Therapeutic Goods Administration (TGA)

Major achievements

- Establishment of the Office of the Gene Technology Regulator.
- New crisis management procedures for product tampering or extortion threats.
- Extension of the TGA's regulatory responsibility to cover all fresh blood.
- Working with New Zealand towards the establishment of a Trans-Tasman Therapeutic Goods Agency.

Outcome summary — the year in review

The key objective of the Therapeutic Goods Administration (TGA) is the regulation of therapeutic products in Australia to ensure they meet high standards of safety, quality and efficacy and are made available to the community in a timely manner.

Over the past year, the TGA has achieved this objective while working successfully with stakeholders and other regulatory agencies internationally to address the increasing demands of rapidly developing technology and consumer expectations of faster availability of a wider range of therapeutic goods.

There were approximately 58,000 products on the Australian Register of Therapeutic Goods (ARTG) as at 30 June 2001. The number of products has risen by 1.9 per cent in the past year.

In addition to its primary responsibility for regulating therapeutic goods, the TGA has advised other regulatory authorities on potential public health risks posed by agricultural, veterinary and industrial chemicals used in the community.

From 1 July 1998, the TGA has been required by the Government to fully recover its operating costs for all activities that fall within the scope of the Act, including regulation of industry and the TGA's public health responsibilities.

Establishment of the Office of the Gene Technology Regulator

The Interim Office of the Gene Technology Regulator (IOGTR) became the Office of the Gene Technology Regulator (OGTR) on 21 June 2001, following the passage of the *Gene Technology Act 2000* through the Commonwealth Parliament on 8 December 2000 and Royal Assent on 21 December that year.

Complementary State legislation and an Inter-Governmental Agreement (IGA) will ensure a truly national scheme.

State and Territory parliaments are expected to consider complementary legislation in the second half of 2001. The IGA commenced circulation to premiers and chief ministers for consideration and signature at the end of April.

The Interim Office of the Gene Technology Regulator was established as a Branch of the Therapeutic Goods Administration in May 1999.

The IOGTR had two major roles:

- to undertake extensive consultation with stakeholder organisations to develop and implement the new national regulatory system for genetically modified organisms (GMOs); and
- to provide support and, where necessary, direction to the previous voluntary administrative arrangements for GMOs,

including providing support for the Genetic Manipulation Advisory Committee (GMAC).

With the Gene Technology Bill 2000 being introduced into Parliament on 22 June 2000, the IOGTR developed and released a draft of the corresponding Gene Technology Regulations 2000. Key stakeholders were invited to attend advertised meetings and/or to provide written submissions in response to the draft regulations. Written submissions were also invited from the public. Various guidelines and licensing arrangements for the new regulatory system were also developed.

Ms Elizabeth Cain, acting Gene Technology Regulator, at the official opening of the Office of the Gene Technology Regulator on 21 June 2001.

Over the past year, the IOGTR/OGTR has maintained its proactive monitoring of field trials and sites subject to post-trial monitoring, for compliance with GMAC recommendations.

Regulatory reform

Medical device reforms

The Therapeutic Goods Amendment (Medical Devices Bill 2001) was introduced to Parliament on 29 March 2001. The Bill provides for a world leading internationally harmonised regulatory framework based on the principles of the Global Harmonisation Task Force. The new system introduces a comprehensive performance based risk assessment system that will facilitate the operation of the Australian–European Union/Mutual Recognition Agreements. This will facilitate trade for both Australian manufacturers and importers.

An initial draft of the Therapeutic Goods (Medical Devices) Regulations 2001 has also been developed and made available for stakeholder comment.

Complementary medicine reforms

New advertising arrangements for therapeutic goods were launched in April 2000. The arrangements include a new principles-based advertising code and clear guidelines on the levels and kinds of evidence sponsors must hold before making claims in relation to listable medicines.

The new guidelines were trialed by stakeholders for the six months to July 2000, with a TGA-convened advisory group to assist sponsors. The trial demonstrated that the new advertising arrangements opened a broad range of opportunities for sponsors to provide evidence-based information about their products to the community.

