

Review of **Pharmacy Remuneration and Regulation**

Final Report

September 2017



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FOREWORD

The Panel is pleased to present to the Minister for Health the Final Report for the Review of Pharmacy Remuneration and Regulation (the Review).

This Report provides the Panel’s recommendations on future remuneration, regulation and other arrangements that apply to pharmacy and wholesalers for the dispensing of medicines and services provided under the Pharmaceutical Benefits Scheme (PBS). The Review intends to ensure that consumers continue to have reliable and affordable access to medicines and utilises significant stakeholder feedback from the Interim Report, which was published in June 2017, to inform the reform options presented in this Final Report. Consequently, the Interim Report acts as an important reference to this Final Report.

Consistent with our Terms of Reference, the Panel’s recommendations take a consumer-focused approach. The Review has scrutinised the current pharmaceutical supply chain, from wholesaling through to the consumer, to determine if it adequately ensures the timely, efficient and sustainable distribution of the medicines listed on the PBS to Australians who need them, regardless of their location. This aligns with the objectives of Australia’s National Medicines Policy (NMP), as well as other reforms in primary, aged care and chronic disease management that are being implemented in the broader health sector.

The recommendations are forward looking and consider the twenty-year outlook for community pharmacy. The Panel envisages a consumer—centred, integrated and sustainable community pharmacy sector which is adaptive to the inevitable changes in healthcare given Australia’s ageing population, rapid advances in technology and ongoing PBS reform.

Community pharmacy is a significant public asset. Australia’s network of over 5700 community pharmacies and pharmacist workforce—over 20,000 in community pharmacy and 30,000 registered pharmacists—play an important role in our healthcare system and are a key enabler to the achievement of the NMP. For many Australians, the community pharmacy network is the most convenient and accessible interface to the primary healthcare system. In addition, pharmacists hold a trusted role within our communities and act as a valued referral point for health and other local services.

Such an important public resource requires appropriate safeguards however, it also needs to operate in an efficient and sustainable manner to maximise the value of taxpayer and patient contributions.

Australia’s ageing population, the increasing incidence of patients with complex and chronic conditions, advances in health technology, and the fiscal constraints across the whole of government were emphasised in submissions to the Review as growing pressures on the Australian healthcare system. Submissions also highlighted the changing role of community pharmacy and the need for pharmacy to enhance its contribution to a health system that will increasingly focus on integrated, rather than episodic, care.

The Panel recognise that parts of the community pharmacy sector are at risk. Submissions and other information available to the Panel have highlighted the stresses within the community pharmacy sector. For example, despite being highly trained healthcare professionals, employee pharmacists often face poor remuneration and uncertain career paths. These are tied to limited opportunities for ownership and the expense of ‘buying in’ to a limited number of community pharmacies, as well as the uncertainties facing the pharmacy sector.

We believe, as do the majority of submissions to the Review, that if pharmacists and pharmacies are to play a bigger role in Australia’s primary healthcare system and preventative health agenda then it is not unreasonable to expect that:

- pharmacy services and programs are more closely integrated with the broader healthcare system (for example digital health initiatives and the implementation of other coordinated care reforms such as Health Care Homes);
- the framework for community pharmacy remuneration and regulation be more flexible and adaptable to the changing needs of the Australian healthcare system, and allows for innovation in healthcare;
- community pharmacy, as an agent of the government, is appropriately remunerated for the services and programs it provides;
- evidence be required and made available in relation to the comparative clinical and cost-effectiveness that community pharmacy services and programs provide; and
- there be greater accountability and transparency from the sector for the expenditure of taxpayer funds.

Our recommendations help to meet these objectives.

The Panel has worked closely with stakeholders to ensure that the issues associated with pharmacy remuneration and regulation have been carefully scrutinised in this Report. Since the Review commenced in November 2015, the Panel has conducted sixteen public forums in metropolitan and rural locations across Australia, attended 101 bilateral meetings with organisations and individuals, visited thirty-two pharmacies, presented at six conferences and conducted one live national webcast. The Panel has also received over 500 submissions in response to the Review Discussion Paper, 197 submissions in response to the Review’s Interim Report, and 381 more responses to the Interim Report’s online questionnaire.

These interactions with the pharmacy sector and individuals have played a significant role in the development of the Panel’s recommendations presented in this Report. We would like to thank all those who provided their time, support and submissions to this Review process.

We commend this Report to the government and look forward to seeing all parties come together to embrace our vision for a more consumer-centred, integrated and sustainable pharmacy sector in the future.



Stephen King



W.J. (Bill) Scott



Jo Watson

TABLE OF CONTENTS

Foreword.....	4
Table of Contents.....	6
Executive Summary.....	7
Summary of Findings and Recommendations	11
Next Steps	27
1. Introduction	28
2. Consumer Access and Experience.....	32
3. Access to PBS Medicines and Community Pharmacy Services for Aboriginal and Torres Strait Islander People	48
4. The Role of Community Pharmacy.....	55
5. Community Pharmacy Remuneration By Government	62
6. The Regulation of Pharmacy For Medicine Supply	74
7. The Distribution of Medicines to Community Pharmacy.....	88
8. Future Community Pharmacy Agreements.....	97
9. Health Programs Offered By Community Pharmacy and the Role of Pharmacy In Primary Healthcare.....	104
10. Chemotherapy Compounding.....	114
11. Hospital Pharmacies.....	119
12. Appendices.....	125
Appendix A: Abbreviations and Explanations	126
Appendix B: Review Terms of Reference	131
Appendix C: Stakeholder Engagement.....	133
Appendix D: Cross-References to Interim Report.....	133
Appendix E: Responses to the Interim Report.....	139

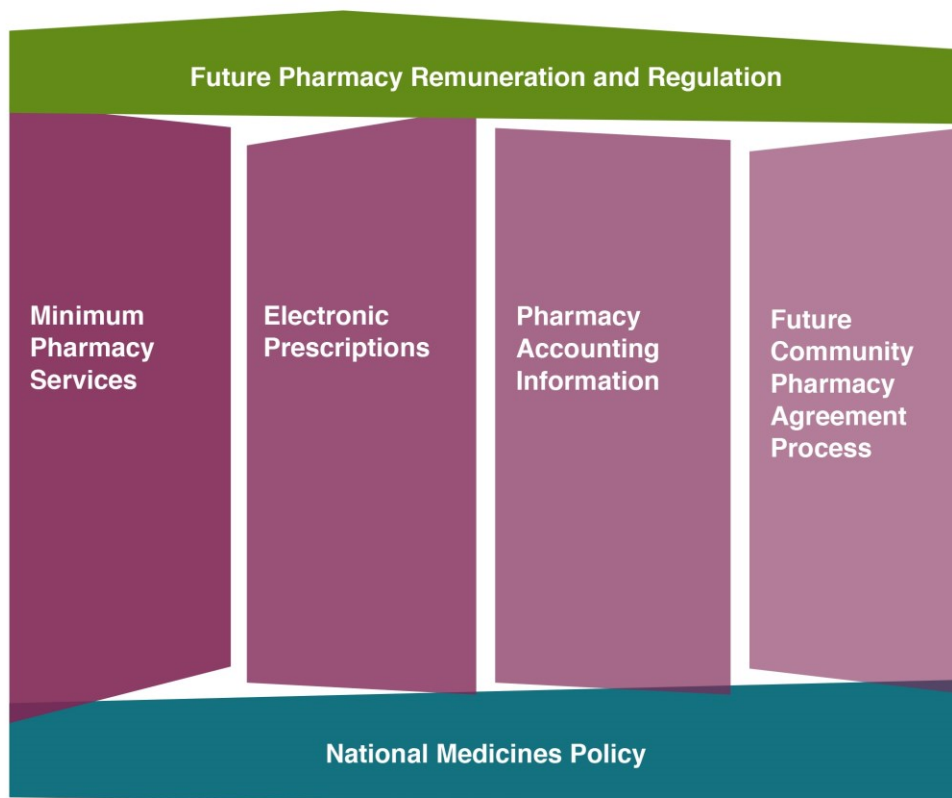
EXECUTIVE SUMMARY

The Panel has completed a comprehensive Review of Pharmacy Remuneration and Regulation (the Review). This has involved consulting broadly with consumers and peak industry bodies that represent areas of the pharmacy and healthcare sector. The Panel has also held public forums and visited individual pharmacies, while commissioning research into overseas arrangements, and a financial analysis of the sector. The Panel has developed a number of recommendations with the intention of removing unnecessary regulation and sustaining both consumer access to pharmacy and government value for money, while also maintaining the viability of the sector.

The recommendations encompass the entire pharmacy sector and have the potential to affect consumers, pharmacists, pharmacy owners, distributors and manufacturers, as well as a number of other stakeholders. These recommendations have been considered carefully and, where appropriate, guidance has been given on how government can positively affect change in the sector.

There are four key elements that shape the Review’s recommendations and underpin the delivery of the National Medicines Policy (NMP)—Minimum Pharmacy Services, Electronic Prescriptions, Pharmacy Accounting Information and Future Community Pharmacy Agreement Process (see Figure 1). These represent foundational recommendations that act as enablers to other issues and should be progressed as a priority by government

FIGURE 1: KEY AREAS FOR REFORM



MINIMUM PHARMACY SERVICES

Community pharmacies in Australia are remunerated through the Pharmaceutical Benefits Scheme (PBS) for the dispensing of medicines and consequently act as agents for government. Government should develop a set of minimum services that it expects community pharmacies to deliver, including the supply of PBS medicines, provision of related advice and information on dispensing-related programs. The Panel believes that to ensure equity of access there should be no variation in the pricing of PBS medicines by pharmacies, thereby encouraging pharmacies to compete on the quality of services, the intention being the provision of more consistent pharmacy services across the network while improving access for all Australians.

Clear and enforceable minimum standards should be developed for the supply of medicines and related services by pharmacies, including dose administration aids (DAAs), with appropriate remuneration provided to community pharmacies. The range of programs provided by community pharmacies should also be underpinned by a number of key principles which articulate costs and funding, where a community pharmacy can choose to provide a service or program and where remuneration may be channelled through the user of the service. This will ensure that critical programs meet quality standards, are adequately funded and are capable of evaluation.

ELECTRONIC PRESCRIPTIONS

The Panel has considered how the pharmacy sector can continue to use technology to improve consumer access and affordability. The adoption of electronic prescriptions, an online pharmacy atlas, universal health and medications record and, where appropriate, the electronic distribution of Consumer Medicines Information (CMI) could all contribute to this end. However, recommendations regarding the development and utilisation of emerging technologies are also presented to safeguard consumer access and choice. The implementation of electronic prescriptions and a universal health record will be a significant paradigm shift in pharmacy, helping to break down geographical barriers to access and improving the ability of the profession to manage medicine risks to consumers.

PHARMACY ACCOUNTING INFORMATION

Over the course of the Review, the Panel has attempted to understand whether the current remuneration to pharmacies is adequate based on the notion of a best practice pharmacy as an appropriate remuneration benchmark.

Professor King and Ms Watson consider that the key challenge has been the lack of pharmacy financial data provided by the sector to the Panel for analysis. For this reason, they have recommended that the government introduce a set of accounting principles for community pharmacies to inform the development of future agreements. This information should also be used to determine the average dispensing cost for a best practice pharmacy, and government remuneration should be based upon this information. The remuneration should be a simple dispense fee based on the average, long-run incremental cost of dispensing in a best practice pharmacy.

Professor King and Ms Watson consider that the provision of accounting information will enable the government and other stakeholders to have more confidence that pharmacy is being adequately remunerated, as well as creating a reference point to assess performance and the viability of the network as a whole.

Mr Scott considers that, while there should be an appropriate level of scrutiny in information supporting the negotiation of remuneration to pharmacy, this needs to be balanced with the administrative burden placed on both the pharmacy sector and the government, when attempting to obtain such information. The focus of remuneration should be on the overall funding required to maintain a viable community pharmacy sector in Australia rather than the determination of an arbitrary cost of dispensing that is unlikely to allow for the variation in pharmacy models and settings. The negotiation should utilise the best available information held by the negotiating parties.

The Panel has also noted the number of additional services provided by pharmacies that are not currently remunerated. The Panel has agreed that, if the same services are provided by alternative primary healthcare providers, the community pharmacist should also be provided with the same remuneration for that service.

FUTURE COMMUNITY PHARMACY AGREEMENT PROCESS

The process for developing Community Pharmacy Agreements (CPAs) has evolved significantly since its inception and requires adjustments to its scope, accountability, negotiation and agreement. The range of stakeholders included for consultation should represent those who deliver on the agreed services. This will improve the overall transparency and sustainability of the sector. This requires cooperation between the government, the Pharmacy Guild of Australia (the Guild), the Pharmaceutical Society of Australia (PSA) and the Consumers Health Forum of Australia (CHF) as national representatives of government, community pharmacy owners, pharmacists and consumers.

To reduce the complexity of future CPAs, the scope of agreements should also be limited to remuneration for dispensing. This means not including wholesaling or other professional programs offered by community pharmacies. Rather, these should be negotiated and agreed separately.

Minimum Pharmacy Services, Electronic Prescriptions, Pharmacy Accounting Information and Future Community Pharmacy Agreement Process inform a series of interdependent recommendations that are designed to achieve an appropriate balance between meeting consumer needs, providing sustainable and cost-effective pharmaceutical services and addressing aspects of regulation to improve access and affordability.

The Report addresses issues relating to the provision of medicine and pharmacy services to Aboriginal and Torres Strait Islander people. This includes improving the capabilities of Aboriginal Health Services (AHSs) and the adoption of a key principle that program benefits should follow the individual, regardless of where their medicines are prescribed.

The Panel has also attempted to address issues relating to the supply of medicines to community pharmacy. However, this was not possible, as the Panel did not receive the data or information required to fully understand the complex issues relating to the medicine supply chain and the

dynamic environment it operates within. The Panel also notes the prevalence of medicine shortages in Australia, and considers that addressing these and other supply chain issues will require a more targeted analysis than has been possible in this Review.

SUMMARY OF FINDINGS AND RECOMMENDATIONS

The following is a summary of the findings and recommendations from the Review:

CHAPTER 2: CONSUMER ACCESS AND EXPERIENCE

Finding	Recommendation
<p>MEDICINE PRICING VARIATIONS</p> <p>The variation in pricing of Pharmaceutical Benefits Scheme (PBS) medicines to consumers has unintended consequences for equity and consumer access.</p>	<p>RECOMMENDATION 2-1: PBS PRICING VARIATIONS</p> <p>The payment made by any particular consumer for a PBS-listed medicine should be the co-payment set by the Australian Government for that consumer or the Dispensed Price for Maximum Quantity for that medicine, whichever is the lower. An Approved Pharmacy should have no discretion to either raise or lower this price.</p>
<p>THE \$1 DISCOUNT</p> <p>The \$1 discount has not led to equitable outcomes for consumers.</p>	<p>RECOMMENDATION 2-2: THE \$1 DISCOUNT</p> <p>The Australian Government should abolish the \$1 discount on the PBS patient co-payment.</p>
<p>PBS SAFETY NET</p> <p>The current PBS Safety Net system lacks sufficient transparency and is difficult for consumers to document and understand. This results in the Safety Net not being utilised to the extent possible, which disadvantages more vulnerable consumers.</p>	<p>RECOMMENDATION 2-3: PBS SAFETY NET</p> <p>In relation to the PBS Safety Net, the Australian Government should:</p> <ol style="list-style-type: none"> require the PBS Safety Net to be managed electronically for consumers. This functionality should be automatic from the consumer’s perspective; investigate whether the PBS Safety Net scheme can be adjusted to spread consumer costs over a twelve-month period; provide sufficient transparency in the way a patient’s progress towards the PBS Safety Net is collated, including information on any gaps in how it is calculated; and investigate and implement an appropriate system which allows payments for opiate dependence treatments to count towards the PBS Safety Net.
<p>CONSUMER INFORMATION ON PHARMACY SERVICES</p> <p>Some consumers are unaware of the range of services available from community pharmacies. Utilising technology to improve consumer awareness could increase overall</p>	<p>RECOMMENDATION 2-4: PHARMACY ATLAS</p> <p>There should be an easily accessible and searchable ‘atlas’ of all community pharmacies in Australia that provides key consumer information, including the services and programs offered by each pharmacy, the opening hours of the pharmacy and any specific accessibility services of the pharmacy (e.g. multilingual staff). The ‘atlas’ should be easily accessible to consumers (e.g. through mobile-</p>

Finding	Recommendation
access.	friendly applications). The Australian Government should also consider the feasibility of a twenty-four hour ‘pharmacy hotline’ to provide pharmacist advice and medicines information to consumers Australia-wide.
<p>CONSUMER MEDICINES INFORMATION</p> <p>While Consumer Medicines Information is generally available, there are inconsistencies in how this is provided to consumers. Some consumers may be unaware of the availability of a Consumer Medicines Information, which could impact on quality of use of medicines.</p>	<p>RECOMMENDATION 2-5: CONSUMER MEDICINES INFORMATION</p> <p>Consumer Medicines Information should be offered and made available to consumers with all medicines dispensed, in accordance with Pharmaceutical Society of Australia guidelines. The Pharmaceutical Society of Australia guidelines and the distribution of Consumer Medicines Information to consumers should be audited and enforced to ensure compliance.</p> <p>Pharmacists and the pharmacy industry should continue to work on the improvement of Consumer Medicines Information and the use of technology to make medicines information more available to consumers.</p>
<p>ELECTRONIC PRESCRIPTIONS</p> <p>There are impediments to the effective use of technology in the community pharmacy network. Encouraging a national adoption of electronic prescriptions will reduce unnecessary administration and better support quality use of medicines.</p>	<p>RECOMMENDATION 2-6: ELECTRONIC PRESCRIPTIONS</p> <p>The Australian Government should initiate an appropriate system for integrated electronic prescriptions and medicine records as a matter of urgency. Under this system the electronic record should become the legal prescription record. Participation in the system should be required for any prescriber of a PBS-listed medicine, any pharmacist wishing to dispense a PBS-listed medicine and any consumer who is seeking to fill a PBS prescription.</p>
<p>A UNIVERSAL HEALTH RECORD</p> <p>Australia lacks an integrated and effective universal health record system. This reduces consumer access to best-practice care and continuity of care between providers. A complete medication history is critical for appropriate prescribing and dispensing.</p>	<p>RECOMMENDATION 2-7: ELECTRONIC MEDICATIONS RECORD</p> <p>There should be one electronic personal medications record system that covers all Australians and ensures appropriate access by, and links between, community pharmacy, hospitals and all doctors. This record system should also include a vaccines register.</p>
<p>MANAGING RISKS ASSOCIATED WITH ‘CHANNELLING’ PRESCRIPTIONS</p> <p>The introduction of a compulsory</p>	<p>RECOMMENDATION 2-8: ELECTRONIC PRESCRIPTIONS—CONSUMER CHOICE</p> <p>The choice of where a consumer has an electronic prescription</p>

Finding	Recommendation
electronic prescriptions record system could introduce risks of inappropriate behaviour, such as channelling of prescriptions that will need to be managed appropriately.	dispensed should remain a decision for the consumer. Any consumer should be able to request at the point of prescribing that their script be directed to a particular community pharmacy for dispensing (including an online pharmacy if that is the consumer's choice). For avoidance of doubt, a prescriber should not be able to direct a consumer's electronic prescription to a particular pharmacy for dispensing without that consumer's consent. This will require appropriate oversight and enforcement by professional bodies.

CHAPTER 3: ACCESS TO PBS MEDICINES AND COMMUNITY PHARMACY SERVICES FOR ABORIGINAL AND TORRES STRAIT ISLANDER PEOPLE

Finding	Recommendation
<p>SECTION 100 REMOTE AREA ABORIGINAL HEALTH SERVICES PROGRAM</p> <p>Access to medicines for Indigenous Australians under the section 100 Remote Area Aboriginal Health Service Program and the Closing the Gap PBS Co-Payment Measure has created a number of challenges in ensuring a consistent level of care to the intended patient group.</p>	<p>RECOMMENDATION 3-1: ACCESS TO MEDICINES PROGRAMS FOR INDIGENOUS AUSTRALIANS</p> <p>The Australian Government should ensure all benefits from the section 100 Remote Area Aboriginal Health Service Program and the Closing the Gap PBS Co-Payment Measure are accessible to Aboriginal and Torres Strait Islander people living in rural areas. This should be based on the principle that the benefits to the individual follow that individual, regardless of where a prescription is written or dispensed.</p>
<p>PHARMACY OWNERSHIP AND OPERATIONS BY ABORIGINAL HEALTH SERVICES</p> <p>Aboriginal Health Services are currently unable to operate a community pharmacy, which may undermine culturally appropriate care in some rural and remote areas of Australia.</p>	<p>RECOMMENDATION 3-2: PHARMACY OWNERSHIP AND OPERATION BY AN ABORIGINAL HEALTH SERVICE</p> <p>The Australian Government should remove any restrictions on the ability of an Aboriginal Health Service to own and operate a pharmacy located at that Aboriginal Health Service. To ensure viability this should be trialled across specific jurisdictions in urban, rural and remote locations, to understand any inadvertent impacts of the removal of restrictions.</p>
<p>PATIENT LABELLING IN BULK SUPPLY</p> <p>There are risks to patients where medicines in bulk supply are not individually labelled to identify a specific patient's medicine with information on that patient's use of</p>	<p>RECOMMENDATION 3-3: PATIENT LABELLING OF MEDICINES UNDER BULK SUPPLY ARRANGEMENTS</p> <p>All PBS medicines provided to a patient should be appropriately labelled and dispensed for that patient's use. Where there is a system in place that involves 'remote' dispensing or 'bulk supply' this would require appropriate monitoring to ensure the quality of</p>

Finding	Recommendation
their medicine.	medicine supply. Aboriginal Health Services and pharmacies in remote areas should be provided training to understand and mitigate the risks associated with remote and bulk supply dispensing.
MACHINE DISPENSING IN REMOTE REGIONS OF AUSTRALIA	RECOMMENDATION 3-4: MACHINE DISPENSING
Overseas experience has demonstrated advantages in the use of remote dispensing machines to improve medicine access for patients living in remote communities.	The Australian Government should trial the use of machine dispensing in a small number of relevant secure locations in communities that are not currently served by a community pharmacy. Such machine dispensing must be appropriately supervised and should allow real-time remote interaction with a pharmacist. The range of PBS medicines available through machine dispensing should be limited based on an assessment of risk.

CHAPTER 4: THE ROLE OF COMMUNITY PHARMACY

Finding	Recommendation
COMMUNITY PHARMACY—MINIMUM SERVICES	RECOMMENDATION 4-1: COMMUNITY PHARMACY—MINIMUM SERVICES
There is a significant variability between pharmacies and the services they offer.	The Australian Government should ensure that all PBS pharmacies offer a range of minimum services expected by Australian consumers. These minimum services should include: the supply of PBS medicines; provision of medicine related advice; and information on relevant programs and services. This will require the Australian Government to establish a process to determine the specific minimum requirements that a community pharmacy must meet in order to receive remuneration for dispensing, as well as update and enforce these requirements.
COMPLEMENTARY MEDICINES IN COMMUNITY PHARMACY	RECOMMENDATION 4-2: COMPLEMENTARY MEDICINES IN COMMUNITY PHARMACY
Consumers value access to complementary medicines in the community pharmacy setting, where they can receive advice on selection and use that is supported by an appropriate level of evidence.	Community pharmacists are encouraged to: <ul style="list-style-type: none"> a. display complementary medicines for sale in a separate area where customers can easily access a pharmacist for appropriate advice on their selection and use; and b. provide appropriate information to consumers on the extent of, or limitations to, the evidence of efficacy of complementary medicines. This could be achieved through the provision of appropriate signage within the pharmacy (in

CHAPTER 4: THE ROLE OF COMMUNITY PHARMACY

the area in which these products are sold), directing consumers to ‘ask the pharmacist for advice’ if required.

PHARMACY ONLY AND PHARMACIST ONLY MEDICINES (SCHEDULE 2 AND SCHEDULE 3 MEDICINES)

Complementary medicines may pose a risk to consumers when they are not clearly distinguished from Pharmacy Only and Pharmacist Only (Schedule 2 and Schedule 3) medicines within a community pharmacy. This is exacerbated by a lack of understanding regarding the distinctions and differences between scheduled medicines and complementary medicines.

RECOMMENDATION 4-3: PLACEMENT OF SCHEDULED MEDICINES WITHIN A COMMUNITY PHARMACY

Access to Pharmacy Only (Schedule 2) and Pharmacist Only (Schedule 3) medicines should be clearly separated from complementary medicines within a community pharmacy. Options to achieve this might include:

- a. ensuring that all Pharmacy Only (Schedule 2) and Pharmacist Only (Schedule 3) medicines are only accessible from ‘behind the counter’ in a community pharmacy so that a consumer must always seek assistance or advice in obtaining these medicines; and
- b. requirements that complementary medicines are not displayed ‘behind the counter’ in a community pharmacy.

HOMEOPATHIC PRODUCTS IN COMMUNITY PHARMACY

The ‘halo’ effect related to homeopathic products may mislead consumers where these products are sold in community pharmacies.

RECOMMENDATION 4-4: SALE OF HOMEOPATHIC PRODUCTS IN PBS APPROVED PHARMACIES

Homeopathy and homeopathic products should not be sold in PBS-approved pharmacies. This requirement should be referenced and enforced through relevant policies, standards and guidelines issued by professional pharmacy bodies.

