practitioner (acupuncture and herbs)	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
47 Chiropractor	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
48 Osteopath	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
49 General medical practitioner	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
50 Medical specialist	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
51 Physiotherapist	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
52 Pharmacist	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
53 Counsellor or psychologist	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
54 Health food store worker (not shop)	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
55 Nurse	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
56 Other (Please specify)	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

## EDUCATION

57 Please provide the following information about qualifications you have in herbal medicine, naturopathy, homeopathy, nutritional medicine, tactile therapies, or other naturopathic modalities, including apprenticeship.

- |   |   |
|---|---|
| 1. Qualification (full title)                 | 5. Length of course (in equivalent full-time years) |
| 2. Abbreviated title                          | 6. Year completed                                   |
| 3. Conferring Institution or body (full name) | 7. Mainly distance (D) or on campus (O) education   |
| 4. City in which qualification obtained       |   |

1. Qualification (full title)	2. Title	3. Conferring Institution	4. City	5. Length	6. Year	7. (D) or (O)



58 Please provide the following information about qualifications you have OTHER THAN the qualifications listed in Q57.

1. Qualification (to full title)	2. Title	3. Conferring Institution	4. City	5. Length	6. Year	7. (D) or (O)

59. Are you currently undertaking any formalised continuing education in herbal medicine, naturopathy, homeopathy, nutritional medicine, tactile therapies, or other naturopathic modalities (including seminars)?

- CPE seminars
- Certificate/Advanced certificate
- Diploma/Advanced diploma
- Bachelor degree
- Graduate diploma
- Masters
- PhD
- Other \_\_\_\_\_
- Not undertaking any education

60. How important do you think participation in continuing education is?

- Not important
- Moderately important
- Very important

61. Do you hold a current first aid qualification?

- Yes
- No

62. What are your four **main** sources of clinical information? *(Please select 4)*

- Professional association conferences
- Industry conferences (Mediherb, PhytoMedicine, Blackmore, etc)
- Professional association newsletter / magazine
- Industry newsletters
- Peer reviewed journals (Complementary Therapies in Medicine, Lancet, etc)
- General Medical Press (Aus Dr, Med Obs)
- Internet (World Wide Web, e-mail)
- Academic textbooks
- General books from the popular press
- Health magazines (Wellbeing, Nature & Health, Diversity, etc)
- General magazine or newspaper articles
- Television or radio
- Professional peers

63. In regards to your main qualification in herbal medicine, naturopathy, homeopathy or nutritional medicine, please rate the following aspects according to how well you believe they prepared you for professional practice.

	Poorly prepared	Adequately prepared	Well prepared
Clinical practice training	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Theoretical training Natural Therapies component	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Theoretical training basic Medical sciences component	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Theoretical training Western diagnostic component	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Inter-professional communications	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

64. How many years, in total, have you been in clinical practice (both in herbal medicine, naturopathy, homeopathy, nutritional medicine and other naturopathic modalities)? *(Count both full-time and part-time years of practice)*

 0  1  2  3  4  5  6  7  8  9  10  11  12  13  14  15  16  17  18  19  20

65. How many years of your total clinical experience in herbal medicine, naturopathy, homeopathy, nutritional medicine and other naturopathic modalities would you consider to be full-time? *(Condense your years worked part-time into full-time equivalent years)*

 0  1  2  3  4  5  6  7  8  9  10  11  12  13  14  15  16  17  18  19  20

66. How many years of clinical experience (equivalent full-time) do you have in health practice modalities OTHER THAN those identified in Q64?

*Please indicate modality and years of clinical experience in each.*

	0	1-5	6-10	11-15	>15
General medical practitioner	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Medical specialist	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Physiotherapist	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Chiropractor	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Osteopath	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Traditional Chinese Medicine Practitioner	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Counsellor or psychologist	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Nurse	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Other (Please specify) \_\_\_\_\_

65. What do you perceive as being the potential positives or negatives of government regulation of herbal medicine and naturopathic practice?

	Positive Change	Negative Change	Unsure
Professional status	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Standards of practice	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Standards of education	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Access to research infrastructure	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Practitioner income	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Litigation (legal cases brought against practitioners)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Postgraduate education	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Patient costs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Quality of herbal medicines, nutritional supplements and homeopathics	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Access to scheduled herbs, homeopathics, nutritional substances	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Definition of occupational boundaries	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Freedom of practice	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Medical influence on practice	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Other (please specify) \_\_\_\_\_

66. It has been suggested that a national accreditation body undertake regulatory functions of Naturopathy and related disciplines. What do you think should be the main functions for a national accreditation body or bodies?  
(You may indicate more than one)

- Assessment of practitioner qualifications
- Maintenance of a national register of qualified practitioners
- Receipt of complaints against registered practitioners and responsibility for disciplinary proceedings where necessary
- Establishment of standards of training and accreditation of training courses
- Issuing codes about standards of practice
- Monitoring compliance with CPE requirements
- Examination of practitioners trained overseas
- Public education
- Other (please specify) \_\_\_\_\_

69. Do you think that the interest of your profession would be adequately served by a single accreditation board covering all naturopaths, Western herbalists, homeopaths, nutritionists and tactile therapists?

Yes  No  Unsure

70. If you could be registered with an accreditation body (e.g. national or state based registration board) without requiring membership of an association, would you retain membership with that association?

Probably yes  Probably no

71. If you were to receive a complaint from a patient would you or do you ...?

(You may select more than one)

	Never	Occasionally	Frequently	Always
Counsel them privately	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Inform them of their rights (e.g. health complaints bodies)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Report any product adverse reaction to Aust. Drug Reaction Advisory Committee	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Phone Insurer	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Seek guidance of professional association	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Other (please specify) \_\_\_\_\_

72. Are you aware of the Australian adverse drug reaction reporting procedures?

Yes  No  Unsure

### DEMOGRAPHICS

73. What is your age in years?

 18  19  20  21  22  23  24  25  26  27  28  29  30  31  32  33  34  35  36  37  38  39  40  41  42  43  44  45  46  47  48  49  50  51  52  53  54  55  56  57  58  59  60  61  62  63  64  65  66  67  68  69  70  71  72  73  74  75  76  77  78  79  80  81  82  83  84  85  86  87  88  89  90  91  92  93  94  95  96  97  98  99  100

74. What is your sex?

Male  Female

75. What do you estimate to be your gross taxable annual income (before tax is deducted), from all herbal medicine, naturopathy, homeopathy, nutritional medicine and other naturopathic modalities?

- Less than \$10 000
- \$10 000 - 20 000
- \$20 001 - 40 000
- \$40 001 - 50 000
- \$50 001 - 60 000
- \$60 001 - 80 000
- \$80 001 - 100 000
- More than \$100 000

76. Are you currently registered with the tax office for GST purposes?

Yes  No

77. What percentage of your gross total income, **from all sources**, do you estimate to be derived from herbal medicine, naturopathy, homeopathy, nutritional medicine and other naturopathic modalities?

- Less than 10%
- 10 - 20%
- 21 - 30%
- 31 - 40%
- 41 - 50%
- 51 - 60%
- 61 - 70%
- 71 - 80%
- 81 - 90%
- More than 90%

78. Do you feel that you are fully employed as a naturopath / herbalist?

Yes  No

7) Please indicate (in order of importance to yourself), the professional complementary medicine associations of which you are a member (please write name in full, and if none, please indicate "none" in the space provided):

i) \_\_\_\_\_  
\_\_\_\_\_  
ii) \_\_\_\_\_  
\_\_\_\_\_  
iii) \_\_\_\_\_  
\_\_\_\_\_  
iv) \_\_\_\_\_  
\_\_\_\_\_

8) Please estimate how many health funds you are registered with as a provider?

- 1-5     6-10     11-20     >20

9) Which health fund, if any, are you personally a member of?

\_\_\_\_\_  
\_\_\_\_\_

10) What form of professional indemnity insurance do you currently hold?

- None  
 Insurance arranged through a professional association  
 Independently arranged insurance

11) What level of cover for professional indemnity do you hold?

- \$1 million  
 \$2 million  
 \$5 million  
 \$10 million

12) If a national / state registration board is established for GST exemption purposes, how would you prefer to register with this board?

- Independently  
 Through your professional association  
 Unsure

*Please check that you have answered all questions. Your participation in this project is very much appreciated. Please add any further comments you wish in the space below.*

\_\_\_\_\_  
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\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**THANK YOU** *for taking the time to complete this survey.*

## Appendix 5.1 Survey of Educational Programs and Providers

**N.B. In the interest of conserving space in the Appendices, lines originally on the questionnaire for answering questions have been reduced to one.**

### ENQUIRY FORM TO NATUROPATHY AND WESTERN HERBAL MEDICINE EDUCATION PROVIDERS

**Research Project on Risks, Benefits and Regulatory Requirements for the Practice of Naturopathy and Western Herbal Medicine (WHM):**

#### Survey of Educational Programs and Providers

**If you would like the questionnaire emailed to you as a word document please contact one of the researchers listed on the Information Sheet. A hard copy can be downloaded from <http://www.latrobe.edu.au/publichealth/rrrch.htm>**

It would be appreciated if Heads of Schools could advise the research team in each of the areas outlined in the questionnaire. Whilst a number of items may not be applicable to courses run by all schools, please proceed to answer all items of relevance to your program.

Apart from the questionnaire, the research team has requested supply of additional documents on a voluntary basis. Please clearly mark documents you wish to remain confidential and indicate if these are to be returned to your organisation. Confidential material should not include documents on the public record, such as an annual report or prospectus. Confidential material will not be provided to individuals, government departments or any other organisation and will be returned at your request, or archived with completed questionnaires according to the processes outlined in the Information Sheet.

***Before proceeding please sign the accompanying Consent Form. Return this with the completed questionnaire and any additional material you wish to provide.***

1. **The educational institution**
  - (a) Contact details

DETAILS	EDUCATIONAL INSTITUTION
Name of the educational institution	
Street Address	
Postal Address ( <i>if different to street address</i> )	
Telephone Numbers	
Facsimile Numbers	
Website address	
Name and position of person filling out questionnaire	
His/her email address	

1 (b) How is the organisation established? As a:

(i) Corporation under the Corporations Act	Yes <input type="checkbox"/>	No <input type="checkbox"/>
(ii) Incorporated Partnership	Yes <input type="checkbox"/>	No <input type="checkbox"/>
(iii) Unincorporated Partnership	Yes <input type="checkbox"/>	No <input type="checkbox"/>
(iv) Incorporated Joint Venture	Yes <input type="checkbox"/>	No <input type="checkbox"/>
(v) Unincorporated Joint Venture	Yes <input type="checkbox"/>	No <input type="checkbox"/>
(iv) Incorporated Association	Yes <input type="checkbox"/>	No <input type="checkbox"/>
(vii) Unincorporated Association	Yes <input type="checkbox"/>	No <input type="checkbox"/>
(viii) Trust	Yes <input type="checkbox"/>	No <input type="checkbox"/>
(ix) Co-operative	Yes <input type="checkbox"/>	No <input type="checkbox"/>
(x) Not for profit organisation	Yes <input type="checkbox"/>	No <input type="checkbox"/>
(xi) Statutory body	Yes <input type="checkbox"/>	No <input type="checkbox"/>
(xii) Other - please describe		

---

(c) Faculty/School/Department responsible for offering the course(s) in naturopathy and/or WHM

---

2(a). Does the school have any affiliations with overseas institutions?

Yes                       No                       If yes, please describe

---

(b) Does the school have any affiliations with Australian education institutions?

Yes                       No                       If yes, please describe

---

3(anat) What was the first year the school ever offered a course in naturopathy? \_\_\_\_\_

3(awhm) What was the first year the school ever offered a course in Western herbal medicine (WHM)? \_\_\_\_\_

**The Course/s**

3. For each current naturopathy and/or WHM course offered, e.g. advanced diploma, Bachelor degree, Masters degree, please list the following: *(If there is insufficient space in the table please provide an attachment).*

	<b>COURSE 1</b>	<b>COURSE 2</b>	<b>COURSE 3</b>	<b>COURSE 4</b>
a) Title of the award				
b) Year of commencement				
c) Is the course: <i>(Please circle answers)</i> (i) ? (If yes, include name of accrediting body) (ii) university accredited?	By: Yes / No  Yes / No	By: Yes / No  Yes / No	By: Yes / No  Yes / No	By: Yes / No  Yes / No
d) Total course contact hours, including compulsory clinical requirements				
e) Average number of contact hours for full-time students per week				
f) Normal length of course in full-time mode				
g) Is the course offered in both full-time mode and part-time mode	Yes / No	Yes / No	Yes / No	Yes / No
h) Maximum time allowed for completion in full-time mode				
i) Maximum time allowed for completion in part-time mode				
j) If part of the course is offered by distance education, please list subjects:				
k) Please list any subjects offered by distance education where students must find their own clinical placements				

	<b>COURSE 1</b>	<b>COURSE 2</b>	<b>COURSE 3</b>	<b>COURSE 4</b>
l) Total tuition fees charged for the course(s)				
m) Minimum requirements for admission				
n) Number of applications for the 2003 intake				
o) Number of enrolments for the 2003 intake				
p) Number of the 2003 intake who were school leavers (i.e. completed secondary school within the last three years)				
q) Number of the 2003 intake who already had a degree level qualification				
r) Number of naturopathy and/or WHM students in the 2003 intake who are already registered health professionals in the following categories:	Chiropractors: Chinese medicine practitioners: Dentists: Medical doctors: Nurses, Division 1: Division 2: Osteopaths: Pharmacists: Physiotherapists: Psychologists:	Chiropractors: Chinese medicine practitioners: Dentists: Medical doctors: Nurses, Division 1: Division 2: Osteopaths: Pharmacists: Physiotherapists: Psychologists:	Chiropractors: Chinese medicine practitioners: Dentists: Medical doctors: Nurses, Division 1: Division 2: Osteopaths: Pharmacists: Physiotherapists: Psychologists:	Chiropractors: Chinese medicine practitioners: Dentists: Medical doctors: Nurses, Division 1: Division 2: Osteopaths: Pharmacists: Physiotherapists: Psychologists:
s) Numerical breakdown of 2003 intake by gender	Male: Female:	Male: Female:	Male: Female:	Male: Female:
t) Number of students currently enrolled in the course	Year 1: Year 2: Year 3: Year 4:	Year 1: Year 2: Year 3: Year 4:	Year 1: Year 2: Year 3: Year 4:	Year 1: Year 2: Year 3: Year 4:



	<b>COURSE 1</b>	<b>COURSE 2</b>	<b>COURSE 3</b>	<b>COURSE 4</b>
u) Year in which the first cohort of graduates completed current course				
v) Estimate of graduate completions expected for 2003 to 2007	2003: 2004: 2005: 2006: 2007:	2003: 2004: 2005: 2006: 2007:	2003: 2004: 2005: 2006: 2007:	2003: 2004: 2005: 2006: 2007:
w) Please indicate whether the school is planning any new naturopathy or WHM courses in the next five years (undergraduate = bachelor degree or below, postgraduate = graduate certificate or above)	Naturopathy undergraduate	Yes <input type="checkbox"/> No <input type="checkbox"/>		
	Naturopathy postgraduate	Yes <input type="checkbox"/> No <input type="checkbox"/>		
	WHM undergraduate	Yes <input type="checkbox"/> No <input type="checkbox"/>		
	WHM postgraduate	Yes <input type="checkbox"/> No <input type="checkbox"/>		
(x) List the professional associations, if any, that have accredited the course(s):				

4. For all current naturopathy and WHM course(s) please provide the following:
- (a) A table of subjects (*Please attach a list of subjects or pamphlet or prospectus that provides name and brief description of each subject*)
- (b) The number of hours in the course(s) that are devoted to: (*Total should add up to total course hours*)

	<b>COURSE 1</b>	<b>COURSE 2</b>	<b>COURSE 3</b>	<b>COURSE 4</b>
i) Naturopathy/WHM theory education (lectures, tutorials, practical classes)				
ii) Naturopathy/WHM clinical education (e.g. clinical observation, student clinic)				
iii) Biomedical and social sciences				
iv) Other				

- (c) What framework(s) was used to guide development of the current course(s) (e.g. Australian Qualifications Framework, FNTT competencies, Australian National Training Board competencies).

<b>COURSE 1</b>	<b>COURSE 2</b>	<b>COURSE 3</b>	<b>COURSE 4</b>

- (d) List the number of assessments for the current herbal medicine subjects in the above course(s) in the following categories: (*This information will provide a snapshot of the major types of educational assessment used; herbal medicine was selected because it is common to both naturopathy and WHM*).

<b>TYPE OF ASSESSMENT</b>	<b>NUMBER OF ASSESSMENTS</b>
Exams/tests – closed book	
Exams – open book or take-home	
Exams - oral	
Literature or other critical reviews	
Annotated bibliographies	
Essays - 1500 words or more	
Projects	
Reports	
Other written assignments	
Case studies	
Demonstration of clinical/practical skills	
Oral presentations	
Journal/Log book	
Thesis (include word length)	
Hurdle requirements (please describe)	
Other (please describe)	

**Clinical Policies and Procedures**

*(Copies of any student clinic policy documents and staff manuals would be welcome).*

5. (a) Does the school operate a naturopathic and/or WHM student clinic in which students undertake supervised clinical practice? *(tick one box)*

Yes  No

- (b) If yes, does the student clinic have in place:

- (i) A protocol for the dispensing of naturopathic and WHM remedies *(tick one box)*

Yes  No

- (ii) A protocol for the notification of adverse reactions experienced by patients *(tick one box)*

Yes  No

- (iii) A protocol for the handling and follow-up of other incidents such as accidents and emergencies *(tick one box)*

Yes  No

- (iv) Guidelines regarding the making of referrals to other health care practitioners *(tick one box)*

Yes  No

- (v) A requirement that all staff and students have a First Aid Certificate?

Yes  No

- (vi) If yes, what level of First Aid Certificate is required? \_\_\_\_\_

- (c) How are the school's clinic supervising staff and lecturers made aware of these policies and protocols?  
\_\_\_\_\_

6. (a) Does the school have written guidelines for students regarding:

- (i) the clinical management of patients who are taking pharmaceutical drugs? *(tick one box)*

Yes  No  If yes, please provide/attach details:  
\_\_\_\_\_

- (ii) advice and information provided to patients about medical immunisation? *(tick one box)*

Yes  No  If yes, please provide/attach details.  
\_\_\_\_\_

- (iii) when and how to make appropriate referral of a patient to a medical practitioner?

Yes  No  If yes, please provide/attach details.  
\_\_\_\_\_

(b) How are lecturers and clinical supervising staff made aware of these policies?

---

**Outcomes**

7. (a) Historically, for all naturopathy and/or WHM courses, please give the number of graduate completions in each of the following years where applicable:

Year of Completion	Number of graduate completions - Naturopathy	Number of graduate completions - WHM
1982		
1987		
1992		
1997		
1998		
1999		
2000		
2001		
2002		

(b) Are graduates followed up to see if they have gained employment in the naturopathic profession/industry? (*tick one box*)

Yes

No

(c) If yes, please provide any relevant figures, e.g. numbers/percentage in employment one year after graduation, whether part-time or full-time

---

**Teaching and staffing**

8. (a) List any components of the current naturopathy and/or WHM course(s) that are taught/provided by other departments/institutions:

---

(b) Please list or attach a list of any components of the current naturopathy and/or WHM course(s) that are taught/provided by product manufacturers:

MANUFACTURER	COURSE COMPONENT	NATURO-PATHY (Tick)	WHM (Tick)

(c) Please provide the number of staff teaching in the following areas:

AREA OF TEACHING	FULL-TIME STAFF	PART-TIME STAFF	SESSIONAL/CASUAL STAFF	GUEST LECTURERS
Naturopathy/WHM theory education (lectures, tutorials, practical classes)				
Naturopathy/WHM clinical education (clinical observation, student clinic)				
Biomedical and social sciences				
Other				

(d) Of the staff positions in your Faculty/Department/School that contribute to teaching the naturopathy and/or WHM course(s), how many were publicly advertised in newspapers over the last five years:

Where Positions were Publicly Advertised	Number of Positions Publicly Advertised
Within State or Territory	
Nationally	
Internationally	

(e) Does the school have any postgraduate research or Honours students currently undertaking naturopathy and/or WHM related projects?