At the request of the complementary medicines industry, the Advisory Group remained in operation until December 2000, to provide support while sponsors began to operate under the new arrangements.

Review of access to unapproved therapeutic goods

The TGA has reviewed and amended the mechanisms and legislation for allowing patients access to unapproved medicines and medical devices in Australia. Detailed reference documents have been produced for stakeholders involved with the supply and use of unapproved therapeutic products. The information is also available in a series of user-friendly information sheets (*At a glance* and *FAQ* sheets). All of these documents are available on the TGA website — www.health.gov.au/tga

Therapeutic Goods Administration

The Commonwealth Government passed a Therapeutic Substances Act in 1937, giving the Minister for Health power to control the importation and exportation of substances which were declared in the Gazette to be therapeutic substances.

In December, 1953, the Commonwealth passed the *Therapeutic Substances Act 1953*, which among other things repealed the 1937 *Act*. This Act also gave the Commonwealth control of the importation into Australia and interstate trading of therapeutic substances or controlled therapeutic substances. It came into operation in 1956 and was administered by the Therapeutic Substances Branch of the Department of Health. In 1959 the National Biological Standards Laboratory (NBSL) began functioning to monitor products imported into Australia or supplied under the Pharmaceutical Benefits Scheme.

The regulation of therapeutic goods in Australia has benefited from the advice of a number of expert committees, the first of which was the Proprietary Medicines Advisory Committee established in 1953 by the Victorian Government. 1991 saw the functions of the Committee being transferred from State to Federal Government, where it became part of the Therapeutic Goods Administration (TGA) as the Medicines Evaluation Committee.

Prescription medicine regulation is assisted by the Australian Drug Evaluation Committee which met for the first time in 1963. The Adverse Drug Reaction reporting scheme for prescription medicines was introduced in 1964.

The thalidomide tragedy highlighted the need for more thorough checks.

In 1966, the Act was reviewed to give the Commonwealth powers to require manufacturers to submit data to establish the quality, safety and efficacy of imported therapeutic goods. The States had separate arrangements which covered locally manufactured over-the-counter products.

In 1984 the Therapeutic Device Program was established in response to community concerns about the many medical devices coming onto the market. The advisory body for this program, the Therapeutic Device Evaluation Committee, held its first meeting in 1987.

By the late 1980s, it had become clear that the patchwork of Commonwealth and State legislation was not the best way to ensure safety. The *Therapeutic Goods Act 1989* came into effect in 1991 giving the Commonwealth more clearly defined regulatory authority.

In 1989 the TGA was created as a Division of the (then) Department of Community Services and Health. After 35 years all the activities were finally under one roof in a purpose built facility in Canberra. Before that, offices and labs had been scattered over numerous sites, including in an old pie factory in an industrial suburb of Canberra and at the bottom of a block of flats.

By the end of the century, the use of medicinal herbs, vitamin and mineral supplements was increasing dramatically. The TGA responded to this consumer trend and become a world leader in the regulation of complementary medicines; the Traditional Medicines Evaluation Committee (later replaced by the Complementary Medicines Evaluation Committee) was established in 1990.

As well as regulation of Medicines and Medical Devices the TGA has been responsible for a number of other functions including public health assessments of agricultural and veterinary chemicals and the establishment of the Office of the Gene Technology Regulator.

Export review implementation

While the primary role of the TGA is to regulate medicines for the domestic market, it is also committed to ensuring the export of high quality, safe medicines. Australia is an active participant in international activities that protect public health and safety through prevention of the manufacture and sale of sub-standard and counterfeit medicines around the world.

The TGA recognises that timeliness and the minimisation of administrative and regulatory obstacles are of significant benefit to the medicines industry engaging in international trade. It has been working, in consultation with industry associations to implement recommendations arising from the Review of the Regulatory Regime for the Export of Therapeutic Goods.

Review of drugs and poisons and controlled substances legislation

The National Competition Review of Drugs, Poisons and Controlled Substances Legislation was completed in 2000. The Review's final report was presented to the Australian Health Ministers' Conference (AHMC) and, after consideration of the report by Australian Health Ministers' Advisory Council (AHMAC), will be forwarded to the Council of Australian Governments.