CHAPTER 5: COMMUNITY PHARMACY REMUNERATION BY GOVERNMENT

Finding	Recommendation
<p>COMMUNITY PHARMACY ACCOUNTING INFORMATION</p> <p>The extent and quality of data and information currently available to the Australian Government is not adequate to inform decisions and determinations about the costs of dispensing in community pharmacies (KING & WATSON).</p> <p>The remuneration for community pharmacy in the dispensing of PBS</p>	<p>RECOMMENDATION 5-1: COMMUNITY PHARMACY ACCOUNTING INFORMATION (KING & WATSON)</p> <p>As soon as possible following the completion of this Review, the Australian Government, in consultation with the Pharmacy Guild of Australia and other stakeholders, should:</p> <ol style="list-style-type: none"> a. determine a set of accounting principles that will apply for community pharmacies to provide the relevant information needed to determine the best-practice benchmark of a dispense; b. require community pharmacy to provide the necessary accounting information to inform consideration in the development of each Community Pharmacy Agreement. The relevant accounting information should be provided for each financial year and no later than 30 April of the following financial year (beginning with 30 April 2019);

Finding	Recommendation
<p>medicines should be based on the amount of funding required by government to maintain a viable community pharmacy network in Australia (SCOTT).</p>	<ul style="list-style-type: none"> c. designate a body within the Australian Government, or an independent statutory authority with the relevant expertise, or some other body with the relevant expertise, to provide a recommendation to the Australian Government on the best practice benchmark cost of a dispense as required over time by the Australian Government. The first such advice should be provided as soon as practical and certainly before the end of 2019. The timing of later recommendations would depend on the process used in the future by the Australian Government to set the remuneration for dispensing PBS medicines; and d. the information and advice submitted to the Australian Government should inform the basis for the remuneration for a 'dispense' to community pharmacy. The provision of the agreed accounting information should be an ongoing requirement. <p>ALTERNATIVE RECOMMENDATION 5-1 (SCOTT)</p> <p>The dispensing fee determined as part of any future negotiations between the Australian Government and the body representing the majority of pharmacy owners (The Pharmacy Guild of Australia), should be based on:</p> <ul style="list-style-type: none"> a. an agreed fee that represents the cost of maintaining a viable community pharmacy network in Australia and which meets the requirements of the National Medicines Policy and the expectations of the Australian community and government; and b. the best available information to both parties at the time of the negotiation and commensurate to the information required of other primary healthcare professionals in determining remuneration levels.
<p>THE BENCHMARK FOR A BEST PRACTICE DISPENSE</p> <p>On the basis of the information that has been made available to the Panel, the Panel considers that the current benchmark for a best practice dispense be set within a range of \$9.00 to \$11.50. However, reflecting the current lack of information available to all parties, the Panel is not recommending a specific level for the future remuneration paid to a community pharmacy for a dispense (KING & WATSON).</p> <p>The remuneration for community</p>	<p>RECOMMENDATION 5-2: REMUNERATION TO BE BASED ON THE COST OF DISPENSING SERVICES ASSOCIATED WITH A BEST PRACTICE PHARMACY MODEL (KING & WATSON)</p> <p>The remuneration for dispensing paid by the Australian Government and consumer co-payments to community pharmacy should be based on the costs of dispensing for a best practice pharmacy.</p> <p>ALTERNATIVE RECOMMENDATION 5-2 (SCOTT)</p> <p>The dispensing fee determined as part of any future negotiations between the Australian Government and the body representing the majority of pharmacy owners (The Pharmacy Guild of Australia), should be based on:</p> <ul style="list-style-type: none"> a. an agreed fee that represents the cost of maintaining a viable community pharmacy network in Australia and which meets the requirements of the National Medicines Policy and the expectations of the Australian community and government; and b. the best available information to both parties at the time of the negotiation and commensurate with the information required of other primary healthcare professionals in determining

Finding	Recommendation
<p>pharmacy in the dispensing of PBS medicines should be based on the amount of funding required by government to maintain a viable community pharmacy network in Australia (SCOTT).</p>	<p>remuneration levels.</p>
<p>REMUNERATION FOR DISPENSING SERVICES</p> <p>Remuneration for dispensing should be based on the best practice incremental costs of dispensing rather than fully distributed or stand-alone costs (KING & WATSON).</p> <p>The remuneration for community pharmacy in the dispensing of PBS medicines should be based on the amount of funding required by government to maintain a viable community pharmacy network in Australia (SCOTT).</p>	<p>RECOMMENDATION 5-3: REMUNERATION FOR DISPENSING— METHODOLOGY (KING & WATSON)</p> <p>The remuneration for dispensing in a community pharmacy should be a simple dispense fee based on the average, long-run incremental cost of dispensing in a best practice community pharmacy.</p> <p>ALTERNATIVE RECOMMENDATION 5-3 (SCOTT)</p> <p>The dispensing fee determined as part of any future negotiations between the Australian Government and the body representing the majority of pharmacy owners (The Pharmacy Guild of Australia), should be based on:</p> <ol style="list-style-type: none"> an agreed fee that represents the cost of maintaining a viable community pharmacy network in Australia and which meets the requirements of the National Medicines Policy and the expectations of the Australian community and government; and the best available information to both parties at the time of the negotiation and commensurate with the information required of other primary healthcare professionals in determining remuneration levels.
<p>STRUCTURE OF REMUNERATION FOR DISPENSING</p> <p>The current formula for the remuneration for dispensing paid by the Australian Government to community pharmacy is overly complex and opaque. The formula should be simplified to improve the transparency over different payments for dispensing.</p>	<p>RECOMMENDATION 5-4: STRUCTURE OF REMUNERATION FOR DISPENSING</p> <p>If the Australian Government does not place an upper limit on the wholesale payment for a community pharmacist then the Australian Government should adopt a two-part tariff payment for the remuneration (i.e. a payment that involves a fixed payment per dispense, plus a payment that varies with the relevant cost of the medicine) to the pharmacist.</p> <p>Under a flat fee or two-part tariff, the average payment for a dispense should equal the required fee determined by the Australian Government, following the acceptance of Recommendation 5-3.</p>

Finding	Recommendation
<p>REMUNERATION—ALTERNATIVE SERVICE CHANNELS</p> <p>The amount paid and the mechanisms for payment by the Australian Government to primary health professionals currently vary for the provision of the same service.</p>	<p>RECOMMENDATION 5-5: REMUNERATION FOR OTHER SERVICES</p> <p>The Australian Government should require that if the same service is offered through alternative primary health outlets then the same Australian Government payment should be applied to that service, regardless of the specific health professional involved.</p>

CHAPTER 6: THE REGULATION OF PHARMACY FOR MEDICINE SUPPLY

Finding	Recommendation
<p>REFORMS TO PHARMACY LOCATION RULES</p> <p>It is unclear whether the current pharmacy location regulations are limiting potential improvements to the community pharmacy network around Australia, and undermining flexibility to meet specific community needs.</p>	<p>RECOMMENDATION 6-1: REFORMS TO PHARMACY LOCATION RULES</p> <p>The Australian Government should:</p> <ol style="list-style-type: none"> reform the Pharmacy Location Rules to remove barriers to community access and competition between pharmacies, and to ensure they continue to support equitable and affordable access to medicines for all Australians, in accord with the National Medicines Policy; establish a working group with the Pharmacy Guild of Australia or other representative of Approved Pharmacists with the aim of reforming the Pharmacy Location Rules to ensure that they remain responsive to the evolving needs of the community while also supporting innovation through competition between pharmacies; and ensure that any reform of the Pharmacy Location Rules is subject to a suitable transition period.
<p>CONCENTRATION OF PHARMACY OWNERSHIP</p> <p>The Pharmacy Location Rules have not established robust competition between independent pharmacies in some locations. Rather, in some locations, either individual pharmacists or small groups of pharmacists have been able to monopolise some or all pharmacies. This is inconsistent with the objective of Australia’s competition laws.</p>	<p>RECOMMENDATION 6-2: PHARMACY LOCATION RULES—CONCENTRATION OF OWNERSHIP</p> <p>For any group of two or more pharmacies with overlapping ownership:</p> <ol style="list-style-type: none"> the Australian Competition and Consumer Commission is to determine if the overlapping ownership of those pharmacies results in a substantial lessening of competition in a market for the provision of pharmacy services, relative to independent ownership; and if so, the Australian Competition and Consumer Commission can require that one or more of the pharmacies in the group be divested. <p>For avoidance of doubt, a group of pharmacies would be considered to have an overlapping ownership if any individual or set of individuals have ownership of at least 20 per cent of the equity in each of the community pharmacies in that group.</p>
<p>TRANSPARENCY IN GOVERNMENT PROGRAMS</p> <p>Community pharmacy expenditure and funding for programs is insufficiently transparent to demonstrate value and performance in meeting the objectives of the National Medicines Policy.</p>	<p>RECOMMENDATION 6-3: TRANSPARENCY IN GOVERNMENT PROGRAMS</p> <p>It is important that, for each community pharmacy program that is Commonwealth funded, there is transparency regarding the:</p> <ol style="list-style-type: none"> amount of funding provided by the Australian Government; amount of funding provided by the recipient of the service; and value derived from the delivery of the program.

Finding	Recommendation
<p>THE RURAL PHARMACY MAINTENANCE ALLOWANCE</p> <p>The current operation and administration of the Rural Pharmacy Maintenance Allowance is based on individual pharmacy locations and prescription volumes rather than consumer access. This reduces the effectiveness of the program.</p>	<p>RECOMMENDATION 6-4: RURAL PHARMACY MAINTENANCE ALLOWANCE</p> <p>The Australian Government should revise the operation of the Rural Pharmacy Maintenance Allowance to ensure that it remains fit for purpose, is sufficiently flexible to meet changing needs, and provides for consumer access beyond the establishment of a pharmacy presence.</p>
<p>HARMONISING PHARMACY LEGISLATION</p> <p>The legislative differences in pharmacy regulation across Australian jurisdictions increase the costs of administration for pharmacies and present risks to patients moving between these regions.</p>	<p>RECOMMENDATION 6-5: HARMONISING PHARMACY LEGISLATION</p> <p>As early as practicable, the Australian Government, through the Australian Health Minister’s Advisory Council, should seek to harmonise all state, territory and Commonwealth pharmacy regulations to simplify the monitoring of pharmacy regulation in Australia for the safety of the public.</p> <p>In the long term, a single pharmacy regulator could be considered.</p> <p>As an interim measure, state and territory registering bodies should coordinate with the Australian Health Practitioner Regulation Agency to ensure that pharmacy regulations are being adequately monitored for best practice of pharmacy and the safety of the public.</p>
<p>EVALUATING, MONITORING AND REPORTING ON REGULATION</p> <p>There is a lack of coordination and consistency in the current monitoring, evaluation and reporting systems relating to the regulations around community pharmacy. This has a potential to undermine community faith in the community pharmacy network in Australia.</p>	<p>RECOMMENDATION 6-6: EVALUATION MECHANISMS</p> <p>As early as practicable, the Australian Government should require the establishment of appropriate evaluation mechanisms for community pharmacy to ensure that policy and delivery requirements are met.</p>

CHAPTER 7: THE DISTRIBUTION OF MEDICINES TO COMMUNITY PHARMACY

Finding	Recommendation
<p>ENSURING TIMELY MEDICINE ACCESS THROUGH COMMUNITY PHARMACY</p> <p>Current pharmacy supply chain arrangements for PBS medicines involve a high degree of regulation, including payments under the Community Service Obligation that appear unconnected with relevant distribution costs. Further, the current remuneration for wholesaling of PBS medicines may be leading to wholesale margins higher than necessary for an effective, efficient and sustainable supply chain.</p>	<p>RECOMMENDATION 7-1: COMMUNITY SERVICE OBLIGATION</p> <p>The Panel believes that the Community Service Obligation should revert to supply of all PBS medicines to any pharmacy within twenty-four hours and that this be considered a minimum standard to ensure that there can be no fragmentation of delivery arrangements across wholesalers or access for consumers through any community pharmacy.</p> <p>RECOMMENDATION 7-2: A COMPREHENSIVE SUPPLY CHAIN ANALYSIS</p> <p>The Australian Government should undertake a comprehensive analysis of the entire pharmaceutical supply chain to ensure that medicine supply risks are addressed and that consumers continue to have timely and affordable access to the medicines they need.</p> <p>This analysis should also seek to validate whether the Community Service Obligation and other mechanisms to support industry and pharmaceutical suppliers are achieving their desired outcomes in relation to the National Medicines Policy.</p> <p>The analysis should be informed by the appropriate data to support future decision making and should be conducted with the full co-operation of all Community Service Obligation distributors and the broader pharmacy supply chain.</p>
<p>SUPPORTING ACCESS TO HIGH-COST MEDICINES THROUGH COMMUNITY PHARMACY</p> <p>The supply of complex and high-cost medicines does not sit well within existing supply chain and pharmacy remuneration arrangements. Supplying these medicines is of significant concern for a number of pharmacies in supporting access to medicines within the community.</p>	<p>RECOMMENDATION 7-3: SUPPORTING ACCESS TO HIGH-COST MEDICINES</p> <p>The Australian Government should investigate alternative payment arrangements for the supply of high-cost PBS medicines from community pharmacy to support their continued availability within the community. A cap should be placed on the amount that a community pharmacy contributes to the cost of any PBS medicine, in the range of \$700 to \$1000, to allow consumers to access high cost PBS medicines from the pharmacy of their choice.</p>
<p>SUPPORTING ACCESS TO HIGHLY SPECIALISED DRUGS THROUGH</p>	<p>RECOMMENDATION 7-4: SUPPORTING ACCESS TO HIGHLY</p>

Finding	Recommendation
<p>COMMUNITY PHARMACY</p> <p>The distinction between highly specialised and other PBS medicines causes administrative inefficiencies for community pharmacy and may compromise patient access to these medicines within the community.</p>	<p>SPECIALISED DRUGS</p> <p>The Highly Specialised Drugs Program under section 100 of the <i>National Health Act 1953</i> (Cth) should be reformed to remove the distinction between section 100 (Community Access) and other medicines listed under section 100 Highly Specialised Drugs arrangements. This should include, for example, harmonising access and fees regardless of where the medicine is dispensed.</p>
<p>LIMITING THE PBS LISTING OF GENERIC MEDICINES</p> <p>A more targeted approach to listing PBS medicines can improve supply chain efficiency and reduce costs to the Australian community.</p>	<p>RECOMMENDATION 7-5: TIGHTENING THE LISTING OF GENERIC MEDICINE</p> <p>When an ‘originator’ (or ‘branded’) medicine comes off patent then the Australian Government should hold a tender for the PBS listing of generic versions of the medicine. The Australian Government should limit the number of generic versions of a particular medicine to be listed to a relatively small number that is still sufficient to allow for patient choice (e.g. four generics and the original brand of the medicine). The chosen generics should be those best able to meet the distribution and other conditions, including the security of supply, required by the Australian Government at the least cost to the PBS.</p>

CHAPTER 8: FUTURE COMMUNITY PHARMACY AGREEMENTS

Finding	Recommendation
<p>THE COMMUNITY PHARMACY AGREEMENT PROCESS</p> <p>The process for successive Community Pharmacy Agreements has evolved to a situation carrying a number of issues regarding transparency and sustainability for the future development of the sector.</p>	<p>RECOMMENDATION 8-1: SCOPE OF COMMUNITY PHARMACY AGREEMENTS—DISPENSING</p> <p>The scope of discussions under future Community Pharmacy Agreements should be limited to the remuneration and associated regulations for community pharmacy for the dispensing of medicines under PBS subsidy and related services, including the pricing to consumers for such dispensing.</p> <p>RECOMMENDATION 8-2: SCOPE OF COMMUNITY PHARMACY AGREEMENTS—WHOLESALE</p> <p>The Australian Government should ensure that the regulation and remuneration of wholesaling of PBS-listed medicines should not form part of future Community Pharmacy Agreements.</p> <p>RECOMMENDATION 8-3: SCOPE OF COMMUNITY PHARMACY AGREEMENTS—PROGRAMS AND SERVICES</p>

Finding	Recommendation
	<p>The regulation and remuneration of professional programs offered by community pharmacies should not form part of future Community Pharmacy Agreements.</p> <p>RECOMMENDATION 8-4: COMMUNITY PHARMACY AGREEMENT PARTICIPANTS</p> <p>The parties invited to participate in future Community Pharmacy Agreements should include The Pharmacy Guild of Australia, the Pharmaceutical Society of Australia and the Consumers Health Forum of Australia.</p>

CHAPTER 9: HEALTH PROGRAMS OFFERED BY COMMUNITY PHARMACY AND THE ROLE OF PHARMACY IN PRIMARY HEALTHCARE

Finding	Recommendation
<p>COMMUNITY PHARMACY PROGRAMS—KEY PRINCIPLES</p> <p>It is important to support a more flexible approach to the delivery of pharmacy programs that will enable a better integration of healthcare services while also encouraging innovation in business models.</p>	<p>RECOMMENDATION 9-1: COMMUNITY PHARMACY PROGRAMS—KEY PRINCIPLES</p> <p>The range of programs offered by community pharmacy should be underpinned by the following principles:</p> <ol style="list-style-type: none"> Programs should be based on evidence of clinical and cost-effectiveness and the health benefits they provide to the community. Programs may or may not involve the Australian Government paying for some or all the costs of the service to some or all patients. Programs may in some cases be offered on the basis of each community pharmacy choosing whether or not to offer the program (with all community pharmacies being eligible to offer the program). In other cases, the program will only be available (with Australian Government payment) through pharmacies/pharmacists that are selected by the Australian Government (e.g. through a tender process or as a result of negotiation between the Australian Government and the relevant pharmacies or pharmacists or their representatives). For some programs, the Australian Government remuneration for the program will be channelled through the users of the program (or their representatives) so that users will decide which community pharmacies (or pharmacists) to use to deliver the program. Adequate funding for the above needs to be found outside

Finding	Recommendation
	<p>PBS expenditure. It is important that similar services are funded in the same way to ensure a level playing field across primary health. For example, this means that where pharmacist administration of drugs or vaccines by injection is authorised, a pharmacist should be able to expect to receive the same level of remuneration for a vaccination as a doctor or nurse.</p>
<p>LEVERAGING PHARMACY AND PHARMACIST CAPABILITY</p> <p>Significant opportunities exist for the better use of community pharmacy and pharmacist programs and services in improving the health of Australians.</p>	<p>RECOMMENDATION 9-2: DOSE ADMINISTRATION AIDS—STANDARDS</p> <p>The Australian Government should establish clear, enforceable minimum standards for the supply of medicines by community pharmacies, including for dose administration aids. There should also be appropriate data for the evaluation of payments provided to community pharmacies for the dispensing of medicines using dose administration aids (in recognition that this tends to be a higher-cost activity than dispensing in manufacturer’s packaging).</p> <p>RECOMMENDATION 9-3: HOME MEDICINES REVIEWS – REMOVAL OF CAPS</p> <p>The Australian Government should abolish ‘caps’ on Home Medicines Reviews and fund the program through the Medicare Benefits Schedule. The Australian Government should set the Medicare Benefits Schedule referral criteria to ensure these services are appropriately targeted and represent value for money.</p> <p>The Australian Government should conduct regular audits of Home Medicines Reviews for quality and compliance with required criteria.</p> <p>RECOMMENDATION 9-4: PHARMACY SUPPORT FOR RESIDENTIAL AGED CARE FACILITIES</p> <p>The Australian Government should explore the provision of dedicated consulting or employee pharmacists in residential aged care facilities to deliver professional pharmacy programs.</p> <p>These residential aged care facilities pharmacists should be actively engaged with their Primary Health Networks to facilitate links with general practitioners, allied health professionals and community pharmacy services (including the provision of dose administration aids) in their area to assist a person with chronic pain (for example) and ensure their continuity care.</p> <p>RECOMMENDATION 9-5: SUPPORT FOR EXPANDED PHARMACY</p>

Finding	Recommendation
SERVICES IDENTIFIED BY PHARMACY TRIAL PROGRAM	
	<p>The Australian Government should continue to support pharmacy programs that have been successful in meeting evidence of comparative clinical value and cost-effectiveness as required by the Medical Services Advisory Committee. Funding for programs that demonstrate these requirements should continue on the basis of merit and not be dependent on the outcomes of any other consideration such as an agreement on pharmacy remuneration.</p>

CHAPTER 10: CHEMOTHERAPY COMPOUNDING

Finding	Recommendation
<p>CHEMOTHERAPY COMPOUNDING STANDARDS</p> <p>The current standards for the compounding of chemotherapy medicines in community pharmacy and other facilities appear to be overly complex. The oversight currently includes legislation, codes and guidelines. The overlap and inconsistency of these across Australia do not provide clear rules or guidance for compounders.</p>	<p>RECOMMENDATION 10-1: CHEMOTHERAPY COMPOUNDING—UNIFORM MINIMUM STANDARDS</p> <p>There should be a clear and uniform minimum set of standards for all approved chemotherapy compounding facilities. These minimum standards should:</p> <ol style="list-style-type: none"> be developed based upon current Good Manufacturing Practice and the Pharmacy Board of Australia compounding standards, therefore ensuring all Therapeutic Goods Administration licensed facilities will meet the minimum standards; not require that a compounding facility be Therapeutic Goods Administration licensed to meet minimum requirements; reflect the various settings that are appropriate for the preparation of chemotherapy medicines, including ‘urgent’ preparations in a hospital or community pharmacy setting; and; detail specific and measurable requirements that will be audited to maintain approval to operate as a chemotherapy compounding facility. <p>The Pharmacy Board of Australia, or appropriate regulatory authority, should be adequately resourced to monitor compliance with these national standards.</p>
<p>CHEMOTHERAPY COMPOUNDING PAYMENTS</p>	<p>RECOMMENDATION 10-2: CHEMOTHERAPY COMPOUNDING—PAYMENTS</p>

CHAPTER 10: CHEMOTHERAPY COMPOUNDING

The rationale for differential payments for compounding of chemotherapy preparations is not substantiated on the basis of patient risks or health outcomes for medicines that must meet an appropriate level of quality, whether prepared at a facility that is Therapeutic Goods Administration licensed or not licensed.

There should be a no difference in the remuneration paid by the Australian Government for the compounding of chemotherapy medicines in any facility that meets the minimum quality and safety standards. In particular, there should be no additional payment for medicines prepared in a facility that meets or exceeds the minimum standards.

CHEMOTHERAPY COMPOUNDING PRACTICE MODELS

There are a number of good practice chemotherapy compounding models that can be leveraged to improve access to existing compounding arrangements.

RECOMMENDATION 10-3: CHEMOTHERAPY COMPOUNDING— PRACTICE MODELS

Existing practice models in place in public hospitals for limited trade of medicines prepared onsite should be considered for providing greater access to chemotherapy arrangements.

CHAPTER 11: HOSPITAL PHARMACIES

Finding	Recommendation
<p>MANAGING MEDICINE RISKS FOR PATIENTS</p> <p>Hospital discharge processes lack a robust framework to support communication between a patient’s hospital, primary care provider and community pharmacy. This can make medicine management difficult while creating risk for the patient.</p>	<p>RECOMMENDATION 11-1: MANAGING PATIENT MEDICINE RISKS ON DISCHARGE FROM HOSPITAL</p> <p>Hospitals should work closely with community pharmacies to ensure patients have access to the medicines they require upon discharge. Consistent policies and procedures are required to ensure each patient has access to the medicines they require as well as appropriate education and information relating to their medications.</p> <p>The Australian Government should also increase national consistency in public hospital discharge practices, including the supply of medicines on discharge.</p>

NEXT STEPS

The issues considered by this Review represent only a segment of the broader landscape in which community pharmacy operates. The Review's recommendations should not be considered in isolation of the broader healthcare system. Government, the pharmacy sector and other stakeholders need to consider the role of community pharmacy in the healthcare system for the future.

There is a significant difference in opinion, among stakeholders on what community pharmacy is and what it should be. This fragmentation exists not only across the health sector but also within the pharmacy profession itself. The Panel has observed tension between parts of the sector in defining the role of pharmacy within the context of the NMP. This has resulted in an ad-hoc and incoherent view on where pharmacy fits within primary healthcare and the role played by community pharmacy in wider reforms to the health system planned over the next decade.

Consumers value the diversity of business models within the community pharmacy sector and the Panel has adopted a flexible, business model neutral approach to its recommendations. This approach is adaptable to any future roles of community pharmacy in the broader healthcare system.

The Panel notes that government has embarked on a commitment to include pharmacy in reforms to primary care, such as Health Care Homes (HCH), without a clear articulation of the role for pharmacy in these settings. Furthermore, there is a risk that the current status and viability of the pharmacy sector may not be adequately acknowledged by government. For example, the Panel found that there is significant uncertainty over the capacity and capability of the pharmacy workforce to take on more collaborative roles in primary health. This includes the readiness of the workforce, and particularly young innovative pharmacists, to be able to step-up and take over from industry elders.

Other partners in the health system would benefit from working in a collaborative manner with government and the pharmacy sector in contributing to the vision for pharmacy as envisaged by the NMP. The broader health sector should embrace the opportunity to better leverage the capability of pharmacists as part of a multidisciplinary team. Community pharmacy needs to be integrated into the broader healthcare system to achieve the objectives of the NMP.

Beyond the recommendations proposed in this Report, there remains much work to do. This includes answering the critical questions of how government wants community pharmacy to act as its agent, how the health system wants to value pharmacy, how this should be remunerated within the current arrangements for health funding and what the pharmacy workforce should look like to be fit for purpose for consumers for the next decade.

1. INTRODUCTION

ABOUT THE REVIEW

The Review is a key component of the Sixth Community Pharmacy Agreement (6CPA) made between the Commonwealth and the Guild. It represents the first independent, comprehensive review of the Australian community pharmacy sector in over two decades.

The Review was based on specific Terms of Reference determined by the Minister for Health following consultation with the Guild and other stakeholders. The purpose of the Review was to provide recommendations on future remuneration, regulation (including Pharmacy Location Rules) and other arrangements that apply to pharmacies and wholesalers for the dispensing of medicines and other services provided under the PBS, and it aims to ensure that consumers continue to have reliable and affordable access to medicines.

In November 2015, the Minister for Health appointed a Panel consisting of three independent members to undertake the Review. The Panel previously presented a range of questions and reform options through its Discussion Paper (July 2016) and Interim Report (June 2017), as well as through extensive consultation with selected stakeholders and public submissions.

The consultations and submissions undertaken have provided the Panel with valuable insights and feedback, and have significantly impacted upon the development of this Final Report. The Panel remains grateful for the information provided by stakeholders and the Australian public during the consultation process.

REVIEW PANEL

The Panel was chaired by Professor Stephen King, an industrial economist, and consisted of two other members—Ms Jo Watson, a consumer representative; and Mr Bill Scott, a pharmacy representative. In conducting the Review, the Panel was supported by a Review Secretariat in the Department of Health.

SCOPE OF THE REVIEW

The Panel was asked to consider:

- pharmacy remuneration for dispensing;
- regulation;
- wholesaling, logistics and distribution arrangements;
- accountability and regulation; and
- consumer experience.

The Review's Terms of Reference is provided at Appendix B.

REVIEW CONSULTATION PROCESS

The Minister for Health released the Review's Interim Report on 22 June 2017 to encourage debate and discussion with the public to assist the Panel's development of its Final Report.

The Panel undertook a five-week period of public consultation which included a call for public submissions and comments, as well as bilateral meetings with selected stakeholder organisations to discuss the future directions and options identified in the Interim Report.

The Panel has engaged with multiple stakeholders as part of its commitment to consult broadly on the Terms of Reference for the Review (see Appendix C: Stakeholder Engagement). Since the Review commenced in November 2015, the Panel has conducted 16 public forums in metropolitan and rural locations across Australia, 101 bilateral meetings with organisations and individuals, thirty-two pharmacy site visits, six presentations and a live national webcast.

The Panel has also received over 500 submissions in response to the Review Discussion Paper, 197 submissions in response to the Interim Report, and 381 responses to the Interim Report online questionnaire (see Appendix E: Responses to the Interim Report). These interactions with the pharmacy sector and individuals have played a significant role in the development of the Panel's recommendations.

INTERACTION WITH OTHER REVIEWS AND INITIATIVES

Other reviews that have implications for pharmacy noted by the Panel include:

- PBS Pharmaceuticals in Hospitals Review (ongoing);
- Medicare Benefits Schedule (MBS) Review Taskforce (ongoing);
- Medicare Compliance Rules and Benchmarks (ongoing);
- Digital Health Initiatives (ongoing);
- Therapeutic Goods Administration (TGA), Reforms to the Regulatory Framework for Complementary Medicines: Assessment Pathways (February 2017)
- Mental Health Reform Package (November 2016); and
- Reform of the Primary Health Care System (December 2015).

The Panel was mindful of these and other ongoing reviews in determining its recommendations.

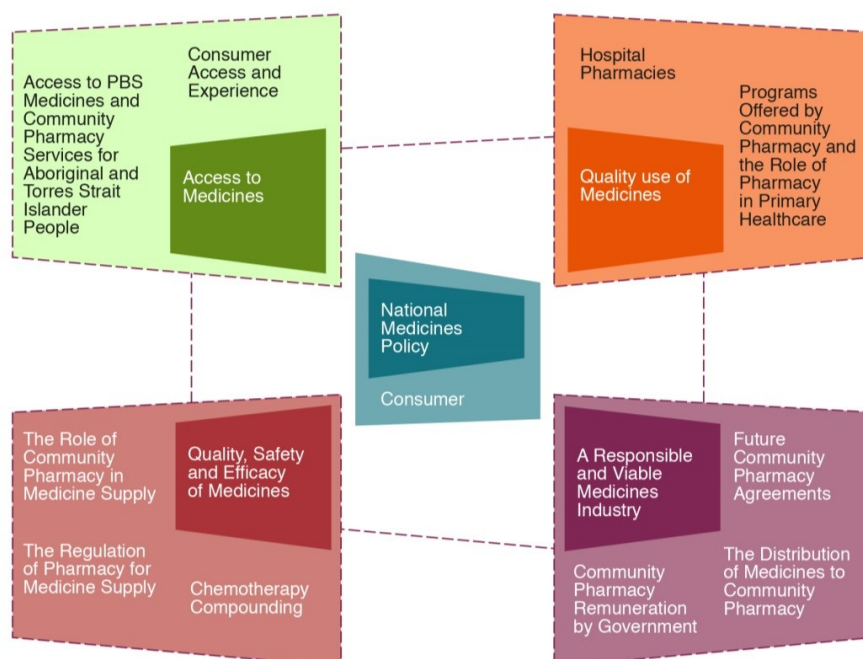
UNDERSTANDING THIS REPORT

The issues in this report are complex and multifaceted, with the potential to impact on varying parts of the community pharmacy sector in Australia. The Review's findings and recommendations are best understood in the context of the NMP and how pharmacy should be positioned to effectively contribute to the achievement of the objectives of the policy.