Yes

No

(f) If yes, how many postgraduate research and Honours students currently undertaking naturopathy/WHM related projects are being supervised by:

Supervised by:	Number of Postgraduate Students
Internal staff	
External supervisors	
Both	

9. (a) Please attach a list set out as per the following table with details for all staff Members (full-time, part-time, sessional) within your Faculty/Department/School teaching in the naturopathy and/or WHM subjects in 2003: *(This question relates to the naturopathy and WHM subjects only, not biomedical or social science subjects)*

Highest qualification and discipline e.g. Bachelor of Science (Nutrition)	Awarding institution	Year awarded	Naturopathy/WHM subjects taught	Naturopathy/WHM clinical practice experience (F/T yrs equivalent)

(b) Please attach a list with the following details for all staff members (full-time, part-time, sessional) within your Faculty/ Department/School teaching in all subjects of the naturopathy and/or WHM course(s) in 2003:

(i) List of refereed publications for the last five years

(ii) List of research grants awarded by external funding bodies for the last five years

- (c) What are the selection criteria for approval of private practitioners (not staff) who are eligible to provide clinical placements for students? (e.g. qualifications, memberships, years of clinical experience)
- 

- (d) Please describe the process for approval of private practitioners:
- 

### Quality Assurance

*Copies of any QA or review documents would be welcome.*

10. For each naturopathy and/or WHM course please provide the following information:

- (a) Is the course advised by a course committee? (*tick one box*)

Yes                          No                     

- (b) If yes, how is the committee membership constituted?
- 

- (c) What are its terms of reference?
- 

- (d) How frequently are internal course reviews conducted? (*i.e. review of whole course conducted by internal course advisory committee*)
- 

- (e) Who initiates these reviews?
- 

- (f) Who conducts these reviews?
- 

- (g) How frequently are external course reviews conducted? (*i.e. review by external experts/academics*)
- 

- (h) Who initiates these reviews?
- 

- (i) Who conducts these reviews?
- 

- (j) How often are subjects evaluated by students (e.g. for content, organisation, teaching)?
- 

- (k) Please list any other quality assurance and quality review processes that are in place for the course(s)
- 

11. Does the school have an agreed position or policy in relation to:

- (a) continuing self-regulation by the profession for naturopathy (*tick one box*)

Yes                          No

- (b) continuing self-regulation by the profession for WHM (*tick one box*)  
Yes      ↑                      No                      ↑
- (c) State government registration of practitioners of naturopathy (*tick one box*)  
Yes      ↑                      No                      ↑
- (d) State government registration of practitioners of WHM (*tick one box*)  
Yes      ↑                      No                      ↑
- (e) Does the organisation have a different option to any of the above?  
Yes      ↑                      No                      ↑
- (f) If 'yes' to any of the above, please describe or provide an attachment.
- 

### Open-ended questions

*This section of the questionnaire makes provision for organisations to express opinions or perspectives on a range of issues that may be of current concern. If there is insufficient space below please include an attachment.*

12. Does the school have any other comment on the issue of regulation?
- 

13. What is the school's position on the appropriate level of education for beginning practitioners of naturopathy and/or WHM?
- 

14. What does the school see as the future of education for naturopathy and/or WHM in Australia?
- 

15. Please provide any other comments about the course(s) and/or naturopathy/WHM education that you consider pertinent to the review.
- 

16. Are there any other political, governmental or legal issues that are causing, or are expected cause, concern regarding education?
- 

If you have any questions regarding the questionnaire please do not hesitate to contact one of the researchers listed at the bottom of the Information Sheet.

Please return the questionnaire by **1<sup>st</sup> December, 2003** with any additional documents in the enclosed pre-paid, self-addressed envelope to the investigator at the address below. If supply of extra documents requires additional postage, please contact one of the researchers on the Information Sheet to arrange reimbursement.

On behalf of the research team I thank you for taking the time to participate in this important national survey.

**Dr Pauline McCabe**  
**Senior Lecturer in Naturopathy,**  
**School of Nursing and Midwifery**  
**La Trobe University, Bundoora, Vic. 3086**  
**Ph: 03 9479 5941**  
**p.mccabe@latrobe.edu.au**

## Appendix 5.2 Naturopathy and WHM Courses Offered in Australia (2003)

Participated in survey	Institution	Courses offered
Yes	Academy of SAFE Therapies (Gold Coast campus) (QLD)	AdDip Naturopathy AdDip WHM
No	Adelaide Training College of Complementary Medicine (SA)	Cert IV Naturopathy AdDip Naturopathy Cert IV WHM Dip Herbal Medicine AdDip WHM
No	Athene College of Traditional Medicine, (WA)	Dip Herbal Medicine Ad.Dip Herbal Medicine
Yes	Australasian College of Natural Therapies (NSW)	AdDip Naturopathy AdDip WHM
Yes	Australasian College of Nutritional and Environmental Medicine (VIC)	GradCert Nutritional and Environmental Medicine
Yes	Australian Centre for Complementary Medicine Education and Research (QLD)	GradCert Evidence Based Complementary Medicine
No	Australian College of Herbal Medicine (VIC)	Grad Cert in Herbal Medicine (not offered 2003) Fellowship in Herbal Medicine
Yes	Australian College of Natural Medicine (Brisbane Campus) (QLD)	BHSc Naturopathy AdDip Naturopathy AdDip WHM
Yes	Australian College of Natural Medicine (Gold Coast Campus) (QLD)	BHSc Naturopathy AdDip Naturopathy AdDip WHM
Yes	Australian College of Natural Medicine (Perth Campus) (WA)	AdDip Naturopathy AdDip WHM
Yes	Australian College of Natural Medicine Inc. (VIC)	AdDip Naturopathy
No	Australian Institute of Applied Sciences (QLD) (formerly National Institute of Health Sciences)	Cert IV Health Care Assistant (Naturopathy) Cert IV Health Care Assistant (WHM) Ad.Dip Naturopathy Ad.Dip WHM
Yes	Australian Institute of Holistic Medicine (WA)	AdDip Naturopathy AdDip WHM
Yes	Canberra Institute of Technology (ACT)	AdDip Naturopathy
Yes	Central TAFE (WA)	AdDip Naturopathy
Yes	Charles Sturt University (NSW)	BHSc Compl Medicine (conversion) MHSc Complementary Medicine
No	College of Somatic Studies (QLD)	Dip Naturopathy AdDip Naturopathy
No	Dorothy Hall College of Herbal Medicine (NSW)*	Dip Classical Herbal Medicine AdDip Classical Herbal Medicine
Yes	Dunn's Private College of Herbalism and Naturopathy (WA)	AdDip Naturopathy AdDip WHM
Yes	Gold Coast Institute of TAFE (QLD)	AdDip Naturopathy AdDip Naturopathy (Conversion)
Yes	Gracegrove College (NSW)	AdDip Medical Herbalism AdDip WHM
Yes	Health Schools Australia (QLD)	AdDip Naturopathy AdDip WHM
Yes	Institute of TAFE (TAS)	AdDip Naturopathy AdDip WHM
Yes	Island Health College (TAS)	AdDip Naturopathy
No	The Kinesiology Academy (QLD)	Ad.Dip. Naturopathy
Yes	La Trobe University (VIC)	BNursing/BNaturopathy
No	Laws College of Naturopathy (VIC)	Naturopathy (award type unknown)



Yes	Melbourne College of Natural Medicine (Box Hill Campus) (VIC)	AdDip Naturopathy AdDip WHM
Yes	Melbourne College of Natural Medicine (Melbourne Campus) (VIC)	BHSc Naturopathy AdDip Naturopathy AdDip WHM
Yes	National College of Traditional Medicine (VIC)	DipMedical Herbalism AdDip Naturopathy
Yes	Nature Care College (NSW)	AdDip Naturopathy AdDip Naturopathy (Flexible) Ad Dip WHM
No	NSW School of Natural Medicine (NSW)	Ad.Dip. Naturopathy DipHerbal Medicine (distance ed) Ad.Dip. WHM
Yes	Paramount College of Natural Medicine (WA)	AdDip Naturopathy
No	Perth Academy of Natural Therapies (WA)	AdDip Naturopathy
No	Robynn Morro's College of Natural Medicine (QLD)	Ad.Dip. Herbalism Ad.Dip. Naturopathy
No	SA College of Natural and Traditional Medicines (SA)	Cert.III & IV Natural & Tradnl Therapies Dip WHM AdDipAppSci (WHM) AdDipAppSci (WHM)Hons Dip Naturopathy AdDipApp Sci(Naturopathy) AdDipApp Sci(Naturopathy)Hons
Yes	SA Health Education Centre (SA)	AdDip Naturopathy AdDip WHM
No	Southern Cross Herbal School (QINS) (NSW)	Cert Herbalism Dip Herbology AdDip Medical Herbalism AdDip Western Herbalism AdDip Naturopathy
Yes	Southern Cross University (NSW)	BNaturopathy BNatural Therapies (conversion)
Yes	Southern School of Natural Therapies (VIC)	BHSc Naturopathy
No	Swinburne University (VIC)	GradCertAppSci Integrative Medicine GradDip Integrative Medicine GradCert AppSci Nutritional and Environmental Medicine GradDip Nutritional and Environmental Medicine
Yes	University of Newcastle Research Associates (NSW)	BHerbal Therapies
Yes	University of New England (NSW)	GradDipHSc Herbal Medicine BHSc Naturopathy BHSc Naturopathy (conversion) MHSc Herbal Medicine
Yes	University of South Australia (SA)	BHSc Naturopathy (conversion)
Yes	University of Sydney (NSW)	MHerbal Medicines
Yes	University of Western Sydney (NSW)	BHSc Complementary Therapies BHSc Naturopathy 1 BHSc Naturopathy 2 BAppSc (Naturopathic Studies)
Yes	Victoria University of Technology (VIC)	GradDip WHM GradDip Complementary Therapies AdDip Naturopathy (2004) BHSc Natural Medicine (conversion) MHealth Science

**Note:** \*Dorothy Hall's College is winding up due to her retirement

### Appendix 5.3 Characteristics of Participating Education Providers

Education Provider	Type of organisation	Faculty or department offering course(s)	Naturopathy course first offered	WHM course first offered	Australian affiliations	Overseas affiliations
Academy of SAFE Therapies (QLD)	Corporation (profit)	AST	2000	2000	yes	no
Australasian College of Natural Therapies (NSW)	Corporation (profit)	ACNT	1986	1986	yes	no
Australasian College of Nutritional and Environmental Medicine (VIC)	Incorporated association (non-profit)	ACNEM	1982*	NA	yes	yes
Australian Centre for Complementary Medicine Education & Research (QLD)	Unincorporated joint venture (non-profit)	School of Pharmacy UQ School of Natural & Comp Med SCU	2003*	NA	yes	no
Australian College of Natural Medicine Pty Ltd (5 campuses: QLD 2; VIC 2; WA 1)	Corporation (profit)	Faculty of Naturopathy	1981	1981	no	yes
Australian College of Natural Medicine Inc (VIC)	Other (profit)	ACNM (VIC)	1988	NA	NP	NA
Australian Institute of Holistic Medicine (WA)	Corporation (profit)	AIHM	1993	NA	yes	yes
Canberra Institute of Technology (ACT)	Statutory body (non-profit)	Faculty of Science & Technology, Dept of Health Sciences	2002	NA	Under negotiation	no
Central TAFE (WA)	Statutory body (non-profit)	School of Health & Community Services, Complementary Health Care Centre	2002	NA	no	no
Charles Sturt University (NSW)	Statutory body (non-profit)	Faculty of Health Studies	1998*	NA	yes	no
Dunn's Private College of Herbalism and Naturopathy (WA)	Unincorporated association (profit)	Dunn's	1978	1978	no	no
Gold Coast Institute of TAFE (QLD)	Statutory body (non-profit)	Faculty of Humanities, Academy of Natural Therapies	1979	1984	yes	yes
Gracegrove College (NSW)	Corporation (profit)	Newcastle College of Herbal Medicine	NA	1986	yes	yes

Health Schools Australia (QLD)	Corporation (profit)	HSA	1967	1967	yes	yes
Institute of TAFE Tasmania (TAS)	Statutory body (non-profit)	Community Services and Health	2000	2000	no	no
Island Health College (TAS)	Corporation (profit)	IHC	2003	NA	no	no
La Trobe University (VIC)	Statutory body (non-profit)	Faculty of Health Sciences, School of Nursing & Midwifery	2001	NA	yes	yes
National College of Traditional Medicine (VIC)	Corporation (profit)	NCTM	1989	1989	No	No
Nature Care College (NSW)	Corporation (profit)	Dept of Naturopathy	1981	1981	yes	no
Paramount College of Natural Medicine (WA)	Corporation (profit)	Paramount	2003	2003	no	yes
SA Health Education Centre (SA)	NP	NP	2002	2002	NP	NP
Southern Cross University (NSW)	Statutory body (non-profit)	School of Natural & Comp. Medicine	1995	NA	yes	yes
Southern School of Natural Therapies (VIC)	Corporation limited by guarantee (non-profit)	Dept of Naturopathy	1961	NA	yes	yes
University of Newcastle (NSW)	Statutory body (non-profit)	Faculty of Science & IT, School of App Science	NA	2002	yes	no
University of New England (NSW)	Statutory body (non-profit)	Faculty of Education, Health & Prof. Studies, School of Health	1994	2004	yes	no
University of South Australia (SA)	Statutory body (non-profit)	School of Health Sciences	2004	NA	No	yes
University of Sydney (NSW)	Statutory body (non-profit)	Faculty of Pharmacy	NA	2000	NP	no
University of Western Sydney (NSW)	Statutory body (non-profit)	College of Social & Health Sciences, School of Exercise & Health Sci.	1999	NA	yes	yes
Victoria University of Technology (VIC)	Statutory body (non-profit)	School of Health Sciences, Natural Medicine Unit	1996*	1995	no	no

NA = Not applicable

NP = Not provided

\* = Generic course, i.e. not specifically naturopathy (mostly conversion courses, e.g. B.Complementary medicine or B.Natural Therapies).

## Appendix 5.4 Affiliations between Private Providers and Universities

Education provider	Affiliated with	Undergraduate course	Postgraduate course	Comments
Academy of SAFE Therapies	University of New England	B. Health Science (Naturopathy)		
Australasian College of Natural Therapies	University of New England Charles Sturt University	B. Health Science (Naturopathy) B. Health Science (Complementary Medicine)		Bachelor degree subjects run concurrently with Ad Dip Naturopathy subjects Graduates of Ad Dip WHM may upgrade to CSU bachelor's degree or to UNE bachelor's degree via upgrade to Ad Dip Naturopathy
Australasian College of Nutritional and Environmental Medicine	Australian College of Herbal Medicine		Grad Cert in Herbal Medicine	
Australian Centre for Complementary Medicine Education and Research	Southern Cross University University of Queensland		Grad Cert Evidence Based Complementary Medicine	
Australian Institute of Holistic Medicine	University of New England	B. Health Science (Naturopathy)		Eight UNE units to be completed. Students can enrol concurrently with AdDip or on completion of AdDip
Gold Coast Institute of TAFE	Southern Cross University	B.Natural Therapies		
Gracegrove College	Charles Sturt University	BHSc Complementary Medicine		
Health Schools Australia	Charles Sturt University University of New England	BHSc Complementary Medicine B. Health Science (Naturopathy)		

Nature Care College	Charles Sturt University Southern Cross University University of New England	BHSc Complementary Medicine B.Natural Therapies B. Health Science (Naturopathy)		
Southern Cross University	ACCMER		Grad Cert Evidence Based Complementary Medicine	
Southern School of Natural Therapies	La Trobe University	B. Nursing / B. Naturopathy		SSNT contracted to teach naturopathy subjects
U. Newcastle Research Associates	Southern Cross Herbal School	B. Herbal Therapies		SCHS diploma/adv dip articulate into B. Herbal Therapies
University of New England	Aust College Nat Therapies Aust Institute Holistic Med Health Schools Australia Nature Care College NSW School of Nat Medicine SA College of Natural & Traditional Medicine			
University of South Australia	No formal affiliations			Accepts graduates with Dip or AdDip into Conversion Course
University of Western Sydney	Endeavour College			UWS has taken over naturopathy with the assistance of Endeavour College

## Appendix 5.5 Table of Subjects (undergraduate courses)

<b>Institution</b>	<b>Course</b>	<b>Total contact hours</b>	<b>Naturopathy/WHM theory education subjects (lectures, tutorials, practical classes) (exemplary range)</b>	<b>Hrs</b>	<b>Naturopathy/WHM clinical education subjects (exemplary range)</b>	<b>Hrs</b>	<b>Biomedical and social science subjects (exemplary range)</b>	<b>Hrs</b>	<b>Other (exemplary range)</b>	<b>Hrs</b>
Academy of SAFE Therapies	Ad Dip Nat (HLT 60501)	1586	Healing philosophies, nutrition, herbal med, massage, homeopathy, naturopathic diagnosis & prescribing, case studies, iridology, law, ethics & practice management	865	Clinical medicine units x 4	198	Anatomy & physiology, chemistry, biochemistry, pathophysiology, communication & counselling, pharmacology, research	507	First aid	16
	Ad Dip WHM (HLT 60501)	1375	Healing philosophies, herbal medicine, aromatherapy, naturopathic diagnosis & prescribing, law, ethics & professional practice	654	As above	198	As above	507	First aid	16
Australasian College of Natural Therapies	Ad Dip Nat (HLT 60502)	3400	Naturopathic philosophy, nutrition, herbal medicine, massage, homeopathy, flower essences, clinical studies, ethical and legal issues, professional studies, practice management	NP	Massage clinic; naturopathy clinic	500	Anatomy & physiol, chemistry, bio-chemistry, patho-physiology, symptomatology & diagnosis, physical examination, communication & counselling, pharmacology, research	NP	Occup. health & safety First aid	N/P

Australasian College of Natural Therapies (cont'd.)	Ad Dip WHM (HLT 60102)	1540	Botany, herbal med, flower essences, nutrition, ethical & legal issues, professional studies, practice management	NP	WHM clinic	250	As above but no research subject	NP	As above	NP
ACNM Pty Ltd	B.Health Sc (Nat) (HLT 60502 plus advanced subjects) Brisbane, Gold Coast, Melb.)	2722	History & philosophy natural med, nutrition, herbal medicine, massage, flower essences, homeopathy, iris analysis, wellness analysis, naturopathy preclinical skills, advanced subjects in herbal medicine and nutrition	1122	Naturopathy clinic & advanced naturopathy clinic	592	Human biology, chemistry, biochem., nutritional biochemistry, clinical examination, pharmacology, human disease processes, communication and counselling, research methods & technology, research project	840	Safe practices, establish a practice, community education & public health, electives	168
	Ad Dip Nat (HLT 60502) Brisbane, Gold Coast, Melb., Perth, Box Hill)	2150	History & philosophy natural med, nutrition, herbal medicine, massage, flower essences, homeopathy, iris analysis, wellness analysis	912	Naturopathy clinic	272	As above except no research project.	840	Safe practices, establish a practice	126
	Ad Dip WHM (HLT 60102) Brisbane, Gold Coast, Melb., Perth, Box Hill)	1814	History & philosophy natural medicine, nutrition, herbal medicine, flower essences, iris analysis, wellness analysis	618	Herbal medicine clinic	272	As above except no nutritional biochemistry and no research project.	798	Safe practices, establish a practice	126

Australian College of Natural Medicine Inc. (VIC)	Ad Dip Nat (accred by OTTE Vic; state VET)	2240	NP	1600	NP	200	NP	300	NP	140
Australian Institute of Holistic Medicine	Ad Dip Nat (HLT 60502)	2854	Naturopathic philosophy, herbal medicine nutrition, massage, iridology, management skills, health retreat, homeopathy (optional), dissertation; plus six electives from a range of complementary therapy subjects—e.g., aromatherapy, yoga, Bowen technique	NP	Clinical practice, supervised clinical training	500	Anatomy & physiology, medical terminology, biochemistry, pathology, pharmacology, microbiology, medical science, behavioural science, research methodology	NP	First aid, management skills	NP
	Ad Dip WHM (HLT 60102)	2044	Naturopathic philosophy, herbal med., nutrition, management skills, dissertation. Plus three electives from a range of complementary therapy subjects, e.g. aroma therapy, yoga, Bowen technique	NP	Clinical practice; in-house clinical training	200	As above	NP	As above	NP
Canberra Institute of Technology	Ad Dip Nat (HLT 60502)	1848	Principles of naturopathy, phytotherapy, introduction to other naturopathic modalities, naturopathic nutrition, massage principles, massage therapy, law. (No homeopathy.)	995	Naturopathic clinic and massage clinic	352	Human biology, microbiology biological chemistry, anatomy & physiol, nutritional biochem, pathology, pharmacol communicating with clients & colleagues, occupational health & safety for the naturopathic industry, client support skills	445	NP	56



Central TAFE WA	Ad Dip Nat (HLT 60502)	2780	Course consists of core subjects (naturopathy & sciences) plus choice of two of four streams (herbal medicine, nutrition, massage and homeopathy).	1570	As per HLT 60502 (see Appendix 1.1)	800	As per HLT 60502 (see Appendix 1.1)	260	NP	150
Dunn's Private College	Ad Dip Nat (HLT 60502)	3780	Philosophy & theory, nutrition, herbal medicine, bodywork, iridology, aromatherapy, auricular acupuncture, clinical & prof. management (no homeopathy)	2426	Student clinic plus compulsory post-graduate internship	441	Anatomy & physiol, body chemistry, pathology, communication & behavioural skills, pharmacotherapy	923		
	Ad Dip WHM (HLT 60102)	3060	Philosophy & theory, nutrition, herbal medicine, bodywork, clinical & professional management	1877	AS above	260	As above	923		
Gold Coast Institute of TAFE	Ad Dip Nat (HLT 60502)	2100	Units are as per HLT 60502 (see below). Course consists of core subjects (naturopathy, sciences, nutrition and herbal medicine) plus electives: choose massage or homeopathy. Also available as a conversion course	1100	Student clinic	500	As per HLT 60502 (see below)	500		
Gracegrove College	Ad Dip Medical Herbalism (industry accredited)	1512	Herbal medicine, botany & plant identification, psychology of flower essences, nutrition, iridology, homeopathy. Incorporates HLT 60102	462	Clinic	238.5	Anatomy & physiol., biochemistry, differential diagnosis 1 & 2, pharmacognosy & toxicology, medical terms and procedures	800		