Review findings include:

- confirmation of the need for Australia to have a comprehensive system of legislative controls regulating drugs, poisons and controlled substances;
- that the level of regulation should be reduced in some areas and, in other areas, a co-regulatory approach introduced;
- proposed changes to administrative and legislative controls to improve the efficiency of the regulatory system; and
- promotion of non-legislative measures to help meet the underlying objectives of drugs, poisons and controlled substances legislation.

An AHMAC Working Party has been established to assist the preparation of comments on the Final Report for the Council of Australian Governments (COAG). The Working Party held meetings in March and May 2001 and reviewed submissions from State and Territory health and agriculture/ veterinary departments, along with those from other stakeholders who had previously submitted to the review process. A comprehensive response is expected towards the end of 2001.

Ongoing regulatory obligations[1]

Post-market issues

Aristolochic acid contamination

In response to increasing international concerns over the presence of aristolochic acid in some herbal products, the Office of Complementary Medicines (OCM) and the TGA Laboratories have surveyed herbal medicines considered to be at risk of contamination with this toxic substance. The TGA found that a small number of these products did contain aristolochic acids and subsequently cancelled permission to continue to trade in these products. The Australian-based sponsor of these products was required to recall all current stocks.

Product tampering and extortion threats

In 2000, two companies which supply over-the-counter medicines to the Australian market conducted national consumer level recalls of products as a result of criminal tampering and extortion threats. These incidents have highlighted the importance of companies, the TGA and Commonwealth and State and Territory health departments having in place up-to-date crisis management protocols to address such situations. A taskforce, comprising representatives from the TGA, therapeutic goods

[1] Relates to Indicators 1 and 2

industry associations, the Consumers' Health Forum, the police and State and Territory health authorities was established to facilitate a systematic approach to these matters.

There has been agreement on a 'whole of industry' approach to crisis management, based on world's best practice. The TGA co-ordinated a review of and refined the existing protocols to provide model crisis management guidelines for adoption by the therapeutic goods industry as a whole.

A new crisis management section has been inserted in the *Uniform recall procedure for therapeutic goods*, requiring that the TGA be notified in the event of a product tampering threat. As part of the new procedure, the TGA will convene a Emergency Reference Group (ERG) comprising representatives of the company, police and relevant health authorities. The ERG's role is to determine an action plan to deal with the crisis, which may or may not involve recall of the relevant product.

The *Therapeutic Goods Act 1989* has also been amended to strengthen the TGA's recall powers in cases of product tampering and extortion.

The TGA also coordinated a review of tamper evident packaging requirements for therapeutic goods. These are currently being trialed by the industry associations with a view to being made a mandatory requirement in three years time.

Transmissible Spongiform Encephalopathies (TSEs)

The TGA has taken further steps to minimising any risk of transmission of bovine spongiform encephalopathy (BSE) — otherwise known as mad cow disease — through the use of medicines and medical devices in Australia.

The TGA's actions reflect those being taken by other leading international regulatory agencies. All new products submitted to the TGA for inclusion on the Australian Register of Therapeutic Goods and which contain or use in their manufacture animal or human products, must use material sourced from BSE-free countries or, where this is not possible, provide evidence as to safety from BSE and other transmissible spongiform encephalopathies (TSEs).

The TGA has also been reviewing existing medicines and medical devices to identify any potential risks of exposure to TSEs, and removing the use of animal or human products sourced from non-BSE-free countries, except where such use can be fully justified. This review has included active and inactive biological ingredients, as well as biological materials used in production processes but which may not be present in significant amounts in the final product.

Regulation of blood and blood products

The TGA became the national regulator of fresh blood and blood products on 1 July 2000. Over the past year, the TGA has implemented the various standards, manufacturing principles (including a revised Code of Good Manufacturing Practice) and recalls procedures for these products. This regulation covers the collection, processing and storage of fresh blood products.