The NMP has been an important focus of the Panel in conducting the Review, consistent with the Terms of Reference, and has been a central theme in framing the recommendations. This is in recognition of the importance of the NMP in bringing about better health outcomes for all Australians, as well as the responsibility placed on all partners to constructively promote the objectives of the policy.

As illustrated in the diagram below, each section of the Report is aligned with an objective of the NMP. It should be noted that many of the findings are interrelated and may contribute to more than one objective of the NMP. These relationships should be considered in the sequencing of any implementation activity designed to address the recommendations.

FIGURE 2: LINKAGES BETWEEN THE REVIEW RECOMMENDATIONS AND THE NMP



The consumer plays a fundamental role in reaching the objectives of the NMP and has underpinned the Panel’s considerations. The Panel has determined its strategic vision and considered recommendations for constructive pharmacy reform by identifying what consumers value from community pharmacy both now and into the future.

The Report therefore commences with a consideration of consumer access and experience, which is followed by consideration of remuneration, regulation and the pharmacy supply chain. The Report concludes with a section on the need to manage risks for patients that transition between health services. Each section contains a number of specific issues with a related recommendation or observation.

In this Final Report, some of the reform options presented in the Review’s Interim Report have been amended or removed. This has occurred in instances where the Panel has been provided with compelling evidence to vary the option. Nonetheless, the Interim Report serves as an important reference to this Report and should be referred to where further context to the findings and recommendations is required (see Appendix D: Cross references to Interim Report).

While acknowledging the highly dynamic environment in which pharmacy operates, as well as the significant challenges currently facing the sector, the Panel has chosen not to prescribe a timeline for the implementation of recommendations. However, the Panel has identified four pillars that shape the Review’s recommendations and underpin the delivery of the NMP—Minimum Pharmacy Services, Electronic Prescriptions, Pharmacy Accounting Information and Future Community Pharmacy Agreement Process. These foundational recommendations act as key enablers to unlocking the value of downstream, interconnected issues. The Panel encourages the government

and industry partners to progress these four elements as a priority as part of any future arrangements for community pharmacy in Australia.

2. CONSUMER ACCESS AND EXPERIENCE

2.1. MEDICINE PRICING VARIATIONS

The variation in pricing of Pharmaceutical Benefits Scheme (PBS) medicines to consumers has undesirable consequences for equity and consumer access.

The PBS is part of the government’s broader NMP.¹ As part of this policy the PBS provides timely, reliable and affordable access to necessary medicines for Australians. In dispensing PBS medicines, the pharmacist acts as an agent of government—preparing, supervising and advising on medicines and their usage.² A pharmacist’s dispensing activities are remunerated through consumer co-payments and remuneration under the PBS scheme. The level of remuneration a pharmacist can receive will vary depending on the totality of these payments, with the payments made by a consumer varying according to the level of co-payment applied. Consumers who are ineligible for a concessional discount pay a ‘general patient’s co-payment’ of up to \$38.80 to the pharmacist. Consumers eligible for a concessional discount pay a ‘concessional patient’s co-payment’ of up to \$6.30 (as at the date of this Report).

The Dispensed Price for Maximum Quantity (DPMQ) is the price for dispensing the maximum quantity of a product under a given prescribing rule.³ When a medicine’s DPMQ is over \$38.80, a general patient’s co-payment will be no more than \$38.80 and a concessional patient’s co-payment will be a maximum of \$6.30. When a medicine costs less than the patient’s co-payment, the pharmacist currently has the discretion to charge any price up to the applicable co-payment. When the cost of a medicine is below the general patient’s co-payment, the price paid by a patient for their medicine may vary from one pharmacy to another, as some pharmacists may make additional charges above the PBS dispensing fee. However, a patient cannot be charged more than the maximum general patient’s co-payment, except when a price premium applies. A price premium, or brand premium, is an additional payment that consumers pay to the supplier of the specified brand of a PBS medicine.

The price a pharmacy charges (and a consumer pays) for a medicine is at the discretion of the pharmacist, who can choose to charge either:

- a higher price—up to \$38.80 for a consumer who is ineligible for a concessional discount, even when the DPMQ is below this level; or
- a lower price—for example, where the \$1 discount is applied.

This price variation can be a significant barrier to the appropriate use of a consumer’s medication. Even small increases in the price of medicines (consumer’s out-of-pocket expenses) can significantly affect medication adherence among low income earners, or those with chronic conditions who need a high volume of medicines.⁴ In turn, the adverse health effects associated with decreases in

¹ Department of Health, About the PBS, (August 2017).

² Pharmaceutical Society of Australia, What pharmacists do and where they work (August 2017).

³ Department of Health, DPMQ, (August 2017).

⁴ Consumers Health Forum of Australia, Interim Report Submission No. 116, page 6.

medication adherence can lead to higher rates of hospitalisation and increased costs for the healthcare system.

The financial analysis completed for the Interim Report demonstrated that, because of pricing variations, PBS-listed medicines were generally cheaper in urban areas and more expensive in remote areas⁵. It was found that increased co-payments were disproportionately charged to people living in remote and very remote areas compared with their counterparts in urban communities—typically, the more remote the location of a consumer’s pharmacy, the greater the co-payment they were charged:

“patients who purchase their medicines from pharmacies in more remote regions of Australia (PhARIA 3 to 6) actually have to pay more for their medicines as a result of the variations in the prices charged by these pharmacies.”⁶

The Panel considers it likely that consumers who have limited mobility or who are less able to ‘shop around’ may pay more for their medicines than other consumers if their local pharmacy is charging more than the DPMQ. This may be exacerbated due to existing restrictions on pharmacy competition (i.e. the Pharmacy Location Rules).

The PBS operates under the umbrella of the NMP, which aims to provide timely access to the medicines that Australians need at a cost that individuals and the community can afford. This goal, which engenders universality and the principle of equity, is compromised by the existing price variations. Consistency in the price that consumers pay for their PBS-listed medicines could improve health outcomes, as echoed by the PSA in relation to ‘discounting’:

“Discounting PBS prescriptions not only undermines the principles of universal access and equality which underpin the PBS, it also results in the commodification of medicines...”⁷

PBS medicines are not normal items of commerce. They are only prescribed to a consumer by a PBS prescriber when they are required to help that consumer to attain an appropriate health outcome. It makes little if any sense for the government to allow a significant variation in pricing across different pharmacies for the same medication provided to the same consumer based on the same prescription. The government subsidises PBS medicines, so it should also determine the dispensed price to support sustainable, efficient and equitable access to medicines across Australia, consistent with the NMP. The Panel considers it inappropriate for community pharmacies to charge discretionary amounts as, it has the potential to undermine access to medicines and effective health services—a position reiterated by the Society of Hospital Pharmacists of Australia (SHPA):

“Competitive discounting by community pharmacies can provide unintended impacts on pharmacy practice and patient outcomes by introducing perverse incentives to dispense. These practices can reduce service quality and are not conducive to patient-centred care...SHPA recognises that [removing pricing variations] would lessen the confusion currently experienced by customers and may motivate pharmacies to compete on models of care revolved around professional services as opposed to medicine price...”⁸

⁵ RSM, Financial analysis of pharmacy regulation and remuneration arrangements, March 2017, page 38.

⁶ Ibid.

⁷ Pharmaceutical Society of Australia, Interim Report Submission No. 183, page 9.

⁸ Society of Hospital Pharmacists Australia, Interim Report Submission No. 194b, page 8.

The removal of pricing discretion may appear to be inconsistent with standard retail competition. Yet PBS medicines are not provided through standard retail mechanisms. A consumer cannot simply demand a PBS-listed medicine. Consumers can only access such medicines when an approved medical practitioner has determined that they are required to treat a medical condition. The government subsidises the distribution of these medicines and, where the dispensed price is above the relevant patient co-payment, it reimburses the community pharmacist for the dispensing services provided.

The Panel considers that, when pharmacies compete for a consumer’s business, it should be on the quality of the service that is provided to the consumer as opposed to PBS medicine prices. If the government believes that the pharmacy is not making sufficient profits then it should directly increase the pharmacy’s remuneration—for example, through increased dispensing fees or supplementary funding such as the Rural Pharmacy Maintenance Allowance (RPMA). If the government believes that consumers are paying too much for a medicine (e.g. due to poor compliance) then it should reduce the price for that medicine, not leave it to the discretion of an individual pharmacist.

Co-payments are generally used in healthcare and other government-supported services to provide a price signal for consumers. The price signal operates as an incentive to moderate the use of the service and minimise wastage, while also ensuring that consumers make, at times, a nominal contribution towards the cost of the relevant medicine:

“Co-payments send a clear price signal that medical services come at a cost. This may help to reduce demand for unnecessary or overused services, as well as encouraging individuals to take greater responsibility for paying for some of the cost commensurate to their health care decisions.”⁹

The Panel has not seen any literature or been provided with any evidence that suggests pricing variation enables compliance with prescribed regimes. On the contrary: the Panel is of the position that the deficit in community understanding of how pricing variations work is in fact a barrier to access, especially when discounts are provided in a varied fashion.¹⁰

RECOMMENDATION 2-1: PBS PRICING VARIATIONS

The payment made by any particular consumer for a PBS-listed medicine should be the co-payment set by the Australian Government for that consumer or the Dispensed Price for Maximum Quantity for that medicine, whichever is the lower. An Approved Pharmacy should have no discretion to either raise or lower this price.

⁹ National Commission of Audit, Report of the National Commission of Audit Phase 2 – Appendix to Volume 1 (March 2014).

¹⁰ Lesley Russel & Jennifer Doggett, Tackling out-of- pocket health care costs. A discussion paper, (January 2015).

2.2. THE \$1 DISCOUNT

The \$1 discount has not led to equitable outcomes for consumers

Since January 2016, the government has allowed community pharmacies to discount the PBS co-payment (currently \$6.30 for concession card holders and \$38.80 for general patients) by up to \$1. The \$1 discount is an optional markdown that any community pharmacy can provide when a patient is making a co-payment on a PBS medicine; however, it is left up to the individual pharmacy to choose whether to give that discount. There is no additional payment to pharmacy by government under the \$1 discount measure.

Although discounting is allowed for both general and concessional co-payments, most pharmacies who choose to provide the \$1 discount usually offer it to consumers who hold a current concession, pension or veteran's health card, but not to general patients.¹¹ The pharmacy or the pharmacist may otherwise choose to offer a discount in some circumstances but not in others.

The \$1 discount was introduced as an option for pharmacies to allow for the introduction of greater competition, which an across-the-board discount would not have achieved. For some pharmacies, this discount was an opportunity for them to explore a new way to compete on price. However, price is only one element of competition and, even with the \$1 discount, pharmacies also compete for consumers on the quality of service they provide, the range of health services and programs that they offer and the broader business model that they adopt with other incentives.

The Interim Report demonstrated that the application of the \$1 discount is highly variable¹². Pharmacies located in urban regions of Australia (i.e. *Pharmacy Accessibility Remoteness Index of Australia* (PhARIA) 1) are more likely to discount than pharmacies located in regional and remote regions (PhARIA 4–6). This can create consumer equity issues. One example raised by the PSA was that Australians living in remote areas could often be required to travel further than their urban counterparts to access the discount on their PBS medicines.¹³ This issue of equity was echoed by the Guild:

“[The \$1 discount] undermines the purpose of having a consistently applied price signal and is contrary to the concept of universality of the PBS in which all Australians can access subsidised PBS medicines at the same price.”¹⁴

However, several submissions suggest that the \$1 discount is actually a competitive mechanism that allows for differentiation in a seemingly homogenous market place. Chemist Warehouse contends that the discount can be used in a twofold manner: to provide competitive prescription pricing, while also using the discount to improve access and compliance with prescribed medication regimes:

“Chemist Warehouse contends affordability in so far as it relates to access is in no way benefited nor enhanced by enforcing a blanket prohibition on discount of a patient's co-payment. Chemist Warehouse further contends that such a prohibition acts to lessens not improves access ... reducing

¹¹ Hall & Partners Open Mind, Qualitative and quantitative consumer research (2016).

¹² RSM, Financial analysis of pharmacy regulations and remuneration arrangements (March 2017).

¹³ Pharmaceutical Society of Australia, Interim Report Submission No. 183, page 9.

¹⁴ Pharmacy Guild of Australia, Discussion Paper Submission No. 486, page 88.

the cost of medicine improves not only access but also medication compliance with prescribed regimes. Regulation that necessitates that Chemist Warehouse increase it [sic] prescription prices will therefore inevitably lead to diminished access [and] reduced medication compliance.”¹⁵

It is undeniable that, given existing co-payments, the \$1 discount policy has saved some consumers—most probably urban consumers—up to \$1 in their co-payment for medicines. Similarly, the financial analysis showed that concessional co-payment consumers derived the greatest benefit from the \$1 discount.¹⁶ However, in line with the previous recommendation, if the government considers that lower co-payments are desirable, they should lower them for all consumers, with appropriate remuneration provided to pharmacies for dispensing.

The \$1 discount comes out of a pharmacist’s margin and, as such, willingness to provide this discount in areas with greater competition between pharmacies shows that some pharmacies can operate with a lower dispensing fee, matching the \$1 reduction in co-payment.

The financial analysis also suggested that competition drives the use of the discount.¹⁷ In areas of low competition, the discount is less likely to be offered. Conversely, where competition is strong, pharmacies will use the discretion given by the \$1 discount as part of their competitive strategy, albeit possibly reducing competition on other dimensions such as service. This will not occur where competition is weak and pharmacies can avoid passing on the \$1 discount.

In this sense, the \$1 discount has highlighted the different levels of competition in community pharmacy around Australia. Having varying levels of competition in community pharmacy in different parts of Australia creates issues of equity for consumers. The \$1 discount simply highlights and possibly exacerbates these inequities. It does not address them.

RECOMMENDATION 2-2: THE \$1 DISCOUNT

The Australian Government should abolish the \$1 discount on the PBS patient co-payment.

2.3. PBS SAFETY NET

The current PBS Safety Net system lacks sufficient transparency and is difficult for consumers to document and understand. This results in the Safety Net not being utilised to the extent possible, which disadvantages more vulnerable consumers.

In Australia, the purpose of the PBS Safety Net system is to protect individual consumers and families who require a large amount of prescription medications.

There are two Safety Net thresholds. The first is the general patient Safety Net, which is currently \$1494.90. When a consumer’s and/or their family’s total applicable co-payments reach this amount, they may apply for a Safety Net concession card and pay the concessional co-payment amount of \$6.30 plus any applicable premium for pharmaceutical benefits for the rest of that calendar year.

¹⁵ Chemist Warehouse, Interim Report Submission No. 189, page 1.

¹⁶ RSM, Financial analysis of pharmacy regulations and remuneration arrangements, (March 2017).

¹⁷ Ibid.

The second is the concessional Safety Net threshold, which is \$378.00. When a concession card holder's and/or their family's total applicable co-payments reach this amount, they may apply for a Safety Net entitlement and may receive pharmaceutical benefits free of charge (except for any applicable premium) for the rest of that calendar year.¹⁸

There are several operational factors that negatively affect the PBS Safety Net system and in some cases prevent it from providing an appropriate level of protection.

Most significantly, the current PBS Safety Net system requires manual coordination for consumers. While individual pharmacists can provide an electronic record for individual consumers, each consumer is required to aggregate these to maintain an ongoing record of expenditure on the PBS to determine whether the Safety Net has been reached. This is not in keeping with developments in the broader healthcare sector and society generally.

There was general consensus in feedback to the Panel that the current recording system for the PBS Safety Net is cumbersome, particularly for disadvantaged patients with literacy issues, patients with culturally and linguistically diverse backgrounds, homeless patients and other vulnerable groups. This manual system also reduces a patients' mobility, as it is difficult for patients to have their Safety Net follow them if they move or travel, further increasing the cost of medicines for vulnerable groups.

The lack of an automated system for the PBS Safety Net is in contrast to the Medicare Safety Net system, which the Department of Human Services uses to automatically record a consumer's out-of-pocket medical expenses. The Panel believes that PBS online could be used as a basis for an automatic Safety Net system.

Many stakeholders, including consumers and consumer groups, pharmacy owners and other healthcare providers, commented that consumers found the PBS Safety Net complicated. They further suggested that, as a result of these complications, consumers are paying more for their PBS medicines than they should be because they have not registered or kept the required records to demonstrate their eligibility for the Safety Net.

There was strong support among all stakeholders for the introduction of an automated PBS Safety Net recording system, which is expected to improve and simplify access for consumers. The current system places a number of administrative responsibilities on pharmacists to ensure the correct recording of a patient's Safety Net. An automated PBS Safety Net would be likely to reduce this administrative burden for pharmacies.

Another issue around the current Safety Net system relates to it being structured over a twelve-month calendar year. Currently, consumers pay their standard co-payment (general or concessional) until they reach their relevant Safety Net limit.¹⁹ Many stakeholders emphasised the need for

¹⁸ As described by Chemist Warehouse, *About Prescriptions*, Brand premiums, therapeutic group premiums and special patient contributions do not count towards the safety net thresholds.

¹⁹ Under the current arrangements, consumers pay their standard co-payment (general or concessional) until they reach their Safety Net limit. These consumers are then able to access their medicines at a significantly reduced price or for free. Submissions recognised that consumer spending on medications tends to be concentrated in that initial period before the

reforms which allow patient contributions to be spread more evenly over the twelve-month period. This includes providing additional support to those patients with multiple chronic conditions for whom reaching the Safety Net is highly likely.

The Panel agrees that a system which works to spread patient contributions more evenly over the twelve-month period would provide better protection for some consumers and merits consideration by government.

Concerns were also expressed to the Panel in relation to treatments for opioid dependence which are not covered by the Safety Net.

The section 100 Opiate Dependence Treatment programs are administered by state and territory governments and are therefore separate from general PBS arrangements. These treatments fall under section 100 of the *National Health Act 1953* (Cth), with different funding arrangements applying across different jurisdictions. This appears to be the reason that payments for opiate dependence treatments have to date not been able to count towards the PBS Safety Net. The Panel considers that this system unfairly discriminates against consumers requiring opiate dependence treatment, and should be rectified by government.

The Panel therefore considers the introduction of an automated recording system for the PBS Safety Net essential. It is the best way to ensure that the PBS Safety Net provides appropriate protection for all consumers who require a large amount of PBS medicines. An automated system would rectify the current issue whereby some consumers, particularly those in more vulnerable groups, are not able to access Safety Net protections, as they are unable to keep track of their medicine expenditure or are unclear as to how the system works, and it would allow the spread of costs to be applied more evenly across the year.

The Panel notes that the creation of a universal medicines record would also enable the automated monitoring and reporting of the Safety Net, as discussed at section 2.7 (A Universal Health Record).

RECOMMENDATION 2-3: PBS SAFETY NET

In relation to the PBS Safety Net, the Australian Government should:

- a. require the PBS Safety Net to be managed electronically for consumers. This functionality should be automatic from the consumer's perspective;
- b. investigate whether the PBS Safety Net scheme can be adjusted to spread consumer costs over a twelve-month period;
- c. provide sufficient transparency in the way a consumer's progress towards the PBS Safety Net is collated, including information on any gaps in how it is calculated; and
- d. investigate and implement an appropriate system which allows payments for opiate dependence treatments to count towards the PBS Safety Net.

Safety Net is reached, and this may cause financial difficulties for some patients during that time, and even deter them from accessing their prescribed medications.

2.4 CONSUMER INFORMATION ON PHARMACY SERVICES

Some consumers are unaware of the range of services available from community pharmacies. Utilising technology to improve consumer awareness could increase overall access.

The diversity of pharmacy businesses is strongly valued by consumers; however, this diversity brings with it a complexity which, for some sections of the community, acts as a barrier to access. The Panel is therefore keen to ensure that all consumers can access an acceptable minimum set of information about the location, opening hours and health services offered by individual pharmacies.

PHARMACY ATLAS

Most consumers appear to have a low awareness of the 6CPA funded programs available from community pharmacies, such as the availability of Home Medicines Reviews (HMRs), and the pharmacy's responsibilities under this program. Similarly, some community pharmacies have tailored their services to help meet the diverse cultural, linguistic and demographic needs of their local communities, whereas other pharmacies in the same region have not. The Panel believes that providing a consumer with this information is of the utmost importance in facilitating consumer access to the most appropriate community pharmacy for an individual's own needs.

The need to improve awareness of specialist programs and services was noted in the Discussion Paper:

“Although programs are in place for the delivery of certain specialist services, not all community pharmacies participate in these programs and in many instances do not promote the services. It was noted to the Panel that consumers accessing these specialist services are hesitant to openly ask about these services owing to privacy concerns and stigma associated with their condition.

Consumer groups suggested that public education and awareness of these specialist services could be improved through an online website or digital application that listed all community pharmacies that delivered specialist services. It was also noted that discreet symbols could be displayed at the front of pharmacy premises to denote participation in specialist programs.”²⁰

An easily accessible national pharmacy atlas covering the specific services offered by individual pharmacies, as well as a clear statement of consumer rights and expectations associated with those services, could help achieve this. As noted in one submission:

“An atlas of community pharmacies can enable increased service integration across several health domains, chronic and acute, and highlight the crucial role pharmacists play in the primary health care of all Australians.”²¹

Many of the respondents that disagreed with the establishment of a national pharmacy atlas did so because they felt that resources could be allocated to a higher healthcare priority or that the current information arrangements are adequate. Datasets like the Guild's Find a Pharmacy and the Australian Government's Health Direct facility²² could be extended to incorporate the potential

²⁰ Department of Health, Review of Pharmacy Remuneration and Regulation – Discussion Paper, page 49, (July 2016).

²¹ ConNetica, Interim Report Submission No. 147, page 2.

²² healthdirect, accessible through the [health direct website](#)

atlas’s data and promoted as an available consumer resource. As the Digital Health Agency has submitted:

“The Guild already has such a database accessible by the public. Some government funding to fill any gaps would be preferable than re-inventing the wheel.”²³

Regardless of how the atlas is delivered, it would be important that all PBS pharmacies are included, irrespective of membership or business model. Furthermore, it would be beneficial for the atlas to be relevant to the multicultural population of Australia so it can be used by people from culturally and linguistically diverse backgrounds.

In urban Australia, there are a number of pharmacies currently operating with extended hours (from around 7 am to 11 pm)²⁴. However, consumers often lack information about these pharmacies and they are not evenly spread through urban areas. The Panel has considered that there is no need for it to recommend extra opening hours in any areas, as this should be a business decision for individual pharmacies to meet the needs of their local community.

This allows pharmacies to differentiate themselves by providing extended consumer access. The Panel also notes that there are state government programs supporting some pharmacies to open after-hours in certain communities. For example, in Victoria this has occurred through a tender process.

Information regarding pharmacy opening hours should be included in the Pharmacy Atlas. This would allow for greater consumer access through an accessible, national database of pharmacy details and services. This would be particularly beneficial in emergency situations, as noted by SHPA’s example of the Victorian ‘thunderstorm asthma’ epidemic, where “the inclusion of opening hours would have been a great aid for consumers and hospital emergency departments”.²⁵

TWENTY-FOUR HOUR MEDICINE INFORMATION AND RELATED SERVICES

To improve consumer understanding and access, the government should examine the feasibility of an Australia wide twenty-four hour telephone and/or internet ‘pharmacy hotline’ to provide pharmacist advice and medicines information. This is supported by the PSA, who agreed that a twenty-four hour medicine information service should be established, potentially by expanding an existing service:

“Funding for this service should be increased to allow for pharmacists to operate the service 24 hours a day.”²⁶

²³ Interim Report Survey Response from an unnamed Community Pharmacy Owner

²⁴ Pharmacy Guild of Australia, Submission to Discussion Paper, No. 496. The Guild reported that “on average community pharmacies in Australia are open 61.7 hours per week, and the average pharmacy is open for 10 hours a day during the week. In addition, 73% of pharmacies are open at 6 pm on a weeknight and 93% are open at 10 am on a Saturday.”

²⁵ Society of Hospital Pharmacists of Australia, Interim Report Submission No. 196, page. 26.

²⁶ Pharmaceutical Society of Australia, Interim Report Submission No. 183, page 26.

Adding to the PSA’s recommendation, SHPA proposed that:

“Innovative hospital pharmacists and hospital pharmacies are already using technology to deliver clinical pharmacy services including medicine information and medicine review to patients who experience access barriers. Hospital pharmacists also currently provide medicines information phone lines for the public in limited capacities. This existing infrastructure in hospitals could provide a cost-effective basis for similar services if expanded. SHPA’s Standards of Practice for Medicine Information Services is highly relevant for this initiative.”²⁷

RECOMMENDATION 2-4: PHARMACY ATLAS

There should be an easily accessible and searchable ‘atlas’ of all community pharmacies in Australia that provides key consumer information, including the services and programs offered by each pharmacy, the opening hours of the pharmacy and any specific accessibility services of the pharmacy (e.g. multilingual staff). The ‘atlas’ should be easily accessible to consumers (e.g. through mobile-friendly applications).

The Australian Government should also consider the feasibility of a twenty-four hour ‘pharmacy hotline’ to provide pharmacist advice and medicines information to consumers Australia-wide.

2.5 CONSUMER MEDICINES INFORMATION

While Consumer Medicines Information is generally available, there are inconsistencies in how this is provided to consumers. Some consumers may be unaware of the availability of a Consumer Medicines Information, which could impact on quality use of medicines.

The CMI is a document that contains information on the safe and effective use of a prescribed over-the-counter medicine.

A CMI document is written by the pharmaceutical manufacturer or sponsor responsible for the medicine. They are important because they provide information aimed at bringing about better health outcomes.²⁸

Whereas CMI documents may not be available for every product in printed form, the TGA regulations require that the CMI be made available to consumers, either in the primary pack of a medicine or in another manner that will enable the information to be given to the person to whom the medicines are administered or otherwise dispensed.

The PSA guidelines for the provision of a CMI by pharmacists states that, while there is no legislative requirement for pharmacists to provide a CMI, pharmacists have a professional obligation to provide medicines information to consumers as part of the counselling process. A CMI is considered a

²⁷ Society of Hospital Pharmacists of Australia, Interim Report Submission No. 196, page. 26.

²⁸ Therapeutic Goods Administration, Consumer Medicines Information (CMI,) (July 2014).

valuable tool for the provision of medicines information, and pharmacists are strongly advised not to withhold the provision of a CMI²⁹.

The Panel notes that consumers are not always aware of the availability of a CMI or, indeed, are not being offered a CMI as part of the dispensing process³⁰. This could result in medication misadventure and loss in quality of care.

Addressing this risk requires a strengthening of the means through which consumer awareness and understanding of CMIs is improved, as well as by strengthening dispensing controls to ensure that consumers actually receive a CMI as required.

It would also be beneficial for prescribers to indicate on prescription forms whether the provision of a particular CMI should be mandatory. This would assist in improving consistency in the supply of CMIs as part of the required dispensing process, particularly for vulnerable patients.

The Panel also notes a number of positive initiatives by the Australian Government and the pharmacy profession to improve consumer awareness of a CMI, including through mobile phone applications.

RECOMMENDATION 2-5: CONSUMER MEDICINES INFORMATION

Consumer Medicines Information should be offered and made available to consumers with all medicines dispensed, in accordance with the Pharmaceutical Society of Australia guidelines. The PSA guidelines and the distribution of Consumer Medicines Information to consumers should be audited and enforced to ensure compliance.