Gracegrove College (cont'd.)	Ad Dip WHM (HLT 60102)	1512	As per HLT 60102	462	Clinic	238.5	As above	800		
Health Schools Australia	Ad Dip Nat (HLT 60502)	3205 approx (mainly DE)	History & philosophy of natural med, herbal medicine, remedial massage, nutrition, iridology, ethics & jurisprudence, practice management, occupational health & safety (No homeopathy)	400 (seminars) plus home study	Clinic	240	Anatomy & physiol, disorder profiles/ clinical practice 1–4, chemistry, biology, biochemistry, pathophysiology & symptomatology, counselling & psychology	NP		
	Ad Dip WHM (HLT 60102)	2665	History & philosophy of natural med, herbal medicine, ethics & jurisprudence, nutrition, practice management, occupational health & fitness	300 (seminars) plus home study	Clinic	100	As above			
Institute of TAFE Tas.	Ad Dip Nat (HLT 60502)	1254–1814 (depending on electives)	As per HLT 60502 (see Appendix 1.1)	NP	NP	NP	As per HLT 60502 (see Appendix 1.1)	NP		
	Ad Dip WHM (HLT 60102)	1274	As per HLT 60102 (see Appendix 1.1); no electives	NP		NP	As per HLT 60502 (see Appendix 1.1)	NP		
Island Health College*	Ad Dip Nat (HLT 60502)	1240	As per HLT 60102 (see Appendix 1.1)	NP	NP	NP	As per HLT 60102 (see Appendix 1.1)	NP		

La Trobe University	B Nursing/B Naturopathy	3220	Foundations of naturopathy, nutrition, herbal medicine, homeopathy, tactile therapies, naturopathic health assessment, naturopathic clinical medicine	917	Naturopathy clinic	348 (plus nursing clinical hours)	Anat. & physiol., biological chem., biochem., psychol., health sociol., pathol. pharmacol., health assessmt., counselling & stress management., research methods, health ed & promotn., primary health care, mental health, law & ethics	1061	Nursing clinical	894
National College of Traditional Medicine	Ad Dip Nat (industry accred)	2000	NP	NP	NP	NP	NP	NP		
	Dip Medical Herbalism (industry accred)	1000	NP	NP	NP	NP	NP	NP		
Nature Care College	Ad Dip Nat (HLT 60502)	2580	Intro to naturopathy, massage, nutrition, herbal medicine, homeopathy, Bach flowers, colloids, naturopathic diagnosis, integrated medicine	1232	Naturopathy clinic	400	Anatomy & physiol, chemistry, wet labs, biochem., symptomatology, diagnosis & pathol., pharmacol. holistic counselling, physical examn. and integrated pathology	804	Safe practices, first aid, four electives	144
	Ad Dip Nat (HLT 60502) Flexible mode	2580	As above	1232	Naturopathy clinic	400	As above	804	As above	144
	Ad Dip WHM (HLT 60102)	2015	Herbal med traditions & manufacturing, botany, phytomed, pharmacog, therapeutics, nutrition, practice management	907	Herbal medicine clinic	250	As above	804	Safe practices, one elective	54

Paramount College of Natural Medicine	Ad Dip Nat (HLT 60502)	1556	Naturopathic philosophy, herbal medicine, homeopathy, massage, nutrition, product knowledge, scientific integration, treatment protocols, dissertation.	706	Naturopathy clinic	450	Anatomy & physiol, biochemistry, diagnostic methods, first aid, counselling, microbiology, medical terminology, pharmacology, pathology	400		
SA Health Educn Centre	Ad Dip Nat (HLT 60502)	4018	Cert IV massage, naturopathic philosophy, herbal medicine, nutrition, tissue salts & Bach flowers, basic homeopathy, iridology, business development	2518	Clinical observation, naturopathy clinic	500	Anatomy & physiol, cellular biology, pathol., symptomatology, pharmacol., diagnosis, counselling	1000		
	Ad Dip WHM (HLT 60102)	NP	NP	NP	NP	NP	NP	NP		
Southern Cross University	B.Nat	3100	Naturopathic foundations, nutrition 1–4, phytotherapy 1–6, introductory homeopathy, tactile therapies, plus six electives (include further massage and homoeopathy)	1530	Clinical studies, naturopathy clinic	765	Anat & physiol, biological chem, biochem, physiological pathol, clinical diagnosis, pharmacol, counselling. Electives: critical reasoning and research methods, research project	805		
Southern School of Natural Therapies	B Health Sc (Nat)	2513	Philosophy, herbal medicine, nutrition, iridology, homeopathy, naturopathic clinical medicine, clinical review, practice establishment	1055	Clinical studies and practicum	528	Anatomy & physiol, bioscience, pathol, biochem, psychology, pharmacol., human ecology, clinical diag. counselling, research studies	930		

University of Newcastle	B Herbal Therapies	1550	Intro to comp medicine, medicinal herb botany and identification, materia medica, herbal therapeutics, electives: e.g. herbal med manufacturing and prescription, nutrition	532	Clinical training in herbalism	100 minimum	Chemistry, biology, biochemistry, pathology, clinical pharmacology and therapeutics, research methods	812	Information systems and technology; new venture creation	100
University of New England	B Health Sc (Nat)	DE or may be delivered by partner college	Students do full Ad Dip with a partner college and enrol concurrently in eight UNE subjects: all biosciences. (Also available as a conversion course: see Appendix 5.7)	0		0	Body chemistry, coverings, support & movement, body maintenance, control coordination & transportation, survival and continuation of life, research methods in health, plus three electives, e.g. health education and promotion, issues in human nutrition.	400		
	B Health Sc (Comp Therapies)	1492	Principles of naturopathy, remedial massage, iridology, nutrition, herbal medicine, homeopathy.	533	Naturopathy clinic	400	Patterns and meanings of health, physical & biological sciences, psychology of health, biochemistry, symptomatology & diagnosis, sociology of health, qualitative research, Australian healthcare system, critical reflective practice, quantitative research.	494	Research, electives	65
	B Health Sc (Nat) 4501	1492	As above	533	As above	400	As above	494	As above	65

University of New England (cont'd.)	B Health Sc (Nat) 4554	1583	As above	546	As above	400	Human medical sciences, intro to health studies, biochemistry, communication for helping professions, symptomatology & diagnosis, intro to research for health sciences, quantitative & qualitative research, ethical & legal issues in health, pharmacology	416	As above	221
	B App Sc (Nat Studies)	1515	Massage, intro to naturopathy, WHM, homeopathic principles, naturopathic nutrition, herbal pharmacognosy, naturopathic practice	585	Massage clinic 100 Nat clinic 180	280 plus a Grad Dip	Human medical sciences, Intro to health studies, biochemistry for naturopathy, communication for helping professions, clinical pharmacol. & microbiology, clinical diagnosis, intro to research for health sciences, pathophysiology.	468	Electives: intro to comp med, iridology	182
Victoria University	Ad Dip Nat (HLT 60502)	1350	As per HLT60502 (see Appendix 1.1)	NP	NP	NP	NP	NP	NP	NP

\*Island Health College closed the Ad Dip Naturopathy after one year due to lack of enrolments for 2004. Students transferred to Institute of TAFE Tas.

The B.AppSci (Naturopathic Studies) at UWS is a new course (2004), a three-year bachelor's degree that will have a compulsory fourth year of part-time clinical practice structured as a graduate diploma commencing in 2007. This will be necessary to enable practice.

N.B. Hours in the above table are approximate only due to choice of electives and streams available to students

CM = complementary medicine

DE = distance education

NP = Not provided

## Appendix 5.6 National Health Training Packages for Naturopathy and Western Herbal Medicine: Competencies and Nominal Hours

### HLT60502: Advanced Diploma of Naturopathy

Competencies	Nominal hours
Contribute to effective workplace relationships	40
Develop professional expertise	40
Manage a practice	50
Communicate effectively with clients/patients	30
Make referrals to other healthcare professionals when appropriate	40
Apply basic first aid	24
Apply advanced first aid	30
Contribute to organisational effectiveness in the health industry	30
Implement and monitor occupational health & safety policies, procedures, and programs	40
Manage control of infection	50
Provide naturopathic treatment	120
Provide Western herbal medicine treatment	60
Provide naturopathic nutritional treatment	80
Plan naturopathic treatment strategy	40
Perform naturopathic health assessment*	200
Manage work within a naturopathic framework	40
Apply naturopathic diagnostic framework	40
Work within a naturopathic framework	20

\*Underpinning knowledge includes biosciences—anatomy, physiology, pathology, etc.

### HLT60102: Advanced Diploma of Western Herbal Medicine

Competencies	Nominal hours
Contribute to effective workplace relationships	40
Develop professional expertise	40
Manage a practice	50
Communicate effectively with clients/patients	30
Make referrals to other healthcare professionals when appropriate	40
Apply basic first aid	24
Apply advanced first aid	30
Contribute to organisational effectiveness in the health industry	30
Implement and monitor occupational health & safety, policies, procedures and programs	40
Manage control of infection	50
Apply Western herbal medicine diagnostic framework	40
Manage work within a Western herbal medicine framework	40
Operate a Western herbal medicine dispensary	80
Perform Western herbal medicine health assessment*	240
Plan a Western herbal medicine treatment strategy	40
Prepare and dispense Western herbal medicine	80
Provide dietary advice	40
Provide specialised Western herbal medicine treatment	260
Provide Western herbal medicine treatment	80

\*Underpinning knowledge includes biosciences—anatomy, physiology, pathology, etc.

Note: The above implementation guides are examples only. Nominal hours may vary between jurisdictions. See Appendix 1.1 for further information on training packages.

## Appendix 5.7 Conversion Courses (upgrade of an existing award)

Institution	Award	Year first offered	Subjects	Clinical component	Entry requirements and comments	Fees
Gold Coast Institute of TAFE (QLD)	Ad Dip Naturopathy (HLT60502)	2003	Nine competency units from HLT60502	No clinical component	Entry: govt-accredited diploma; all by distance education	\$1000
Charles Sturt University (NSW)	B.Hlth. Science (Complementary Medicine)	1998	Three core subjects plus one elective: nutritional biochemistry pathophysiology 1 pathophysiology 2 elective	No clinical component	Entry: govt.-accredited advanced diploma or equivalent All distance education	\$3800 (most students full fee-paying)
Southern Cross University (NSW)	B.Natural Therapies	2001	Four core units and four electives Core units: contemporary issues in the practice of natural medicine clinical diagnosis for natural medicine I clinical diagnosis for natural medicine II critical reasoning and research methods in natural medicine Examples of electives: clinical examination in natural medicine natural medicine and reproduction natural medicine and the aged research project in natural medicine	400 hours	Entry: govt.-accredited diploma or adv diploma or equivalent. Distance education plus compulsory residential schools	\$5100
University of New England (NSW)	B.Hlth. Science (Naturopathy)	1994	One compulsory subject plus three electives Compulsory: research methods in health Examples of electives: health education and promotion complementary therapies in the healthcare system stress and stress management physiology special topic in human health bioscience issues in human nutrition	No clinical component	Entry: adv. diploma naturopathy from a recognised VET sector partner. All distance education.	HECS – \$5479



University of South Australia (SA)	BHlthSc (Naturopathy)	2004	<p>Must complete 4 of 6 core subjects, 3 naturopathy subjects*, and one elective, e.g.:</p> <ul style="list-style-type: none"> <li>critical enquiry in health practice</li> <li>changing trends in health</li> <li>perspectives in health research</li> <li>evidence based practice</li> <li>*contemporary issues in naturopathic practice</li> <li>*advanced clinical practice in naturopathy</li> <li>*complementary &amp; alternative therapies project</li> </ul> <p>Plus one elective</p>	Will have a clinical component	<p>Entry: adv. diploma naturopathy or diploma naturopathy + 3 yrs equiv. full-time practice</p> <p>New course; not fully developed</p> <p>Flexible delivery; considerable online content</p>	HECS – \$5479
Victoria University (VIC)	BHlthSc (Natural Medicine)	1996	<p>Six compulsory subjects plus a research project:</p> <ul style="list-style-type: none"> <li>philosophical concepts</li> <li>ethical and legal issues</li> <li>research skills</li> <li>developing pharmacological understanding</li> <li>counselling skills for natural medicine practitioners</li> <li>professional writing in natural medicine</li> <li>research project</li> </ul>	No clinical component (unless part of a research project)	Entry: diploma or adv diploma in an area of natural medicine	<p>\$7088 on campus; \$10,764 online.</p> <p>Full fee-paying; no HECS available</p>

## Appendix 5.8 Education providers offering Subjects by Distance Education in Full Undergraduate Programs

Education provider	Course	Number/example of subjects	Comment
Academy of SAFE Therapies (QLD)	AdvDip Naturopathy	14 subjects including: basic sciences, herbal med, clinic	Flexible mode
ACNM Pty Ltd (all five campuses)	BHlthSc (Naturopathy)	First 3 yrs of degree	Clinical experience occurs in fourth year in college clinics
Australasian College of Natural Therapies (NSW)	AdvDip Naturopathy	Some subjects available by distance education	Flexible mode*
Australian Institute of Holistic Medicine	AdvDip Naturopathy AdvDip WHM	Naturopathic philosophy, nutrition	
Gracegrove College (NSW)	AdDip Med Herbalism AdDip WHM	Selected first-year subjects only	
Health Schools Australia (NSW)	AdDip Nat AdDip WHM	Whole courses provided by distance education	Supported by seminars; clinical experience with approved practitioners and in HSA clinics
National College of Traditional Medicine (VIC)	AdDip Naturopathy Dip Herbal Medicine	All subjects except for clinic and massage	Flexible mode*
Nature Care College NSW	AdvDip Naturopathy AdvDip WHM AdvDip Nat (Conv)	Chemistry, anatomy and physiology, nutrition	Flexible mode*
SA Health Education Centre (SA)	AdvDip Nat AdDip WHM	Anatomy and physiology, business development	
University of New England (NSW)	BHSc Naturopathy	Human health sciences 1–4, research methods in health Plus 3 electives: e.g. health education and promotion, complementary therapies in the healthcare system	Offered concurrently with partner provider. The eight UNE subjects can be done by distance education or offered on private provider campus

\* Flexible = subjects available either in-class or distance education; student can choose preferred mode.

## Appendix 5.9 Undergraduate Programs: Course Details and Accreditation

Institution	Course	Contact hrs/wk (full-time)	Normal full-time length (yrs)	Maximum full-time completion	Maximum part-time completion	Accreditation	Association recognition	Cost (AUDS)
Academy of SAFE Therapies	AdDip Naturopathy	20	3	7	6	VET	ANTAsn, AANMP, ANPA	16,800
	AdDip WHM	17	3	7	6	VET	ANTAsn, AANMP, ANPA	15,000
Australasian College of Natural Therapies	AdDip Naturopathy	20	4	4.5	No max.	VET	ATMS, NHAA	28,000
	AdDip WHM	20	2	4.5	No max.	VET	ATMS, NHAA	15,900
ACNM Pty Ltd	BHSc (Naturopathy)	21	4	4	8	Office of Higher Educn (QLD, VIC)	ANTAsn, ATMS, NHAA	28,070
	AdDip Naturopathy	21	3	3	6	VET	ANTAsn, ATMS, NHAA	21,545
	AdDip WHM	18	3	3	6	VET	ANTAsn, ATMS, NHAA	18,405
ACNM Inc. (VIC)	AdDip Naturopathy	12	4	6	6	VET	ANPA, FNTP	18,000
Australian Institute of Holistic Med (WA)	AdDip Naturopathy	18	3	No max.	No max.	VET	ANTAsn, CMA, NHAA	16,000
	AdDip WHM	15	3	No max.	No max.	VET	ANTAsn, CMA, NHAA	12,000
Canberra Institute of Technology	AdDip Naturopathy	23	3	NP	NP	VET	ANTAsn, ATMS, CMA	2,308
Central TAFE (WA)	AdDip Naturopathy	20	3	3	NA	VET	NP	1,010
Dunn's Private College (WA)	AdDip Naturopathy	21	4.5	5	6	VET	None yet	20,600
	AdDip WHM	17	4.5	5	6	VET	None yet	16,400
Gold Coast Institute of TAFE (QLD)	AdDip Naturopathy	22	3	3	6	VET	ANTAsn, ATMS	17,000

### Appendix 5.10 Table of Subjects (postgraduate courses)

Institution	Award	Year commenced	Total contact hours	Subjects (exemplary range)	Total lecture hours	Clinical component	Clinical hours	Entry requirements	Comments	Fees
ACNEM	Grad Cert Nutritional and Environmental Medicine	1982	37	Herbal medicine, nutrition, mind/body (psycho-immunology), environmental medicine, management of selected health disorders	37	No	N/A	Practising recognised health professionals	Designed originally for medical doctors but will accept natural therapists with degree education or equivalent	\$1760
ACCMER	Grad Cert Evidence-Based Comp Medicine	2003	DE	Introduction to CM, evidence-based CM, CM & professional practice, CM therapeutics	DE	No	N/A	Undergraduate degree or approved post-secondary study		Local: 6,800 O'seas: \$13,600
Charles Sturt Uni	M. Health Science Comp. Medicine	2000	All DE	Dissertation, philosophies of complementary medicine, issues of CM, reading in professional practice, research methods in health science, health planning, plus four electives (e.g. clinical judgment and decision making, epidemiology in public health, health promotion & community development, rural health practice)	DE	No	NA	4 year bachelor's degree or equivalent	Credit of 32 points given for 4-yr bachelor's degree or equivalent	\$12,100
University of New England	Grad Dip Health Sc (Herbal	2004	60 res	Foundations of herbal medicine, herbal therapeutics, advanced herbal therapeutics, herbal pharmacy &	60 (1140 nomin	No		Relevant degree or other approved qual,	Articulates into M. Hlth Sci (Herbal	\$8,800

## Appendix 5.11 Clinical Policies and Guidelines

Education provider	Clinic	Dispensing remedies	Management of patients on pharmaceutical drugs	Medical immunisation	Notification of adverse reaction	Incident follow-up	Referrals	First-aid require	First-aid level
AST (QLD)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Level 2
ACNT (NSW)	Yes	Yes	No	No	No	No	No	Yes	Level 2
ACNEM	No: postgrad course only								
ACCMER	No: postgrad course only								
ACNM Pty Ltd. (Brisbane campus)	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Level 2
ACNM Pty Ltd (Gold Coast campus)	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Level 2
ACNM Pty Ltd (Melbourne campus)	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Level 2
ACNM Pty Ltd Box Hill campus)	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Level 2
ACNM Pty Ltd (Perth campus)	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Level 2
ACNM Inc. (VIC)	Yes	Yes	NA	No	Yes	Yes	Yes	Yes	Level 2
AIHM (WA)	Yes	Yes	No	No	Yes	Yes	Yes	No	
CIT, ACT	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Level 2
Central TAFE (WA)	Commencing 2004	TBD	TBD	TBD	TBD	TBD	TBD	yes	Level 1
Charles Sturt University	No: conversion course for practitioners								
Dunn's (WA)	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Level 2
GC TAFE (QLD)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Level 2
Gracegrove (NSW)	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Level 2
HAS (QLD)	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Level 2
I.TAFE (TAS)	Yes	NP	NP	NP	NP	NP	NP	NP	NP
IHC (TAS)	Yes	NP	NP	NP	NP	NP	NP	NP	NP

LTU (VIC)	No: student clinic operated by partner college (see SSNT)								
NCTM (VIC)	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Level 2
NCC (NSW)	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Level 1
PCNM (WA)	Clinic under development	Yes	No	No	Yes	Yes	Yes	Yes	Level 2
SA HEC (SA)	Yes	Yes	Yes	NP	Yes	Yes	Yes	Yes	Level 2
SCU (NSW)	Yes	Yes			Yes	Yes	Yes	Yes	Level 2
SSNT (VIC)	yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Level 2
UN (NSW)	Clinic under development								
UNE (NSW)	No: student clinics operated by partner colleges	NP	No	No	No	NP	No	NP	NP
UniSA (SA)	No: conversion course for practitioners		Under development						
Usyd (NSW)	No: postgraduate course only	NP	No	No	NP	NP	NP	NA	NA
UWS (NSW)	Yes	Yes	No	No	Yes	Yes	Yes	No	
VU (VIC)	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Level 2

Notes:

NA = not applicable

NP= not provided

TBD = to be developed

## Appendix 5.12 Quality Assurance Procedures

<b>Education provider</b>	<b>Advised by course committee</b>	<b>Internal course reviews</b>	<b>External course reviews</b>	<b>Student subject evaluations</b>
Academy of SAFE Therapies (QLD)	Yes	yearly	yearly	each semester
Australasian College of Natural Therapies (NSW)	No	NA	NA	other
Australasian College of Nutritional and Environmental Medicine (VIC)	Yes	5-yearly	never	each semester
Australian Centre for Complementary Medicine Education & Research (QLD)	Yes	quarterly	other	monthly
ACNM Pty Ltd (all campuses)	Yes	yearly	yearly	quarterly
Australian College of Natural Medicine Inc. (VIC)	Yes	yearly	NA	other
Australian Institute of Holistic Medicine (WA)	Yes	NP	NP	NP
Canberra Institute of Technology (ACT)	Yes	semester	yearly	each semester
Central TAFE (WA)	NP	NP	NP	each semester
Charles Sturt University (NSW)	Yes	5-yearly	Never	each semester
Dunn's Private College of Herbalism and Naturopathy (WA)	Yes	ongoing	3-yearly	each semester
Gold Coast Institute of TAFE	Yes	NP	NP	yearly
Gracegrove College (NSW)	Yes	NP	yearly	NP
Health Schools Australia (QLD)	Yes	yearly	yearly	other
Institute of TAFE Tasmania TAS	Yes	NP	NP	NP
Island Health College (TAS)	NP	NP	NP	NP
La Trobe University (VIC)	Yes	biannually	yearly	each semester
National College of Traditional Medicine (VIC)	Yes	2 per annum	NP	NP
Nature Care College (NSW)	Yes	yearly	other	each semester or 2 yearly

Paramount College of Natural Medicine (WA)	Yes	monthly	5-yearly	other
SA Health Education Centre (SA)	NP	NP	other	NP
Southern Cross University (NSW)	Yes	5-yearly	5-yearly	each semester
Southern School of Natural Therapies (VIC)	Yes	annually	5-yearly	each semester
University of Newcastle (NSW)	No	NA	biannually	yearly
University of New England (NSW)	Yes	other	5 yearly	other
University of South Australia (SA)	NP	NP	NP	NP
University of Sydney (NSW)	Yes	as necessary	as necessary	each semester
University of Western Sydney (NSW)	Yes	yearly	yearly	each semester
Victoria University (VIC)	Yes	NA	NA	NA



## Appendix 6.1 Enquiry Form to Naturopathy and Western Herbal Medicine Professional Associations

**N.B. In the interest of conserving space in the Appendices, lines provided on the original questionnaire for responses have been reduced to one.**

### RESEARCH PROJECT ON RISKS, BENEFITS AND REGULATORY REQUIREMENTS FOR THE PRACTICE OF NATUROPATHY AND WESTERN HERBAL MEDICINE (WHM)

#### Enquiry Form to Naturopathy and Western Herbal Medicine Professional Associations

**If you would like the questionnaire emailed to you as a word document please contact one of the researchers listed on the Information Sheet. A hard copy can be downloaded from <http://www.latrobe.edu.au/publichealth/rrrch.htm>**

It would be appreciated if the principal office bearers of associations could advise the research team in each of the areas outlined in the following questionnaire.

Apart from the questionnaire, the research team has requested supply of additional documents on a voluntary basis. If any are provided, please clearly mark documents you wish to remain confidential and indicate if these are to be returned to your organisation. Confidential material should not include documents on the public record, such as an annual report or prospectus. Confidential material will not be provided to individuals, government departments or any other organisation and will be returned at your request, or archived with completed questionnaires according to the processes outlined in the Information Sheet. Whilst a number of items below may not be applicable to all associations, please answer all items of relevance.

***Before proceeding please sign the accompanying Consent Form. Return this with the completed questionnaire and any additional material you wish to provide.***

#### 1. Contact details

DETAILS	PROFESSIONAL ASSOCIATION
Name of Association	
Street Address	
Postal Address ( <i>if different to above</i> )	
Telephone Numbers	
Facsimile Numbers	
Website address	
Name and position of person filling out questionnaire	
His/her e-mail address	

**The Professional Association**

2. (a) How is the organisation established? As a:
- |  |     |                          |    |                          |
|--|-----|--------------------------|----|--------------------------|
| (i) Corporation under the Corporations Act | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| (ii) Incorporated Partnership              | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| (iii) Unincorporated Partnership           | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| (iv) Incorporated Joint Venture            | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| (v) Unincorporated Joint Venture           | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| (iv) Incorporated Association              | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| (vii) Unincorporated Association           | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| (viii) Trust                               | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| (ix) Co-operative                          | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| (x) Not for profit organisation            | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| (xi) Other - please describe               |     |                          |    |                          |

(b) If the organisation is incorporated, in which States or Territories is it incorporated?

---

(c) Is the membership national or state-based? (*tick one box*)

National  State-based

(d) Does the organisation have its own premises/location? (*tick one box*)

Yes  No

(e) How is the Board constituted\*, as identified in the organisation's constitution?

---

(\*A copy of the association's constitution would be appreciated).

(f) Are there regular meetings of the Board? (*tick one box*)

Yes  No

(g) If so, how often? (*tick one box*)

Weekly  Fortnightly  Monthly  Quarterly   
 Half-Yearly  Annually (AGM)  Never  Other

(h) Does the organisation have any paid staff? (*tick one box*)

Yes  No

If yes, please list their positions (e.g. office-bearers, administration/office support, policy writer, journal editor), and the number of staff in each position. If one person has several functions, please apportion fractions under Number of Staff (e.g. librarian 0.5, journal editor 0.5)

POSITION	Number of Staff	POSITION	Number of Staff



- (d) What is the eligibility of the various member groups regarding voting for, or holding, office?  
(Questions (d) and (e) may not need to be answered here if a copy of the organisation's constitution is attached).

<b>CATEGORY OF MEMBERSHIP</b>	<b>ELIGIBLE TO HOLD OFFICE</b> <i>Please circle answer</i>	<b>ELIGIBLE TO VOTE FOR OFFICE BEARERS</b> <i>Please circle answer</i>
Fellows	Yes / No	Yes / No
Full members	Yes / No	Yes / No
Student members	Yes / No	Yes / No
Associate/friends	Yes / No	Yes / No
Corporate members	Yes / No	Yes / No
Other	Yes / No	Yes / No
	Yes / No	Yes / No

- (e) Please briefly describe the process the organisation uses for:

(i) Election of office bearers

---

(ii) Changes to the constitution

---

(iii) Decisions on important association issues

---

- (f) What is the distribution of naturopathy/WHM members by States and Territories?

<b>STATES/TERRITORIES</b>	<b>NUMBER OF NATUROPATHS</b>	<b>NUMBER OF WHM PRACTITIONERS</b>
A.C.T.		
New South Wales		
Northern Territory		
Queensland		
South Australia		
Tasmania		
Victoria		
Western Australia		

- (g) What are the annual membership fees for the following categories:

<b>MEMBERSHIP STATUS</b>	<b>MEMBERSHIP FEES</b>
Full member	
Student member	

- (h) Are you aware of any members who are currently practising overseas? (*tick one box*)

Yes

↑

No

↑

- (i) If yes, please estimate number
    - (i) Naturopaths \_\_\_\_\_
    - (ii) WHM practitioners \_\_\_\_\_
    - (iii) In what countries are they practising?
- 

(j) Does the organisation regularly schedule meetings of members? (*tick one box*)

Yes	↑	No	↑
If so, how often? ( <i>tick one box</i> )			
Weekly	↑	Fortnightly	↑
Monthly	↑	Quarterly	↑
Half-Yearly	↑	Annually (AGM)	↑
		Never	↑
		Other	↑

**Qualifications**

7. (a) What are the organisation’s methods for accrediting Australian-trained naturopathy/WHM applicants?

---

(b) How many members have overseas naturopathy or WHM qualifications?

\_\_\_\_\_

(c) How were any overseas qualifications assessed to determine eligibility for accreditation?

---

**Policies and procedures**

N.B. The researchers would welcome copies of any of the following documents. Please clearly mark as 'Confidential' those that are not on the public record. Confidential documents will only be accessed by the three researchers listed at the bottom of the Information Sheet and will not be provided to any individuals, government departments or any other organisation. Any information used from these documents will be generalised in the final report so that the sources of the original documents and data will not be disclosed. Confidential documents will be returned at your request, or archived according to the processes outlined in the Information Sheet.

8. (a) Does the organisation have a code of ethics and/or a code of professional conduct of members? (*tick one box*)

Yes	↑	No	↑
-----	---	----	---

(b) Does the organisation have written guidelines for practitioners on:

(i) When and how to make suitable referrals to medical practitioners? (*tick one box*)

Yes	↑	No	↑
-----	---	----	---

(ii) Collection of details of accidents, injuries or adverse events resulting from practice by members? *(tick one box)*

Yes  No

(iii) The use of herbs restricted or scheduled under the Drugs and Poisons legislation? *(tick one box)*

Yes  No

(iv) Medical immunisation? *(tick one box)*

Yes  No

(v) Practice requirements such as dispensary setup, dispensing practices, or manufacture by practitioners of their own remedies as allowed under TGA regulations? *(tick one box)*

Yes  No

If yes, please list the various guidelines available under (v)

---

(c) Does the organisation have:

(i) A procedure for dealing with complaints? *(tick one box)*

Yes  No

(ii) A procedure for collecting data on accidents, injuries or adverse events resulting from practice by members? *(tick one box)*

Yes  No

If Yes for (ii), in what form is the data collected and what is it used for?

---

(iii) A requirement that members hold professional indemnity insurance? *(tick one box)*

Yes  No

(iv) A requirement that members hold a current first aid certificate *(tick one box)*

Yes  No

If yes, what level of first aid certificate is required?

---

(v) A policy concerning continuing professional education and recency of practice? *(tick one box)*

Yes  No

(d) Does the organisation conduct a course accreditation process for courses that train naturopaths and WHM practitioners for entry to these professions? *(tick one box)*

Yes  No

If yes, please briefly described the process of accreditation:

---

9. (a) Does the organisation have an agreed position or policy in relation to:  
*N.B. Further comment on regulation can be made in Question 13.*
- (i) continuing self-regulation by the profession for naturopathy (*tick one box*)  
 Yes  No
- (ii) continuing self-regulation by the profession for WHM (*tick one box*)  
 Yes  No
- (iii) State government registration of practitioners of naturopathy (*tick one box*)  
 Yes  No
- (iv) State government registration of practitioners of WHM. (*tick one box*)  
 Yes  No
- (v) Does the organisation have a different option to any of the above?  
 Yes  No

If 'yes' to any of the above, please describe or provide an attachment.

- 
- (b) Has the organisation made any submissions to government relevant to naturopathy and/or WHM in the last five years? (*tick one box*)  
 Yes  No

If yes, please list titles of any submission/s and advise if/where the researchers could locate them.

---

### Complaints mechanisms

*N.B. Due to privacy considerations, responses to questions (a) and (b) will be collated on an aggregate basis, that is, no individual association will be identified as the source of any information.*

10. (a) If the organisation has a complaints procedure, please indicate the nature and number of any complaints received in the last five years, and whether made against a naturopath or WHM practitioner. *Definitions of the complaints categories are derived from the Health Services Commissioner Annual Report 2002-3*

CATEGORY OF COMPLAINT	NO. OF COMPLAINTS AGAINST NATUROPATHS	NO. OF COMPLAINTS AGAINST WHM PRACTITIONERS
<b>Access:</b> refers to the availability of services in terms of location, waiting times and other constraints that limit use of the service	1998: 1999: 2000: 2001: 2002:	1998: 1999: 2000: 2001: 2002:
<b>Treatment:</b> refers to diagnosis, testing, medication and other therapies provided	1998: 1999: 2000: 2001: 2002:	1998: 1999: 2000: 2001: 2002:
<b>Communication:</b> refers to the manner of communication such as rudeness, disinterest, quality and quantity of information provided about treatment, risks and outcomes and prognosis	1998: 1999: 2000: 2001: 2002:	1998: 1999: 2000: 2001: 2002:
<b>Cost:</b> refers to information about costs and fees, discrepancies between advertised and actual costs, charges and rebates	1998: 1999: 2000: 2001: 2002:	1998: 1999: 2000: 2001: 2002:
<b>Rights:</b> refers to rights to privacy and dignity, consent to treatment, reasonable access to records	1998: 1999: 2000: 2001: 2002:	1998: 1999: 2000: 2001: 2002:
<b>Administration:</b> refers to support services for providers such as reception, waiting lists, cleaning services, etc.	1998: 1999: 2000: 2001: 2002:	1998: 1999: 2000: 2001: 2002:

(b) As a result of any complaints, please indicate outcomes as follows:

MEMBER OUTCOME	NUMBER OF NATUROPATHS	NUMBER OF WHM PRACTITIONERS
Cautioned		
Reprimanded		
Counselled		
Membership suspended		
Membership withdrawn		
Cleared (complaint/s not upheld)		
Other (briefly describe)		

(c) Does the organisation have insurance to provide for the cost of legal expenses incurred as a result of complaints? (tick one box)

Yes

No



11. Is the organisation affiliated with, or connected to:
- (a) Other representative naturopathy/natural therapy/WHM professional or accrediting organisations? *(If yes, please indicate name of organisation(s) and nature of affiliation, or attach list)*
- 
- (b) Naturopathy and/or WHM teaching institutions? *(If yes, please indicate name of organisation and nature of affiliation, or attach list)*
- 
- (c) Any other types of organisations or bodies? (e.g. government organisations, manufacturers) *(If yes, please indicate name of organisation and nature of affiliation, or attach list)*
- 

**Benefits to members**

12. (a) Does the organisation publish, or is it associated with a group which publishes, any periodical covering naturopathy and/or WHM topics? *(tick one box)*

Yes  No

If yes:

- (i) Please provide the name of the publication(s)
- 

- (ii) Which, if any, of the publications is peer-reviewed?
- 

- (iii) How often is it/are they published?
- 

*A copy of the latest issue of each publication would be appreciated.*

- (b) How does the organisation facilitate dialogue with members? e.g. website, email, newsletter, phone advisory service
- 

- (c) Does the organisation conduct regular seminars or conferences on topics relevant to naturopathy and/or WHM? *(tick one box)*

Yes  No

If yes, please provide details as follows:

**Seminars:** *(defined as an event where the organisation provides all speakers/materials)*

SEMINAR TITLE (2002 Only)	LOCATION (City)

**Conferences:** (defined as an event where the organisation invites submission of papers)

YEAR	CONFERENCE TITLE	LOCATION (City)
2000		
2001		
2002		

- (d) Were any of the above conferences: (tick one box)
- (i) National (*Call for abstracts and participants national only*)  
 Yes  No
- (ii) International (*International call for abstracts and participants*)  
 Yes  No
- (e) Does the organisation have a library of professional texts and/journals relevant to naturopathy and/or WHM that can be accessed by members? (tick one box)  
 Yes  No
- (f) Is the organisation listed by the Therapeutic Goods Administration as a Schedule 1 Association? (tick one box)  
 Yes  No
- (g) Does the organisation have a private ruling from the Australian Tax Office as a 'recognised professional association'?  
 Yes  No
- (h) Is the organisation a member of the Complementary Medicine Practitioner Associations Council (CMPAC)?  
 Yes  No
- (i) Is the organisation accredited by any health insurance providers so that clients of naturopathy and/or WHM members can obtain rebates for consultations? (tick one box)  
 Yes  No

If yes, please list or attach list of current accrediting health funds

---

### Open-ended questions

*This section of the questionnaire makes provision for organisations to express concerns or perspectives on a range of issues that may be of current concern. If there is insufficient space below, please include an attachment.*

13. Does the organisation have any further comment on the issue of regulation?

---

14. Are there any concerns regarding access to medicines by practitioners?

---

15. Are there any current educational issues (e.g. undergraduate, postgraduate, continuing professional education) relating to naturopathy and/or WHM that are causing, or are expected to cause, concern?

---

16. Are there any other political, governmental or legal issues relating to naturopathy and/or WHM that are causing, or are expected to cause, concern?

---

17. Has the organisation experienced any difficulties in dealing with or adequately addressing complaints? (*Please indicate the nature of any problems experienced*)

---

18. What does the organisation see as the future of naturopathy and/or WHM?

---

19. Please provide any other comments that you consider pertinent to the review.

---

If you have any questions regarding the questionnaire please do not hesitate to contact one of the researchers listed at the bottom of the Information Sheet. Please return the questionnaire by **5<sup>th</sup> December, 2003** and any documents in the enclosed pre-paid, self-addressed envelope to the investigator at the address below. If supply of extra documents requires additional postage, please contact one of the researchers on the Information Sheet to arrange reimbursement. On behalf of the research team I thank you for taking the time to participate in this important national survey.

**Dr Pauline McCabe**  
**Senior Lecturer in Naturopathy,**  
**School of Nursing and Midwifery**  
**La Trobe University**  
**Bundoora, Vic. 3086**

## Appendix 6.2 Structure and Administration of Participating Professional Associations

Association	Incorporated	Membership base	Board elected by members	Frequency of board meetings	Members can vote on changes to constitution	Members consulted on important issues
Alumni Association of Natural Medicine Practitioners (AANMP)	QLD	National	Yes	Quarterly	Yes	Yes
Australian Association of Homotoxicology (AAH)	SA	National	Yes	Monthly	Yes	Yes
Australian College of Nutritional and Environmental Medicine (ACNEM)	VIC	National	Yes	Quarterly	Yes	Yes
Australian Committee of Natural Therapies (ACONT)	SA	National	Yes	Quarterly	Yes	Yes
Australian Complementary Health Association (ACHA)	VIC	National	Yes	Monthly	Yes	No
Australasian Federation of Natural Therapists (AFNT)	WA	National	Yes	Monthly	Yes	Yes
Australasian Integrative Medicine Association (AIMA)	VIC	National	Yes	Annually	Yes	Yes
Australian Naturopathic Practitioners Association (ANPA)	VIC	National	Yes	Other	Yes	Yes
Australian Natural Therapists Association (ANTAsn)	QLD	National	Yes	Quarterly	Yes	Yes
Australian Traditional-Medicine Society (ATMS)	All states	National	No	Quarterly	Yes	Yes
Complementary Medicine Association (CMA)	All States	National	Yes	Quarterly	Yes	Yes
Federation of Natural and Traditional Therapists (FNTT)	SA	National	Yes	Quarterly	Yes	Yes
National Herbalists Association of Australia (NHAA)	NSW	National	Yes	3/year (and as required)	Yes	Yes
Society of Natural Therapists and Researchers (SNTR)	QLD	National	Yes	Monthly	Yes	Yes

Note: NP = not provided

## Appendix 6.3 Members Eligible to Hold Office and to Vote for Office Bearers

	Fellows		Full members		Associates		Students		Corporate members	
	Can hold office	Can vote for office bearers	Can hold office	Can vote for office bearers	Can hold office	Can vote for office bearers	Can hold office	Can vote for office bearers	Can hold office	Can vote for office bearers
AANMP	Yes	Yes	Yes	Yes	No	No	No	Yes	No	No
AAH	N/A	N/A	Yes	Yes	No	No	No	No	No	No
ACNEM	Yes	Yes	Yes	Yes	No	No	No	No	No	No
ACONT	N/A	N/A	Yes	Yes	N/A	N/A	Yes	Yes	Yes	Yes
ACHA	N/A	N/A	Yes	Yes	N/A	N/A	N/A	N/A	Yes	Yes
AFNT	N/A	N/A	Yes	Yes	Yes	Yes	No	Yes	N/A	N/A
AIMA	N/A	N/A	Yes	Yes	No	No	No	Yes	No	No
ANPA	N/A	N/A	Yes	Yes	N/A	N/A	No	No	N/A	N/A
ANTASN	Yes	Yes	Yes	Yes	No	No	No	No	No	N/A
ATMS	N/A	N/A	No	No	N/A	N/A	No	No	N/A	N/A
CMA	Yes	Yes	Yes	Yes	No	No	No	No	N/A	N/A
FNTT	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
NHAA	Yes	Yes	Yes	Yes	No	No	No	No	No	No
SNTR	Yes	Yes	Yes	Yes	No	No	No	No	No	No

N/A = membership category not available.