The TGA provided key scientific input into government decisions aimed at protecting the Australian fresh blood supply from potential risks of transmission of variant Creutzfeldt-Jakob Disease (vCJD, the human form of BSE).

Strategic Information Management Environment (SIME)

The SIME project is an initiative of the TGA to improve the way in which regulatory information is managed. This will establish a base for electronic commerce, electronic lodgement of data packages in support of applications for entry of products onto the Australian Register of Therapeutic Goods (ARTG) and will enable on-line client access to

legally appropriate information. Over the last 12 months the SIME initiative has produced the following:

- delivery of an on-line facility for the registration of devices manufacturing certificates and an electronic assessment engine for the validation of listed medicines submissions.
- progress on replacing the current ARTG, electronic lodgement facilities (for listed medicines) and adverse drug reaction systems, as well as work flow systems to progress and track submissions through the TGA.
- completion of industry pilots for the Devices Electronic Application Lodgement (DEAL) and the Electronic Lodgement Facilities (ELF) systems.

Chemical regulation

Chemical Adverse Experience Reporting Scheme

The TGA Chemicals Unit is coordinating the Government's response to a push from various sections of the Australian community to monitor adverse health events arising from exposure to chemicals, particularly agricultural and veterinary (agvet) chemicals. The Chemicals Unit chaired a Working Party, including representatives from the Departments of Health and Aged Care, Agriculture Forestry and Fisheries and Employment, Workplace Relations and Small Business. The Working Party considered the development of a 'Chemical Adverse Experience Reporting Scheme' (CAERS) that would be used to identify adverse health outcomes associated with identifiable (or probable) chemical exposures.

National intake standard for dioxins

Dioxins and related compounds are formed by combustion processes such as industrial chemical synthesis, waste incineration and bushfires. Because some of these compounds may be highly toxic at quite low levels, relevant government agencies are undertaking programs to determine whether measurable levels of dioxins and related compounds are present in the environment and in certain agricultural commodities. As part of these monitoring programs and their reporting, Environment Australia (EA) and Agriculture, Fisheries and Forestry Australia (AFFA) sought advice from the Department of Health and Aged Care on a tolerable daily intake (TDI) standard for dioxins and related compounds.

The Chemicals Unit of the TGA has drafted a proposal for a TDI, largely based on the deliberations of a consultation between technical experts representing the WHO European Centre for Environmental Health and the WHO/ILO/UNEP International Programme on Chemical Safety in May 1998. A report including a proposed Provisional Tolerable Daily Intake (PTDI) was formally provided to EA, AFFA and the Australia–New Zealand Food Authority (ANZFA) in January 2001.

International activities

Trans-Tasman Therapeutic Goods Agency

In mid-2000, a taskforce was established to consider the administrative arrangements for chemical safety assessments, regulation of medicines, medical devices, gene technology and food and to develop options that would harmonise Australian and New Zealand's regulatory arrangements for therapeutic goods.

Therapeutic goods, such as medicines, medical devices and complementary health care products, have a special exemption from harmonisation under the Trans Tasman Mutual Recognition Agreement (TTMRA) until 1 May 2002. This places an obligation on Australian and New Zealand regulators to resolve differences in regulating these goods, with a view to protecting public health and safety.

Australian and New Zealand health ministers agreed last year to explore the feasibility of establishing a joint agency to harmonise therapeutic goods regulation between both countries. In December 2000, the New Zealand government supported 'in principle' the establishment of a joint agency, subject to certain issues being addressed. In January 2001, Australian State and Territory Health Ministers' accepted a TTMRA report that recommended the establishment of a single joint agency and, in July 2001, the Commonwealth government agreed to continue further work on assessing the feasibility of establishing a joint agency.

Subject to the government's final agreement, the new agency would be recognised in law in both Australia and New Zealand. It would assume responsibility for all regulatory functions currently undertaken by the Australian Therapeutic Goods Administration and New Zealand's Medsafe, including the power to implement and enforce decisions in both jurisdictions.

International agreements

This year has seen the development of a number of key international agreements in therapeutic goods and chemicals regulation.