Pharmacists and the pharmacy industry should continue to work on the improvement of Consumer Medicines Information and the use of technology to make medicines information more available to consumers.

2.6 ELECTRONIC PRESCRIPTIONS

There are impediments to the effective use of technology in the community pharmacy network. Encouraging a national adoption of electronic prescriptions will reduce unnecessary administration and better support quality use of medicines.

In Australia, the Electronic Transfer of Prescriptions (ETP) involves an electronic system known as the Prescription Exchange Service (PES). There are two PES systems operating in Australia: eRx Script Exchange and Medisecure, which are in widespread use.

When a prescriber writes a prescription, the electronic copy is encrypted and uploaded to one or both PES systems. A pharmacy is then able to download and decrypt the prescription. Linking the prescriber and pharmacist in this way greatly improves messaging and coordination while reducing

²⁹ Pharmaceutical Society of Australia, Consumer medicine information and the pharmacist – Guidelines for pharmacists, (January 2007).

³⁰ Health Care Consumer Association, Discussion Paper Submission No. 248, page 9.

transcription errors and the likelihood of preventable adverse medication events. Similarly, time and workflow efficiencies can occur for pharmacists, as they do not need to manually enter prescription information into their dispensing system.

Electronic prescriptions also provide consumers with greater choice in accessing their medications.

Despite the technology in place, electronic prescriptions do not satisfy current regulatory requirements. Pharmacists are still legally obligated to sight the paper script prior to dispensing, and consumers must present the original paper version to be able to collect their medicine.

The Panel therefore considers that the first step in promoting greater access and quality use of medicines should begin with government recognising an electronic prescription as a valid legal record. Paper prescriptions could still be used as a transitional measure where the technology has not been implemented or as a redundancy under a ‘paper-optional’ approach.

Submissions to the Review were strongly in support of the use of electronic prescriptions, provided that access to the PES remains open.

Some implementation concerns were raised, highlighting the importance of providing open access to the PES systems so as to allow the development of a competitive marketplace for electronic prescription software.³¹

The Australian Digital Health Agency (ADHA), while supporting the introduction of paperless prescribing, has noted a number of transitional risks that need to be addressed. These are of a ‘technical, regulatory and commercial nature’, so the ADHA advocates for a risk assessment to be conducted in respect of a paperless prescribing initiative with collaboration from regulators, peak bodies, industry and clinicians. The Panel favours this approach.

The Panel also endorses the following principles and capabilities of paperless prescriptions put forward by the ADHA:

- Include dispensing at the pharmacy of the consumer’s choice.
- Do not require explicit consumer consent.
- Ensure privacy and security requirements associated with the protection of personal information are met.
- Provide support for a multi-solution environment to allow diverse prescribing and dispensing arrangements to effectively integrate with prescription exchange requirements and associated system workflows.
- Involve effective business continuity arrangements in place and the continued availability of paper prescriptions where appropriate.
- Address the need for consumers to view a history of current and previous electronic prescriptions.
- Provide for mobile use, including by having suitable arrangements in place where there is no or limited connectivity.

³¹ Interim Report Submission No. 616575180, page 1.

- Provide assistance for vulnerable consumers to nominate a pharmacy where their medicines are dispensed.³²

The Panel acknowledges that access is the most important component of the e-prescription solution, and that infrastructure limitations or consumer preference may limit the uptake or use of e-prescription technology. The Panel therefore considers that the traditional paper-based system should continue to exist to allow those who depend upon it sustained access to medicines. However, the paper-based system should be an optional addition to the system of electronic prescriptions, not an alternative. Similarly, the consumer should be able to choose where they present their script, as this reinforces consumer choice, and the continuity of service and/or convenience they may be selecting.

The introduction of electronic prescriptions also serves as a key enabler for online dispensing, which increases access to quality medicines and overcomes geographical barriers. This could have significant advantages for rural and remote communities and in supporting machine dispensing.³³

RECOMMENDATION 2-6: ELECTRONIC PRESCRIPTIONS

The Australian Government should initiate an appropriate system for integrated electronic prescriptions and medicine records as a matter of urgency. Under this system the electronic record should become the legal prescription record. Participation in the system should be required for any prescriber of a PBS-listed medicine, any pharmacist wishing to dispense a PBS-listed medicine and any consumer who is seeking to fill a PBS prescription.

2.7. A UNIVERSAL HEALTH RECORD

Australia lacks an integrated and effective universal health record system. This reduces consumer access to best-practice care and continuity of care between providers. A complete medication history is critical for appropriate prescribing and dispensing.

The government has endorsed the MyHealth Record and it is currently an opt-in system requiring patients, prescribers and pharmacists to register for access and use.³⁴ Prescribers and pharmacists must also have clinical software able to produce and send records to the MyHealth Record system.

Currently, the voluntary nature of the MyHealth Record means that there is no comprehensive record of a patient's medicine that can be accessed by a general practitioner (GP), specialist or other healthcare professional at the time of prescribing. Rather, the patient's medical history is

³² Australian Digital Health Agency, Interim Report Submission No. 190, page 2.

³³ Department of Health, Review of Pharmacy Remuneration and Regulation – Discussion Paper, pages 44 - 49, (July 2016).

³⁴ Noting that an 'Opt out' approach is currently being trialled and this will have relevance to how a future system is implemented.

fragmented across a variety of insufficiently integrated platforms, resulting in reduced continuity of care as well as increased hospital readmissions due to medicine misuse.³⁵

The Panel has heard concerns raised about the current state of the electronic healthcare system and notes the importance and urgency of implementing a nationally consistent and comprehensive technology enabler, such as electronic medication records, that could help reduce medical wastage and medicine misuse. The Australian Commission on Safety and Quality in Health Care (ACSQHC) states there are 230,000 medication related hospital admissions at a cost of \$1.2billion.

The Panel takes the view that this electronic record should work in tandem with e-prescriptions, both feeding into the MyHealth Record database and accessible to relevant healthcare providers. This should also include a vaccines register, with prescribers and pharmacists required to update the register in real time. This would facilitate continuity of care and minimise the risk of medicine misadventure.

The option for an integrated universal health record received strong support during the submission process. Certain issues regarding data storage and privacy were raised, along with the importance of retaining the paper-based method as an optional system for regions with low internet connectivity and as a safeguard against technology failures. While agreeing with the principle of an electronic record, the ADHA suggested that:

“[The] digital health ecosystem is a long way from having a single medicines record that can be updated dynamically by a consumer’s multiple healthcare providers, and that will be comprehensive, accurate and up to date.”³⁶

The Panel considers that a universal, comprehensive medicines record is at present the best solution to ensure accurate information is available to support appropriate communication and prescription between healthcare providers.

The Panel also notes the ongoing initiatives to improve digital services, such as the Aged Care Digital Payments Platform and the MyGov portal, and initiatives required across state and territory based health systems to integrate patient records with various providers and settings. The Panel also notes that dialogue around these issues has been continuing for some time now and provides an impression of stagnation in this area. Although, the issues are complex, it is paramount that pharmacists have a complete understanding of a patient’s health to mitigate medicines risks and provide appropriate treatment.

RECOMMENDATION 2-7: ELECTRONIC MEDICATIONS RECORD

There should be one electronic personal medications record system that covers all Australians and ensures appropriate access by, and links between, community pharmacy, hospitals and all doctors. This record system should also include a vaccines register.

³⁵ The Digital Health Agency, in Australia’s National Digital Health Strategy, has advised of nearly 230,000 hospital admissions for misadventure that cost Australia \$1.2 billion, with some 10,000 deaths.

³⁶ Australian Digital Health Authority, Interim Report Submission No. 190, page 3.

2.8. MANAGING RISKS ASSOCIATED WITH CHANNELLING PRESCRIPTIONS

The introduction of a compulsory electronic prescriptions record system could introduce risks of inappropriate behaviour, such as the channelling of prescriptions that will need to be managed appropriately.

The Panel is aware of the concern that electronic prescriptions could lead to script channelling, whereby prescribers direct patient scripts to a specific pharmacy, based on existing relationships or other incentives. This concern was echoed by Fred IT, the PSA and the CHF in their submissions to the Interim Report, with general agreement that this practice should be managed through legislation and appropriate monitoring.

The electronic prescription system should not require that a prescription is directed at the time of prescribing. Rather, it should allow consumers the ability to have their medicines dispensed after leaving a medical practice, in a secure and verifiable way, at any community or online pharmacy of their choice.

The electronic system should also allow consumers to direct their script to any specific community or online pharmacy of their choice, at the point of prescribing, where this would benefit a consumer's access to their medicines.

An appropriate system should be put in place to assist and educate consumers about their rights, to ensure that scripts are not directed to a particular pharmacy against their preference.

While the PSA agrees with the need to manage the risk of script channelling, they also raised possible unintended consequences that need to be considered during the design and implementation of an electronic prescription system:

“As such, while PSA agrees with the need for consumer choice to be protected, care is required to ensure that the use of an electronic prescription and online pharmacies does not create unintended consequences such as fragmentation of care—minimising the opportunity for a pharmacist to meaningfully interact with a consumer.”³⁷

The Panel agrees that appropriate steps should continue to be taken by prescribers, community and online pharmacies to ensure that consumers receive relevant advice regarding access to and appropriate use of their medicines.

This is an area of practice that needs to be monitored for compliance by pharmacy professional bodies themselves, such as through setting of professional standards and inclusion in codes of conduct or other integrity-related frameworks.

RECOMMENDATION 2-8: ELECTRONIC PRESCRIPTIONS—CONSUMER CHOICE

The choice of where a consumer has an electronic prescription dispensed should remain a decision for the consumer. Any consumer should be able to request at the point of prescribing that their script be directed to a particular community pharmacy for dispensing (including an online pharmacy

³⁷ Pharmaceutical Society of Australia, Interim Report Submission No. 183, page 13.

RECOMMENDATION 2-8: ELECTRONIC PRESCRIPTIONS—CONSUMER CHOICE

—if that is the consumer’s choice). For avoidance of doubt, a prescriber should not be able to direct a consumer’s electronic prescription to a particular pharmacy for dispensing without that consumer’s consent. This will require appropriate oversight and enforcement by professional bodies.

3. ACCESS TO PBS MEDICINES AND COMMUNITY PHARMACY SERVICES FOR ABORIGINAL AND TORRES STRAIT ISLANDER PEOPLE

3.1. SECTION 100 REMOTE AREA ABORIGINAL HEALTH SERVICES PROGRAM

Access to medicines for Indigenous Australians under the section 100 Remote Area Aboriginal Health Services Program and the Closing the Gap PBS Co-Payment Measure has created a number of challenges in ensuring a consistent level of care to the intended patient group.

The section 100 RAAHS Program established under the *National Health Act 1953* (Cth), was established to address barriers to access to PBS medicines experienced by Aboriginal and Torres Strait Islander people living in remote areas of Australia. In addition to standard PBS arrangements through community pharmacy, patients of an approved AHS in remote areas are able to obtain PBS medicines without a prescription and without charge.

Each participating AHS maintains a stock of PBS medicines that are ordered on a bulk supply basis (i.e. not labelled for individual patients) from an approved supplier of PBS medicines. This is either a community pharmacy or a hospital pharmacy. Medicines are then supplied directly to patients as needed, at no cost to the patient, under the supervision of a qualified health professional.

However, there are certain medicines that are currently not made available under section 100 RAAHS Program arrangements. These medicines include:

- extemporaneously prepared medicines;
- highly specialised drugs;
- emergency drug (doctor's bag) supplies;
- medicine subsidised under the Repatriation Pharmaceutical Benefit Scheme; and
- Schedule 8 medicines (Control Drugs).

Schedule 8 or extemporaneously prepared medicines must be prescribed on an approved prescription form and dispensed under standard PBS arrangements.

For a RAAHS to receive PBS medicines, the medicines must come from an authorised supplier, such as a community or hospital pharmacy. The participating RAAHS is required to keep a bulk supply of stock from an approved supplier for dispensing to patients when required. However, the Panel understands that the current bulk supply arrangements may lead to wastage and storage issues for remote healthcare services and that the bulk supply handling fee does not cover the costs of transporting PBS medicines to remote locations.

In addition to bulk supply arrangements, some jurisdictions require pharmacists to individually label a medicine for patients of a RAAHS on the basis of a 'rural script'. Whereas a rural script and PBS script can vary depending on jurisdiction, the principal difference is that the pharmacist has no direct contact with the patient at the time of dispensing.

Prior to 1 January 2017, pharmacists dispensing medicines on a rural script were only able to claim the bulk handling fee (\$2.96), rather than the full PBS dispensing fee (\$7.02), even though they

undertook the same type of work. The introduction of a new fee (\$4.57) per PBS item is now provided under a rural script and is equivalent to a payment of (\$4.00) as a top-up of the bulk handling fee to the standard PBS dispensing fee, together with a proportion of the standard premium free dispensing incentive fee (\$0.51).³⁸ Under section 100 RAAHS arrangements, all PBS medicines continue to be eligible for a handling fee whether they are supplied in bulk or as a rural script.

From the submissions and questionnaires received in response to the Interim Report, there was no new evidence provided on the regulation of medicines programs for Indigenous Australians. The peak bodies and consumers who responded agreed that the benefits from the section 100 RAAHS Program and Closing the Gap PBS Co-Payment Measure should be applied irrespective of where the prescription was written or dispensed. This was supported by the PSA which submitted that:

“Eligibility for medication access programs and services should be based on consumer need, not their location.”³⁹

However, there were a number of suggestions on how to further improve access to medicine programs. These included the creation of a universal medicines access program to ensure continuity of access to medicines for both Indigenous and non-Indigenous people living in remote areas. There was also a recommendation by the National Aboriginal Community Controlled Health Organisation (NACCHO) that a new framework with additional resourcing to employ practice pharmacists where appropriate, be introduced. The NACCHO further recommended:

“An integrated practice pharmacist model to be embedded in ACCHOs to address these issues. This model can improve clinical care and cultural safety, transitions of care, staff medicines knowledge and add great value to the health system in which ACCHOs operate. Practice pharmacists are entirely synergistic to community pharmacy activities, they can ensure that the medicines supply chain is effective and efficient.”⁴⁰

The Panel agrees that such arrangements would help to ensure that medicine supply is delivering value for Indigenous people living in remote areas and can also help to ensure that pharmacists are appropriately distributed across urban and non-urban locations.

RECOMMENDATION 3-1: ACCESS TO MEDICINES PROGRAMS FOR INDIGENOUS AUSTRALIANS

The Australian Government should ensure that all benefits from the section 100 Remote Area Aboriginal Health Services Program and the Closing the Gap PBS Co-Payment Measure are accessible to Aboriginal and Torres Strait Islander people living in rural areas. This should be based on the principle that the benefits to the individual follow that individual, regardless of where a prescription is written or dispensed.

³⁸ The amounts used here are based on current allocations.

³⁹ Pharmaceutical Society of Australia, Interim Report Submission No. 183, page 35.

⁴⁰ National Aboriginal Community Controlled Health Organisation, Interim Report Submission No. 112, attachment 1, page 2.

3.2. PHARMACY OWNERSHIP AND OPERATION BY ABORIGINAL HEALTH SERVICES

Aboriginal Health Services are currently unable to operate a community pharmacy, which may undermine culturally appropriate care in some rural and remote areas of Australia.

While there has been improved access to both the QUMAX⁴¹ and Section 100 Pharmacy Support Allowance programs for Aboriginal and Torres Strait Islander people, the Panel considers there is still a need to address the increasing demand for flexibility in medication dispensing and support services.

The Panel notes that AHSs in the Northern Territory are able to own and operate a community pharmacy, subject to ministerial discretion. This provides access to community controlled and culturally responsive services for Indigenous patients and is of particular value to those living in underserved communities. Additionally, any profits from these activities are able to be reinvested into additional programs or initiatives to support community healthcare.

The expansion of this program in other Australian jurisdictions is supported by the NACCHO:

“some communities and ACCHOs could also benefit from a culturally responsive pharmacy goods and services model within their organisation that meets the distinct needs of their community.”⁴²

While permitting AHSs to own and operate pharmacies presents a number of significant benefits to both remote and urban communities, there are some associated risks that need to be managed. The PSA has identified a number of challenges that need to be overcome, including the continued viability of existing pharmacies in those regions:

“it is unlikely that many AHSs would have capacity to absorb the risk and liability associated with operating a pharmacy business ...”⁴³

It was also noted in an individual consumer’s response to the Interim Report, that the operation of a pharmacy by an AHS should not reduce existing community services and access to medicine:

“As long as this does not affect the viability of already existing pharmacies. The ATSI community may get a convenient service while the non-indigenous community loses one.”⁴⁴

The PSA suggested an alternative to an AHS owning and operating a pharmacy:

“Instead, PSA would strongly recommend that a pharmacist was employed through the AHS to ensure quality use of medicines.”⁴⁵

The Panel accepts this as one approach and considers that an AHS should employ a pharmacist where it is appropriate to do so. The Panel also notes that the ability of an AHS to own and operate a

⁴¹ Quality Use of Medicines Maximised for Aboriginal and Torres Strait Islander People to support urban and rural clinics to assist Indigenous patients to comply with their prescribed medication regimes.

⁴² National Aboriginal Community Controlled Health Organisation, Interim Report Submission No. 112, page 38.

⁴³ Pharmaceutical Society of Australia, Interim Report Submission No. 183, page 35.

⁴⁴ Interim Report Questionnaire Response No. 449606047.

⁴⁵ Ibid.

pharmacy would facilitate this, while potentially also providing and significant additional benefits through improved access to medicines and advice for Aboriginal and Torres Strait Islander people.

The Panel advocates for such programs to be trialled and evaluated prior to implementation in other jurisdictions. Such a trial should measure and evaluate the outcomes of increased access to specific services due to the establishment of an AHS pharmacy. This should be assessed across urban, rural and remote contexts to identify any factors and unintended consequences flowing from the introduction of an AHS pharmacy to the specific community of scope.

RECOMMENDATION 3-2: PHARMACY OWNERSHIP AND OPERATION BY ABORIGINAL HEALTH SERVICES

The Australian Government should remove any restrictions on the ability of an Aboriginal Health Service to own and operate a pharmacy located at that Aboriginal Health Services. To ensure viability, this should be trialled across specific jurisdictions in urban, rural and remote locations, to understand any inadvertent impacts of the removal of restrictions.

3.3. PATIENT LABELLING IN BULK SUPPLY

There are risks to patients where medicines in bulk supply are not individually labelled to identify a specific patient's medicine with information on that patient's use of their medicine.

Medication errors are a significant contributor to healthcare costs in Australia. Many of these errors are associated with consumers or healthcare practitioners having difficulty locating and understanding critical information on medicine labels.⁴⁶

The selection of a medicine, whether by a pharmacist, nurse, doctor or consumer, requires understanding of the information provided on the label to identify the medicine and, if applicable, to administer the medicine. Therefore, medicine labelling must clearly identify the particular medicine and provide sufficient information to allow people to make safe and informed decisions about its use. The label must also identify the right patient to whom the medicine is to be supplied.

The pharmacist's requirements in respect to labelling and bulk supply of dispensed medicines are specified in legislation and enforced in the jurisdiction where a pharmacist practices.⁴⁷

The Panel has noted some instances of inadequate patient specific labelling, particularly in the context of remote dispensing arrangements.

Clients of AHS clinics, including Aboriginal community controlled AHSs and remote services operated by states and territories, benefit from improved PBS access through these remote dispensing arrangements.

⁴⁶ Therapeutic Goods Administration, Regulation Impact Statement: General requirements for labels for medicines page 7, (2015).

⁴⁷ Pharmacy Board of Australia, *Guidelines for dispensing of medicines*, page 7, (September 2015).

However, in the provision of bulk supplies, the Panel has been made aware of concerns that patient-specific medicine labels are not being supplied as required.

Irrespective of the dispensing system being used by an AHS, clear and consistent placement of important information on a medicine label is critical. It ensures that, from the very first interaction, a medicine is selected properly and used safely.

The legislative and professional requirements for the labelling of PBS medicines should not vary in their application due to the supply arrangement or dispensing setting. Best practice suggests that every patient requires a patient specific label. This is critical in ensuring that medicines are used as effectively as possible to improve health outcomes. Further, appropriate monitoring is required by regulators to manage compliance and to support a consistent approach to labelling.

Bulk supply to an AHS has a number of specific requirements that need to be met by both the AHS and the supplying pharmacy. These include medicine management, training of Aboriginal Health Workers in the handling of medicines and pharmacy supervision of medicines held by remote communities, such as out of date stock. The NACCHO has noted remote dispensing and bulk supply as an issue and has provided a recommendation to help reduce related risks:

“NACCHO recommends that the solution for this perceived problem is to build knowledge and capacity within the local, community-controlled and culturally responsive health services to identify labelling or dispensing issues against the appropriate standards and legislation. ACCHOs should determine how individual challenges can be addressed in the context of their services’ broader systems, including Continuing Quality Improvement (CQI) systems.”⁴⁸

The Panel agrees that AHSs should have the flexibility to deal with individual challenges as they arise. However, as the point of contact for patients, AHSs should ensure that appropriate labelling and physical usage information is provided to patients to help ensure Quality Use of Medicines (QUM). As NACCHO recommends, the improvement in education for local health services in relation to the risks associated with bulk supply dispensing would assist in this regard.

As noted above in this report (see to section 3.1: Section 100 RAAHS Program), a number of initiatives have recently been announced by the Australian Government to improve the quality use of medicines for Aboriginal and Torres Strait Islander people. This includes improvements to ensure that medicines associated with rural prescriptions are dispensed safely and that patients are properly identified. This will ensure that the medicine is dispensed to the person for whom it is intended, and that an appropriate label for the dispensed medicine is generated.

RECOMMENDATION 3-3: PATIENT LABELLING OF MEDICINES UNDER BULK SUPPLY ARRANGEMENTS

All PBS medicines provided to a patient should be appropriately labelled and dispensed for that patient’s use. Where there is a system in place that involves ‘remote’ dispensing or ‘bulk supply’ this would require appropriate monitoring to ensure the quality of medicine supply. Aboriginal Health Services and pharmacies in remote areas should be provided with training to understand and —

⁴⁸ National Aboriginal Community Controlled Health Organisation, Interim Report, Submission No. 112, page 5.

RECOMMENDATION 3-3: PATIENT LABELLING OF MEDICINES UNDER BULK SUPPLY ARRANGEMENTS

mitigate the risks associated with remote and bulk supply dispensing.

3.4. MACHINE DISPENSING IN REMOTE REGIONS OF AUSTRALIA

Overseas experience has demonstrated advantages in the use of remote dispensing machines to improve medicine access for patients living in remote communities.

Machines have been used successfully to assist dispensing in Australia and overseas for a number of years. Robotic product selection machines to assist dispensing in hospitals is also commonplace in the United Kingdom and allows staff more time to deliver more direct patient care and allow for medicines optimisation. This is also occurring in community pharmacy, where recent studies of incorporating robotics into pharmaceutical dispensing have yielded positive results.⁴⁹

Fully automated dispensing machines have also been used in Canada to improve access to medicines for people living in rural and remote regions. The remote dispensing machines used in Canada typically incorporate a television screen and a phone to facilitate the provision of medicine advice. Patients input their script into the machine, which is linked via video to a registered pharmacist who has full control over the dispensing process. This includes being able to ask questions and provide patients with advice in relation to the medicine being dispensed. Pharmacies that intend to operate these machines are required to be accredited by the relevant government authority.

The Panel considers that these dispensing machines may help to address some of the challenges of providing clinical consultation and timely medication supply for rural and remote communities. For example, such machines could be of benefit to remote Indigenous Australian communities that are not served by a community pharmacy in their location.

The Panel considers that a trial of remote dispensing machines is warranted provided the following conditions are met:

- There is access to real time advice from a registered pharmacist.
- There is adequate and secure storage of medicines.
- There is oversight and operation by a pharmacist that holds a PBS approval number.
- There is approval by the Australian Community Pharmacy Authority for the location of dispensing machines (to ensure that services of physically present pharmacists are not undermined).
- There is adequate monitoring and supervision of machine dispensing to facilitate an evaluation of trial outcomes.

These conditions are consistent with those suggested by the PSA in its support of a trial of remote dispensing machines.⁵⁰

⁴⁹ R. Beard, e-Prescribing and robotic dispensing part 1, (February 2014).

⁵⁰ Pharmaceutical Society of Australia, Interim Report Submission No. 183, page 38.

As noted in the Interim Report, machine dispensing arrangements can be assisted and facilitated by a system of electronic prescriptions. However, if the government does not institute a system of electronic prescriptions, the feasibility of remote machine dispensing under the current ‘paper-based’ prescription system should be investigated.

RECOMMENDATION 3-4: MACHINE DISPENSING

The Australian Government should trial the use of machine dispensing in a small number of relevant secure locations in communities that are not currently served by a community pharmacy. Such machine dispensing must be appropriately supervised and should allow real-time remote interaction with a pharmacist. The range of PBS medicines available through machine dispensing should be limited based on an assessment of risk.

4. THE ROLE OF COMMUNITY PHARMACY

4.1. COMMUNITY PHARMACY—MINIMUM SERVICES

There is a significant variability between pharmacies and the services they offer.

As an agent of government, the key role of community pharmacy is the dispensing of PBS medicines and the delivery of medicine-related services. Pharmacies also occupy a broader role in the primary healthcare system, dispensing pharmacy-only medicines and non-PBS and private prescriptions, providing advice across a range of healthcare services, and supplying or advising on other health-related products. The range of products and services offered by community pharmacies can vary depending, for example, upon the location or local demographic in which the pharmacy operates.

The Panel recognises that it is important for pharmacies to be able to tailor services and supply products that best meet local needs. However, it is also important that a minimum set of services exist across pharmacies so as to provide consistency to the community as a whole. It is logical that this role be defined as a minimum set of obligations, which would be developed from community and consumer expectations. As the government provides funding for pharmacies, it has the right and obligation to specify the minimum set of services that consumers should be able to access from a pharmacy that benefits from this government funding.