## Appendix 6.4 Membership Numbers and Requirements for Accreditation

Association	Total number of members*	Accredits naturopaths for practice	Number of accredited naturopaths	Accredits Western herbalists for practice	Number of accredited Western herbalists	Number accredited in both naturopathy & WHM	Requirements for accreditation to practice	Accredits naturopathy and WHM courses	Process for accreditation of courses
AANMP	612	Yes	192	Yes	NP		Advanced diploma plus individual consideration. Challenge test by senior members if required.	Yes	Review of content, legal standing, past performance
AAH	350	Yes	300	No	N/A	0	Diploma	No	
ACNEM	1140	No	N/A	No	N/A	N/A	N/A	No	N/A
ACONT	60	Yes	16	No	N/A	N/A	Applicants assessed individually, must meet standards and levels of practice set out in Health & Aged Care competencies	No	N/A
ACHA	800	No	N/A	No	N/A	N/A	N/A	No	N/A
AFNT	280	Yes		Yes		30	Diploma or advanced diploma	No	N/A
AIMA	350	No	N/A	No	N/A	N/A	N/A	No	N/A
ANPA	487	Yes	487	No	0	0	Advanced diploma of naturopathy	Yes	Advanced diploma. Others may submit curriculum and other documents for formal assessment.
ANTAsn	2300	Yes	1006	Yes	421	339	Advanced diploma from an ANTAsn recognised course	Yes	Advanced diploma; application assessed by ANTAsn academic committee with review and decision by ANTAsn national council.

ATMS	9163	Yes	1932	Yes	1067		Graduates from ATMS-recognised colleges and courses	Yes	Courses must be at Diploma or Advanced Diploma level and meet the ANTAu competency standards. Accreditation provisional for first three years.
CMA	NP	Yes	NP	No			Diploma of naturopathy	No	
FNTT	2000	Yes	1030	Yes	400		Member associations set accreditation criteria.	No	
NHAA	1551	Yes, if meet herbal medicine and nutrition requirements		Yes	823		Graduates of NHAA accredited advanced diploma courses Others: point system based on full course details, evidence of at least 5 yrs clinical practice, and proof that CPE maintained	Yes	Standard raised to advanced diploma in June 2003 All courses currently accredited being reassessed Applications are evaluated by NHAA examiners
SNTR	132	Yes	54	Yes	9		Diploma level from accredited college or a govt. accredited course	Yes	Course content measured against industry standards

Notes:

\*Number of members includes all practitioner types plus associates and students, not just naturopaths and WHMs

NP= not provided

## Appendix 6.5 Categories of Membership and Requirements for Admission

Association	Fellow	Full member	Associate member	Student member
AANMP	Advanced diploma / bachelor's degree; 5 years practice	Advanced diploma	No qualifications required	Proof of enrolment
AAH	N/A	Government accredited diploma	NP	NP
ACNEM	N/A	MB,BS	Natural therapists must have a bachelor's degree or ACNEM training.	N/A
ACONT	N/A	Appropriate qualifications and accreditation standards	N/A	N/A
ACHA	N/A	Members of the public and natural therapists who support ACHA's aims	N/A	N/A
AFNT	N/A	Diploma or advanced diploma	N/A	Proof of enrolment
AIMA	N/A	Legally qualified and registered medical practitioners who are involved in the practice and teaching of integrated medicine	Members of the public and natural therapists	Member of a medical students' society
ANPA	N/A	Government accredited advanced diploma of naturopathy	N/A	Bona fide student of naturopathy
ANTAsn	Bachelor's degree from an ANTAsn-recognised course	Advanced diploma from an ANTAsn recognised course	Not available for naturopaths and WHM practitioners	Proof of enrolment
ATMS	N/A	Diploma from an ATMS accredited course (will require advanced diploma from 2004)	No qualifications required (non-practitioner)	Proof on enrolment in an ATMS accredited course
CMA	Full member who has provided some outstanding service to the association or profession	Government accredited diploma of naturopathy	No qualifications required	Proof of enrolment in a government accredited diploma of naturopathy
FNTT#	N/A	Member associations must have an acceptable code of ethics and membership requirement that satisfies competency-based standards (ANTAu)	N/A	N/A



NHAA	More than ten years in practice and exceptional service to the profession	Graduate of NHAA advanced diploma accredited course, or evidence of qualifications and practice. Working towards bachelor's degree as minimum requirement.	N/A	Currently undertaking studies in medical herbalism
SNTR	Fellowship: associate diploma Senior fellowship: diploma Honorary research fellowship: master's or doctorate Senior research fellowship: diploma degree and minimum of 5 years clinical practice	Completion of an acceptable course of study	Natural health practitioner	Proof of enrolment at approved teaching establishment

Notes:

N/A = not applicable

NP = not provided

## Appendix 6.6 Professional Association Fees and Professional Requirements of Full Members

Association	Full member fees	Student fees	Adherence to code of ethics	Professional-indemnity insurance	First-aid certificate	Continuing professional education
AANMP	200	50	Yes	Yes	St John's certificate	Yes
AAH	50	50	Yes	Yes	Level 1	Yes
ACNEM	220	N/A	Yes	Yes	No	N/A
ACONT	150	52	Yes	Yes	Yes	No
ACHA	55	44	N/A	N/A	N/A	N/A
AFNT	120	30	Yes	Yes	Level 2 Senior	Yes
AIMA	120	33	Yes	Yes	No	No
ANPA	300	40	Yes	Yes	Level 2	No
ANTAsn	300	free	Yes	Yes	Level 2 Senior	Yes
ATMS	130	20	Yes	Yes	Level 2 Senior	Yes
CMA	220	33	Yes	Yes	Level 2 Senior	Yes
FNTT	N/A*	N/A	Yes*	Yes	Level 2	Yes
NHAA	220	55	Yes	Yes	Level 2 Senior	Yes
SNTR	300	10	Yes	Yes	Level 1 Basic	No

*Notes:*

All fees expressed in Australian dollars (AUD\$)

\*FNTT levies a fee on member associations based on membership numbers. It requires that its member associations have a professional code of ethics.

## Appendix 6.7 Professional Association Guidelines for Practitioners

Association	Referral to medical practitioners	Accidents, injuries, and adverse events	Use of scheduled or restricted herbs	Medical immunisation	Practice guidelines
AANMP	Yes	No	Yes	No	No
AAH	No	No	No	No	No
ACNEM	N/A	N/A	N/A	N/A	N/A
ACONT	No	No	No	No	No
ACHA	N/A	N/A	N/A	N/A	N/A
AFNT	No	No	No	No	No
AIMA	N/A	No	No	No	No
ANPA	Yes	No	No	No	No
ANTAsn	Yes	Yes	Yes	No	Yes
ATMS	Yes	Yes	No	No	No
CMA	Yes	Yes	Yes	No	Yes
FNTT	N/A	N/A	N/A	N/A	N/A
NHAA	Yes	No	Yes	No	Yes
SNTR	No	No	No	No	No

N/A = not applicable

## Appendix 6.8 Seminars Provided by Professional Associations in 2002

Seminar title	Location
<b>ACNEM</b> Nutrition and environmental medicine (5 days) Sports nutrition (2 days) Pain and inflammation Multiple chemical sensitivities Women's health Cancer treatment	Melbourne & Perth Melbourne Melbourne Byron Bay Perth Perth
<b>AIMA</b> Upskill days in complementary medicine	Various (Australia)
<b>ATMS</b> March: Multidisciplinary April: Massage April: Massage May: Massage May: Multidisciplinary May: Massage June: Massage June: Massage June: Multidisciplinary August: Massage: Arthritis September: Massage: Sciatica October: Multidisciplinary October: Massage: Sciatica November: Massage: Sciatica November: Herbal Medicine November: Multidisciplinary December: Multidisciplinary	Adelaide Coffs Harbour Newcastle Blue Mountains Gold Coast Newcastle Brisbane Sunshine Coast Adelaide Dubbo Dubbo Adelaide Canberra Central Coast NSW Sydney Perth Cairns
<b>SNTR</b> Naturopath's guide to natural HRT	Sydney
<b>NHAA</b> Women in health	Melbourne, Hobart, Perth, Adelaide, Brisbane, Sydney

## Appendix 6.9 Conferences Held in Australia 2000–2002

Year	Conference title	Location
2000	ACHA 'Other Healers': 150 years of Complementary Medicine in Victoria (Exhibition)	Melbourne (VIC): Medical History Museum, Melbourne Uni.
2000	AIMA 6th Holistic Health Conference (convened by Monash Institute of Health Services Research in conjunction with AIMA)	Lorne (VIC)
2001	AIMA 7th Annual Holistic Health Conference	Lorne (VIC)
2001	NHAA 4th International Conference on Phytotherapeutics	Sydney (NSW)
2002	AIMA 8th Annual Holistic Health Conference	NSW

## Appendix 6.10 Professional Association Policies and Procedures

Association	Complaints procedure	Insurance for legal costs due to complaints	Collects data on accidents, injuries, adverse events	Manner of collecting data	Purpose of data
AANMP	Yes	No	Yes	Not answered	Indemnity-insurance claims
AAH	Yes	N/P	No	N/A	N/A
ACNEM	Yes	No	No	N/A	N/A
ACONT	Yes	Yes	Not answered	Not answered	Not answered
ACHA	N/A	N/A	N/A	N/A	N/A
AFNT	Yes	Yes	Not answered	Not answered	Not answered
AIMA	Yes	No	No	N/A	N/A
ANPA	Yes	Yes	No	N/A	N/A
ANTAsn	Yes	Yes	Yes	By surveys	To assist association, governments, public, practitioners and other industry organisations in analysis and decision-making.
ATMS	Yes	Yes	Not answered	Not answered	Not answered
CMA	Yes	Yes	Yes	Complaints-based	To assist in complaints process.
FNTT	Yes	No	No	N/A	N/A
NHAA	Yes	No	No	N/A	N/A
SNTR	Yes	No	Yes	N/A	Independent committee investigates

N/A = not applicable

# Appendix 7.1 Outline of Wentworth Area Health Service's 'Complementary Medicine/Therapy Policy and Procedures'

## Executive Summary

### Introduction

- Definitions
- Principles
- Clinical Governance
- Procedure Development
- Credentialing: External practitioners complementary Health
- Management of a complaint/concern about a complementary health practitioner

### Complementary Medicines (CM) and Complementary Therapies (CT)

- Quality, safety and efficacy of CM
- Medication/Treatment History
- Therapeutic choice
- Documentation
- Supply of CM
- Storage of CM
- Discharge
- Patient's acknowledgement
- Adverse drug reaction reporting

### Procedures for Use of CM/CT

- Staff initiated use of CM and/or CT in Wentworth Area Health Service (WAHS) facilities
- Staff initiated aromatherapy
- Criteria for recognition of clinical staff who can initiate CM/CT
- Staff initiated use of an external complementary health practitioner (CHP) of CM/CT
- Patient initiated use of CM/CT - approved by the attending medical officer
- Patient request for treatment by a CHP in hospital
- Patient initiated use of CM/CT - Not approved by the attending medical officer

### Community Health Services

- Introduction
- Request for information or discussion on CM/CT
- Use of CM/CT by the client - Without the doctor's knowledge or against his/her advice
- Use of CM/CT whilst refusing conventional medicine.

### Appendices

- Request form for CHP to tend an inpatient
- Application for CHP's temporary appointment to WAHS
- Part 1: Process for credentialing, appointment and performance review of a CHP  
Part 2: Management of a complaint or concern about a clinician
- WAHS Clinical Governance Policy and Clinicians Toolkit
- Medication form for self/relative administration of CM remedies
- Disclosure of Risk Guidelines, Australian Professional Liability - Medical (CCH Australia Ltd 2000). (Re providing information to patients).
- Duties of a medical officer.

Source: Wentworth Area Health Service, Penrith NSW, 2004

## Appendix 7.2 Guidelines for the Use of Complementary Medicines and Therapies in Hospitals

- All hospital clinical staff and general practitioners should ask patients about their use of complementary medicines and this use should be documented in medical records and care plans.
- Complementary medicine use in hospitals should be recorded on the medication chart and included in discharge summaries.
- Adequate training is required to ensure hospital staff members have the appropriate skills to advise patients about complementary medicine use, and appropriate resources should be available and able to be accessed by all staff members.
- Hospitals should appoint a dedicated staff member, ideally with both mainstream and CAM qualifications, to take a leadership role in regard to maintaining and disseminating information about complementary medicine use. Communication with patients may also be part of this person's role.
- Where appropriate, hospital staff should communicate with patients' usual healthcare practitioners including naturopaths and herbalists on admission and discharge.
- In cases where patients want to continue or initiate use of complementary medicine in hospital, they should have access to a suitably trained practitioner able to ensure their needs are met in a safe and appropriate way.
- Clinical staff practicing CAM in hospitals should ensure that they have appropriate qualifications in the CAM therapy and adequate professional indemnity insurance, and that they practice collaboratively. Staff members are referred to guidelines produced by their registration board and professional associations.

### Reference

Cohen, M. & Braun, L. 2004, 'Towards the evidence-based integration of complementary medicines into hospital settings', *Evidence-Based Integrative Medicine*, vol. 1, no. 4, pp. 241-244.



# Appendix 8.1 Complementary Therapies and the Medical Profession: a Survey for General Practitioners

15. Are you aware of the following professional associations or colleges providing education/support to doctors on complementary therapies?

	NOT AWARE OF	AWARE OF BUT NO INVOLVEMENT	PAST OR CURRENT INVOLVEMENT
i) Australasian Integrative Medicine Association (AIMA)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ii) Australian College of Nutritional and Environmental Medicine (ACNEM)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
iii) Australian Medical Acupuncture College (AMAC)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
iv) Other _____ <i>(please specify)</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

16. If you have any other comments, please add them here:

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17. Demographic data. Your responses to these questions are strictly confidential. Only pooled data will be used for analysis.

Age:  25 - 34     35 - 44     45 - 54     55 - 64     >65

Sex:  Male     Female

Year of Graduation \_\_\_\_\_    Years in General Practice \_\_\_\_\_

Main type of practice:  Solo GP     Group  
 Full-time     Part-time    →    No. of sessions \_\_\_\_\_

Average number of patients seen each week:

<50     51-100     101-150     151-200     >200

Location of main practice:  Urban     Rural

Additional qualifications:  FRACGP     Diploma RACOG  
 Other *(please specify)* \_\_\_\_\_

Please put the survey in the **Reply Paid envelope** and return it to the address below.  
 Complementary Therapies Survey  
 School of Health Sciences  
 RMIT University  
 PO Box 71 Bundoora 3083

Thank you very much for your time and assistance.



## Complementary Therapies and the Medical Profession

A Survey for General Practitioners

### Complementary Therapies Survey

School of Health Sciences  
 RMIT University  
 PO Box 71  
 Bundoora West VIC 3083

This survey has been approved by the Human Research Ethics Committee at RMIT University, 2004.  
 This survey has been sponsored by the Victorian Department of Human Services and supported by the Health Insurance Commission.

1. Indicate your opinion of the potential effectiveness of the following complementary therapies by ticking one of the following categories:

	NO OPINION 1	NOT EFFECTIVE 2	SELDOM EFFECTIVE 3	MODERATELY EFFECTIVE 4	HIGHLY EFFECTIVE 5
a) Acupuncture	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Aromatherapy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) Chinese Herbal Medicine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) Chiropractic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e) Herbal Medicine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f) Homeopathy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g) Hypnosis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h) Massage	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i) Meditation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j) Naturopathy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
k) Osteopathy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
l) Reflexology	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
m) Spiritual Healing e.g. Reiki	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
n) Vitamin and Mineral Therapy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
o) Yoga	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
p) Other _____ <i>(please specify)</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Comments**

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2. Indicate your opinion of the potential harmfulness of the following complementary therapies by ticking one of the following categories:

	NO OPINION 1	NOT HARMFUL 2	SELDOM HARMFUL 3	OCCASIONALLY HARMFUL 4	FREQUENTLY HARMFUL 5
a) Acupuncture	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Aromatherapy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) Chinese Herbal Medicine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) Chiropractic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e) Herbal Medicine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f) Homeopathy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g) Hypnosis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h) Massage	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i) Meditation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j) Naturopathy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
k) Osteopathy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
l) Reflexology	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
m) Spiritual Healing e.g. Reiki	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
n) Vitamin and Mineral Therapy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
o) Yoga	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
p) Other _____ <i>(please specify)</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Comments**

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3. Please indicate your response to the following questions for each type of complementary therapy:  
 i) In your opinion, is it appropriate for GPs to practise the following therapies?  
 ii) Should GPs be eligible for Medicare rebates when practising these therapies?

	i) APPROPRIATENESS		ii) MEDICARE REBATES		
	DON'T KNOW 1	NO 2	YES, IF TRAINED 3	YES, IF TRAINED 1	NO 2
a) Acupuncture	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	<input type="checkbox"/>	<input type="checkbox"/>
b) Aromatherapy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	<input type="checkbox"/>	<input type="checkbox"/>
c) Chinese Herbal Medicine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	<input type="checkbox"/>	<input type="checkbox"/>
d) Chiropractic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	<input type="checkbox"/>	<input type="checkbox"/>
e) Herbal Medicine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	<input type="checkbox"/>	<input type="checkbox"/>
f) Homeopathy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	<input type="checkbox"/>	<input type="checkbox"/>
g) Hypnosis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	<input type="checkbox"/>	<input type="checkbox"/>
h) Massage	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	<input type="checkbox"/>	<input type="checkbox"/>
i) Meditation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	<input type="checkbox"/>	<input type="checkbox"/>
j) Naturopathy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	<input type="checkbox"/>	<input type="checkbox"/>
k) Osteopathy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	<input type="checkbox"/>	<input type="checkbox"/>
l) Reflexology	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	<input type="checkbox"/>	<input type="checkbox"/>
m) Spiritual Healing e.g. Reiki	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	<input type="checkbox"/>	<input type="checkbox"/>
n) Vitamin and Mineral Therapy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	<input type="checkbox"/>	<input type="checkbox"/>
o) Yoga	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	<input type="checkbox"/>	<input type="checkbox"/>
p) Other _____ <i>(please specify)</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	<input type="checkbox"/>	<input type="checkbox"/>

Comments

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4. (a) If one of your patients asked you whether they should use, or consult a practitioner of one of the following therapies how would you respond?  
 (b) Do you think it is appropriate for the Government to regulate/register non medically qualified practitioners of complementary therapies?

	(a) NOT CONFIDENT TO DISCUSS THE ADVANTAGES AND DIS- ADVANTAGES WITH PATIENTS 1	(a) ACTIVELY DISCOURAGE 2	(a) NEITHER ENCOURAGE NOR DISCOURAGE 3	(a) ACTIVELY ENCOURAGE 4	(b) UNSURE ABOUT GOVERNMENT REGULATION 5	(b) GOVERNMENT SHOULD REGULATE 6	(b) GOVERNMENT SHOULD NOT REGULATE 7
	a) Acupuncture	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Aromatherapy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) Chinese Herbal Medicine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) Chiropractic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e) Herbal Medicine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f) Homeopathy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g) Hypnosis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h) Massage	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i) Meditation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j) Naturopathy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
k) Osteopathy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
l) Reflexology	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
m) Spiritual Healing e.g. Reiki	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
n) Vitamin and Mineral Therapy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
o) Yoga	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
p) Other _____ <i>(please specify)</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments

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**5. In the past year how often have you suggested/referred a patient to consult a practitioner of the following therapies?**

	NEVER 1	A FEW TIMES 2	AT LEAST MONTHLY 3	AT LEAST WEEKLY 4	AT LEAST DAILY 5
a) Acupuncture	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Aromatherapy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) Chinese Herbal Medicine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) Chiropractic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e) Herbal Medicine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f) Homeopathy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g) Hypnosis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h) Massage	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i) Meditation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j) Naturopathy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
k) Osteopathy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
l) Reflexology	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
m) Spiritual Healing e.g. Reiki	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
n) Vitamin and Mineral Therapy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
o) Yoga	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
p) Other _____ (please specify)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**If you refer patients for these therapies, do you distinguish between medical and non-medical practitioners? (please tick)**

- I only refer to medically trained practitioners
- I refer to both medically and non-medically trained practitioners
- I only refer to non-medically trained practitioners

**Why?**  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**6. Have you received, or considered receiving, treatment yourself with any of the following therapies?  
Have you practised or considered practising, any of the following therapies?**

	WOULD NOT CONSIDER receiving or practising 1	WOULD CONSIDER receiving treatment 2	HAVE RECEIVED treatment in the last 12 months 3	WOULD CONSIDER practising 4	HAVE PRACTISED in past 12 months 5
a) Acupuncture	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Aromatherapy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) Chinese Herbal Medicine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) Chiropractic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e) Herbal Medicine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f) Homeopathy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g) Hypnosis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h) Massage	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i) Meditation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j) Naturopathy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
k) Osteopathy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
l) Reflexology	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
m) Spiritual Healing e.g. Reiki	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
n) Vitamin and Mineral Therapy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
o) Yoga	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
p) Other _____ (please specify)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Have you personally taken any vitamin, mineral, herbal or other supplement in the past 4 weeks?  
If so please list them.**

\_\_\_\_\_  
\_\_\_\_\_

**Do you use any complementary medicine technologies in your practice: (for example electro-acupuncture stimulators, lasers or other devices)? If so please specify.**

\_\_\_\_\_

**7. Please indicate what training you have previously undertaken in the therapies listed below:**

	NIL 1	SELF TAUGHT 2	INTRODUCTORY WORKSHOP 3	CERTIFICATE COURSE 4	DIPLOMA COURSE 5	DEGREE COURSE 6
a) Acupuncture	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Aromatherapy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) Chinese Herbal Medicine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) Chiropractic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e) Herbal Medicine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f) Homeopathy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g) Hypnosis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h) Massage	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i) Meditation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j) Naturopathy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
k) Osteopathy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
l) Reflexology	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
m) Spiritual Healing e.g. Reiki	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
n) Vitamin and Mineral Therapy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
o) Yoga	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
p) Other _____ <i>(please specify)</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Please list any formal qualifications received and where they were obtained.**

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**8. Please indicate your interest in receiving different levels of training in the therapies listed below: (tick as many boxes as appropriate)**

	NO INTEREST 1	INTRODUCTORY WORKSHOP 2	CERTIFICATE COURSE 3	DIPLOMA COURSE 4	DEGREE COURSE 5
a) Acupuncture	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Aromatherapy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) Chinese Herbal Medicine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) Chiropractic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e) Herbal Medicine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f) Homeopathy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g) Hypnosis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h) Massage	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i) Meditation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j) Naturopathy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
k) Osteopathy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
l) Reflexology	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
m) Spiritual Healing e.g. Reiki	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
n) Vitamin and Mineral Therapy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
o) Yoga	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
p) Other _____ <i>(please specify)</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Comments**

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**9. In the past 4 weeks how many patients have you seen in your practice who have experienced the following:**

\*NOTE:

- A mild outcome indicates a self-limiting or minor health complaint, requiring minimal or no corrective intervention.
- A serious outcome indicates a potentially dangerous situation requiring active medical intervention.