United States: On 11 October 2000, the TGA signed a cooperative arrangement with the US Food and Drug Administration (FDA), regarding the exchange of information on current Good Manufacturing Practice (GMP) inspections of human pharmaceutical manufacturing facilities. The information shared would include inspection timetables, recall information and forecasts of shortages of medically necessary human pharmaceuticals.

China: In November 2000, the TGA signed a MoU with the State Drug Administration (SDA) of China to strengthen the relationship and collaboration between the two countries on pharmaceutical regulation. An agreement of intention of collaboration with the State Administration of Traditional Chinese Medicines (SATCM) has been in place since 1997.

Singapore: A mutual recognition agreement (MRA) on GMP inspections, between Australia and Singapore, was signed in Canberra on 26 February 2001. As a result of this international treaty the TGA will recognise Singapore's GMP certificates in support of applications for entry on the Australian Register of Therapeutic Goods (ARTG).

United Nations: Staff of the TGA Chemicals Unit contributed to Australian Government inputs into the development of two United Nations Environment Program (UNEP) chemicals treaties — one on the control of Persistent Organic Pollutants (the so-called POPs Convention) and the other on the control of certain hazardous chemicals in trade (the Rotterdam, or PIC Convention). In addition, arising from Australia's recent decision to remove the pesticide, monocrotophos, from the national market, Chemicals Unit staff were asked to present its toxicology and public health risk assessment to a meeting of the Interim Chemical Review Committee of the Rotterdam convention. This, together with a similar 'notification of regulatory action' from Hungary, led to the international decision to PIC-list monocrotophos. This means that future international movements of this chemical will have to be notified by exporting countries, with importing country governments having the right to refuse import shipments under international law.

OECD: In early 2001 the OECD published an environment, health and safety monograph drafted by staff of the TGA's Chemicals Unit on an agreed approach to the analysis and reporting of toxicology studies, titled *Guidance Notes for Analysis and Evaluation of Repeat-Dose Toxicity Studies*.

WHO: Under the auspices of the WHO/ILO/UNEP International Programme on Chemical Safety (IPCS), Chemicals Unit staff

participated in the development of an harmonising approach to cancer risk assessment, and the publication of a document titled *IPCS Conceptual Framework for Evaluating a Mode of Action for Chemical Carcinogenesis*. This framework will be used by agencies responsible for assessing the carcinogenicity of chemicals.

European Free Trade Association (EFTA): A Mutual Recognition Agreement on medicinal products, GMP inspections and medical device premarket assessment with the EFTA was implemented in July 2000. This extends the MRA in place with the European Union and will now cover the European economic area. The EFTA countries included in the agreement are Norway, Liechtenstein and Iceland.

Global Harmonisation Task Force

The Global Harmonisation Task Force (GHTF) was conceived in 1992 in an effort to respond to the growing need for international harmonisation in the regulation of medical devices. The Task Force comprises five founding members — Canada, USA, the European Union, Australia and Japan representing three regions, North America, Europe and Asia/Pacific.

In January 2001, Australia, represented by the TGA, assumed the GHTF Chair and Secretariat for 18 months.

The GHTF provides a forum in which official representatives of national regulatory bodies, working with medical device manufacturers and other organisations possessing relevant expertise, can harmonise global approaches to regulating the safety, clinical performance and quality of medical devices in ways that protect public health, promote technological innovation and facilitate international trade.

GHTF achieves its mandate via the publication and dissemination of harmonised guidance documents on basic regulatory practices. Once endorsed by the GHTF, national regulatory authorities are encouraged to adopt the documents, where appropriate, into their medical device regulatory systems.

In February and June 2001, TGA convened the first two meetings of the newly established GHTF Steering Committee in Sydney and Brussels respectively. The Committee is responsible for management oversight and policy setting for the organisation. Its membership comprises 32 government regulators and medical device industry representatives from the five founding member countries.

TGA's key task as GHTF Chair is to undertake a strategic review of the organisation and develop a strategic plan for the next five years.