Submissions to the Interim Report support the notion of a minimum set of standards for pharmacies. However, some concerns were expressed in relation to a possible duplication of activities with the Quality Care Pharmacy Program (QCPP). As noted by the PSA, the QCPP does not operate to manage outputs, health outcomes or care delivery at a pharmacy level.⁵¹ While the PSA in principle supported the development of minimum standards, it also suggested that:

“the development of indicators for pharmacist practice would address the challenge of setting the minimum requirements a community pharmacy should meet in order to receive remuneration ... these quality indicators would be a discrete piece of work, to be led by the PSA and involve stakeholders from the pharmacy sector, the broader health sector, the Australian Commission on Safety and Quality in Health Care and Government to ensure that they reflect contemporary pharmacist practice, including multidisciplinary care.”⁵²

The Panel considers that these quality indicators could also be adapted to the PSA’s comprehensive list of professional practice standards and the Pharmacy Board of Australia (PBA) *Guidelines for Dispensing of Medicines*, developed under section 39 of the *Health Practitioner Regulation National Law (2010)*. Pairing this with SHPA’s model of care could serve to standardise minimum service requirements for all pharmacists.⁵³ As outlined in the SHPA submission, pharmacists are required to:

- be appropriately skilled;
- deliver in an appropriate setting;
- have access to appropriate clinical information;
- collaborate with the patient, carer and medical team; and

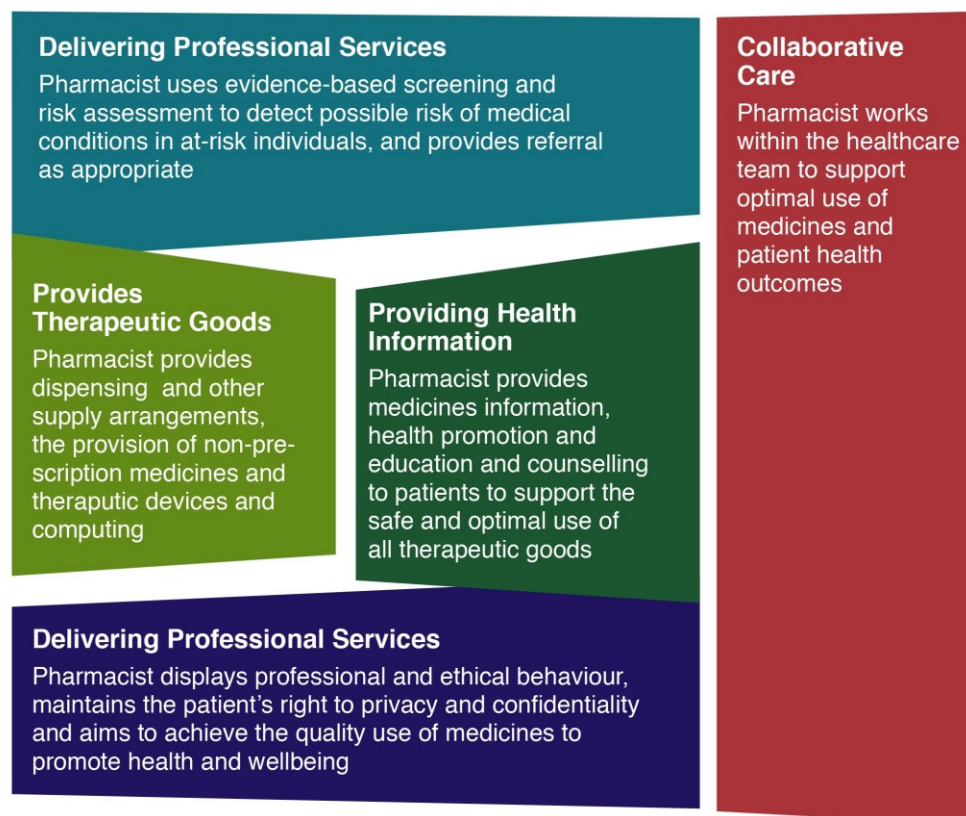
⁵¹ Pharmaceutical Society of Australia, Interim Report Submission No. 183, page 15.

⁵² Ibid.

⁵³ Society of Hospital Pharmacists of Australia, Interim Report Submission No. 194b, page 16.

- deliver timely care for the patient.

FIGURE 3: PSA PROFESSIONAL PRACTICE STANDARDS



Quality indicators, while important, are different from the minimum set of services being considered by the Panel. A set of core dispensing and service obligations would frame the minimum services that all community pharmacies should provide and comply with. This would improve consumer access by creating certainty for consumers about what, at a minimum, they can expect to receive from any community pharmacy. They can also inform the calculation of appropriate remuneration for dispensing services, which is dealt with in Chapter 5 (Community Pharmacy Remuneration by Government).

Establishing a minimum set of services for all community pharmacies does not prevent individual pharmacies from offering other products and services through their chosen business model. Rather, it sets a baseline for consumer expectations and experience.

As stated in the Interim Report, it is not the intention of the Panel to comprehensively define a set of minimum requirements. This should be determined by government through consultation with key stakeholders and consumers.

At a minimum, however, the requirement to cover-off on the 'minimum' services should include:

- the supply of all PBS medicines;
- the provision of related advice; and

- information on relevant programs and services.

While some of these requirements already exist, it is desirable that they are regularly revisited and set as a standard for each community pharmacy before that pharmacy can receive government remuneration for dispensing. It may also involve the requirement to supply certain non-medicine items (e.g. sterile syringes) or to have appropriate consulting areas for consumers who wish to discuss their medicines in private with a pharmacist.

RECOMMENDATION 4-1: COMMUNITY PHARMACY—MINIMUM SERVICES

The Australian Government should ensure that all PBS pharmacies offer a range of minimum services expected by Australian consumers. These minimum services should include the supply of all PBS medicines; provision of medicine related advice; and information on relevant programs and services. This will require the Australian Government to establish a process to determine the specific minimum requirements that a community pharmacy must meet in order to receive remuneration for dispensing, as well as update and enforce these requirements.

4.2. COMPLEMENTARY MEDICINES IN COMMUNITY PHARMACY

Consumers value access to complementary medicines in the community pharmacy setting where they can receive advice on selection and use that is supported by an appropriate level of evidence.

The National Strategy for Quality Use of Medicines aims to optimise health outcomes for consumers through the best possible use of medicines.⁵⁴ One of the essential components that support this objective is medicines meeting quality, safety and efficacy standards.⁵⁵ Pharmacists play a key role in upholding these standards and providing advice to consumers on how to use medicines correctly. Further, pharmacists provide assistance by supplying patients with information on quality, validity and efficacy.

Submissions to the Interim Report noted ambiguity over the meaning of ‘complementary medicines’.

The TGA defines ‘complementary medicines’ as products that contain herbs, vitamins, minerals, nutritional supplements and homeopathic and specific aromatherapy preparations⁵⁶. On the basis of the information available to this Review, it appears that a majority of both consumers and pharmacists support the continuing access to complementary medicines through community pharmacies. For example, some pharmacists argued that complementary medicines should be provided along with professional advice in order to provide consumers with greater awareness about which complementary medicines are supported by scientific research. Community pharmacists are well placed to provide this advice.

⁵⁴ Commonwealth of Australia, The National Strategy for Quality use of Medicines, (2002).

⁵⁵ Ibid.

⁵⁶ Therapeutic Goods Administration, An overview of the regulation of complementary medicines in Australia, [retrieved from the TGA website](#), (2013).

However, the Panel remains concerned that self-assessed products with a limited evidence base, or in some cases no evidence base at all, are sold in pharmacies alongside independently assessed, evidence-based prescription and other scheduled medicines. Consumers see community pharmacies as a health provider and a source of scheduled medicines with proven efficacy. Having complementary medicines sold alongside scheduled medicines risks creating a ‘halo effect’, where consumers assume that complementary medicines must have desirable properties because they are sold in a community pharmacy.

Pharmacists need to be able to give advice on the differences between scheduled, prescription and complementary medicines. This is the first step toward ensuring patients more easily recognise the differences in evidence that underpins the efficacy and effectiveness of the types of medicines available.

If community pharmacies are to continue to sell both scheduled medicines and complementary medicines then pharmacists must be the specialists that support education and informing activities. As suggested by the PSA:

“Pharmacists, as medicine and medication management experts, have a fundamental role in ensuring consumers have access to safe and effective medicines...When discussing the use of complementary medicines with consumers, pharmacist must ensure they are provided with the best available information about the current evidence for efficacy...Pharmacists should be guided by the PSA Code of ethics, which states that the pharmacist must respect the autonomy and rights of the consumer to actively participate in the decision making and must balance this with the health and wellbeing of the consumer—the pharmacist’s first priority ...”⁵⁷

To support this, the pharmacy retail environment should clearly separate scheduled and prescription medicines from complementary products and apply appropriate signage on the effectiveness and evidence base of the complementary medicine. As the CHF notes:

“[Separating complementary medicines from prescription and scheduled medicines] would help minimise consumer confusion with over the counter medicines. We also support the proposal to have clearer signage and better information for consumers on the limitation of the evidence for effectiveness of such products ...”⁵⁸.

The Panel contends that these changes will enable consumers to make more informed choices around their medicine use and reduce medicine misadventure and associated risks. However, pharmacists being accessible to provide timely advice on the demarcation of different medicines, and their respective evidence bases, are integral components to supporting consumer choice and quality of use.

RECOMMENDATION 4-2: COMPLEMENTARY MEDICINES—SUPPLY FROM COMMUNITY PHARMACY

Community pharmacists are encouraged to:

- a. display complementary medicines for sale in a separate area where customers can easily access a pharmacist for appropriate advice on their selection and use; and

⁵⁷ Pharmaceutical Society of Australia, Interim Report Submission No. 183, page 16.

⁵⁸ Consumer Health Forum of Australia, Interim Report Submission No. 116, page 8.

RECOMMENDATION 4-2: COMPLEMENTARY MEDICINES—SUPPLY FROM COMMUNITY PHARMACY

- b. provide appropriate information to consumers on the extent of, or limitations to, the evidence of the efficacy of complementary medicines. This could be achieved through the provision of appropriate signage within the pharmacy (in the area in which these products are sold), directing consumers to ‘ask the pharmacist for advice’ if required.

4.3. PHARMACY ONLY AND PHARMACIST ONLY MEDICINES (SCHEDULE 2 AND SCHEDULE 3 MEDICINES)

Complementary medicines may pose a risk to consumers when they are not clearly distinguished from Pharmacy Only and Pharmacist Only (Schedule 2 and Schedule 3) medicines within a community pharmacy. This is exacerbated by a lack of understanding regarding the distinctions and differences between scheduled medicines and complementary medicines.

Controls on the availability and use of medicines within Australia are maintained under drugs and poisons legislation specific to each state and territory. The level of control placed on each medicine is determined on the basis of risk to health by scheduling classifications made under the (Commonwealth) Poisons Standard.

Prescription Only (Schedule 4) medicines and Pharmacist Only (Schedule 3) medicines can only be provided over the counter. This ensures that any necessary information is provided to the consumer to ensure safe and appropriate use of the medication. This also affords the pharmacist an opportunity to provide any related professional advice to assist consumers.

Due to differing legislation, Pharmacy Only (Schedule 2) medicines may be stocked behind the counter or in front of the counter, depending on the state or territory in which the pharmacy is located. For example, in Queensland and Western Australia, Pharmacy Only (Schedule 2) medicines are only accessible with the assistance of a pharmacy employee. In jurisdictions where there are no restrictions to the provision of Schedule 2 medicines in a pharmacy, they are displayed alongside complementary medicines.

Displaying complementary medicines behind the counter in a pharmacy has the potential to increase the perceived efficacy of these products to a level similar to a Schedule 2 or Schedule 3 medicine due to their placement. This may confuse or mislead consumers with limited health literacy, as they will not be able to differentiate between the efficacies of products. This is supported by the Consumers Health Forum of Australia:

“We also support Option 3-3 which precludes complementary medicines being behind the counter with the proviso that if they are a TGA registered product they can be behind the counter. Their placement behind the counter is misleading as it makes consumers think they are the same as S2 and S3 medicines which have had to satisfy a higher level of evidence on efficacy.”⁵⁹

⁵⁹ Consumer Health Forum of Australia, Interim Report Submission No. 116, page 8.

This position is also supported by the PSA:

“some pharmacies might stock complementary medicines out of reach of the consumer / behind the counter to prompt intervention by the pharmacist—particularly in the case of complementary medicines with higher risk profiles and those that have demonstrated the efficacy and safety data required to meet TGA requirements for registered complementary medicines”.⁶⁰

The Panel has agreed that it is appropriate to keep some complementary medicines behind the counter if they present a significant risk to patient health when misused. In doing so, however, the placement of complementary medicines should be clearly separated from Schedule 2 and Schedule 3 medicines that are stored ‘behind the counter’ in a community pharmacy.

RECOMMENDATION 4-3: PLACEMENT OF SCHEDULED MEDICINES WITHIN A COMMUNITY PHARMACY

Access to Pharmacy Only (Schedule 2) and Pharmacist Only (Schedule 3) medicines should be clearly separated from complementary medicines within a community pharmacy. Options to achieve this might include:

- a. ensuring that all Pharmacy Only (Schedule 2) and Pharmacist Only (Schedule 3) medicines are only accessible from ‘behind the counter’ in a community pharmacy so that a consumer must always seek assistance or advice in obtaining these medicines; and
- b. requirements that complementary medicines are not displayed ‘behind the counter’ in a community pharmacy.

4.4. HOMEOPATHIC PRODUCTS IN COMMUNITY PHARMACY

The ‘halo’ effect related to homeopathic products may mislead consumers where these products are sold in community pharmacies.

In the Interim Report the Panel provided an option for the removal of homeopathic products from PBS pharmacies.

The Panel’s reasoning for this reform was based on broad consensus, demonstrated in submissions to the Discussion Paper and face-to-face consultations, that homeopathy and homeopathic products do not belong in community pharmacy.

The Panel was particularly concerned that continued sale of these products in pharmacies would create a risk that, in the mind of a consumer, these products had evidence of efficacy, similar to other medicines sold in the pharmacy. The Panel considers that this could result in patients choosing a homeopathic product over a conventional medicine, which may further compromise their health.

This position is supported by many of the professional pharmacy bodies, including the PSA, SHPA and Professional Pharmacists Australia (PPA). The Australian Medical Association (AMA) and the CHF have also supported the Panel’s position on this issue.

⁶⁰ Pharmaceutical Society of Australia, Interim Report Submission No. 183, page 17.

While most stakeholders supported the continued sale of complementary medicines in community pharmacy, the practice of homeopathy and sale of homeopathic products did not receive such support.

As stated by SHPA:

“SHPA supports the provision of evidence-based medicines, and given the lack of evidence for the efficacy of homeopathy does not support their use, endorsement or sale through PBS-approved pharmacies. This position has been previously referenced publicly by the Australian Pharmacy Liaison Forum of which SHPA is a member.”⁶¹

The Panel subsequently received over 200 submissions and survey responses to the Interim Report that express disagreement with the suggestion that homeopathic products be removed from PBS pharmacies.

The reasons for disagreement range from the need to maximise consumer choice in their continued availability to arguments about their medicinal efficacy.

For clarity, the Panel recommends the removal of homeopathic products from PBS pharmacies only. Homeopathic goods can continue to be sold in a non-pharmacy environment, along with other natural remedies and complementary medicine as approved by the TGA.

In determining efficacy, the Panel has relied on the findings of the 2015 National Health and Medical Research Council (NHMRC) conclusion that:

“There are no health conditions for which there is reliable evidence that homeopathy is effective. ... People who choose homeopathy may put their health at risk if they reject or delay treatments for which there is good evidence for safety and effectiveness.”⁶²

While recent submissions indicate that the homeopathic sector has issues with the validity of the NHMRC review and appears to have referred the matter to the Ombudsman, the Panel has no compelling evidence to overturn the conclusions of the NHMRC.

Although number of submissions point to overseas studies in support of homeopathic products, the Panel understands that these have been considered by the NHMRC in their review of homeopathy.

The Panel also notes that homeopathic products have recently been delisted from the National Health System in the United Kingdom on the basis that these products provide no evidence beyond their use as a placebo.

RECOMMENDATION 4-4: SALE OF HOMEOPATHIC PRODUCTS IN PBS APPROVED PHARMACIES

Homeopathy and homeopathic products should not be sold in PBS-approved pharmacies. This requirement should be referenced and enforced through relevant policies, standards and guidelines issued by professional pharmacy bodies.

⁶¹ Society of Hospital Pharmacists of Australia, Interim Report Submission No. 194b, page 18.

⁶² National Health and Medical Research Council, NHMRC Statement: Statement on Homeopathy (2015).

5. COMMUNITY PHARMACY REMUNERATION BY GOVERNMENT

5.1. COMMUNITY PHARMACY ACCOUNTING INFORMATION

The extent and quality of data and information currently available to the Australian Government is not adequate to inform decisions and determinations about the costs of dispensing services in community pharmacies.

Community pharmacies draw funding from a range of federal, state and territory government programs. As with nearly all government activities, funding has to be accounted for in a transparent manner to demonstrate the appropriate use of public money. Pharmacies that dispense PBS items should not be an exception to this, yet currently there is limited information to properly account for the funds that community pharmacies receive from government for dispensing.

The Review commissioned financial analysis and modelling work that examined the structure of remuneration for community pharmacy for dispensing medicines under the PBS, as well as analysis of the financial costs flowing through the pharmacy supply chain. The results were based on limited information, and it was the Panel's hope that alternative sources of data may be presented, challenging the figures offered in the Interim Report.

This is specifically in relation to the suggested benchmark for a best practice dispense.⁶³ While there was criticism of the methodology used to derive the estimated range (\$9.00–\$11.50) quoted in the Interim Report, the pharmacy industry did not provide any alternative benchmarks in submissions to the Review. This reinforces the conclusion that currently no single pharmaceutical group or representative body can accurately account for the costs associated with dispensing PBS items within a community pharmacy.

This lack of accountability is not appropriate for such an important use of public funds. At present no party (including the government) appears able to provide evidence as to whether community pharmacies are being under-remunerated, over-remunerated or appropriately remunerated, for dispensing.

Therefore, it is imperative that data begin to be collected to inform decisions made around the future funding of community pharmacies. This data will contribute to the attainment of NMP objectives, specifically the overall aim to meet medication and related service needs, so that both optimal health outcomes and economic objectives are achieved for patients and consumers.⁶⁴ As noted by PPA:

“We believe, as agents of the Government, that pharmacy owners should be required to provide appropriate data to enable the Government, on behalf of taxpayers, to determine a FAIR level of remuneration for the proposed dispense service.”⁶⁵

⁶³ Department of Health, Review of Pharmacy Remuneration and Regulation –Interim Report, page 84, (May 2017).

⁶⁴ Department of Health, National Medicines Policy (2000).

⁶⁵ Professional Pharmacists Australia, Interim Report Submission No. 104, page 7.

Professor King and Ms Watson recommend that, for the future determination of pharmacy remuneration, the government and those stakeholders engaged in the process be privy to the data which best informs the appropriate remuneration of pharmacy services. Such data would comprise:

- PBS data from the government, which would include prescription volumes;
- data currently collected by the government which would detail business activity and financial accounting information; and
- pharmacy reporting and accounting information, which contains data on the costs of dispensing PBS medicines. This information should encompass all pharmacy models to avoid remuneration being based upon a subset of pharmacies that use a ‘particular’ business model.

The current lack of transparency, particularly in relation to dispensing, is troubling from the perspective of public accountability. The collection and collation of relevant information will create an evidence base for government and the community pharmacy sector, allowing for appropriate forecasting. This will enable the maintenance of a viable and effective pharmacy network and appropriate accountability for the use of public funds, which is standard practice in other areas involving government funds. The collection and collation of this information is not just in the interests of the government and medicine consumers but also in the long-term interest of community pharmacies themselves. Without relevant information being available, community pharmacies risk having decisions about the future remuneration for their services being made on a basis that is disconnected to the true costs of running their businesses.

Despite the pharmacy sector receiving a significant amount of government funding to support access to PBS medicines, there is a general reluctance by the sector to provide the government with the information. This limits proper accountability and transparency for the public money that is being used to remunerate community pharmacy for this activity.

As agents of government, it is not unreasonable that community pharmacies be expected to provide the government with the relevant financial accounting data to calculate the ‘best practice costs’ for pharmacy in dispensing medicines on behalf of the government. At the moment, there is relatively little information available to the government in this regard.

In seeking this information, Professor King and Ms Watson do not consider that they are singling out the pharmacy sector and note that similar expectations for the acquittal of funds exist for most sectors that receive significant amounts of government funding to deliver essential services to the Australian community.

RECOMMENDATION 5-1: COMMUNITY PHARMACY ACCOUNTING INFORMATION (KING & WATSON)

As soon as possible following the completion of this Review, the Australian Government in consultation with the Pharmacy Guild of Australia and other relevant stakeholders, should:

- a. determine a set of accounting principles that will apply for community pharmacies to provide the relevant information needed to determine the best-practice benchmark for dispense;

RECOMMENDATION 5-1: COMMUNITY PHARMACY ACCOUNTING INFORMATION (KING & WATSON)

- b. require community pharmacy to provide the necessary accounting information to inform consideration in the development of each Community Pharmacy Agreement. The relevant accounting information should be provided for each financial year and no later than 30 April of the following financial year (beginning with 30 April 2019);
- c. designate a body within Australian Government, or some other body with the relevant expertise, to provide a recommendation to Australian Government on the best-practice benchmark cost of a dispense as required over time by the Australian Government. The first such advice should be provided as soon as practical and certainly before the end of 2019. The timing of later recommendations would depend on the process used in the future by the Australian Government to set the remuneration for dispensing PBS medicines; and
- d. the information and advice submitted to the Australian Government should inform the basis for the remuneration for a 'dispense' to community pharmacy. The provision of the agreed accounting information should be an ongoing requirement.

5.2. THE BENCHMARK FOR A BEST PRACTICE DISPENSE

On the basis of the information that has been made available to the Panel, the Panel considers that the current benchmark for a best-practice dispense be set within a range of \$9.00 to \$11.50. However, reflecting the current lack of information available to all parties, the Panel is not recommending a specific level for the future remuneration paid to a community pharmacy for a dispense.

Submissions to the Review have made it clear that there is no single 'best practice' community pharmacy model. Different consumers value different business models. However, the Panel believes that an overarching best practice framework for dispensing should encompass these differing models.

Differentiation should continue to be encouraged to allow greater choice to consumers. Community pharmacies should be encouraged to adopt business models that suit their customer demographics and requirements while focusing on providing an appropriate level of healthcare. In doing so, the pharmacy network will be better able to serve the needs of different segments of the community.

Currently pharmacies are paid different fees for supplying different types of medicines and related services which have not been estimated using information on the efficient costs of supplying those medicines and services. These fees have been arrived at by successive rounds of negotiation between the Guild and the government.

Professor King and Ms Watson note the lack of information available to all parties, including government, about the costs of dispensing. This issue is addressed in Recommendation 5.1 (Community Pharmacy Accounting Information). Based on the best information available to the Panel, and noting the shortcoming of that information, the Interim Report noted that the current benchmark for a best practice dispense appears to sit between \$9.00 and \$11.50. A flat fee of \$10.00

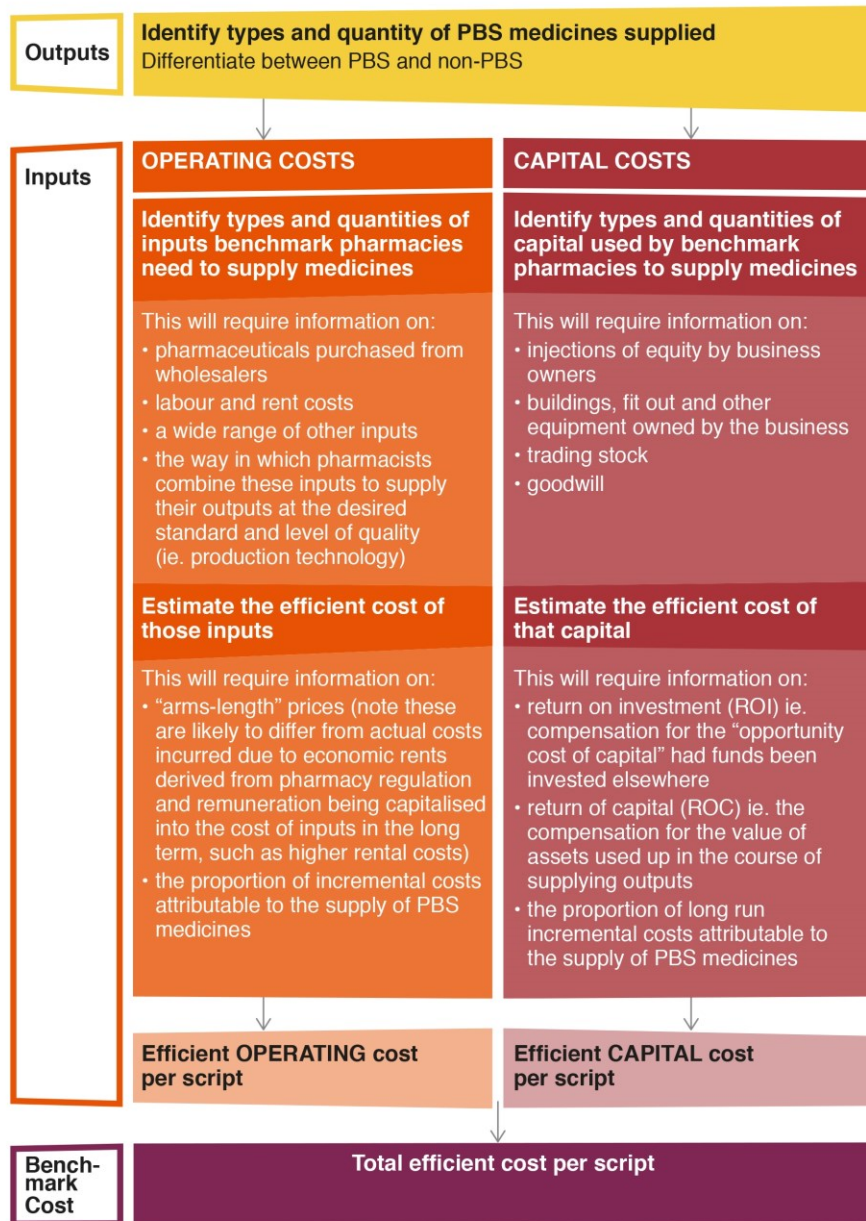
was used in the Interim Report to model the impact on pharmacy remuneration and was used for illustrative purposes only.

Providing a flat fee within this range would encourage pharmacies to continue to innovate and differentiate based on services, while ensuring they are remunerated appropriately for dispensing. This would render community pharmacies as ‘business model neutral’.

As already discussed, this benchmark was disputed by some parties. However, those same parties did not provide relevant information to underpin a more accurate estimate of an appropriate dispensing fee. For this reason, and recognising the lack of available information, the Panel has decided not to make a specific recommendation on the level of the fee for dispensing going forward. Rather, a set of recommendations are proposed that will enable appropriate information to be gathered, analysed and applied to future decisions on pharmacy remuneration.

The Panel has noted the preference by both consumers and community pharmacists for diversity in business models. However, the payment by government for dispensing PBS medicines should not depend on the business model chosen by a community pharmacy for other parts of its operations. A business model neutral approach to remuneration for dispensing means that the government sets the same level of remuneration to each community pharmacy independent of its particular business model, structure, layout, product mix and other commercial features. The objective of this approach is to provide community pharmacies with the opportunity to recover operating and capital costs that are efficiently incurred to support dispensing over the long term. Figure 4 outlines the approach to estimating the costs associated with dispensing for a best practice benchmark pharmacy.

FIGURE 4: ILLUSTRATION OF THE ‘BUILDING BLOCK’ APPROACH TO ESTIMATING BEST PRACTICE PHARMACY COST OF DISPENSING



A business model neutral approach does not mean that the government should take an ‘anything goes’ approach to community pharmacy. Community pharmacies are regulated agents of the government, tasked with the safe, effective dispensing of medicine to Australians and the provision of associated medicine services. The Panel considers that a best practice pharmacy is one that is consumer-centric and focused on quality health outcomes as opposed to dispensing volumes. The core components of a best practice pharmacy are discussed throughout this Report and are highlighted in Figure 5.

FIGURE 5: A FRAMEWORK FOR A BEST PRACTICE PHARMACY⁶⁶

A flat fee for each dispense based on a best practice pharmacy would safeguard proper remuneration for community pharmacy while achieving taxpayer value and enabling a diversity of services to evolve within the community pharmacy sector. The benchmark would fully reward an efficient pharmacy for all the costs associated with dispensing, separate from other non-dispensing retail operations. The remuneration for dispensing would also provide each community pharmacy with a strong signal about its performance in dispensing relative to other community pharmacies.

RECOMMENDATION 5-2: REMUNERATION TO BE BASED ON THE COST OF DISPENSING SERVICES ASSOCIATED WITH A BEST PRACTICE PHARMACY MODEL (KING & WATSON)

The remuneration for dispensing paid by the Australian Government and consumer co-payments to community pharmacy should be based on the costs of dispensing for a best practice pharmacy.

5.3. REMUNERATION FOR DISPENSING SERVICES

Remuneration for dispensing should be based on the best practice incremental costs of dispensing rather than fully distributed or standalone costs.

⁶⁶ Adapted from Pharmaceutical Society of Australia, Professional Practice Standards—Version 5 (2017).

There is a range of different costs that need to be considered when compiling an equitable dispensing fee that fairly remunerates pharmacists while providing value to tax payers.