*Please write the number of corresponding patients in each box or place a zero or line through boxes that do not apply to your patients*

	Adverse event from a complementary therapy		Interaction between complementary therapy and medical therapy		Inappropriately withdrawn from a medical therapy by a complementary therapist		Delay in diagnosis or effective treatment due to inappropriate use of a complementary therapy	
	Mild Outcome	Serious Outcome	Mild Outcome	Serious Outcome	Mild Outcome	Serious Outcome	Mild Outcome	Serious Outcome
	No. of patients	No. of patients	No. of patients	No. of patients	No. of patients	No. of patients	No. of patients	No. of patients
a) Acupuncture	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
b) Aromatherapy	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
c) Chinese Herbal Medicine	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
d) Chiropractic	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
e) Herbal Medicine	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
f) Homeopathy	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
g) Hypnosis	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
h) Massage	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
i) Meditation	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
j) Naturopathy	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
k) Osteopathy	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
l) Reflexology	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
m) Spiritual Healing e.g. Reiki	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
n) Vitamin and Mineral Therapy	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
o) Yoga	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
p) Other _____ <i>(please specify)</i>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

**Comments**

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**10. Do you think it is appropriate for GPs to sell/dispense complementary medicines such as herbs, vitamins and supplements from their practice?**

YES     NO     UNSURE

**Why?**

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**11. How important do you think it is to have education on complementary therapies in the core medical undergraduate curriculum?**

NOT IMPORTANT     1     2     3     4     5    EXTREMELY IMPORTANT

**12. Do you believe that the demand for complementary therapies from your patients is...**

INCREASING     NOT CHANGING     DECREASING     DON'T KNOW

**13. What percentage of your patients has asked you about any complementary therapies in the past month?**

<5%     6 – 10%     11 – 30%     31 – 50%     51 – 70%     >70%

**14. Where do you obtain information about complementary therapies? Overall do you think this information positive, negative or neutral towards complementary therapies? (Please tick as many boxes as appropriate)**

	POSITIVE	NEUTRAL	NEGATIVE
i) Mainstream media	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ii) Medical journals	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
iii) Medical conferences	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
iv) Medical information services (Medline etc)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
v) Anecdotes from patients, family or friends	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
vi) Friends or colleagues who practice complementary medicine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
vii) Personal treatment by a complementary practitioner—medical	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
viii) Personal treatment by a complementary practitioner—non-medical	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ix) Formal training in complementary medicine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
x) Other _____ <i>(please specify)</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## Appendix 8.2 Comparison of 1999 GP Workforce Data with Present Sample

Comparison of the 1999 GP workforce data with present sample, respondents, and non-respondents

	1999 GP workforce data	Present sample (1916 GPs)	Respondents (636)	Non-respondents (1280)
<b>Sex</b>				
Male	66%	69%	64%	71%
Female	34%	31%	36%	29%
<b>Age distribution</b>				
<34	12%	7%	8%	7%
35-44	32%	26%	26%	26%
45-54	30%	36%	37%	35%
55-64	15%	23%	23%	24%
>65	11%	8%	7%	8%
Average age:	49.3 years**	49.5 years	49.3 years	49.7 years
<b>State</b>				
NSW	34%	35%	31%	38%
VIC	24%	24%	27%	23%
QLD	18%	18%	18%	19%
WA	9%	8%	8%	8%
SA	9%	9%	12%	7%
TAS	3%	3%	2%	3%
ACT	2%	1%	2%	1%
NT	1%	1%	1%	0%***
<b>Location</b>				
Capital city	68%	68%	67%	69%
Other metro	7%	7%	6%	8%
Large rural	6%	6%	7%	6%
Small rural	6%	7%	6%	7%
Other rural	10%	11%	14%	10%
Remote	1%	1%	1%	0%***
Other remote	1%	1%	1%	1%

\* Commonwealth Department of Health and Ageing. General Practice Workforce. Feb 2000

\*\* Australian Institute of Health and Welfare: Medical Labour Force 2001

\*\*\* less than 1%

## Appendix 8.3 GPs' Opinions on Effectiveness and Harmfulness of Complementary Therapies

	Opinions re potential effectiveness				Opinions re potential harmfulness			
	Not	Seldom	Moderately	Highly	Not	Seldom	Occasionally	Frequently
Acupuncture	1% 8/612	15% 92/612	69% 425/612	14% 87/612	38% 220/585	48% 282/585	14% 81/585	0%* 2/585
Aromatherapy	46% 221/484	39% 190/484	15% 71/484	0% 2/484	63% 325/520	31% 159/520	6% 33/520	1% 3/520
Chinese herbal medicine	10% 50/496	40% 197/496	46% 226/496	5% 23/496	6% 30/530	28% 147/530	61% 323/530	6% 30/530
Chiropractic	6% 35/597	22% 131/597	65% 389/597	7% 42/597	2% 11/588	23% 133/588	69% 407/588	6% 37/588
Herbal medicine	17% 92/552	47% 257/552	34% 185/552	3% 18/552	4% 24/555	33% 185/555	58% 320/555	5% 26/555
Homeopathy	53% 273/512	29% 150/512	16% 80/512	2% 9/512	35% 176/500	34% 171/500	27% 134/500	4% 19/500
Hypnosis	5% 26/569	30% 169/569	56% 321/569	9% 53/569	29% 161/558	52% 292/558	18% 102/558	1% 3/558
Massage	2% 13/607	14% 85/607	68% 412/607	16% 97/607	46% 270/590	45% 267/590	9% 51/590	0%* 2/590
Meditation	3% 15/592	15% 91/592	61% 359/592	21% 127/592	78% 451/578	19% 107/578	3% 19/578	0%* 1/578
Naturopathy	33% 173/531	38% 203/531	26% 138/531	3% 17/531	17% 86/516	43% 222/516	36% 186/516	4% 22/516
Osteopathy	26% 131/509	30% 155/509	38% 194/509	6% 29/509	14% 67/474	43% 205/474	39% 184/474	4% 18/474
Reflexology	66% 315/478	24% 114/478	10% 49/478	0% 0/478	53% 235/440	32% 142/440	11% 49/440	3% 14/440
Spiritual healing (eg Reiki)	42% 193/464	39% 183/464	17% 80/464	2% 8/464	53% 246/462	32% 148/462	11% 50/462	4% 18/462
Vitamin and mineral therapy	24% 141/576	46% 264/576	25% 143/576	5% 28/576	17% 93/561	47% 265/561	34% 193/561	2% 10/561
Yoga	3% 16/587	21% 124/587	61% 359/587	15% 88/587	59% 330/563	33% 184/563	8% 44/563	1% 5/563

Note: \* less than 1%



## Appendix 8.4 GP Training in Complementary Therapies

**Previous training (and level of interest in further training) in complementary therapies**

	Previous level training			Interest in further training		
	None	Self-taught or introductory workshop	Cert., dip., degree	None	Introductory workshop	Cert., dip., degree
Acupuncture	77% 483/627	11% 69/627	12% 75/627	58% 344/595	18% 106/595	24% 145/595
Aromatherapy	96% 590/615	4% 23/615	0%* 2/615	89% 528/594	9% 55/594	2% 11/594
Chinese herbal medicine	96% 589/615	3% 21/615	1% 5/615	77% 455/591	14% 83/591	9% 53/591
Chiropractic	93% 570/612	6% 36/612	1% 6/612	85% 503/592	10% 58/592	5% 31/592
Herbal medicine	86% 531/614	11% 66/614	3% 17/614	68% 401/592	21% 127/592	11% 64/592
Homeopathy	95% 586/615	3% 19/615	2% 10/615	89% 527/592	7% 42/592	4% 23/592
Hypnosis	86% 528/614	8% 49/614	6% 37/614	64% 383/594	22% 128/594	14% 83/594
Massage	83% 509/613	15% 93/613	2% 11/613	65% 384/593	25% 148/593	10% 61/593
Meditation	75% 459/614	23% 139/614	3% 16/614	57% 342/596	27% 161/596	16% 93/596
Naturopathy	95% 579/612	4% 27/612	1% 6/612	83% 490/589	13% 74/589	4% 25/589
Osteopathy	97% 593/614	3% 17/614	1% 4/614	89% 525/589	8% 45/589	3% 19/589
Reflexology	97% 594/614	3% 20/614	0% 0/614	94% 554/589	5% 30/589	1% 5/589
Spiritual healing (eg Reiki)	97% 594/613	3% 18/613	0% 1/613	90% 530/592	8% 48/592	2% 14/592
Vitamin and mineral therapy	77% 475/615	18% 111/615	5% 29/615	69% 407/589	18% 107/589	13% 75/589
Yoga	88% 528/603	12% 70/603	1% 5/603	67% 388/581	22% 130/581	11% 63/581

## Appendix 8.5 GPs' opinions on GPs Practising Complementary Therapies and Attracting Medicare Rebates

### Appropriateness of trained GPs practising complementary therapies and attracting Medicare rebates

	Appropriate to practise			Appropriate for rebates	
	Don't know	No	Yes, if trained	Yes, if trained	No
Acupuncture	2% 14/569	5% 28/569	93% 527/569	91% 507/559	9% 52/559
Aromatherapy	14% 84/583	67% 393/583	18% 106/583	17% 50/286	83% 236/286
Chinese herbal medicine	11% 64/580	40% 230/580	49% 286/580	49% 195/394	51% 199/394
Chiropractic	7% 43/577	46% 263/577	47% 271/577	58% 220/380	42% 160/380
Herbal medicine	10% 60/580	39% 224/580	51% 296/580	49% 193/393	51% 200/393
Homeopathy	13% 75/584	63% 365/584	25% 144/584	32% 94/293	68% 199/293
Hypnosis	5% 26/567	8% 47/567	87% 494/567	85% 454/537	15% 83/537
Massage	5% 31/581	46% 266/581	49% 284/581	48% 183/382	52% 199/382
Meditation	7% 39/575	29% 166/575	64% 370/575	57% 251/437	43% 186/437
Naturopathy	10% 61/586	57% 336/586	32% 189/586	39% 126/323	61% 197/323
Osteopathy	14% 83/581	57% 329/581	29% 169/581	43% 134/314	57% 180/314
Reflexology	14% 79/584	72% 423/584	14% 82/584	18% 46/256	82% 210/256
Spiritual healing (e.g. Reiki)	15% 91/589	65% 384/589	19% 114/589	19% 51/272	81% 221/272
Vitamin and mineral therapy	11% 62/582	36% 210/582	53% 310/582	54% 220/411	46% 191/411
Yoga	9% 51/571	48% 272/571	43% 248/571	34% 120/352	66% 232/352

## Appendix 8.6 GPs' Use and Practice of Complementary Therapies

**Respondents who have personally received or practised (or considered doing so) a complementary therapy in the previous 12 months**

	Receive				Practise		
	Would not consider receiving	Would consider receiving	Received in past 12 mths		Would not consider practising	Would consider practising	Practised in past 12 mths
Acupuncture	32% 181/561	56% 313/561	12% 67/561		51% 181/356	31% 110/356	18% 65/356
Aromatherapy	81% 491/604	15% 93/604	3% 20/604		96% 491/513	3% 16/513	1% 6/513
Chinese herbal medicine	74% 441/600	23% 136/600	4% 23/600		91% 441/482	7% 36/482	1% 5/482
Chiropractic	66% 403/607	27% 161/607	7% 43/607		94% 403/428	5% 20/428	1% 5/428
Herbal medicine	69% 410/596	26% 157/596	5% 29/596		86% 410/479	11% 51/479	4% 18/479
Homeopathy	86% 521/609	12% 71/609	3% 17/609		95% 521/549	4% 20/549	1% 8/549
Hypnosis	52% 305/584	45% 260/584	3% 19/584		77% 305/394	16% 64/394	6% 25/394
Massage	19% 115/601	55% 331/601	26% 155/601		60% 115/192	29% 55/192	11% 22/192
Meditation	33% 183/549	56% 307/549	11% 59/549		59% 183/309	22% 69/309	18% 57/309
Naturopathy	81% 487/602	16% 98/602	3% 17/602		93% 487/521	4% 23/521	2% 11/521
Osteopathy	77% 469/609	20% 119/609	3% 21/609		96% 469/489	3% 16/489	1% 4/489
Reflexology	87% 532/611	11% 65/611	2% 14/611		98% 532/542	2% 9/542	0%* 1/542
Spiritual healing (e.g. Reiki)	83% 505/612	15% 89/612	3% 18/612		97% 505/521	2% 13/521	1% 3/521
Vitamin and mineral therapy	60% 348/580	27% 156/580	13% 76/580		81% 348/430	10% 44/430	9% 38/430
Yoga	39% 217/563	52% 291/563	10% 55/563		74% 217/293	18% 53/293	8% 23/293

\* less than 1%

## Appendix 8.7 GPs' Recommendations to Patients about Complementary Therapies

**GPs' responses to patient's suggestion to use or consult a complementary therapist**

	Not confident to discuss	Actively discourage	Neither encourage nor discourage	Actively encourage
Acupuncture	5% 28/570	1% 7/570	37% 209/570	57% 326/570
Aromatherapy	20% 112/568	24% 134/568	49% 281/568	7% 41/568
Chinese herbal medicine	18% 104/566	14% 79/566	58% 327/566	10% 56/566
Chiropractic	5% 31/567	16% 90/567	55% 313/567	23% 133/567
Herbal medicine	14% 80/566	17% 98/566	56% 317/566	13% 71/566
Homeopathy	17% 95/564	37% 208/564	39% 222/564	7% 39/564
Hypnosis	7% 41/564	3% 15/564	47% 266/564	43% 242/564
Massage	4% 23/565	2% 11/565	25% 141/565	69% 390/565
Meditation	6% 34/565	2% 10/565	27% 154/565	65% 367/565
Naturopathy	16% 91/562	26% 147/562	47% 262/562	11% 62/562
Osteopathy	19% 105/563	21% 120/563	45% 251/563	15% 87/563
Reflexology	22% 124/565	38% 216/565	36% 202/565	4% 23/565
Spiritual healing (e.g. Reiki)	23% 127/563	22% 124/563	48% 272/563	7% 40/563
Vitamin and mineral therapy	9% 48/564	18% 100/564	56% 317/564	18% 99/564
Yoga	6% 34/555	3% 15/555	29% 162/555	62% 344/555

## Appendix 8.8 GPs' Attitudes to Role and Regulation of Complementary Therapists

GPs' attitudes to appropriateness of government regulation or registration of non-medically trained complementary therapists

	GP attitude to government regulation of CAM		
	Unsure	Govt should regulate	Govt should not regulate
Acupuncture	8% 41/524	87% 454/524	6% 29/524
Aromatherapy	26% 130/501	40% 200/501	34% 171/501
Chinese herbal medicine	13% 65/508	80% 405/508	7% 38/508
Chiropractic	8% 42/515	88% 452/515	4% 21/515
Herbal medicine	15% 74/504	77% 388/504	8% 42/504
Homeopathy	22% 108/502	66% 331/502	13% 63/502
Hypnosis	13% 65/514	79% 404/514	9% 45/514
Massage	18% 92/520	49% 255/520	33% 173/520
Meditation	19% 97/518	37% 194/518	44% 227/518
Naturopathy	16% 81/502	73% 365/502	11% 56/502
Osteopathy	18% 93/506	72% 362/506	10% 51/506
Reflexology	26% 128/501	46% 232/501	28% 141/501
Spiritual healing (e.g. Reiki)	25% 127/501	39% 194/501	36% 180/501
Vitamin and mineral therapy	15% 78/509	66% 337/509	18% 94/509
Yoga	18% 93/512	33% 170/512	49% 249/512

## Appendix 8.9 GP Referral to Complementary Therapists

**Frequency of doctor's suggestion or referral to consult a complementary therapist in the previous 12 months**

	Never	Few times	At least monthly	At least weekly	At least daily
Acupuncture	17% 97/575	58% 332/575	18% 105/575	5% 31/575	2% 10/575
Aromatherapy	92% 525/572	6% 37/572	2% 9/572	0%* 1/572	0% 0/572
Chinese herbal medicine	80% 461/573	16% 94/573	2% 14/573	1% 3/573	0%* 1/573
Chiropractic	40% 228/572	43% 245/572	14% 79/572	3% 19/572	0%* 1/572
Herbal medicine	74% 421/572	19% 110/572	5% 27/572	2% 11/572	1% 3/572
Homeopathy	90% 516/571	8% 44/571	1% 8/571	1% 3/571	0% 0/571
Hypnosis	41% 233/573	50% 284/573	7% 42/573	2% 11/573	1% 3/573
Massage	13% 73/569	45% 255/569	27% 155/569	14% 81/569	1% 5/569
Meditation	35% 199/571	41% 233/571	15% 87/571	8% 45/571	1% 7/571
Naturopathy	78% 448/572	17% 97/572	3% 15/572	2% 10/572	0%* 2/572
Osteopathy	76% 432/570	16% 94/570	5% 31/570	2% 13/570	0% 0/570
Reflexology	95% 544/573	4% 25/573	1% 4/573	0% 0/573	0% 0/573
Spiritual healing (e.g. Reiki)	89% 509/572	10% 55/572	1% 6/572	0%* 2/572	0% 0/572
Vitamin and mineral therapy	63% 358/571	23% 134/571	7% 41/571	4% 24/571	2% 14/571
Yoga	37% 205/554	40% 224/554	15% 83/554	6% 36/554	1% 6/554

\* less than 1%

# Appendix 9.1 Patient Profile



Australian Centre for  
Complementary Medicine  
EDUCATION & RESEARCH

NATUROPATHIC  
HERBAL MEDICINE

## Patient Profile

### INSTRUCTIONS

- Use blue/black pen or pencil
- Do not use red or felt tip pen
- Do not fold or bend this form
- Make no stray marks
- Please erase mistakes fully
- Cross out pen errors

Please  
MARK LIKE THIS ONLY:



Where the answer requires a number,  
first write the number in the area provided  
then mark the corresponding circle below.



Eg. If the patient's postcode is 2011:

PLEASE FILL IN THE APPROPRIATE RESPONSE AND WRITE DETAILS WHERE REQUIRED.

1. Patient's postcode:

POSTCODE

0	1	2	3	4
5	6	7	8	9
0	1	2	3	4
5	6	7	8	9
0	1	2	3	4
5	6	7	8	9
0	1	2	3	4
5	6	7	8	9

2. Patient's sex:

- Male
- Female

3. Patient's age  
in years:

AGE

0	1
2	3
4	5
6	7
8	9
0	1
2	3
4	5
6	7
8	9
0	1
2	3
4	5
6	7
8	9

4. What is the patient's first language?

- English
- Chinese (including dialects)
- Other Asian language
- Other Western European language
- Eastern European
- Middle Eastern
- Other (please specify) \_\_\_\_\_

5. What is the patient's highest level of formal education?

- Primary School
- High School Year 10 (or equivalent)
- High School Year 12 (or equivalent)
- Private college course
- Partially completed university / TAFE study
- TAFE qualification
- University diploma or degree
- University postgraduate diploma or degree

6. Does the patient have health insurance which covers naturopathy, herbal medicine, homeopathy or nutritional medicine, at least in part?