Other key activities include hosting the ninth GHTF Conference in London (October 2001), developing and hosting a training program for south-east Asian regulators in Australia (March 2002), convening the third and fourth Steering Committee meetings in conjunction with these events, continuing the review of regulatory guidance documents being developed by the GHTF Study Groups and outlining Founding Members' progress with the adoption of GHTF guidance documents.

Further information on the GHTF may be obtained from the website — www.ghtf.org

Training

The TGA has provided training on the regulation and testing of therapeutic goods to a number of regulators in the Asia–Pacific region over the past year.

Vietnam: The TGA provided technical assistance and training to staff from the Drug Administration of Vietnam, with funding from AusAID under the Asia Pacific Economic Cooperation (APEC) Support Program. The TGA also provided training on vaccine quality control in cooperation with the International Vaccine Institute.

Taiwan: The TGA assisted the Centre for Drug Evaluation of Taiwan to build its capability for drug evaluation on a consultancy basis.

Hong Kong: The TGA provided two GMP training programs, on a cost recovery basis, to the Hong Kong Department of Health.

Papua New Guinea: The TGA conducted a one-week training program on therapeutic goods regulation for the Medical Supplies Division of the Department of Health, Papua New Guinea.

Thailand: Senior officers of the TGA and the Thai Ministry of Public Health visited each other in 2000 to develop an appropriate training program regarding therapeutic goods regulation. In May 2001, two senior inspectors of the Thai Food and Drug Administration participated in a comprehensive surveillance training program in Canberra, with funding provided by the Department.

Indonesia: TGA officers delivered three evaluation training courses to the Indonesia Directorate of Drug Control in 2000. These training activities focused on pharmaceutical chemistry, toxicology and clinical evaluation. This was undertaken thorough an APEC Support Program funded mainly by AusAID.

Regional cooperation

In November 2000, the TGA chaired a Regulators' Forum in Sydney, in conjunction with the 4th Asia Pacific Regional Conference of the World Self-Medication Industry (WSMI). The Forum was designed to develop a regional approach to fostering closer relations between regulatory authorities in the region and to and lead towards increased harmonisation in the regulation of therapeutic goods.

Presentations and reports were given by regulators from Australia, Canada, the European Commission, Fiji, Indonesia, Japan, Korea, Myanmar, Nepal, New Zealand, the Philippines, Singapore, Taiwan, Thailand and Vietnam. In addition to government regulators, there were industry representatives and a consumer advocate, with 120 invited guests acting as observers.

The forum also prepared and unanimously agreed to the *Sydney 2000 Declaration*, drawing on the key principles underpinning good regulatory practice and pointing towards future collaboration between regulators in the region.

The success of the forum has highlighted the TGA's position as a regional leader for therapeutic goods regulation. It has also greatly increased the level of cooperation and understanding between stakeholders, such as the self-medication industry, and consumers.

Other notable achievements

Support for the Sydney 2000 Olympics

The TGA played a valuable role in the Government's support of the 2000 Olympic and Paralympic Games. In the months leading up to the Games, the TGA was involved in a number of activities to assist in ensuring timely and efficient entry to Australia for all overseas participants and visitors. These included:

- advice to the Australian Sports Drugs Agency and the Australian Customs Service on scientific, technical and administrative aspects of substances of interest, medicinal products and the import to Australia of medicines kits by athletes, officials and passengers; and
- definition and clarification of suspected performance enhancing substances at the entry point to Australia.

During the period of the Games, the TGA provided round-the-clock advice to many organisations and individuals. The arrangements worked flawlessly.

TGA open day

As part of the Australian Science Festival 2001, and in conjunction with the Department's 80th birthday celebrations, the TGA held an Open Day on Saturday 5 May 2001. Tours of the TGA building in Symonston (ACT) were conducted, and TGA staff were available to explain the role of the TGA and how it operates.

Performance indicators

Indicator 1:
Proportion of products on the Australian Register of Therapeutic Goods (ARTG) withdrawn from the market, or requiring a change of condition of approval for safety related reasons.