Professor King and Ms Watson reject the position, such as that presented by the Guild, that suggests that remuneration reform ignores NMP objectives, and that the only way to save tax payer money is to close pharmacies.⁶⁷ Rather, Professor King and Ms Watson contend that a fair and equitable dispensing price can be reached if, as mentioned in section 5.1 above, proper data is disclosed and used to inform future remuneration decisions.

As noted in the Interim Report, this data would inform a dispensing remuneration methodology and would include information on:

- the pharmacist’s economic and accounting costs;
- stand alone and incremental costs;
- long-run and short-run costs;
- remuneration per dispense; and
- medicine-specific costs.

Ideally, an activity analysis would need to be conducted to best inform the practices that underpin the above list.

A fair dispensing price would support business model neutrality, allowing pharmacies to drive differentiation through healthcare efficiencies and overall service quality, instead of forcing them to compete over the price of PBS medicines.

Consistent with the Guild’s submission,⁶⁸ the Panel acknowledges that prior community pharmacy agreements have resulted in cost saving opportunities for the government. Preceding CPAs have also enabled the community pharmacy network to develop to its current point. However, the CPAs represent a negotiated outcome and it would be a mistake to suggest that the Guild’s negotiations with the government have resulted in savings that have supported the development of the sector. Also, it cannot be expected that, just because prior community pharmacy agreements may have heralded savings and supported the sector’s viability, this will continue in the future.

Rather, as stated in section 5.2 (The Benchmark for A Best Practice Dispensing) above the Panel firmly considers that the viability of the community pharmacy network should be strongly linked to pharmacies being able to provide the best health outcomes to patients. This means linking the costs of dispensing to the running of a best practice PBS pharmacy⁶⁹ because such a pharmacy is considerate of health outcomes as opposed to dispensing practices alone. This is a significant departure from how pharmacies have been remunerated to date, and dispensing fees negotiated in prior CPAs insufficiently disclose the appropriate remuneration level for a pharmacist’s core activities.

The methodology for dispensing, informed by data, is the first step toward fair remuneration for pharmacy within a consumer-centric framework. Effective decision-making is best supported by the

⁶⁷ Pharmacy Guild of Australia, Interim Report Submission No. 196, page iii.

⁶⁸ Pharmacy Guild of Australia, Interim Report Submission No. 196, page 6.

⁶⁹ Ibid, page 7.

provision of quality data and should not necessarily be viewed as a budget savings tool. Any claims about savings also need to be demonstrable in practice, and this is currently not possible without the required accounting information, as previously discussed.

Remuneration for dispensing should compensate pharmacists for both the capital and operational costs of a best practice dispensary. A ‘long-term’ approach to costs ensures that all relevant costs are taken into account. While it would be preferable to provide a simple dispensing fee, there may be some dispensing activity that requires specific fees.

Most pharmacists will have shared costs between the dispensing and related health operations of the pharmacy and any other activities carried out by the pharmacy, such as other retail activities. The size of these costs will depend on the specific pharmacy business model. A business model neutral approach will separate these costs so that taxpayer remuneration for dispensing does not depend on (and potentially subsidise) non-dispensing activities in the pharmacy.

One way to do this could be to remunerate dispensing on the basis that the pharmacy had no activities except dispensing. The Panel does not consider that this ‘standalone’ cost approach is appropriate. In response to the Discussion Paper, the Panel received significant feedback that a ‘standalone’ pharmacy would not be viable. It would be undesirable therefore to base the remuneration for dispensing on a theoretical model of a stand-alone pharmacy that the profession itself considers is unviable and inefficient.

An alternative approach is to consider the costs of establishing a dispensary and associated healthcare services within a retail space. This approach reflects the actual operations of the majority of Australian community pharmacies. It considers, for example, the cost of the extra space required for dispensing (including ‘front of counter’ areas for waiting and consulting and ‘back of counter’ areas such as the ‘dispensary’ and storage areas for inventory), the additional labour needed to operate the dispensary (including all pharmacists and any additional workers needed to support the pharmacists) and additional capital equipment (e.g. the cost of relevant equipment to assist dispensing). Formally, this is called ‘incremental’ cost. Professor King and Ms Watson recommend this average incremental cost as the preferred methodology, where the ‘average’ refers to the average over the full range of relevant activities relating to dispensing that are carried out by a best practice pharmacy.

This incremental cost methodology is a business-neutral approach and allows for a fair remuneration for pharmacists and accountability for government and consumers.

RECOMMENDATION 5-3: REMUNERATION FOR DISPENSING—METHODOLOGY (KING & WATSON)

The remuneration for dispensing in a community pharmacy should be a simple dispense fee based on the average, long-run incremental cost of dispensing in a best practice community pharmacy.

ALTERNATIVE RECOMMENDATION FOR 5.1, 5.2 AND 5.3

The remuneration for community pharmacy in the dispensing of PBS medicines should be based on the amount of funding required by government to maintain a viable community pharmacy network in Australia.

Submissions to the Review have highlighted the complexity and practicalities of calculating a single dispensing fee to remunerate pharmacists that would be representative of the entire pharmacy network and that would disaggregate dispensing activity from the other interrelated services and products offered by pharmacy. This has been demonstrated in the lack of consistency in the principles or approaches that could be used to calculate an efficient dispense fee suggested by the Guild, Green Square Associates, other pharmacy stakeholders and the Review's financial analyst.

The Panel has previously recognised that there is no 'one size fits all' model for community pharmacy in Australia. This is an acknowledgment of the variety of different business models that operate across the sector and the different geographical settings that pharmacists operate.

Given these factors, there is significant concern that the cost for both government and the pharmacy sector of designing and administering a system to calculate an average best practice dispense fee is unlikely to outweigh the benefits from this increased level of regulation. It is generally recognised that the current pharmacy network and the provisions of medicines and pharmacy services works for the community. In addition, the Review's financial analyst concluded that there is little evidence to suggest that pharmacies are earning economic rents (rates of return higher than normal rates of return on their capital) and that 15.4 per cent of all pharmacies are not generating taxable profits.⁷⁰

Rather than focusing on an average dispense in a 'best practice' pharmacy, Mr Scott considers that dispensing remuneration should reflect the funding required by government to maintain a viable pharmacy network. It is ultimately the network of the pharmacies that the government is remunerating for the dispensing of PBS medicines. In addition, a focus on a viable network, rather than the cost of an individual dispense, is more closely aligned with the principles of the NMP. This approach would overcome arguments over the methodology for calculating a dispense fee and ensure that the remuneration paid to pharmacies reflects the total cost of maintaining the network.

A viable pharmacy network should be one that meets the expectations of both the government and the Australian community. This includes the volumes of PBS medicines and the dispensing-related services that government forecasts for the period of a future pharmacy agreement. Consistent with the NMP, a viable network should also match the needs of consumers and the minimum expectations of community pharmacy (as discussed in section 4.1).

The negotiation of the level of funding required to maintain a viable pharmacy network should be informed by the best available information held by the Australian Government and the Guild and should be shared in a transparent manner between both negotiating parties. While there should be an appropriate level of scrutiny and accountability of information to support the negotiation process, parties will need to consider the administrative costs on the pharmacy sector and the government in obtaining such information. In the interests of equity, this should be consistent with

⁷⁰ Source: RSM, Financial analysis of pharmacy regulations and remuneration arrangements (March 2017), page 50.

what is relied upon in determining remuneration levels for other parts of the health sector, including primary health professionals.

ALTERNATIVE RECOMMENDATION FOR 5-1, 5-2 AND 5-3 (SCOTT)

The dispensing fee determined as part of any future negotiations between the Australian Government and the body representing the majority of pharmacy owners (the Pharmacy Guild of Australia) should be based on:

- a. an agreed fee that represents the cost of maintaining a viable community pharmacy network in Australia and which meets the requirements of the National Medicines Policy and the expectations of the Australian community and Government; and
- b. the best available information to both parties at the time of the negotiation and commensurate with the information required of other primary healthcare professionals in determining remuneration levels.

5.4. STRUCTURE OF REMUNERATION FOR DISPENSING

The current formula for the remuneration for dispensing paid by the government to community pharmacy is overly complex and opaque. The formula should be simplified to improve the transparency over different payments for dispensing.

There is a lack of consistency in the PBS remuneration for community pharmacy and hospitals, particularly in the case of high-cost medicines, where substantially different payments are made to community pharmacies and hospitals for dispensing the same medicine.

The Panel cannot determine how this difference is justified on the basis of the available information. It is further noted that there is no equivalent to the Price Disclosure process for PBS payments made to hospitals.

Because of this lack of clarity, the Panel has chosen not to provide recommendations to address the inconsistency in payments for dispensing. However, the Panel notes that it would be desirable to have more transparency around these different payments for dispensing.

The Panel notes that community pharmacies face high levels of cost and risk when dispensing high-cost medicines. The establishment of an upper limit on the amount a community pharmacy contributes to the cost of any PBS medicine is proposed as one response to this issue - see Section 7.2 (Supporting Access to High-Cost Medicines through Community Pharmacy) of the Report.

Should this and other related recommendations not be implemented by government, the Panel considers that a two-part tariff remuneration for community pharmacists be paid for dispensing. The dispensing remuneration would then consist of a fixed component as well as a variable component related to the cost of the medicine. The variable component would increase with the cost of the medicine being dispensed, to ensure that community pharmacies are appropriately rewarded for the additional risks and financial burden (such as overdraft payments and GST payments) associated with dispensing high-cost medicines.

The Panel notes that either a simple payment or a two-part tariff payment to community pharmacy for dispensing will be significantly simpler and more transparent than the existing range of fees associated with dispensing most PBS medicines.

RECOMMENDATION 5-4: STRUCTURE OF REMUNERATION FOR DISPENSING

If the Australian Government does not place an upper limit on the wholesale payment for a community pharmacist then the Australian Government should adopt a two-part tariff payment for the remuneration (i.e. a payment that involves a fixed payment per dispense plus a payment that varies with the relevant cost of the medicine) to the pharmacist.

Under either a flat fee or two-part tariff, the average payment for a dispense should equal the required fee determined by the Australian Government, following the acceptance of Recommendation 5-3.

5.5. REMUNERATION—ALTERNATIVE SERVICE CHANNELS

The amount paid and the mechanisms for payment by the Australian Government to primary health professionals currently vary for the provision of the same service.

The Australian Government pays different amounts to GPs, nurses and pharmacists to deliver the same flu vaccination. Yet, in evaluations of pharmacist-delivered immunisation services in Queensland and Western Australia, the consumer experience was reported in the PSA submission as proficient and comparable to that of other primary healthcare providers:

“95% of consumers surveyed [were] completely satisfied that the vaccination was provided in a professional manner and that they were comfortable with the skills of the pharmacist providing the vaccination.”⁷¹

In the view of the Panel, if the service provided by the pharmacist or any such healthcare provider satisfies a set minimum standard, it makes no sense to provide differing remuneration amounts for the services. The government should be paying for a particular health outcome, regardless of which health professional delivers the outcome.

As noted by the PSA, fairly remunerating pharmacists as an alternative service channel could lead to better outcomes for patients by optimising the contribution of the pharmacist as part of a multidisciplinary care team within the primary health setting.⁷² This sentiment was also expressed by Medicines Australia:

“[Option 4-6] supports access for patients who may not otherwise receive the service and therefore lead to improved health outcomes. One example of this would include vaccination being provided by pharmacists, in addition to general practitioners, with associated benefits to patients and the community through herd immunity.”⁷³

⁷¹ Pharmaceutical Society of Australia, Interim Report Submission No. 183, page 22.

⁷² Ibid.

⁷³ Medicines Australia, Interim Report Submission No. 195, page 11.

Delivery should also be 'location neutral' unless location is a key element of the service. A vaccine delivered in a pharmacy, general practice, community health centre or elsewhere should receive the same level of government funding. In contrast, a HMR is clearly a location-based service and needs to be provided in the home or other appropriate location.

However, the Panel notes that there should be no requirement for all community pharmacies to provide all health program services (with the exception of the range of minimum services recommended above). In fact, the opposite is preferred, where pharmacies can determine which programs to offer based on demand and the local demographics and health needs.

Specific advanced training, supported by robust accreditation mechanisms, should be required before a community pharmacist can provide a service. This would ensure that the services are appropriately supplied. To assure service standards, audit requirements or other approaches should be utilised to control compliance.

RECOMMENDATION 5-5: REMUNERATION FOR OTHER SERVICES

The Australian Government should require that if the same service is offered through alternative primary health outlets then the same Australian Government payment should be applied to that service, regardless of the specific health professional involved.

6. THE REGULATION OF PHARMACY FOR MEDICINE SUPPLY

6.1. REFORMS TO PHARMACY LOCATION RULES

It is unclear whether the current pharmacy location regulations are limiting potential improvements to the community pharmacy network around Australia, and undermining flexibility to meet specific community needs.

Regulation surrounding the distribution of community pharmacies in Australia has been an area of significant interest and deliberation for the Review. The Pharmacy Location Rules (the Rules) set out the location-based criteria which must be met in order for the Australian Community Pharmacy Authority to recommend approval of a pharmacist to supply PBS medicines. This regulatory mechanism limits the potential for new pharmacies to open and or for existing pharmacies to relocate.

There were a multitude of views put to the Panel regarding the effect of the Rules on consumer access and affordability, as well as competition and viability in the pharmacy sector. Competing evidence was offered to support both the retention and the reform of the Rules. This evidence was closely considered by the Panel in informing its analysis of the merits, or otherwise, of the Rules provided in the Interim Report.⁷⁴

The Interim Report presented several options addressing the Rules which generated a broad range of responses. A number of submissions noted the stated policy objectives of the Rules as outlined in the Fifth Community Pharmacy Agreement (5CPA) and suggested that these objectives provide an effective baseline against which to evaluate the appropriateness of the Rules.

The 5CPA⁷⁵ states that the objectives of the Rules are to ensure:

- all Australians have access to PBS medicines;
- a commercially viable and sustainable network of community pharmacies dispensing PBS medicines;
- improved efficiency through increased competition between pharmacies;
- improved flexibility to respond to the community need for pharmacy services;
- increased local access to community pharmacies for persons in rural and remote regions of Australia; and
- continued development of an effective, efficient and well-distributed community pharmacy network in Australia.⁷⁶

These objectives remained unchanged for the continuation of the Rules under the 6CPA and reflect some of the central objectives of the NMP.

Stakeholders advocating reform of the Rules considered that the existing arrangements do not appropriately address the policy objectives and substantially undermine consumer access and

⁷⁴ Department of Health, Review of Pharmacy Remuneration and Regulation—Interim Report, page 94, (May 2017).

⁷⁵ Department of Health, The Fifth Community Pharmacy Agreement between The Commonwealth of Australia and The Pharmacy Guild of Australia, page 25.

⁷⁶ Ibid.

affordability. For example, Ramsay Pharmacy Group suggested that the current iteration of the Rules do not, “improve efficiency...through competition”⁷⁷. Similarly, Chemist Warehouse argued that the Rules preclude “increased local access to community pharmacies”⁷⁸ and are “plainly inconsistent with the NMP [objective to provide access to medicines at a cost individuals and the community can afford]”⁷⁹. This was further highlighted in its submission to the Interim Report:

“It is undeniable that Chemist Warehouse sells not only its prescription but also its non-prescription and complimentary [sic] medicines at prices far below those of most if not all of its competitors...The relocation rules have and continue to restrict Chemist Warehouse from opening stores across the country. Denying Chemist Warehouse access to communities it wishes to serve, denies those communities access to (more) affordable healthcare which by definition is a denial of access and hence contrary to the NMP ...”⁸⁰

Advocates for the retention of the Rules suggested that the regulation continues to satisfy the policy intent, as the Rules support the maintenance of a commercially viable network. The Guild contended in its submission:

“Analysis compiled by the University of Adelaide shows, over 200 communities nationwide have secured the services of a new pharmacy as a result of the restriction placed on locations in more densely populated areas. The results highlight the movement of pharmacies away from over-served areas and into areas of unmet community need. Pharmacy numbers in large population centres (CAT A) reduced from 3,745 from 1990 to 3,464 in 2014, while less populous centres (CAT B and CAT C) increased from 1,833 to 1,990 over the same period.”⁸¹

Furthermore, the Guild suggested that the Rules have facilitated equitable and affordable access to consumers:

“The mapping analysis of community pharmacy prepared by MacroPlan Dimasi showed that the Location Rules overwhelmingly achieve their intended accessibility and cost effectiveness objectives. [As a result of location rules] Australians—especially older and disadvantaged consumers—have a very high level of access to community pharmacy. In the capital cities, the average resident is located 1 kilometre from the nearest pharmacy, while 95 per cent of consumers are no further than 2.5 kilometres from a pharmacy. Outside of capital cities, Australians are just 6.5 kilometres on average from the nearest pharmacy, and 72 per cent have a pharmacy within 2.5 kilometres.”⁸²

Financial analysis commissioned by the Review concluded that the current Rules are limiting equitable and affordable access for consumers in some areas.

“Levels of competition between pharmacies across Australia ... [do] not appear to have resulted in lower medicine prices for all Australians. Rather, it appears to have resulted in lower prices of medicines for some patients, but higher prices of medicines for other patients ... patients that purchase their medicines from PhARIA 1 pharmacies with a 9% rate of assistance, whereas those who purchase their medicines from PhARIA 3 to PhARIA 6 pharmacies actually have to pay progressively more for their medicines ...”⁸³

⁷⁷ Ibid.

⁷⁸ Ibid.

⁷⁹ Chemist Warehouse, Interim Report Submission No. 189, page 11.

⁸⁰ Ibid.

⁸¹ Pharmacy Guild of Australia, Interim Report Submission No.196, page 16.

⁸² Ibid.

⁸³ RSM, Financial analysis of pharmacy remuneration and regulation, page 8, (May 2017).

The financial analysis also found that those in remote and very remote areas of Australia would travel the furthest to access their nearest pharmacy.⁸⁴ This supports the position put forward by stakeholders such as Ramsay, which suggests that Rules are undermining the ability of pharmacists to set up in existing healthcare sites and improve access for regional and remote communities.⁸⁵

These arguments represent only a subset of the broad spectrum of opinions on the appropriateness of the Rules and highlight the complexity of any potential reform in this area.

Given the body of informal and formal evidence available that seemingly contradicts the achievement of the objectives of the Rules, there is a need for government to clarify the purpose and intent of the Rules. This is a critical first step in establishing the policy rationale for the retention of the Rules, if considered appropriate, and will support a more transparent and robust evaluation of the Rules as a regulatory mechanism.

There are clearly aspects of the existing Rules that require reform to address unintended consequences to consumer access and affordability noted in submissions and the Interim Report. Even staunch advocates of the Rules acknowledge that their operation in some instances, such as relocating existing pharmacies, are not optimal and require amendment.

In reforming the Rules, the Panel considers that it is the viability of the overall network of pharmacies, rather than individual pharmacists, that is critical and provides the most value to the government and consumers. In addition, emphasis should be placed on ensuring that any regulatory mechanism is responsive to innovation and positive change in the sector and does not place an unnecessary burden on the public or pharmacy.

RECOMMENDATION 6-1: REFORMS TO PHARMACY LOCATION RULES

The Australian Government should:

- a. reform the Pharmacy Location Rules to remove barriers to community access and competition between pharmacies, and to ensure they continue to support equitable and affordable access to medicines for all Australians, in accord with the National Medicines Policy;
- b. establish a working group with the Pharmacy Guild Australia or other representative of Approved Pharmacists with the aim of reforming the Pharmacy Location Rules to ensure that they remain responsive to the evolving needs of the community while also supporting innovation through competition between pharmacies; and
- c. ensure that any reform of the Pharmacy Location Rules is subject to a suitable transition period.

⁸⁴ Ibid page 7.

⁸⁵ Ramsay Pharmacy, Interim Report Submission No. 181, page 2.

6.2. CO-LOCATION OF COMMUNITY PHARMACIES WITH SUPERMARKETS

The current restriction on public accessibility between a pharmacy and a supermarket is limiting business models that may benefit both consumers and pharmacists.

The current Rules require that a community pharmacy is not directly accessible by the public from within a supermarket.

The Panel considers that this is a very broad restriction. It is based on a ‘retail model’ (a supermarket) rather than particular products (such as alcohol or tobacco). As such, it may prevent community pharmacists from adopting legitimate business models that would benefit both consumers and the pharmacist.

For example, the current Rules would prevent a community pharmacist from expanding an existing community pharmacy’s retail offering by securing an independent supermarket franchise.

The Rules may constrain a community pharmacy from stocking products, such as full-range pre-prepared nutritious meals and a range of other healthy food items (such as, say, fresh fruit and vegetables, milk and bread), which may be complementary to the pharmacist’s business and both convenient and desirable to consumers, if this led the store to being legally considered a ‘supermarket’. The Panel has seen a pharmacy which, because it adopted this business model prior to the Rules being introduced, currently offers these types of products to consumers. The pharmacy was consistent with a quality health destination, and the range of products on offer were clearly desired by, and sought out by, consumers.

A number of overseas countries, such as the United Kingdom and the United States, have deregulated pharmacy ownership and location rules to allow the co-location of pharmacies with supermarkets. Both supporters of the current restrictions on ownership and location and proponents for their removal have referred to such overseas experience in justifying their alternative points of view.

Few submissions to the Interim Report addressed co-location of pharmacies within a supermarket. The PSA provided the following insights:

“Having a pharmacy located in a supermarket has the potential for consumers to develop the notion that potent, scheduled medicines are safe enough to be allowed into an unregulated environment. The PSA believes it undesirable and in fact unsafe to portray this type of message as it can dilute and possibly undermine the rigour of underpinning the extensive regulatory and scheduling requirements that therapeutic goods are subjected to for the safety and benefit of consumers, as outlined in the NMP.”⁸⁶

However, despite the current restrictions, the Panel has observed that some pharmacy groups have expanded their retail offerings into a range of unregulated products. In some cases, these products go well beyond complementary medicines and vitamins and include a large range of health and beauty products and more general household products. In that sense, it is unclear that the PSA’s concern about an ‘unregulated environment’ is valid. Rather, what is important is that the

⁸⁶ Pharmaceutical Society Australia, Interim Report Submission No. 183, page 23.

dispensary and the area where medicines are for sale (including over the-counter and complementary medicines) are clearly under the pharmacist’s professional oversight:

- that consumers can access professional advice;
- that there is a relevant separation between scheduled products and other products (including complementary medicines—see Recommendation 4-3: Placement of Scheduled Medicines Within a Community Pharmacy); and
- that there is labelling and signage to help guide consumers.

This is consistent with consumer research that “if pharmacies were able to be located within supermarkets in the future, this would require stringent quality controls, well considered layouts, and perhaps would only be appropriate in specific locations where other options for out of hours access are unavailable”⁸⁷.

Some submissions to the Review noted that supermarkets may sell products that are inconsistent with a health destination such as a community pharmacy.⁸⁸ The Panel agrees and sees merit in requiring that a retail outlet that houses a community pharmacy not sell such products—for example, tobacco and alcohol. However, the current restriction does not do this. It is based on a ‘supermarket’ and not individual products. It would apply even if the supermarket sold no such undesirable products.

The current restriction on accessing a pharmacy from within a supermarket is not appropriate provided that, and consistent with any community pharmacy, scheduled medicines are dispensed in accordance with existing legislative and professional obligations. The Panel would have sympathy with specific product-based restrictions—for example, tobacco and alcohol; however, these should apply to all premises that house a community pharmacy.

The current restriction on the accessibility by the public to a community pharmacy from within a supermarket should be discontinued, provided that any pharmacy located within a supermarket is required to operate in accord with all relevant practice requirements for an Approved Pharmacy.

6.3. CONCENTRATION OF PHARMACY OWNERSHIP

The Pharmacy Location Rules have not established robust competition between independent pharmacies in some locations. Rather, in some locations, either individual pharmacists or small groups of pharmacists have been able to monopolise some or all pharmacies. This is inconsistent with the objective of Australia’s competition laws.

The Panel has found that the current iteration of the Rules allows for cross-ownership in certain locations (generally regional and remote). Cross-ownership is the ownership of different companies with related interests by overlapping entities. An example in the pharmacy industry is the ownership of multiple pharmacies, located near each other, by a single person or group of people. Cross-ownership reduces competition and harms consumers, such as through higher prices, less variety,

⁸⁷ Hall & Partners/Open Mind, Review of Pharmacy Remuneration and Regulation: Qualitative research findings, September 2016, page 46.

⁸⁸ Pharmaceutical Society of Australia, Interim Report Submission No. 183, page 23.

lower-quality service (e.g. reduced opening hours) or increased travel costs for consumers who wish to access independent outlets. As noted by the CHF:

“It is clear that where there is less competition amongst pharmacies that the price is often higher and this seems inequitable. It gives pharmacies, which have localised monopolies through the location and ownership rules the opportunity to take windfall profits through open ended pricing to the co-payment.”⁸⁹

In the absence of cross-ownership, pharmacies in a particular location are more likely to compete to the benefit of consumers. The incentive to differentiate and compete can be strong and, in the absence of cross-ownership, individual and independent pharmacies may choose to offer a more personalised service, longer opening hours, a more expansive range of products, better quality medicines advice or lower prices to better serve the consumer and gain their continued support.

Cross-ownership mutes, and potentially eliminates, the incentive to improve services and benefit consumers. Under competition, if one pharmacy innovates and better serves consumers, it will gain custom and increase its revenues and profits. Of course, other competing pharmacies may lose custom, which, in turn, spurs them to innovate. In contrast, with cross-ownership, any innovation in one pharmacy simply shifts custom, revenue and profit around the group of pharmacies. The owners of the pharmacies do not see a net gain and will have little if any incentive to compete against themselves.

The harm created by cross-ownership is reflected in the *Competition and Consumer Act 2010* (Cth). Section 50 of this Act makes it illegal for cross-ownership to arise through the purchase of a share or other assets in a business where, “the acquisition would have the effect, or be likely to have the effect, of substantially lessening competition”.⁹⁰ It therefore be would appropriate to refer overlapping ownership in the pharmacy sector to the Australian Competition and Consumer Commission (ACCC).

The Panel understands that the ACCC’s remit also allows it to approve arrangements that may reduce competition (under certain circumstances) but is unaware that any such approval has been made for pharmacies. If not approved then, in light of the strong claims made in submissions to this Review, it would be prudent for the ACCC to examine the current practices associated with overlapping ownership and location of some community pharmacies.

The Panel has used 20 per cent ownership as the starting point for cross-ownership that may create concerns. This level of ownership is consistent with the definition of a ‘relevant interest’ and potential control under the takeover provisions of Australia’s corporations law. However, the Panel recognises that any specific share will be somewhat arbitrary and that the ACCC does not make its decisions regarding competition and control simply based on such numbers. The Panel considers that cross-ownership arrangements involving less than a 20per cent ownership would not create competition concerns.

⁸⁹ Consumer Health Forum, Interim Report Submission No. 116 page 5.

⁹⁰ Australian Competition and Consumer Commission, *Informal Merger Review Process Guidelines 2013*, (2013).

The Panel also notes that the ‘substantial lessening of competition’ test in Recommendation 6.2 is a standard test under Australian competition law. It is likely that pharmacy cross-ownership will often not breach this test, and the Panel expects that actual divestitures will be rare.

RECOMMENDATION 6-2: PHARMACY LOCATION RULES—CONCENTRATION OF OWNERSHIP

For any group of two or more pharmacies with overlapping ownership:

- a. the Australian Competition and Consumer Commission is to determine if the overlapping ownership of those pharmacies results in a substantial lessening of competition in a market for the provision of pharmacy services, relative to independent ownership;
- b. if so, the Australian Competition and Consumer Commission can require that one or more of the pharmacies in the group be divested.

For avoidance of doubt, a group of pharmacies would be considered to have an overlapping ownership if any individual or set of individuals have ownership of at least 20 per cent of the equity in each of the community pharmacies in that group.

6.4. TRANSPARENCY IN GOVERNMENT PROGRAMS

Community pharmacy expenditure and funding for programs is insufficiently transparent to demonstrate value and performance in meeting the objectives of the National Medicines Policy.