- Yes
- No
- If YES, please specify fund \_\_\_\_\_

7. What is the patient's employment status?  
(More than one may be selected)

- Home duties
- Unemployed
- Part-time work
- Full-time work
- Retired
- Student

8. If employed, which of the following best describes the patient's work?

- Manager or Administrator
- Trade or craft person
- Sales or personal service work
- Labourer or related work
- Professional
- Clerical work
- Plant, machine operator or driver
- Other (please specify) \_\_\_\_\_

9. This patient was referred by:

- Self referred (including friends, other patients)
- Advertising (including the Yellow Pages)
- Professional association
- Another complementary medicine practitioner
- General Practitioner (GP)
- Medical Specialist
- Chiropractor
- Osteopath
- Physiotherapist
- Traditional Chinese Medicine practitioner
- Pharmacist
- Counsellor or Psychologist
- Health food store worker
- Nurse
- Other (please specify) \_\_\_\_\_

10. What is the patient's principal medical diagnosis as given by medical practitioner (if known)?

NATUROPATHIC / HERBAL MEDICINE PATIENT PROFILE

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11. Is the patient's condition a chronic or recurrent complaint?

- Yes  No

12. How long has the patient had this complaint?

- 1 week or less  
 1 - 4 weeks  
 1 - 3 months  
 3 - 6 months  
 6 - 12 months  
 More than 12 months

13. How many consultations, including today's has the patient had with you for this complaint?

- First visit  
 2 - 5 visits  
 6 - 10 visits  
 11 - 15 visits  
 More than 15 visits

14. Has the patient consulted other practitioners for the presenting condition prior to seeing you?

- Yes  No → If NO go to question 16

15. If YES to question 14, please complete the following:

Has there been contact between you and this other practitioner?

Is treatment continuing?

Type of Practitioner seen	Yes		No	
	Yes	No	Yes	No
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

16. How many naturopathic, herbal, homeopathic or nutritional consultations or treatments per month is this patient receiving from you?

- <1  3  
 1  4  
 2  >5

17. Has the patient received a naturopathic, herbal, homeopathic or nutritional consultations prior to this course of treatment for this or any other complaint?

- Yes  No

18. Approximately how much is the treatment (including herbs and supplements) costing the patient per month?

\$ 

0	0	0
1	0	0
2	0	0
3	0	0
4	0	0
5	0	0
6	0	0
7	0	0
8	0	0
9	0	0

19. How much do you estimate the full course of consultations including herbs and / or supplements will cost?

\$ 

0	0	0
1	0	0
2	0	0
3	0	0
4	0	0
5	0	0
6	0	0
7	0	0
8	0	0
9	0	0

20. What specific treatments or other advice have you given the patient? (You may choose more than one)

- Western herbal medicine  
 Dietary advice  
 Exercise advice  
 Referral to another practitioner  
 Acupuncture  
 Massage  
 Chinese herbs  
 Lifestyle advice  
 Recommended diagnostic tests  
 Homeopathy  
 Aromatherapy  
 Nutritional supplements  
 Other (please specify) \_\_\_\_\_

21. Is the patient currently taking pharmaceutical medication?

- Yes  No

22. Please list all pharmaceutical medications (excluding vitamin supplements) regularly used by your patient.

\_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_



## Appendix 10.1 Transcript of Schedule 14 of the Therapeutic Goods Regulations 1990 (Cwlth)

### Designated active ingredients (Act, section 52F)

Item	Ingredient or kind of ingredient
1	an amino acid
2	charcoal
3	a choline salt
4	an essential oil
5	plant or herbal material (or a synthetically produced substitute for material of that kind), including plant fibres, enzymes, algae, fungi, cellulose and derivatives of cellulose and chlorophyll
6	a homeopathic preparation
7	a microorganism, whole or extracted, except a vaccine
8	a mineral including a mineral salt and a naturally occurring mineral
9	a mucopolysaccharide
10	non-human animal material (or a synthetically produced substitute for material of that kind) including dried material, bone and cartilage, fats and oils and other extracts or concentrates
11	a lipid, including an essential fatty acid or phospholipid
12	a substance produced by or obtained from bees, including royal jelly, bee pollen and propolis
13	a sugar, polysaccharide or carbohydrate
14	A vitamin or provitamin

## Appendix 10.2 Relevant Provisions of the *Therapeutic Goods Act 1989* (Cwlth)

### Section 3 - Interpretation

“*therapeutic goods*” means goods:

- (a) that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be:
  - (i) for therapeutic use; or
  - (ii) for use as an ingredient or component in the manufacture of therapeutic goods; or
  - (iii) for use as a container or part of a container for goods of the kind referred to in subparagraph (i) or (ii); or
- (b) included in a class of goods the sole or principal use of which is, or ordinarily is, a therapeutic use or a use of a kind referred to in subparagraph (a)(ii) or (iii);  
and includes medical devices and goods declared to be therapeutic goods under an order in force under section 7, but does not include:
  - (c) goods declared not to be therapeutic goods under an order in force under section 7; or
  - (d) goods in respect of which such an order is in force, being an order that declares the goods not to be therapeutic goods when used, advertised, or presented for supply in the way specified in the order where the goods are used, advertised, or presented for supply in that way; or
  - (e) goods (other than goods declared to be therapeutic goods under an order in force under section 7) for which there is a prescribed standard in the Australia New Zealand Food Standards Code as defined in subsection 3(1) of the Australia New Zealand Food Authority Act 1991; or
  - (f) goods which, in Australia or New Zealand, have a tradition of use as foods for humans in the form in which they are presented.

“*Therapeutic Goods Advertising Code*” means the Code known as the Therapeutic Goods Advertising Code notified in the Gazette with effect from the date of commencement of Schedule 1 to the Therapeutic Goods Amendment Act (No.1) 2003 together with any amendments of the Code published by the Minister in the Gazette from time to time.

“*therapeutic use*” means use in or in connection with:

- (a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons or animals; or
- (b) influencing, inhibiting or modifying a physiological process in persons or animals; or
- (c) testing the susceptibility of persons or animals to a disease or ailment; or
- (d) influencing, controlling or preventing conception in persons; or
- (e) testing for pregnancy in persons; or
- (f) the replacement or modification of parts of the anatomy in persons or animals.

### Section 52F Definitions

Unless the contrary intention appears:

*active ingredient* means the therapeutically active component in a medicine's final formulation that is responsible for its physiological or pharmacological action.

*complementary medicines* means therapeutic goods consisting wholly or principally of one or more designated active ingredients, each of which has a clearly established identity and:

- (a) a traditional use; or

- (b) any other use prescribed in the regulations.

*designated active ingredient* means an active ingredient, or a kind of active ingredient, mentioned in Schedule 14 to the Therapeutic Goods Regulations.

*traditional use*, in relation to a designated active ingredient, means use of the designated active ingredient that:

- (a) is well documented, or otherwise established, according to the accumulated experience of many traditional health care practitioners over an extended period of time; and
- (b) accords with well-established procedures of preparation, application and dosage.

Note: An example of traditional use is use in Chinese traditional medicine.

## **Appendix 10.3 Report of Expert Committee on Complementary Medicines in the Health System: Excerpt of Recommendations**

*Reference:* Expert Committee on Complementary Medicines in the Health System 2003, 'Complementary Medicines in the Australian Health System. Report to the Parliamentary Secretary to the Minister for Health and Ageing', Commonwealth of Australia, Canberra.

### **Recommendation 27**

All jurisdictions introduce legislation to regulate practitioners of traditional Chinese medicine and dispensers of Chinese herbs, based on existing Victorian legislation, as soon as possible.

### **Recommendation 28**

Health Ministers review the findings of the current New South Wales and Victorian reviews concerning regulation of complementary healthcare practitioners and move quickly to implement statutory regulation where appropriate.

### **Recommendation 29**

All jurisdictions adopt the following as necessary attributes of effective, transparent and accountable self-regulatory structures for complementary healthcare practitioners:

- (a) a certification system which incorporates:
  - (i) appropriate standards of training for membership, established via a consultative process with the profession and endorsed by the relevant educational/industry authorities
  - (ii) an established, transparent procedure for assessing practitioner qualifications, incorporating an examination where necessary
  - (iii) effective incentives to ensure practitioners seek and maintain certification
  - (iv) annual requirements for continuing professional development as a condition of continued certification
- (b) a code of ethics with which certified practitioners agree to comply
- (c) effective procedures for receiving, investigating and resolving consumer complaints
- (d) an established disciplinary system for enforcing conduct and continuing professional development requirements, able to investigate and apply sanctions where necessary, together with a process for appeals
- (e) effective incentives for compliance with codes of practice as well as sanctions for non-compliance with standards of practice and other membership requirements
- (f) external scrutiny and involvement of experts who are not members of the profession, to promote transparency, accountability and credibility.

### **Recommendation 30**

The Australian government give consideration to revising the definition of organisations whose members satisfy requirements for 'recognised professionals' for the provision of GST-free services, in line with the criteria listed in Recommendation 29.

### **Recommendation 31**

Regulatory bodies for healthcare practitioners who are currently regulated by statute (for example, medical practitioners) ensure that their policies and membership standards require their members who practise complementary healthcare or advise on complementary medicines to acquire appropriate skills and competencies.

**Recommendation 32**

The Australian government and states/territories work together with the various professions to promote development of strong, independent and accountable self-regulatory arrangements for complementary medicine professions that satisfy the criteria listed in Recommendation 29, through:

- (a) support and advice, including short-term financial assistance where deemed necessary
- (b) involvement of the professional associations in policy development and committee processes
- (c) encouraging health funds and workers compensation insurers to restrict 'approved provider' status to members of an independent and accountable self-regulatory body
- (d) accreditation of education and training courses up to degree and diploma level, by vocational education and training and higher education bodies.

## **Appendix 10.4 American Association of Naturopathic Physicians: Licensed States and Licensing Authorities**

### **Licensed States**

Currently, 13 states and the US territories of Puerto Rico and the US Virgin Islands have licensing laws for naturopathic doctors. In these states, naturopathic doctors are required to graduate from a four-year, residential naturopathic medical school and pass an extensive postdoctoral board examination in order to receive a license.

Licensed naturopathic physicians must fulfil state-mandated continuing education requirements annually, and will have a specific scope of practice defined by their state's law.

The states that currently have licensing laws for naturopathic physicians are Alaska, Arizona, California, Connecticut, Hawaii, Kansas, Maine, Montana, New Hampshire, Oregon, Utah, Vermont, Washington; US Territories: Puerto Rico and Virgin Islands.

### **Licensing Authorities**

Federation of Naturopathic Physicians Licensing Authorities

Naturopathic Physicians Licensing Examination Board North American Board of Naturopathic Examiners Alaska Department of Community and Economic Development, Division of Occupational Licensing Naturopathic Section

Arizona Naturopathic Board of Medical Examiners

Connecticut Board of Naturopathic Examiners

Hawaii Board of Examiners in Naturopathy

Maine Board of Complementary Health Care Providers

Montana Alternative Health Care Board

State of New Hampshire Department of Health and Human, Board of Naturopathic Examiners

Oregon Board of Naturopathic Examiners

Junta Examinadora de Doctores en Naturopathia Oficina de Regiamentacion y Certification Para Profesionales de La Salud, (Puerto Rico)

Vermont Office of the Secretary of State

Office of Professional Regulation Naturopathic Physicians Advisors

Washington State Naturopathic Physician Licensing Program

Canadian Provincial Licensing Boards

The College of Naturopathic Physicians of British Columbia Saskatchewan Association of Naturopathic Practitioners

Manitoba Naturopathic Association

Ontario Board of Directors, Drugless Therapy/Naturopathy

## Appendix 10.5 UK Health Professions: Regulators and Professional Bodies

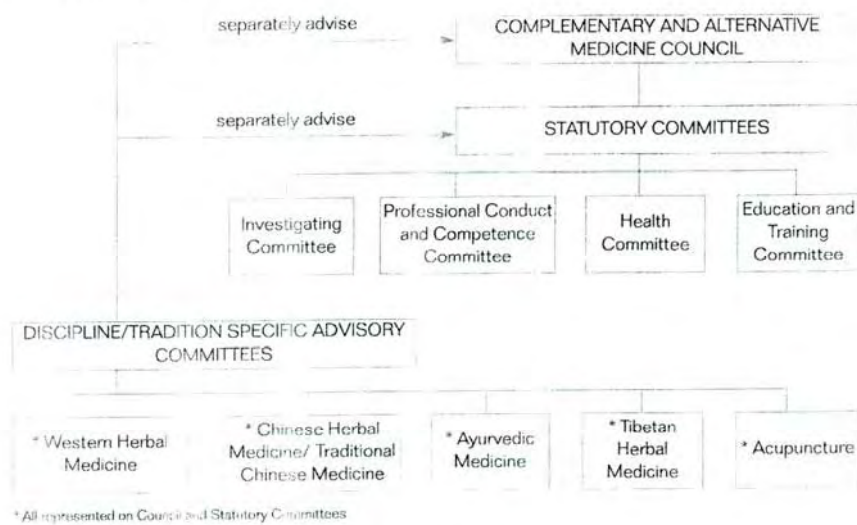
(Health Professions Council, *Health Regulation Worldwide*, accessed at <http://www.hpc-uk.org/worldwide/uk.html> on 10 February 2004)

Profession	Regulator	Professional Body
Arts Therapists	<i>Health Professions Council</i>	British Association of Art Therapists British Association for Dramatherapists Association of Professional Music Therapists
Biomedical Scientists	<i>Health Professions Council</i>	Institute of Biomedical Science
Chiropodists/Podiatrists	<i>Health Professions Council</i>	Society of Chiropodists & Podiatrists
Chiropractors	The General Chiropractic Council	–
Clinical Scientists	<i>Health Professions Council</i>	Association of Clinical Scientists
Dentists	General Dental Council	British Dental Association
Dietitians	<i>Health Professions Council</i>	British Dietetic Association
Medical Practitioners	General Medical Council	British Medical Association
Midwives	Nursing and Midwifery Council	Royal College of Midwives
Nurses	Nursing and Midwifery Council	Royal College of Nursing
Occupational Therapists	<i>Health Professions Council</i>	College of Occupational Therapists
Operating Department Practitioners	–	Association of Operating Department Practitioners
Opticians	General Optical Council	College of Optometrists Association of Optometrists
Orthoptists	<i>Health Professions Council</i>	British Orthoptic Society
Osteopaths	The General Osteopathic Council	–
Paramedics	<i>Health Professions Council</i>	British Paramedic Association
Pharmacists	Royal Pharmaceutical Society of Great Britain	Royal Pharmaceutical Society of Great Britain
Physiotherapists	<i>Health Professions Council</i>	Chartered Society of Physiotherapy
Prosthetists & Orthotists	<i>Health Professions Council</i>	British Association of Prosthetists & Orthotists

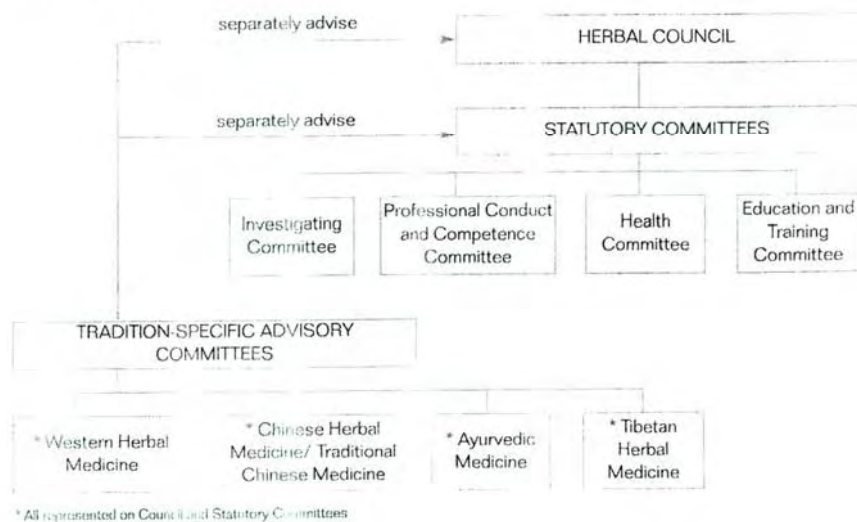
# Appendix 10.6 Suggested Organisational Structures for CAM Medicine (UK)

Report from the Herbal Medicine Regulatory Working Group 2003 (HMRWG)

## Suggested Organisational Structure for the Proposed CAM Council



## Suggested Organisational Structure for the Proposed Herbal Council





# Appendix 10.7 European Commission Project on Unconventional Medicine (1993–1998)

## Executive Summary, Final Report of the European Commission Sponsor COST Project on Unconventional Medicine (1993–1998)

### Background

Many are making use of unconventional therapies in order to promote health trends or restore well-being. It remains unclear to what extent current trends are being driven by patients' own convictions as to which treatments are effective or helpful, by the evidence of scientific research, by misleading claims or marketing campaigns, or by dissatisfaction with options offered by conventional medicine.

It is possible that for the foreseeable future unconventional medicine will continue to have some impact on healthcare across Europe. All who make use of therapies, whether practitioners or patients, should be concerned that the treatments being offered are both effective and safe.

### Method

Direct interaction with patients was not a major part of the work of the committee. We undertook to look at key areas of debate within healthcare that could lead to more informed discussions in the future: the social context of unconventional medicine, clinical and basic research, and constraints for research results being applied in practice. Experts were invited to provide input on differing aspects of the committee's work. The report that follows presents an overview of the principal findings of the different working parties that were established by the management committee.

### Results

The committee strongly recommends that those determining the availability, acceptance or delivery of healthcare treatments in the future, particularly with regard to options provided by unconventional medicine, should ensure that the perceptions and interests of patients are respected. A co-ordinated strategy for research in unconventional medicine would help users to make informed choices.

The existing procedures for validation of practice and accreditation of practitioners within medicine should also apply to those offering unconventional healthcare options. Ethical accountability and disciplinary codes should apply equally to unconventional practitioners as they do to conventional medical practitioners. Great care should also be taken to ensure that no new therapies emerge in practice without the support of research evidence of the highest standards.

### The Future

It is clear, at the moment, that there is a mismatch between the beliefs and expectations of unconventional medicine practitioners and patients, and the evidence being produced by researchers. The challenge in the coming months and years will be for all those involved in providing healthcare to ensure that treatments are safe and effective. There is a need for professionalism and rigour in research, training and practice of unconventional medicine.

Unconventional medicine is a subject of great complexity and fluidity. In the future it is important that those responsible for making decisions as to the provision of such therapies have some understanding of their underlying concepts, the evidence of research and the confidence of patients who make use of them. This requirement for 'familiarisation' with unconventional medicine would be of benefit to both conventional and unconventional medical practitioners.

A dedicated independent European Office where reliable research data can be gathered in an impartial way would be of value to all health professionals and users of unconventional medicine.

According to current practice, the principal criterion used when determining appropriate therapeutic options is effectiveness. This is ideally demonstrated through randomized controlled clinical trials. Such studies should also look at the evidence of patients' satisfaction and well-being following treatment by conventional or unconventional practitioners.

Patients are making their own choices of treatment based on experience or personal/professional recommendation. These choices are often made without knowledge of any of the scientific evidence. Patients are often led to use therapies having heard their friends benefit from unconventional medicine treatments. It is the responsibility of health authorities to make available reliable information to help users make their choices in an informed way.

The challenge in the years ahead will be to develop care which builds on the confidence and expectations of patients and is supported by scientific 'evidence based' medicine.

Those agencies, whether governmental or voluntary, who currently make funds available for research should be encouraged to allow for submissions from those working in the unconventional medical field. Researchers in unconventional medicine should ensure that their methodologies are in accordance with standards of good quality research.

### **General Recommendations**

1. The management committee recognizes that significant numbers of European citizens are making frequent use of unconventional medicine. This makes it essential that:
  - there is defined minimum European standard of medical knowledge among unconventional therapists
  - there is further support, funding and co-ordination of national and international research in unconventional medicine
  - medical practitioners are informed and are able to discuss unconventional medicine options with their patients.
2. The management committee recommends that national and international agencies do all they can to ensure that the unconventional medical treatment people receive is safe and effective. To do this the management committee proposes the following:
  - The creation of an independent European Healthcare Office in collaboration with experts from conventional or unconventional medicine where appropriate to:
    - recommend guidelines for research in unconventional medicine
    - consider a pan-European strategy to help training of researchers
    - develop a system of registration of practitioners
    - establish criteria for the validation of practice
  - The establishment of a pan-European advisory group on healthcare options in unconventional medicine to:
    - provide reliable scientific information
    - offer practical research and education advice
    - liaise with patients, practitioners, health authorities and government agencies
    - ensure that existing European guidelines on ethical standards of practice in research are applied to those working in the unconventional medicine field.
3. The management committee is aware that research evidence in unconventional medicine is still scarce. While recognizing that more research is now being carried out each year, claims made in this field are often anecdotal, exaggerated or unsubstantiated. The management committee recommends that:
  - new European research programmes and initiatives be developed
  - consideration be given to funding of unconventional medicine research.
4. The management committee recognizes that market forces are determining current trends in unconventional medicine. There is a need to balance the individuals' freedom of choice with the duty to protect them from harm. In the light of the above the management committee recommends that:
  - unconventional medicine practitioners be subject to the same or similar codes of conduct, discipline and accountability as other medical practitioners
  - new therapies or healthcare treatments be subject to the normal process of appraisal through research approved by ethical committees prior to availability in general medical practice
  - evidence-based research is used to inform practitioners on appropriate use of unconventional medicine where possible.
5. The management committee is conscious that different countries have different legal perspectives in this field. It recommends:
  - a minimum standard for accreditation and certification for all practitioners of therapies.
6. The management committee appreciates the help of the European Commission during its deliberations, and recommends that:
  - continued support be given to initiatives in the field of unconventional medicine, through the COST mechanism and/or other Community programmes that may be appropriate.