Target:
No more than 2 per cent of products (on the ARTG) withdrawn for safety related reasons.

Information source/reporting frequency:
Therapeutic Goods Administration Reporting Systems.

Indicator 2:
Proportion of products failing to meet a quality or efficacy standard as a result of post market surveillance.

Target:
A decrease in the percentage of product failures as a result of post market surveillance.

Information source/reporting frequency:
Therapeutic Goods Administration Quarterly Performance Reports.

OUTCOME 1 : FINANCIAL RESOURCES SUMMARY

	[1] (A) Budget Estimate 2000/2001 $'000	(B) Actual Expenses 2000/2001 $'000	Variation (Column B minus Column A)	[2] Budget 2001/2002 $'000
Administered Expenses				
Administered Item 1: *Population Health*				
National Health Act 1953 - Essential Vaccines	94,580	93,852	(728)	86,902
Total Special Appropriations	94,580	93,852	(728)	86,902
Appropriation Bill 1/3	122,796	116,549	(6,247)	114,252
Appropriation Bill 2/4	185,036	157,151	(27,885)	171,603
Total Administered Expenses	402,412	367,552	(34,860)	372,757
Departmental Appropriations				
Health & Aged Care				
Output Group 1 - Services to the Minister & Parliament	14,701	14,747	46	19,860
Output Group 2 - National Leadership	12,585	12,613	28	-
Output Group 3 - Information	8,540	8,584	44	-
Output Group 4 - Program Management	8,539	8,958	419	26,973
Output Group 5 - Regulatory Activity	449	9,031	8,582	-
Output Group 6 - Direct Delivery of Services	-	-	-	-
Total price of departmental outputs *(total revenue from Government & other sources)*	44,814	53,933	9,119	46,833
Total revenue from Government (appropriations) contributing to price of departmental outputs	44,315	50,810	6,495	46,465
Total revenue from other services	499	3,123	2,624	368
Total price of departmental outputs *(total revenue from Government & other sources)*	44,814	53,933	9,119	46,833
Therapeutic Goods Administration				
Output Group 1 - Services to the Minister & Parliament	2,391	2,144	(247)	1,786
Output Group 2 - National Leadership	5,112	2,238	(2,874)	-
Output Group 3 - Information	2,495	3,286	791	52,982
Output Group 4 - Program Management	-	-	-	-
Output Group 5 - Regulatory Activity	45,527	39,955	(5,572)	-
Output Group 6 - Direct Delivery of Services	-	-	-	-
Office of Gene Technology Regulator				
Output Group 3 - Agency Specific Service Delivery	-	-	-	7,947
Total price of TGA outputs *(total revenue from Government & other sources)*	55,525	47,623	(7,902)	62,715
Total revenue from Government (appropriations) contributing to price of departmental outputs	6,262	60	(6,202)	11,409
Total revenue from other services	49,263	47,563	(1,700)	
TGA	-	-	-	49,234
Miscellaneous	-	-	-	2,072
Total price of TGA outputs *(total revenue from Government & other sources)*	55,525	47,623	(7,902)	62,715
Total revenue from Government (appropriations) contributing to price of departmental outputs	50,577	50,870	293	57,874
Total revenue from other services	49,762	50,686	924	51,674
Total price of departmental (including) TGA outputs	100,340	101,557	1,217	109,548
Total price of outputs for Outcome 1 *(total revenue from Government & other sources)*	100,340	101,557	1,217	109,548
Total estimated resourcing for Outcome 1 *(total price of outputs & admin expenses)*	502,752	469,109	(33,643)	482,305

1 The Budget Estimate 2000/2001 includes the appropriations as per the 2000-2001 Portfolio Budget Statements (PBS), 2000-2001 Portfolio Additional Estimates and Advances to the Finance Minister. This amount may differ to the revised estimates for 2000/2001 published in the 2001/2002 PBS. Such differences can arise from updated estimates and rephasings.

2 Budget prior to additional estimates. The number of output groups has reduced from 5 in 2000-2001 to 2 in 2001-2002. It is not possible to show direct comparatives