As recognised in the Interim Report, there is a need for improvement in the transparency of community pharmacy programs in demonstrating value and performance to the government and the public.

Improvements in transparency are not isolated to the pharmacy sector. Most modern governments, recognise the importance of transparency, being able to demonstrate value in the expenditure of public money and in holding people and organisations accountable for their performance:

“Without transparency government accountability is not possible.”⁹¹

For the Australian Government, these principles are enshrined in the *Public Governance, Performance and Accountability Act 2013* (Cth), which sets out the requirements for ‘accountable authorities’.

This gives rise to a strong community expectation that all government funds are spent on worthwhile purposes that demonstrate value and that there is sufficient accountability over performance. For programs as important as the PBS, these expectations are high and there is an increasing demand to ensure that objectives are met and clear value is achieved through such a significant level of expenditure.

These obligations can only be met where programs are sufficiently transparent, so that consumers understand what is required, where resources have been committed and what the results were.

⁹¹ T. Andrews, *Towards true transparency*, Institute of Public Affairs (2015).

While there is sufficient transparency over PBS outlays at a whole-of-government budget level, there is not necessarily this same level of transparency to inform decisions on pharmacy remuneration and performance.

This is a key reason for strengthening the level of accounting information that should be provided to support CPA negotiations and decision-making (see Recommendation 5-1: Community Pharmacy Accounting Information (King & Watson)). It is the Panel’s view that this type of information should be available as a normal course of managing public programs and not require separate collection as a special or one-off exercise.

It is clear that, while Australia has developed excellent capacity in the availability of community pharmacy services to consumers, it does not have sufficient information to demonstrate capability.

This has an adverse impact on the pharmacy sector’s ability to grow sustainably. Without being able to demonstrate its capability, the pharmacy profession will not be able to expand into more integrated healthcare settings. This would represent a significant lost opportunity to utilise the unique skills associated with this important sector of the health system.

Overall, the Panel has received strong support for its option to improve transparency, including from the PPA, which submitted that:

“The lack of transparency and poor reporting, evaluating and monitoring mechanisms have been a trademark of all CPA (6CPA being no different). We fail to understand how successive Governments have allowed this to occur.”⁹²

The CHF submitted:

“[CHF has] argued over many years for greater transparency in how the funds under the Community Pharmacy Agreements are allocated and what they are spent on.”⁹³

The PSA is a strong advocate for transparency over the funding of government programs and has submitted that:

“There has been a complete lack of transparency around the development, negotiation and funding allocations of Community Pharmacy Agreements—this lack of transparency has a flow on effect on data collection and evaluation...

PSA believes that remuneration for medicines supply, dispensing activities and clinical services must be based on pre-established transparent criteria so that the important contribution pharmacists make to health is more visible to consumers, payers and policy makers.”⁹⁴

The link between transparency, data collection and evaluation noted by the PSA underpins the Panel’s recommendations in this area.

RECOMMENDATION 6-3: TRANSPARENCY IN GOVERNMENT PROGRAMS

It is important that, for each community pharmacy program that is Commonwealth funded there is transparency regarding the:

⁹² Professional Pharmacists Australia, Interim Report Submission No. 197, page 10.

⁹³ Consumers Health Forum of Australia, Interim Report Submission No. 116, page 10.

⁹⁴ Pharmaceutical Society of Australia, Interim Report Submission No. 183, page 27.

RECOMMENDATION 6-3: TRANSPARENCY IN GOVERNMENT PROGRAMS

- a. amount of funding provided by the Australian Government;
- b. amount of funding provided by the recipient of the service; and
- c. value derived from delivery of the program.

6.5. THE RURAL PHARMACY MAINTENANCE ALLOWANCE

The current operation and administration of the Rural Pharmacy Maintenance Allowance is based on individual pharmacy locations and prescription volumes rather than consumer access. This reduces the effectiveness of the program.

The RPMA is a monthly allowance paid to eligible proprietors of section 90 approved pharmacies. The allowance recognises the additional financial burden of maintaining pharmacies in rural and remote areas of Australia and the need to provide access to PBS medicines and pharmacy services for people in these regions.

While the Panel acknowledges the benefits of the policy and associated payment as an important contributor towards the maintenance of a viable community pharmacy network, the Panel has noted some issues in the way the RPMA is currently administered.

These issues were set out in the Interim Report and centre on multiple community pharmacies being situated in the same region and receiving the allowance, even though this was not required to support consumer access.⁹⁵

This is because the method used to calculate the RPMA applies a supply centric approach, rather than a consumer centric approach. Eligibility to receive the allowance and the amount allocated is currently based on the PhARIA in which the pharmacy is located and the individual pharmacies' script volumes as the key parameters.

This method has resulted in some pharmacies in the same locality receiving the allowance and others not.

SHPA suggested an alternative approach that used a combination of elements (both supply based and access-based) as used for the establishment of Primary Health Networks (PHNs) and the Independent Hospital Pricing Authority's method for adjusting metropolitan and regional values.⁹⁶

Submissions to the Interim Report have continued to demonstrate that the equitable distribution of the RPMA is an important mechanism to ensure the sustainability of community pharmacies in rural areas.

However, contrary to the option presented in the Interim Report⁹⁷, the PSA considers that the RPMA should be provided as a core payment to all eligible pharmacies in the same locality, to ensure the continued viability of the rural pharmacy network.⁹⁸

⁹⁵ Department of Health, Review of Pharmacy Remuneration and Regulation – Interim Report, page 114, (May 2017).

⁹⁶ Society of Hospital Pharmacists of Australia, Discussion Paper Submission No. 497, page 19.

This suggestion is also supported by SHPA, which noted in its more recent submission that some rural pharmacies had made joint applications for RPMA-funded roles and preferred this approach to achieving the benefits of the allowance, as against the current approach that arbitrarily excludes some pharmacies from applying.⁹⁹

The Panel is attracted to the merits associated with the provision of a local pool of funds for allocation to pharmacies in approved localities, as suggested by the PSA.

This could involve allocation through a tender, or other equitable process, that is based on consumer need or the quality or range of pharmacy services on offer.

The Panel considers that the intent of the allowance as originally framed may have been superseded through the growth of pharmacies in rural areas of Australia. It would be prudent therefore, for government to consider the operation of such an allowance to ensure that it remains fit for purpose, is sufficiently flexible to meet changing requirements, and operates to better meet consumer access, beyond just the establishment of a pharmacy presence.

It is also essential that the body making the decision to allocate the RPMA works closely with the Australian Community Pharmacy Authority. There may also be a need to re-base the objectives of the RPMA in the light of any changes to the Rules.

RECOMMENDATION 6-4: RURAL PHARMACY MAINTENANCE ALLOWANCE

The Australian Government should revise the operation of the Rural Pharmacy Maintenance Allowance to ensure that it remains fit for purpose, is sufficiently flexible to meet changing needs, and provides for consumer access beyond the establishment of a pharmacy presence.

6.6. HARMONISING PHARMACY LEGISLATION

The legislative differences in pharmacy regulation across Australian jurisdictions increases the costs of administration for pharmacies and presents risks to patients moving between these regions.

While there have been attempts to harmonise federal, state and territory legislation that impacts the day-to-day operations of a pharmacy, significant legislative and regulatory differences still exist. These inconsistencies adversely impact on the operating costs for pharmacies and patient health.

These differences operate at a number of levels and impact on the types of regulatory bodies involved; pharmacy operations and pharmacy premises; and medicine distribution, storage and security.

⁹⁷ Refer to Option 5-8 Rural Pharmacy Maintenance Allowance suggested that in situations where there is more than one pharmacy in a 10km area: Department of Health, Review of Pharmacy Remuneration and Regulation – Interim Report, page 114 (May 2017).

⁹⁸ Pharmaceutical Society of Australia, Interim Report Submission No. 183, page 26.

⁹⁹ Society of Hospital Pharmacists of Australia noted that “rural hospital pharmacies are unable to assess the RPMA despite the benefit it would offer for improving the delivery of PBS medicines...”, Interim Report Submission No. 196, pages 26 and 27.

A number of examples of the differences in legislation and their impacts were cited in the section 5.10 of the Interim Report, together with submissions calling for harmonisation. This led the Panel to include an option to harmonise all state, territory and federal pharmacy regulation and consider the need for a single pharmacy regulator (coordination with AHPRA being suggested as an interim measure).¹⁰⁰

Submissions to the Interim Report have again confirmed strong support for the harmonisation of pharmacy legislation as a matter of priority. The following submissions provide two examples:

“SHPA supports in principle any measures that reduce the inconsistencies in pharmacy regulation between different jurisdictions, noting that it contributes to both practitioner and consumer confusion, and can lead patients being unable to access medicines.”¹⁰¹

“In our view, a National Pharmacy Code would bring greater stability and commercial confidence right across the pharmaceutical supply chain, and encourage service provision of even higher quality. We also suggest that a single pharmacy regulator is not just something that could be considered, it is essential.

We also note that moving to a single national regulator would require all relevant states and territory regulation to be reviewed, presumably under a set of guiding principles that would be determined by the Council of Australian Governments. This could allow a measured debate about a range of regulatory restrictions that hamper good and coordinated healthcare, including pharmacy ownership.

Whether that single national regulator should be affiliated with the Australian health Practitioner regulation Agency is something that would need careful consideration.”¹⁰²

The Panel notes that while the PSA has agreed with the need to consider harmonisation in the context of how medicines are prescribed and dispensed, it has advised on the need for caution in relation to the harmonisation of the ownership of pharmacy premises.¹⁰³

The importance of harmonised legislation to support a future paper-optional e-prescribing environment will also be crucial to any successful implementation. Currently, certain medications cannot be dispensed if the prescription comes from an interstate prescriber. This should not be the case in an environment where the geography in which the patient lives and the medicine that is supplied will be less relevant.

RECOMMENDATION 6-5: HARMONISING PHARMACY LEGISLATION

As early as practicable, the Australian Government, through the Australian Health Minister’s Advisory Council, should seek to harmonise all state, territory and Commonwealth pharmacy regulations to simplify the monitoring of pharmacy regulation in Australia for the safety of the public.

In the long term, a single pharmacy regulator could be considered.

As an interim measure, state and territory registering bodies should coordinate with the Australian Health Practitioner Regulation Agency to ensure that pharmacy regulations are being adequately—

¹⁰⁰ Department of Health, Review of Pharmacy Remuneration and Regulation—Interim Report, page 119, (May 2017).

¹⁰¹ Society of Hospital Pharmacists of Australia, Interim Report Submission No. 196, page 27.

¹⁰² Ramsay Pharmacy Group, Interim Report Submission No. 181, page 4.

¹⁰³ Pharmaceutical Society of Australia, Interim Report Submission No. 183, page 27.

RECOMMENDATION 6-5: HARMONISING PHARMACY LEGISLATION

monitored for best practice pharmacy and for the safety of the public.

6.7. EVALUATING, MONITORING AND REPORTING ON REGULATION

There is a lack of coordination and consistency in the current monitoring, evaluation and reporting systems relating to the regulations around community pharmacy. This has a potential to undermine community faith in the pharmacy network in Australia.

The ability to monitor and evaluate programs and performance is an important obligation for governments. This concept underpins the Australian Government’s Expenditure Review Principles that programs are sufficiently evidence-based and that:

“[When] assessing programs or activities against the principles, evidence must be used to demonstrate whether or not they are the most appropriate, efficient and effective way to achieve the government’s outcomes and objectives.”¹⁰⁴

These principles are grounded in notions of appropriateness, effectiveness, efficiency, integration and performance assessment. Strategic policy alignment therefore follows:

- *appropriateness*: activities are directed to areas where there is a role for government to fill a gap left by the market as a result of social inequities or market failure;
- *effectiveness*: activities have clear and consistent objectives, are effective in achieving their objectives and represent value for money for the expenditure of taxpayer funds;
- *efficiency*: government programs should be administered and delivered in the most efficient way achievable;
- *integration*: government agencies are able to work together effectively to consistently deliver the required policy objectives within clearly defined areas of responsibility;
- *performance assessment*: government activity should be subject to robust performance assessment and measurement; and
- *strategic policy alignment*: the activity is consistent with the government’s strategic long-term policy priorities—in particular, in areas that help sustain economic growth through improved productivity and participation.

The Panel notes that, while community pharmacy programs demonstrate their ability to meet these principles, they are constrained by a lack of transparency, as well as the lack of established measures to evaluate program performance. There is evidence that recent evaluations of certain health programs have difficulty in demonstrating value beyond confirming that expenditure has reached the target group. While this is important, evaluations need to be able to consider cause and effect in relation to how inputs and outputs contribute to policy and program outcomes for the benefit of the Australian community. Without this, the government would have difficulty in balancing health program expenditure priorities from those other programs that contain the required evaluation information and outcomes. This also has an impact on the extent of regulation required to support the pharmacy sector.

¹⁰⁴ Department of Finance, Commonwealth Expenditure Review Principles (2013).

The CHF has indicated strong support for strengthening evaluation capability in community pharmacy and has submitted that:

“In our submission to the ANAO audit of 5 CPA we highlighted the absence of a robust independent evaluation as a cause for concern. We called for this to be included into 6 CPA but this did not happen. Any such evaluation should look at how 6 CPA meets its stated objective, what are the outcomes from the various components of the agreement. A more robust evaluation would have helped inform this review and would certainly help to inform the development of future arrangements.”¹⁰⁵

RECOMMENDATION 6-6: EVALUATION MECHANISMS

As early as practicable, the Australian Government should require the establishment of appropriate evaluation mechanisms for community pharmacy to ensure that policy and delivery requirements are met.

6.8. THERAPEUTIC GOODS ADMINISTRATION RESOURCING AND ROLE IN MONITORING PERFORMANCE

There are gaps in the compliance monitoring of the quality use of complementary medicines.

The Panel has noted in the Interim Report that there are a number of compliance gaps when monitoring the quality use of complementary medicines.¹⁰⁶

The Panel has also noted that many of these issues and the role of the TGA in the regulation of therapeutic goods in Australia have been explored in the 2015 Expert Review of Medicines and Medical Devices Regulation.¹⁰⁷

The government’s September 2016 response to the Expert Review of Medicines and Medical Devices Regulation presents a strategic approach to improving access to therapeutic goods for Australian consumers while maintaining the safety of these goods in Australia.

This includes planned improvements to enhance consumer protection and increased compliance powers to monitor the supply and use of these products—in particular, where:

- consumer protection will be enhanced through the development of a more comprehensive system of post-market monitoring, which will provide the TGA with better information about emerging safety issues. This will ensure that therapeutic goods in Australia continue to be safe for use, efficacious and of good quality; and
- the regulation of complementary medicines will be reformed to provide new pathways where evidence of efficacy will be reviewed by the TGA prior to market and compliance

¹⁰⁵ Consumers Health Forum of Australia, Interim Report Submission No. 116 page 10.

¹⁰⁶ Department of Health, Review of Pharmacy Remuneration and Regulation –Interim Report, page 120, (May 2017).

¹⁰⁷ Expert Panel, Review of Medicines and Medical Devices Regulation: Report to the Minister for Health on the Regulatory Framework for medicines and Medical Devices, (31 March 2015).

powers being strengthened while recognising the low-risk nature of complementary medicines.¹⁰⁸

The Panel supports the government’s plan for comprehensive reform in this area and has accordingly provided no additional recommendations.

It should be noted that Recommendation 4-2 (Complementary Medicines—Supply From Community Pharmacies) above is designed to address the potential for consumer misconceptions about the medical efficacy of complementary medicines (i.e. in the context of TGA’s perceived role versus its actual role in regulating the listing and advertising of these products). This recommendation to separate PBS medicines, which have a proven scientific efficacy, from those without this level of evidence is specifically aimed at improving practices in community pharmacies to support quality use of medicines and not towards the TGA’s role as a regulator.

¹⁰⁸ Department of Health, Therapeutic Goods Administration, Australian Government response to the Review of Medicines and Medical Devices Regulation (September 2016).

7. THE DISTRIBUTION OF MEDICINES TO COMMUNITY PHARMACY

7.1. ENSURING TIMELY MEDICINE ACCESS THROUGH COMMUNITY PHARMACY

Current pharmacy supply chain arrangements for PBS medicines involve a high degree of regulation, including payments under the Community Service Obligation that appear unconnected with relevant distribution costs. Further, the current remuneration for wholesaling of PBS medicines may be leading to wholesale margins higher than necessary for an effective, efficient and sustainable supply chain.

The distribution of medicines through national and regional supply chains is critical to the NMP's objective of providing timely and affordable access to medicines for all Australians. Government currently supports this process through support payments to eligible pharmaceutical wholesalers through CSO arrangements. The objective is to ensure that all Australians have access to the full range of PBS medicines, regardless of where they live, and usually within twenty-four hours.

The Panel recognises that payments under the CSO have underpinned the wholesaling and distribution of PBS medicines throughout Australia since it was introduced.

The CSO funding pool financially supports pharmaceutical wholesalers to supply the full range of PBS medicines to pharmacies across Australia, regardless of pharmacy location and the relative cost of supply. Under these arrangements, payments are provided directly to eligible wholesalers who supply the full range of PBS medicines to any pharmacy, within twenty-four hours or in some cases seventy-two hours¹⁰⁹, and meet audited compliance requirements and service standards. These payments are over and above those made directly to pharmacists to cover the costs of supply from the wholesaler.

There are currently five pharmaceutical wholesalers approved as CSO distributors (CSODs), each eligible for a proportion of the \$195 million per annum CSO funding pool, provided over the life of the 6CPA.

Direct supply arrangements also exist whereby pharmaceutical manufacturers, such as Pfizer, have partnered with a single logistics provider to deliver PBS medicines directly to community pharmacies across Australia. This occurs independently of CSO funding, while still providing access to medicines in an effective and timely manner.

Following the wealth of responses to the distribution of PBS medicine reform options proposed in the Interim Report, the Panel remains committed to the position that:

- there is a need to regulate the PBS medicines supply chain to ensure twenty-four hour delivery nationwide for the full range of PBS medicines;
- there are alternative approaches to this regulation; and
- there is a need to ensure that, under any approach to regulation, community pharmacies do not face increased administrative or financial burden.

¹⁰⁹ While seventy-two hour arrangements have not yet been invoked by wholesalers the Panel has noted that these arrangements, newly introduced under the 6CPA, are causing concern amongst community pharmacists.

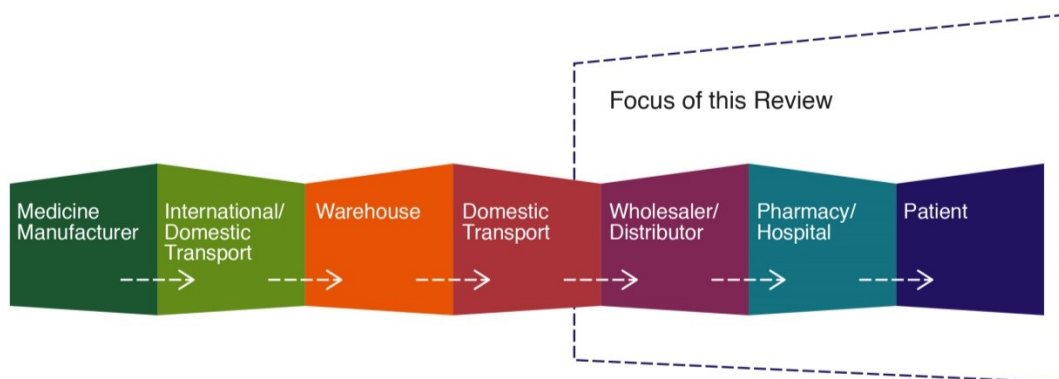
RECOMMENDATION 7-1: COMMUNITY SERVICE OBLIGATION

The Panel believes that the Community Service Obligation should revert to supply of all PBS medicines to any pharmacy within twenty-four hours, and that this be considered a minimum standard to ensure that there can be no fragmentation of delivery arrangements across wholesalers or access for consumers through any community pharmacy.

The National Patient Safety Agency (NPSA), and others, have stated that the current remuneration arrangements for CSODs are not sufficient to support the distribution of PBS medicines. The Panel has undertaken a considered analysis of the available information and concludes that the current payments to CSODs, including CSO payments and the agreed mark-up on PBS medicines, indicate that wholesalers are making at least a standard commercial return on capital for the distribution of PBS medicines across Australia¹¹⁰.

This Review has not been able to focus on the whole medicine supply chain as comprehensively as needed to address this area of the Terms of Reference. This is due to the complexity of the regulatory and administrative arrangements applying to the entire PBS medicines supply chain—not just wholesaling—as well as the limited extent of information made available to the Panel on these issues. Rather the Panel’s focus has been directly concentrated on issues affecting the remuneration and regulation of pharmacy in the various environments in which pharmacy operates (see Figure 6).

FIGURE 6: FOCUS OF THE REVIEW IN THE DISTRIBUTION OF MEDICINES



The Interim Report proposed a number of alternatives to current support arrangements for pharmaceutical wholesalers under the CSO, including government removing or updating the CSO, tendering for supply, and conducting a separate review of CSO arrangements.

However, responses to the Interim Report have been generally supportive of the current CSO arrangements and have also identified potential adverse impacts from the removal of the CSO.

One option presented in the Interim Report was that manufacturers have responsibility for the distribution of PBS medicines to community pharmacies nationwide through a small panel of wholesalers.

¹¹⁰ National Patient Safety Authority, Interim Report Submission No. 192, page. 7.

Some stakeholders, such as Chemist Warehouse, suggested that this option had the potential to transfer negotiating power from pharmacies to pharmaceutical manufacturers.¹¹¹ Other submissions suggested that this option would result in a transfer of bargaining power to larger pharmacy groups and the wholesalers and away from smaller medicine manufacturers.

Medicines Australia, while supportive of a review of current wholesaling arrangements, also voiced concern regarding the pressure that changes may place on existing wholesalers:

“Enforcing a ‘one-size-fits-all’ supply chain arrangement would put considerable pressure on existing wholesalers with the risk that some of them would no longer continue operations. Suppliers are free to take on direct arrangements where it is commercially suitable for them. However, for many smaller manufacturers, this is not a viable option due to scale limitations.”¹¹²

The Guild and the NPSA argued that current wholesale remuneration is inadequate and that trading terms from the sale of non-PBS products have been necessary to cross-subsidise the sale of PBS medicines. Each suggested that this was due to price disclosure. The Panel has looked closely at the issue of cross-subsidies and has a different view.

The standard definition of a ‘cross-subsidy’, as used in the economics literature, is where the sale of one of a number of jointly produced products results in product-specific revenues that are less than the incremental cost of producing that product. Specifically, the wholesaling of PBS medicines would only be cross-subsidised by the wholesaling of non-PBS products if the revenue from wholesaling PBS medicines was less than the incremental cost of wholesaling those PBS medicines.

The Panel’s own analysis of evidence presented in submissions to the Review, notably that of NPSA, indicates that the revenue that full-line wholesalers receive from the supply of PBS medicines is approximately the same as the standalone cost of wholesaling PBS medicines, allowing for a commercial return on capital.¹¹³

The Panel therefore considers that, as the incremental cost for wholesaling PBS medicines would be less than the stand-alone cost (potentially considerably less) and allowing for a standard commercial return on capital (and potentially considerably higher), there is almost certainly no cross-subsidy afforded to the wholesaling and distribution of PBS medicines from non-PBS lines (using the standard economic definition of a ‘cross-subsidy’).

In its response to the Interim Report the Guild presented a number of specific options to assist wholesalers:

“Positive recommendations by the Panel to address this funding anomaly should have included:

- a floor on wholesaler mark-up to delink wholesaler remuneration from PBS medicine prices;
- alignment of the level of remuneration caps with that of community pharmacies;
- fees that reflect the actual service costs for distribution of items listed on the PBS, RPBS and NDSS, including S100 medicines;
- recognition of the additional costs associated with the distribution of Controlled Drugs, fridge lines and high-cost items;

¹¹¹ Chemist Warehouse, Interim Report Submission No. 189, page 14.

¹¹² Medicines Australia, Interim Report Submission No. 195, page 12.

¹¹³ NPSA Discussion Paper Submission No. 482A, page 6.

- To implement these changes, the Federal Government must commit to fully expend the wholesaler funding of \$2.803 billion (inclusive of CSO and NDSS) committed in the 6CPA.”¹¹⁴

While the Panel recognises these options put by the Guild, it does not consider there has been sufficient information made available during this Review, particularly in relation to actual service costs, to support such recommendations to government.

So, while there is strong support for the current CSO arrangements to remain, the current cost to the government, together with an absence of information to adequately evidence its need has reinforced the Panel’s position that this complex environment is deserving of further separate analysis.

It should also be recognised that the CSO was introduced over a decade ago to address ‘cherry picking’ by a number of short-line wholesalers at the time. Since then the pharmaceutical logistics chain has seen significant change, including considerable technological advance, which may change the assumptions on which the CSO was established.

The Panel is also concerned over the growing risk of medicine shortages in Australia as reported by the pharmacy industry and in the media, and referenced in the recent survey of shortages in Australian hospitals.¹¹⁵

Although, SHPA survey has concentrated on medicine shortages in Australian hospitals, the analysis has highlighted a number of systemic issues relating to medicine supply and reporting that have broader implications for community pharmacy.

SHPA has demonstrated that:

“[The risk of medicine shortages is very real where] the burden of managing medicine shortages is currently being borne by individual pharmacy departments across the country, where it is a destabilising factor in efforts to improve clinical collaboration and patient care.”¹¹⁶

SHPA has also noted that hospitals have implemented a range of ‘workarounds’ to mitigate medicine shortages, including use of the Special Access Scheme (SAS), and the increased risks associated with procuring medicine from overseas at short notice.¹¹⁷

Although the framework underpinning the PBS is aimed at ensuring medicine supply, it is clear from SHPA’s analysis that the emerging problem is increasing and may require a range of new interventions to address these risks. This should be addressed through the more comprehensive review recommended below.

¹¹⁴ The Pharmacy Guild of Australia, Interim Report Submission No. 196, page 23.

¹¹⁵ Society of Hospital Pharmacists of Australia, Medicine shortages in Australia: A snapshot of shortages in Australian hospitals (June 2017).

¹¹⁶ Ibid, page 8.

¹¹⁷ Ibid, page 7.

RECOMMENDATION 7-2: A COMPREHENSIVE SUPPLY CHAIN ANALYSIS

The Australian Government should undertake a comprehensive analysis of the entire pharmaceutical supply chain to ensure that medicine supply risks are addressed and that consumers continue to have timely and affordable access to the medicines they need.

This analysis should also seek to validate whether the Community Service Obligation and other mechanisms to support industry and pharmaceutical suppliers are achieving their desired outcomes in relation to the National Medicines Policy.

The analysis should be informed by the appropriate data to support future decision making and should be conducted with the full co-operation of all Community Service Obligation distributors and the broader pharmacy supply chain.

7.2. SUPPORTING ACCESS TO HIGH-COST MEDICINES THROUGH COMMUNITY PHARMACY

The supply of complex and high-cost medicines does not sit well within existing supply chain and pharmacy remuneration arrangements. Supplying these medicines is of significant concern for a number of pharmacies in supporting access to medicines within the community.

Increasingly complex and expensive medicines are being listed on the PBS. The Panel noted that the supply of high-cost medicines cause problems within the existing community pharmacy supply chain and remuneration arrangements. This can lead to a number of issues for community pharmacies in ensuring supply of high cost medicines within the community.

Community pharmacies are generally at risk of financial loss where the timeframes for payments to wholesalers are shorter than the timeframes for PBS reimbursement by the government. This is increasingly the case for high cost medicines for which there has been strong demand within the community following their entry on the PBS. A key example is the Hepatitis C medicine Sovaldi, listed in March 2016 with a price to pharmacy of \$19,367 plus GST.¹¹⁸

The GST payable through the medicine supply chain is also problematic in that it places additional financial burden on community pharmacy. Whereas a community pharmacy is required to pay GST on the purchase of all PBS medicines, GST is not included in the price reimbursed by the government under the PBS. Pharmacies must reclaim any GST paid when submitting their Business Activity Statement at the end of each month. For high-cost medicines in particular, this can leave community pharmacies significantly out of pocket over the course of the year.