## Appendix 10.8 Schedule 1 Regulated Health Professions Act 1991 (Ontario)

<b>Health Profession Acts</b>	<b>Health Profession</b>
<i>Audiology and Speech-Language Pathology Act, 1991</i>	Audiology and speech-language pathology
<i>Chiropody Act, 1991</i>	Chiropody
<i>Chiropractic Act, 1991</i>	Chiropractic
<i>Dental Hygiene Act, 1991</i>	Dental hygiene
<i>Dental Technology Act, 1991</i>	Dental technology
<i>Dentistry Act, 1991</i>	Dentistry
<i>Denturism Act, 1991</i>	Denturism
<i>Dietetics Act, 1991</i>	Dietetics
<i>Massage Therapy Act, 1991</i>	Massage therapy
<i>Medical Laboratory Technology Act, 1991</i>	Medical laboratory technology
<i>Medical Radiation Technology Act, 1991</i>	Medical radiation technology
<i>Medicine Act, 1991</i>	Medicine
<i>Midwifery Act, 1991</i>	Midwifery
<i>Nursing Act, 1991</i>	Nursing
<i>Occupational Therapy Act, 1991</i>	occupational therapy
<i>Opticianry Act, 1991</i>	Opticianry
<i>Optometry Act, 1991</i>	Optometry
<i>Pharmacy Act, 1991</i>	Pharmacy
<i>Physiotherapy Act, 1991</i>	Physiotherapy
<i>Psychology Act, 1991</i>	Psychology
<i>Respiratory Therapy Act, 1991</i>	Respiratory therapy

## Appendix 10.9 Comparative Table: Definitions of Naturopathy and Accreditation Requirements (USA)

State	Definition	Accreditation requirements
Alaska	'Naturopathy' means the use of hydrotherapy, dietetics, electrotherapy, sanitation, suggestion, mechanical and manual manipulation for the stimulation of physiological and psychological action to establish a normal condition of mind and body; in this paragraph, 'dietetics' includes herbal and homeopathic remedies." ALASKA STAT. § 08.45.200(3) (1962).	Received degree from an accredited four-year college or university; * Received degree from a school of naturopathy, which is accredited or that is a candidate for accreditation by the Council on Naturopathic Medical Education, and which required four years of attendance; * On or before December 1987, received a license to practice naturopathy in a state that required an examination for the license; * After December 1987, graduated from a school of naturopathy, which is accredited or is a candidate for accreditation and which required four years of attendance; * Passed the Naturopathic Physicians Licensing Examination sponsored by the American Association of Naturopathic Physicians and administered by the state where the exam was taken. ALASKA STAT. § 08.45.030 (1962 & Supp. 1994).
Arizona	'Naturopathic medicine' means medicine as practiced by a recipient of a degree of doctor of naturopathic medicine licensed pursuant to this chapter." ARIZ. REV. STAT. ANN. § 32-1501(10) (1992 & Supp. 1994-1995).	* Graduated from a school of naturopathic medicine approved by the board; * Completed an internship, preceptorship or clinical training program in naturopathic medicine approved by the board; * Possess a good moral and professional reputation; * Not be guilty of any act of unprofessional conduct or any other conduct which would be grounds for refusal, suspension or revocation of a license under this chapter; * Have no license to practice any profession refused, revoked, or refused; * File application and pay appropriate fees. ARIZ. REV. STAT. ANN. § 32-1522(A) (1992 & Supp. 1994-1995).
Connecticut	'The practice of naturopathy' means the science, art and practice of healing by natural methods as recognized by the council of naturopathic medical education and approved by the State Board of Naturopathic Examiners, with the consent of the commissioner, and shall include: (1) counselling and (2) the practice of the mechanical and material sciences of healing as follows: The mechanical sciences such as mechanotherapy, articular manipulation, corrective and orthopaedic gymnastics, physiotherapy, hydrotherapy, electrotherapy and phototherapy; and the material sciences such as nutrition, dietetics,	* Pass an examination prescribed by the department; * Graduated from an approved high school; * Begin study before 1963: Completed a course of study consisting of not less than thirty-two weeks duration; * Begin study after 1963: completed a course of study of an academic year consisting of not less than sixty-four weeks' duration, in a college or scientific school approved by the board; OR * Possessed educational qualifications equivalent to those required for graduation from such school before beginning the study of naturopathy; * Is a graduate of a legally chartered, reputable school or college of naturopathy, which is approved by the board and which required the applicant a course of resident instruction of at

	<p>phytotherapy, treatment by natural substances and external applications." CONN. GEN. STAT. ANN. § 20-34(a) (West 1958 &amp; Supp. 1995).</p>	<p>least four years (each year consists of thirty-six weeks of actual attendance). * File application and appropriate fees. CONN. GEN. STAT. ANN. § 20-37 (West 1958 &amp; Supp. 1995).</p>
District of Columbia	<p>A person registered to practice naturopathy or naturopathic healing may counsel individuals and treat human conditions through the use of naturally occurring substances in accordance with the requirements of this chapter. D.C. CODE ANN. § 2-3309.1(b) (1994).</p>	<p>* Register prescribed forms with the Mayor; * Pay registration fee. D.C. CODE ANN. § 2-3309.1 (1994).</p>
Florida	<p>'Naturopathy' and 'Naturopathy' shall be construed as synonymous terms and mean the use and practice of psychological, mechanical, and material health sciences to aid in purifying, cleansing, and normalizing human tissues for the preservation or restoration of health, according to the fundamental principles of anatomy, physiology, and applied psychology, as may be required. Naturopathic practice employs, among other agencies, phytotherapy, dietetics, psychotherapy, suggestotherapy, hydrotherapy, zone therapy, biochemistry, external applications, electrotherapy, mechanotherapy, mechanical and electrical appliances, hygiene, first aid, sanitation, and heliotherapy; provided, however, that nothing in this chapter shall be held or construed to authorize any naturopathic physician licensed hereunder to practice materia medica or surgery or chiropractic, nor shall the provisions of this law in any manner apply to or affect the practice of osteopathy, chiropractic, Christian Science, or any other treatment authorized and provided for by law for the cure or prevention of disease and ailments." FLA. STAT. ANN. § 462.01(1) (West 1991). (**This was repealed Oct. 1995)</p>	<p>Does not have requirements listed.</p>
Hawaii	<p>'Naturopathy' means the practice of: (1) Natural medicine, natural therapeutics, and natural procedures, for the purpose of removing toxic conditions from the body and improving the quality, quantity, harmony, balance, and flow of the vital fluids, vital tissues, and vital energy; and (2) Diagnosing, treating, and caring for patients using a system of practice that bases its treatment of physiological functions and abnormal conditions on natural laws governing the human</p>	<p>* Graduated from a school, university or college of naturopathy, which is accredited; * Receive a converted score of seventy-five on each part of the examination, which is administered by the board; HAW. REV. STAT. § 455-3, § 455-7 (1995 &amp; Supp. 1994).</p>

	<p>body; utilizing physiological, psychological, and mechanical methods, such as air, water, light, sunshine, heat and cold, earth, phytotherapy, physiotherapy, mechanotherapy, naturopathic corrections and manipulation, and natural methods or modalities, together with natural or homeopathic medicines, natural food and herbs, and nature's remedies of the type taught in education and training at naturopathic medical colleges. The practice of naturopathy excludes surgery, application of x-rays, and prescribing, dispensing, or using prescription drugs except as provided for in the definition of natural medicine."</p> <p>HAW. REV. STAT. § 455-1 (1995 &amp; Supp. 1994).</p>	
Montana	<p>'Naturopathic medicine', 'naturopathic health care', or 'naturopathy' means a system of primary health care practiced by naturopathic physicians for the prevention, diagnosis, and treatment of human health conditions, injury, and disease. Its purpose is to promote or restore health by the support and stimulation of the individual's inherent self-healing processes. This is accomplished through education of the patient by a naturopathic physician and through the use of natural therapies and therapeutic substances."</p> <p>MONT. CODE ANN. § 37-26-103(7) (1993).</p>	<ul style="list-style-type: none"> <li>* Graduated from a school, university or college of naturopathy, which is accredited;</li> <li>* Receive a converted score of seventy-five on each part of the examination, which is administered by the board;</li> </ul> <p>HAW. REV. STAT. § 455-3, § 455-7 (1995 &amp; Supp. 1994).</p>
New Hampshire	<p>'Naturopathic medicine' means a system of primary health care practiced by doctors of naturopathic medicine for the prevention, diagnosis, and treatment of human health conditions, injuries, and diseases that uses education, natural medicines and therapies to support and stimulate the individual's intrinsic self-healing processes."</p> <p>N.H. REV. STAT. ANN. § 328-E:2(IX) (Supp. 1994).</p>	<ul style="list-style-type: none"> <li>* Applicant is of good moral character as determined by the board;</li> <li>* Graduated from an approved naturopathic medical college;</li> <li>* Passed an examination prescribed and endorsed by the board.</li> </ul> <p>MONT. CODE ANN. § 37-26-402 (1993).</p>
Oregon	<p>'Naturopathic medicine' means the discipline that includes physiotherapy, natural healing processes and minor surgery and has as its objective the maintaining of the body in, or of restoring it to, a state of normal health."</p> <p>OR. REV. STAT. § 685.010(5) (1989 &amp; Supp. 1994).</p>	<ul style="list-style-type: none"> <li>* Graduated from a naturopathic medical college which is accredited;</li> <li>* Pass examination administered by the board;</li> <li>* Possess a good moral and professional reputation;</li> <li>* Be mentally and physically fit to practice naturopathic medicine;</li> <li>* Have no naturopathic license, certificate or registration revoked, refused or suspended;</li> <li>* File application and pay fees.</li> </ul> <p>N.H. REV. STAT. ANN. § 328-E:9(I) (Supp. 1994).</p>

Tennessee	<p>'Naturopathy' means nature cure or health by natural methods and is defined as the prevention, diagnosis and treatment of human injuries, ailments and disease by the use of such physical forces, as air, light, water, vibration, heat, electricity, hydrotherapy, psychotherapy, dietetics or massage, and the administration of botanical and biological drugs." TENN. CODE ANN. § 63-6-205(1) (1990 &amp; Supp. 1994).</p>	<ul style="list-style-type: none"> <li>* Satisfactory liberal arts and sciences study, or either, for at least two years in an accredited college or university;</li> <li>* Graduate from an approved naturopathic school or college;</li> <li>* Pass examination, which is administered by the board,</li> <li>* File application and pay fees.</li> </ul> <p>OR. REV. STAT. §§ 685.060, 685.080 (1989 &amp; Supp. 1994).</p>
Washington	<p>"Naturopathic medicine or naturopathy is the practice by naturopaths of the art and science of the diagnosis, prevention, and treatment of disorders of the body by stimulation or support, or both, of the natural processes of the human body. A naturopath is responsible and accountable to the consumer for the quality of naturopathic care rendered. The practice of naturopathy includes manual manipulation (mechanotherapy), the prescription, administration, dispensing, and use, except for the treatment of malignancies or neoplastic disease, of nutrition and food science, physical modalities, homeopathy, certain medicines of mineral, animal, and botanical origin, hygiene and immunization, common diagnostic procedures, and suggestion; however, nothing in this chapter shall prohibit consultation and treatment of a patient in concert with a practitioner licensed under chapter 18.57 or 18.71 RCW." WASH. REV. CODE ANN. § 18.36A.040 (West 1989 &amp; Supp. 1995).</p>	<ul style="list-style-type: none"> <li>* Graduated from a Naturopathic School approved by the Secretary, Department of Health</li> <li>* Pass, with a score of 75: the Naturopathic Physicians Licensing Examinations: <ul style="list-style-type: none"> <li>- Basic Science Examinations: Anatomy, Biochemistry, Microbiology, Pathology, Physiology;</li> <li>- Part ii Clinical Science Examinations: Physical clinical diagnosis, Lab diagnosis and Diagnostic imaging, Emergency Medicine, Botanical medicine, Pharmacology, Nutrition, Psychology, Physical medicine;</li> <li>- Add-on Examinations: Homeopathy and Minor surgery</li> </ul> </li> </ul> <p>Washington State Jurisprudence Examination. * complete the application form and pay fee Washington State Department of Health, Health Professions Quality Assurance, Naturopathy Program, General Information for Naturopathy Licensure, available at:  <a href="https://fortress.wa.gov/doh/hpqa/hps7/naturopathy/licensure.htm">https://fortress.wa.gov/doh/hpqa/hps7/naturopathy/licensure.htm</a> (accessed 15 December 2004).</p>

## **Appendix 10.10 Naturopathic Doctors Act 2002 (California)**

### **Overview of intent**

The Naturopathic Doctors Act provides for the licensure of naturopathic doctors who have successfully completed a full-time, doctoral-level, accredited naturopathic medical program and passed approved board exams. Under this legislation, consumers will have access to the full range of diagnostic evaluation, natural treatments, disease prevention, and health promotion that licensed naturopathic doctors provide. In addition, consumers will be assured that their naturopathic doctor is accountable for their care and subjected to the same standards of regulation and oversight as other licensed health care professionals.

- Key points of the Act: The Act does not prevent or restrict the practices, services, or activities of any other practitioner, consultant, or individual; nor does it restrict or prevent individuals engaged in the sale of vitamins, nutritional supplements, herbs, homeopathic remedies, etc.
- Naturopathic medicine is a distinct and comprehensive system of primary health care practiced by naturopathic doctors for the diagnosis, treatment, and prevention of human health conditions, injuries, and disease that employs natural therapies, therapeutic substances, and education to promote and restore health by supporting and stimulating the individual's self-healing processes.
- Naturopathic Doctors will be permitted to practice to the scope of their training, including diagnosis and treatment modalities such as natural substances, herbs, nutritional supplements, homeopathic remedies, physical medicine, and minor office procedures.
- NDs completing additional training in natural childbirth will be eligible for a specialty certificate in naturopathic childbirth attendance which will allow for the management of normal pregnancy, labor, delivery, and postpartum care.
- The titles and professional abbreviation reserved for individuals licensed under this legislation are: licensed naturopathic doctor, naturopathic doctor, doctor of naturopathic medicine, doctor of naturopathy, naturopathic medical doctor, and "N.D.". Naturopathic Doctors licensed under this act will be subject to the same standards of regulatory oversight and peer review as other licensed health care professionals.



## Appendix 10.11 American Herbalists Guild's Primary Goals and Code of Ethics

### a) Primary goals

- Honor diversity in herbal medicine, ranging from traditional indigenous models of herbalism to modern clinical phytotherapy.
- Establish AHG professional membership as a recognizable standard of competency in botanical medicine.
- Encourage the development of high standards of education that promote well-trained professional practitioners who offer high quality herbal care.
- Promote ecological health and increase awareness of issues surrounding plant sustainability.
- Strengthen the network of support and communication between herbal practitioners nationally and internationally.
- Foster high standards of ethics and integrity in the education and the practice of therapeutic herbalism.
- Promote cooperation between herbal practitioners and other health care providers, integrating herbalism into community health care.
- Serve as a liaison to other professional associations and regulatory agencies.
- Promote research in herbal medicine.

### b) Membership

The American Herbalists Guild (AHG) is a non-profit, tax-exempt educational organization that relies on donations to continue its work of representing the goals and voices of herbalists. The AHG receives thousands of dollars in direct contributions each year from corporations and individual supporting members, to whom it owes its existence.

All current members are eligible to vote, in person or by proxy, in Council elections and on member issues. One seat on the Governing Council is reserved for General Members. There are three categories of membership:

#### (i) Professional Members

Professional members have had their credentials evaluated by the Admissions Committee of the AHG through our Peer Review Process ([Criteria for Professional Membership](#)). Applicants must complete the AHG application, submit a personal and professional biography outlining their experience and training in the field of herbal medicine, have at least four years experience working with clients, provide three case histories, and provide three letters of reference from professional herbalists (or other health professionals proficient in herbalism). All professional members update their knowledge according to the [Continuing Education Guidelines for Professional Members](#). There is a one-time, non-refundable application fee of \$50 (\$60 for non-members).

In addition, Professional Members are recognized with the title "Herbalist, AHG" (or "AHG" for short). Professionals may also choose to be included in the AHG's referral list. Election to the Governing Council is open to all professional members.

Professional Membership annual dues: \$120 (Foreign members: \$130).

#### (ii) General Members

General members are individuals who are interested in herbal medicine or who are working towards professional status in the AHG. All General Members agree to abide by the Code of Ethics and Standards of Practice of the AHG.

General Membership annual dues: \$60 (Foreign members: \$70).

Students in herbal study programs receive a \$10 discount on their general membership dues, provided they submit evidence of enrollment in a program upon joining and every year upon renewal.

General Membership/student discount annual dues: \$50 (Foreign members \$60).

### **(iii) Supporting Members**

Supporting members are schools, herb companies, individuals or business entities who wish to support the Guild.

## **c) Code of Ethics**

### **Informed Consent/Full Disclosure**

AHG members shall provide clients and potential clients with informed consent/full disclosure information outlining scope of practice, services rendered, experience, training, client expectations, practitioner's expectation, payment structure, disclosure of financial interests if they can present a conflict in practice, and information about client redress in the event of a disagreement between client and practitioner. Client redress can take the form of an informal review by the AHG Grievance Committee, or a review by appropriate state associations where the member is operating under a state license.

### **Confidentiality**

Personal information gathered in the herbalist/client relationship will be held in strict confidence by the AHG member unless specifically allowed by the client.

### **Professional Courtesy**

AHG members shall present opinions about and experiences with other practitioners and healing modalities in an ethical and honorable manner.

### **Professional Networking**

Clients shall be encouraged to exercise their right to see other practitioners and obtain their botanicals from the source of their choosing.

### **Practitioner as Educator**

AHG members shall assume the role of educators, doing their best to empower clients in mobilizing their own innate healing abilities and promotion the responsibility of clients to heal themselves.

### **Peer Review**

AHG members shall welcome a peer review of their publications, lectures, and/or clinical protocols. Peer review is a primary means of enhancing our level of knowledge and expertise and should be encouraged.

### **Referring Out**

AHG members shall recognize their own limitations when they feel a condition is beyond their scope of expertise and practice as an herbalist, or when it is clear that a client is not responding positively to therapy.

### **Avoiding Needless Therapy**

Recommendations shall be based solely on the specific needs of the client, avoiding excessive or potentially needless supplementation.

### **Environmental Commitment**

AHG members should acknowledge that individual health is not separate from environmental health and should counsel clients to embrace this same Earth-centered awareness.

### **Sexual Harassment**

AHG members shall not use their position as teachers or consultants to seek sexual encounters with students or clients.

## Appendix 11.1 Summary of Options for Reform

Options	Characteristics	Countries/Professions
1. Statutory Self Regulation	<ul style="list-style-type: none"> <li>• Profession specific statutes</li> <li>• Single Register</li> <li>• Protection of title</li> <li>• Self regulating profession specific councils (and overarching council)</li> </ul>	UK - Applies to some CAM professionals eg. Osteopathy and Chiropractic
2. State Registration	<u>Model 1</u> <ul style="list-style-type: none"> <li>• Registration with and governed by independent regulatory body</li> <li>• Protection of title</li> </ul>	UK - Applies to 13 professions, not including CAM practitioners
	<u>Model 2</u> Regulation under 3 different licensing systems: <ul style="list-style-type: none"> <li>• <i>monopolistic</i> (conventional health professions only)</li> <li>• <i>tolerant</i> (CAM professionals are tolerated but may not encroach on prescribed medical acts)</li> <li>• <i>mixed</i> (law tolerates practice in non-reserved areas)</li> </ul>	Austria, Belgium, France, Greece, Iceland, Italy, Latvia, Luxembourg, Malta, Poland, Portugal, Spain, Ukraine Germany Denmark, Finland, Hungary, Norway, Sweden
	<u>Model 3</u> Registration under system of exclusive scope of practice, restrictive activities and right to title in one overarching system	NZ - (to be implemented late 2004)
	<u>Model 4</u> Regulation by brief statement of each profession, controlled acts, harm clause and title protection. <ul style="list-style-type: none"> <li>• Must belong to professional college.</li> </ul>	Ontario, Canada
	<u>Model 5</u> Regulation under exclusive scope of practice system	British Columbia, Canada

	<u>Model 6</u> Regulation through licensing, title licensure or registration through approved administrative body <ul style="list-style-type: none"> <li>• Includes scope of practice statements</li> </ul>	US
3. Voluntary Regulation	<ul style="list-style-type: none"> <li>• Free of regulatory controls</li> <li>• No protection of title</li> <li>• Cannot encroach on territory of health professionals who are protected</li> <li>• No state recognition</li> </ul>	UK - Applies to most CAM professionals