From responses to the Interim Report, it remains clear that the financial risks and cash-flow issues associated with the dispensing of high-cost medicines continue to be a significant area of concern for community pharmacy owners, particularly given the low dispensing margin (e.g. Solvaldi, which has a margin for pharmacy of 0.3 per cent). The Panel recognises that, if this is not satisfactorily addressed, it could lead to some community pharmacies not supporting the supply of high-cost PBS medicines, which would adversely affect consumer access and health outcomes.

¹¹⁸ Goods and Services Tax

Pharmacy owners have also continued to express concern around the risk of patients failing to return to pick up their high-cost medicines after the pharmacy has ordered the supply. These items become a loss to the pharmacy as they are not able to be returned to the wholesaler or manufacturer. There were additional concerns noted in relation to the potential for stocks of these valuable products to be destroyed or scripts lost, particularly for medicines costing more than \$1000 per item.

The Panel remains convinced of the need to consider alternative mechanisms for the supply of high cost medicines to reduce risk to community pharmacy owners.

One approach would be to cap the amount paid by community pharmacy for high cost medicines. In response, Medicines Australia noted the need to identify where any additional risk would be borne within the supply chain. The Panel agrees and notes that the risk could be borne by the manufacturer and/or the government.

RECOMMENDATION 7-3: SUPPORTING ACCESS TO HIGH-COST MEDICINES

The Australian Government should investigate alternative payment arrangements for the supply of high-cost PBS medicines from community pharmacy to support their continued availability within the community. A cap should be placed on the amount that a community pharmacy contributes to the cost of any PBS medicine, in the range of \$700 to \$1000, to allow consumers to access high-cost PBS medicines from the pharmacy of their choice.

7.3. SUPPORTING ACCESS TO HIGHLY SPECIALISED DRUGS THROUGH COMMUNITY PHARMACY

The distinction between highly specialised and other PBS medicines causes administrative inefficiencies for community pharmacy and may compromise patient access to these medicines within the community.

The Highly Specialised Drugs (HSD) Program, which operates under section 100 of the *National Health Act 1953* (Cth), provides access to specialised PBS medicines for the treatment of chronic conditions which, because of their clinical use and other special features, have restrictions on where they can be prescribed and supplied.

Previously, PBS medicines supplied under the HSD Program were restricted to supply through public or private hospitals, due to them having access to appropriate specialist facilities. However, this has expanded with the introduction of community access arrangements for medicines for the treatment of Hepatitis B and HIV/AIDS, maintenance therapy for schizophrenia and, more recently, new medicines for Hepatitis C.

HSD community access arrangements allow for a better alignment of existing program arrangements with current clinical practice and models of care. Patients also have greater choice over where they can access their medicines—either from a community pharmacy, or a private or public hospital pharmacy.

However, the increasing availability of highly specialised drugs within the community continues to raise similar issues and risks for community pharmacies to those discussed above for high-cost

medicines. The PSA has expressed a concern over the need to mitigate these risks by suggesting that:

“The Government should take steps to mitigate the risks associated with the stocking and supply of these high cost drugs, to avoid problems similar to those experienced with the introduction of HIV and Hepatitis C treatments through community pharmacy.”¹¹⁹

While expanding access to these medicines in the community has brought with it the opportunity to support an increased role for community pharmacy in primary care, it remains that the complexity of dispensing across hospitals and community pharmacy can make the system unduly difficult for consumers to navigate, and presents risks to pharmacies in holding stock that may not be dispensed.

There has been a significant issue with regard to the financial burden for pharmacy in providing access under current arrangements, including for smaller facilities in rural and remote areas in particular. For example, the Metro South Hospital and Health Service stated that:

“For smaller hospitals, rural and remote centres where the cost of such drugs may constitute a large proportion of the facility drug budget, the requirement to fund these drugs impacts upon the ability for the service to procure further medications.”¹²⁰

There is a priority need to address the complexities associated with the HSD program. The majority of submissions received agreed that the HSD Program should be reformed, as the current fees are too high, complex and commercially unviable. Such reform should not be at the cost of access by consumers, as the objective of ensuring fair and equitable access irrespective of location should be maintained.

SHPA suggested:

“[The reform should include] greater harmonising of medicine and consumer categories in the PBS would be beneficial for both hospital and community settings. However the supply of medicines in both hospital and community settings such as those under the HSD program cannot be easily harmonised due to pre-existing differences in PBS funding. These include the lack of dispensing fees as discussed in option 4-3. Without certainty as to the reform of PBS in hospitals and an alternative pathway for fee revision, the CPA remains the key conduit for pharmacy remuneration and regulation.”¹²¹

The Panel agrees that the distinction between highly specialised medicines and other high-cost PBS medicines covered under section 100 HSD arrangements should be harmonised to improve administration and reduce risks to patients and pharmacies.

RECOMMENDATION 7-4: SUPPORTING ACCESS TO HIGHLY SPECIALISED DRUGS

The Highly Specialised Drugs Program under section 100 of the *National Health Act 1953* (Cth) should be reformed to remove the distinction between section 100 (Community Access) and other medicines listed under section 100 Highly Specialised Drugs arrangements. This should include, for— example, harmonising access and fees regardless of where the medicine is dispensed.

¹¹⁹ Pharmaceutical Society of Australia, Interim Report Submission No. 183, page 36.

¹²⁰ Metro South Hospital and Health Service, Interim Report Submission No. 188, page 2 and 3.

¹²¹ Society of Hospital Pharmacies of Australia, Interim Report Submission No. 194b, page 36.

7.4. LIMITING THE PBS LISTING OF GENERIC MEDICINES

A more targeted approach to listing PBS medicines can improve supply chain efficiency and reduce costs to the Australian community.

While the listing of PBS medicines is outside the scope of the Review, the number of different types of a particular medicine has consequences for the effectiveness and efficiency of the supply chain. Having a large number of types of a particular medicine listed on the PBS results in both wholesalers and pharmacies needing to supply each available brand if requested. This increases potential inventory and stock-ordering costs throughout the supply chain. These costs can be avoided if the government limits the number of generic medicines through a tender process when a medicine comes off patent.

However, there is some disagreement with this approach—organisations such as the PSA noted that:

“While PSA recognises that an efficient and effective pharmacy supply chain is critical, PSA has concerns that the above proposal could have a significant impact on the medicines industry in Australia, leading to medicines access issues.”¹²²

The Panel appreciates the point that there are ongoing issues with the supply of medicines within Australia, and as such, a category for any successful tenderer would be the consistent provision of the listed medicine. The advantages of having a small number of generic medicines allows for redundancy, without the stocking costs related to the entire range of generics listed on the PBS.

Medicines Australia also disagreed with the Panel noting similar issues to the PSA with the additional point:

“There is no evidence provided that limiting the number of medicines arbitrarily on the PBS would provide additional sustainable savings whilst maintain patient access.”¹²³

Nevertheless, the Panel considers that the examples provided in the Interim Report provide better practice guidance in tendering generic and high volume medicines in both the Netherlands and Denmark. Specifically, the Interim Report discusses reforms in Denmark to curb expenditure growth on pharmaceuticals through allowing insurance providers to adopt ‘preferential pricing policies’:

“The result of these reforms were that list prices of the ten highest-volume generics fell by between 76% and 93%, which generated savings of €348 million per year (Schut et al, 2013).”¹²⁴

It is for these reasons that the Panel has maintained its position that generic medicines should be tendered and listed to help reduce operating costs for wholesalers and pharmacists.

¹²² Pharmaceutical Society of Australia, Interim Report Submission No. 183, page 37.

¹²³ Medicines Australia, Interim Report Submission No 195, page 17.

¹²⁴ Deloitte Access Economics, Remuneration and regulation of community pharmacy: Literature review, page 10 (November 2016).

RECOMMENDATION 7-5: GENERIC MEDICINES – LISTING ARRANGEMENTS

When an ‘originator’ (or ‘branded’) medicine comes off patent then the Australian Government should hold a tender for the PBS listing of generic versions of the medicine. The Australian Government should limit the number of generic versions of a particular medicine to be listed to a relatively small number that is still sufficient to allow for patient choice (e.g. four generics and the originator brand of the medicine). The chosen generics should be those best able to meet the distribution and other conditions, including the security of supply, required by the Australian Government at the least cost to the PBS.

8. FUTURE COMMUNITY PHARMACY AGREEMENTS

8.1. THE COMMUNITY PHARMACY AGREEMENT PROCESS

The process for successive Community Pharmacy Agreements has evolved to a situation carrying a number of issues regarding transparency and sustainability for the future development of the sector.

The CPAs impact upon a broad group of stakeholders that have not been appropriately represented by the two current signatories to the agreement. All stakeholders need to understand in sufficient depth the implications of what has been agreed. This requires additional transparency.

Since 1990, the remuneration that pharmacists receive for dispensing PBS medicines and the regulations regarding the location of pharmacies have been governed by a series of five-year agreements between the Australian Government and the Guild.

Successive CPAs have increased in scope beyond the requirement for an agreement on pharmacy remuneration for the provision of pharmaceutical benefits (section 98BAA of the *National Health Act 1953* (Cth)).

These agreements have evolved to include funding for professional programs and other services delivered through community pharmacy, consultant pharmacists, remuneration to wholesalers, the CSO funding pool, supply arrangements for products provided on the National Diabetes Services Scheme and payments to support the preparation of infusions or injections for chemotherapy provided under the PBS.

The Panel notes that the Guild has been the only signatory party to each successive agreement with the government. The Guild has continued to hold this role as a representative of a majority of Approved Pharmacists, in line with requirements under the National Health Act. However, the Panel also notes broad concern among the sector and consumers that this has translated to successive CPAs having been negotiated only between government and a representative of pharmacy owners.

CPAs affect all community pharmacists, not simply pharmacy owners. Further, CPAs also directly affect consumers of PBS medicines, in that each agreement has described how and when consumers will access PBS medicines.

The Panel notes that, prior to the negotiation of the 6CPA, which commenced on 1 July 2015, the Minister and the Department of Health conducted a series of bilateral and multilateral consultations with a broad range of stakeholders that had an interest in potential outcomes of the 6CPA. However, from this, neither consumers nor the broader community pharmacy profession were represented as direct signatories to the 6CPA.

This concern was reflected in a number of submissions to the Review, including the following:

National Pharmaceutical Services Association

“While Government ‘contracts’ with community pharmacy to dispense PBS prescriptions in support of the National Medicines Policy, the Guild cannot be expected to speak on behalf of, or be accountable to Government for the performance of, these third parties. That is not to say, however, that the Guild

should not remain the most important party in any post-6CPA Agreement, as PBS dispensing remuneration always will be the key deliverable of the CPA.”¹²⁵

Consumers Health Forum of Australia

“There should not be another Community Pharmacy Agreement. Instead there should be separate negotiations and agreements on the dispensing fee and the professional services programme. The pharmacist’s role in providing consumers with information about their prescription medicines needs to be clarified and explicitly included in the dispensing fee.

The funding for professional services should be put into a separate programme administered by the Department of Health with overarching direction from a Programs Advisory Committee which includes all the key stakeholders. This could be delivered through the Primary Health Networks. All negotiations should be multilateral involving all the relevant stakeholders.”¹²⁶

The value of the CPA process would be maximised if CPAs were more closely focused on the dispensing of PBS medicines, those services directly related to the dispensing function and responsibilities, and the pricing to consumers for such dispensing.

The CPA is not the right mechanism to attempt to capture broader health programs and services or supply chain activities. These involve multiple key stakeholder groups and extend beyond the funding of PBS-related services.

While there is an argument for a more integrated approach to public healthcare arrangements, including for community pharmacy, the Panel considers that the CPA process should be limited purely to an agreement on remuneration to community pharmacy for the dispensing of PBS medicines.

In this way the government would have flexibility to determine the most efficient ways in which to fund other non-PBS related health services that have the best outcomes for the broader community. This position is echoed by the PSA’s response to the Interim Report, which notes:

“There is a genuine need for future Community Pharmacy Agreements to support a viable sector, and to consider all aspects of the supply chain, including manufacturing, wholesaling, distribution, community pharmacy infrastructure and pricing, including to consumers. However, PSA is of the view that this should be considered independent of the investment in dispensing and other clinical services, as the supply infrastructure needs to be sustainable on its own, without reliance on cross-subsidisation through program/service funding.”¹²⁷

In refocusing the CPA, the Panel considers that it would be appropriate to continue to include the Guild in negotiations on pharmacy remuneration. As already noted, the Guild represents a majority of owners of community pharmacies, which act as agents of government in supporting consumer access to PBS medicines.

While the Panel understands that membership of the Guild is open to all community pharmacy owners, except friendly society pharmacies (which are not directly owned by pharmacists),¹²⁸ the

¹²⁵ National Pharmaceutical Services Australia, Interim Report Submission No. 482.

¹²⁶ Consumers Health Forum of Australia, Interim Report Submission No. 483.

¹²⁷ Pharmaceutical Society of Australia, Interim Report Submission No. 183, page 30.

¹²⁸ Noting that these organisations have a memorandum of understanding with the Guild to represent their interests in negotiations related to the CPA.

Panel is also aware that some pharmacy owners may consider that the Guild does not represent their own interests.

Should the government become aware of any substantial proportion of pharmacy owners not considering the Guild as representing their interests, then the Panel believes the government should consider alternative ways to have these owners participate in the CPA process.

The Panel strongly recommends that other directly affected parties also need be represented in future negotiations on pharmacy remuneration. To this end, the Panel's consultations with peak representative bodies, as well as responses to the Interim Report were useful in reinforcing who should be involved in negotiations of future CPAs. For example, the CHF noted in their submission:

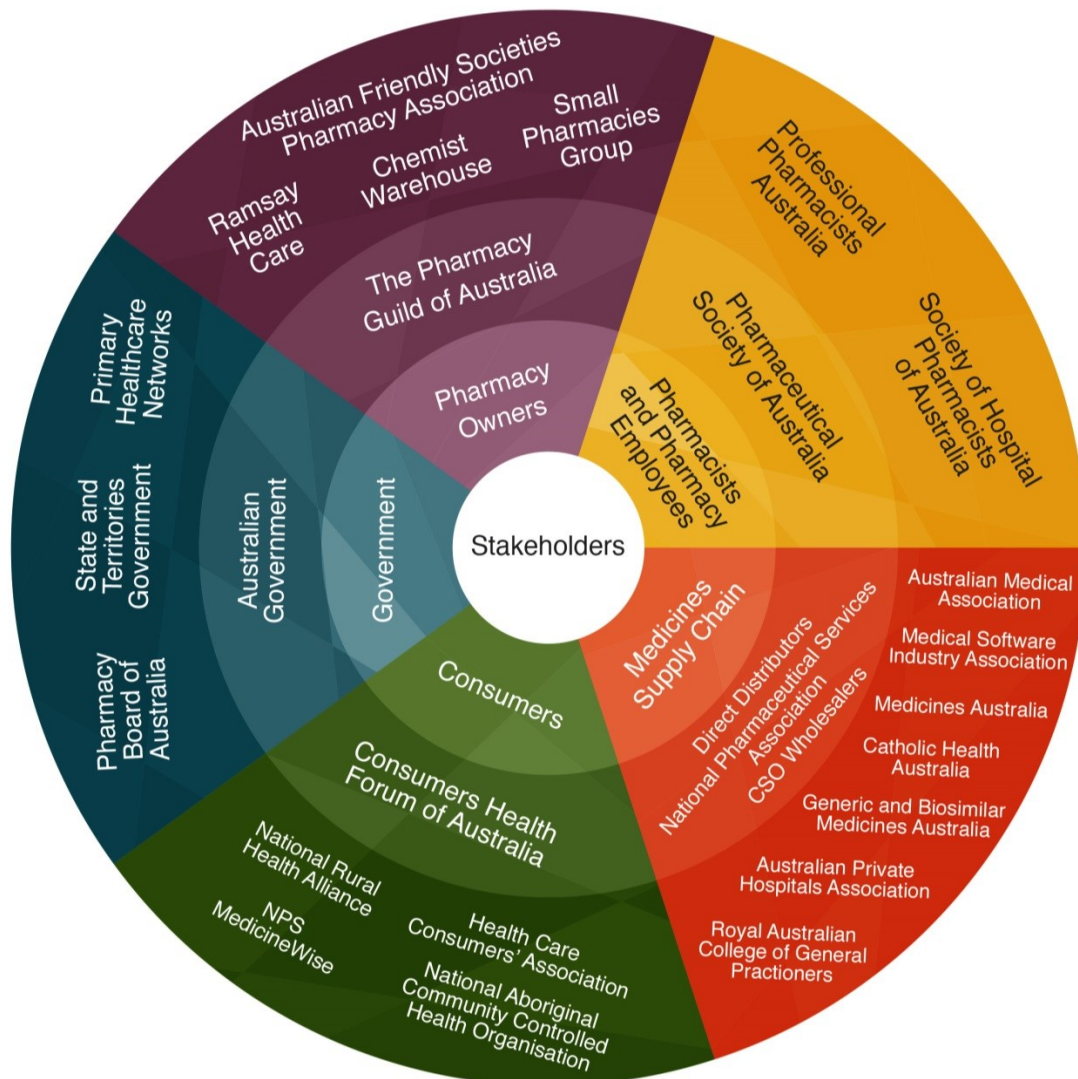
“As we move to a more consumer centred health system then consumers' needs to be actively involved in all parts of the system not just as passive recipients of services. This includes being involved in service design and planning and being part of governance structure for the system such as the Community Pharmacy Agreement.”¹²⁹

In particular, the Panel recommends that CHF (as the peak representative consumer body in Australia on health-related matters) and the PSA (as the peak representative body for pharmacists in Australia), should also be included in the negotiations of future CPAs. Should the process still lead to 'signatories', then these parties should also be signatories to the agreement.

Even where there is a broader range of signatories to future CPAs, there will still remain a need to consult closely with all relevant stakeholders in the pharmacy and health sectors as appropriate. The range of pharmacy stakeholders that the Panel considers should be consulted is represented in the Figure 7.

¹²⁹ Consumers Health Forum of Australia, Interim Report Submission No. 116, pages 10 and 11.

FIGURE 7: PHARMACY STAKEHOLDERS



Additionally, the Panel notes that recent CPAs have introduced a variety of programs that are not directly related to the dispensing and quality use of medicines. While such healthcare programs may be desirable, the Panel considers that the CPA process is not the appropriate forum to determine these programs. In many cases, the appropriate source of funding for medical programs that do not focus on medicine supply warrants broader consideration by government. Indeed, the PSA's response to the Interim Report notes:

“Professional programs offered by community pharmacies need to be considered in the context of consumer health needs and the evolving way in which people are accessing care. Pharmacist services remunerated by government should allow for flexibility in terms of service setting to most appropriately meet consumers' needs.”¹³⁰

These concerns were also echoed in the response of the Royal Australian College of General Practitioners (RACGP), which noted:

¹³⁰ Pharmaceutical Society of Australia, Interim Report Submission No. 183, page 6.

“The RACGP supports the options presented in the Report regarding changes to future CPA. As identified by the Review Panel, the CPA is complicated and includes many variants of pharmacy including aspects that have poor transparency and no health outcome metrics. The CPA should be limited to remuneration and associated regulations regarding the dispensing of medicines that attract PBS subsidies.”¹³¹

The AMA also argued the benefits of limiting the scope of future CPAs:

“The AMA agrees there are benefits in future community pharmacy agreements being limited to remuneration for the dispensing of PBS medicines and associated regulation.

This would allow pharmacy programs, such as medication adherence and management services currently funded under the Agreement, to be funded in ways that are more consistent with how other primary care health services are funded.

Given these programs are about providing health services, rather than medicines dispensing per se, it makes sense for them to be assessed, monitored, evaluated and audited in a similar way to medical services under the MBS. Approximately \$1.2 billion has been provided to pharmacies under the current community pharmacy agreement without this level of transparency and accountability. No evaluations of pharmacy programs under the Sixth Community Pharmacy Agreement have been made public.

Moving pharmacist health services outside of the Agreement would also open the way for more flexible models of funding, for example, support for pharmacists working within a general practice team and other innovative, patient-focused models of care.¹³²

The Panel agrees that it is inappropriate for services not related directly to dispensing to be remunerated through the CPA. However, due to the wide scope of dispensing and the related services, it is recommended that a set of minimum dispensing requirements be defined to decide which participants and services are remunerated. This should include the provision of any required information and/or counselling by the pharmacist. The costs associated with these activities can then be built into the dispensing fee that community pharmacies receive.

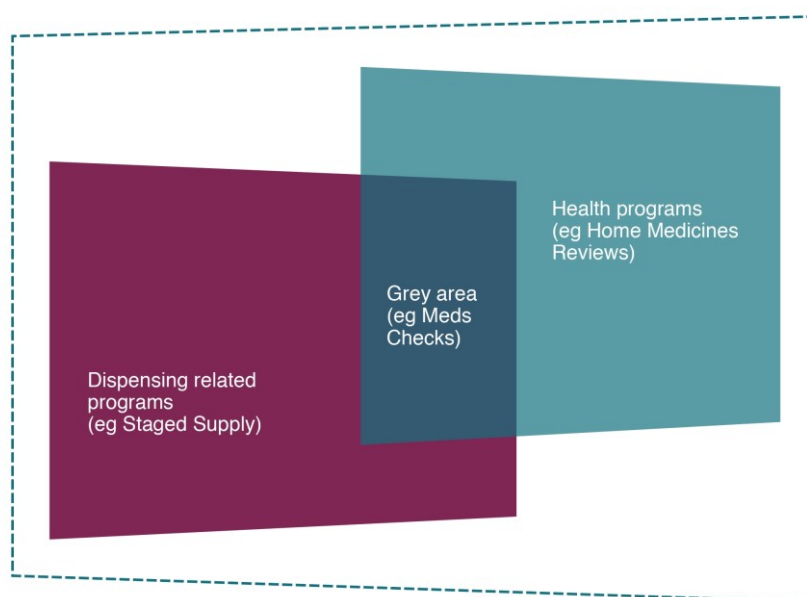
Additional services beyond dispensing offered by community pharmacies or hospitals, such as HMRs, residential medication management reviews and diabetes screening, should be defined and remunerated through alternative mechanisms such as the MBS, similar to current Practice Incentive Payments. This would allow the government to periodically improve access to specific services as needed by urban, rural and remote areas independent of each other.

The services to be remunerated should be negotiated with both pharmacy and consumer groups to understand the most valuable services, including how costs should balance with the required expertise for a service. Remuneration would be negotiated with peak community pharmacy bodies, taking into account the current cost for the provision of the service that is being considered for remuneration. An example of this would be analysing the provision of DAAs by different pharmacy groups to determine an equitable payment to ensure cost efficiencies within the sector.

¹³¹ Royal Australian College of General Practitioners, Interim Report Submission No. 95, page 5.

¹³² Australian Medical Association, Interim Report Submission No. 53, pages 3 and 4.

FIGURE 8: DETERMINING SERVICES TO BE REMUNERATED THROUGH THE CPA



Recent CPAs have also set aspects of the government funding for medicine wholesalers. This is inappropriate, as wholesalers have not been appropriately represented in the CPA discussions. SHPA’s response to the Interim Report noted, in particular:

“SHPA supports the recommendation that regulation and remuneration of wholesalers is not best placed in Community Pharmacy Agreements. However, greater clarity is required around how this important area of supply could be more effectively managed. Recognising the limitations inherent in Australia’s geographic size and location we would not support a completely ‘free market’ solution that might reduce timely access to medicines.”¹³³

The Panel has presented a preferred alternative approach to wholesaling and medicine distribution in Chapter 7 (The Distribution of Medicines to Community Pharmacy).

It should be noted in relation to the below recommendations that there will always be a need for the interrelationships and synergies between medicine dispensing, the medicine supply chain and pharmacy programs and services to be managed. This may require a shared vision and principles that inform the CPA and other negotiations.

RECOMMENDATION 8-1: SCOPE OF COMMUNITY PHARMACY AGREEMENTS—DISPENSING

The scope of discussions under future Community Pharmacy Agreements should be limited to the remuneration and associated regulations for community pharmacy for the dispensing of medicines under PBS subsidy and related services, including the pricing to consumers for such dispensing.

¹³³ Society of Hospital Pharmacists of Australia, Interim Report Submission No. 196, page 31.

RECOMMENDATION 8-2: SCOPE OF COMMUNITY PHARMACY AGREEMENTS—WHOLESALING

The Australian Government should ensure that the regulation and remuneration of wholesaling of PBS-listed medicines should not form part of future Community Pharmacy Agreements.

RECOMMENDATION 8-3: SCOPE OF COMMUNITY PHARMACY AGREEMENTS—PROGRAMS AND SERVICES

The regulation and remuneration of professional programs offered by community pharmacies should not form part of future Community Pharmacy Agreements.

RECOMMENDATION 8-4: COMMUNITY PHARMACY AGREEMENT PARTICIPANTS

The parties invited to participate in future Community Pharmacy Agreements should include the Pharmacy Guild of Australia, the Pharmaceutical Society of Australia and the Consumers Health Forum of Australia.

9. HEALTH PROGRAMS OFFERED BY COMMUNITY PHARMACY AND THE ROLE OF PHARMACY IN PRIMARY HEALTHCARE

9.1. COMMUNITY PHARMACY PROGRAMS—KEY PRINCIPLES

It is important to support a more flexible approach to the delivery of pharmacy programs that will enable a better integration of healthcare services while also encouraging innovation in business models.

Community pharmacy plays a vital role in the Australian healthcare system by acting as an accessible source of reliable healthcare advice and services. The Panel therefore encourages pharmacy programs to continue to be delivered in community pharmacy and other areas of private practice—for example, pharmacists located in general practice, conducting private consulting businesses, or operating in other interdisciplinary settings within the primary care system.

Overall, a more flexible approach to the delivery of pharmacy services will support integration of healthcare services while also encouraging innovation in business models.

Submissions in response to the Interim Report that were in favour of community pharmacy programs have suggested that specific government funding for the provision of pharmacy programs would encourage innovation within pharmacies and expand healthcare opportunities for patients.

SHPA specifically noted that:

“Greater flexibility of criteria for eligibility of settings to provide programs would be beneficial for innovation and enhancement of pharmacist roles and services. The transition of care area would benefit from greater flexibility of such criteria to enable innovative forces in hospital pharmacy to scale up long established trial programs.”¹³⁴

There was also a call for pharmacy programs and services to be integrated with more aspects of the broader healthcare system. It was considered that pharmacists have the ability to make a positive contribution outside of just dispensing medicines.

SHPA also noted in its response that pharmacy programs should be based on evidence of effectiveness:

“SHPA believes that the evidence-base showing improvements for patients in blood pressure and cholesterol control, diabetes, and medication management, resulting from pharmacist-led medication review, justifies the expansion of the HMR program for high-risk patients. Equally strong evidence supports the widespread introduction of a hospital referral pathway with a study showing patients aged 51-65 years exhibited a 25 per cent reduction in hospital admissions.”¹³⁵

It would be an oversight not to consider how hospital pharmacies could contribute to the community, particularly through providing assistance to patients with chronic conditions or high risk of readmission. This is supported by the Australian Private Hospitals Association (APHA) submission that stated:

¹³⁴ The Society of Hospital Pharmacists of Australia, Interim Report Submission No. 194, page 33.

¹³⁵ Ibid.

“Although the focus of the program has traditionally community based, APHA contents that it is counterproductive not to also consider the role of hospital based pharmacy services in providing programs, particularly programs targeted at people living with chronic conditions and people at high risk or potentially preventable admission/readmission to hospital.”¹³⁶

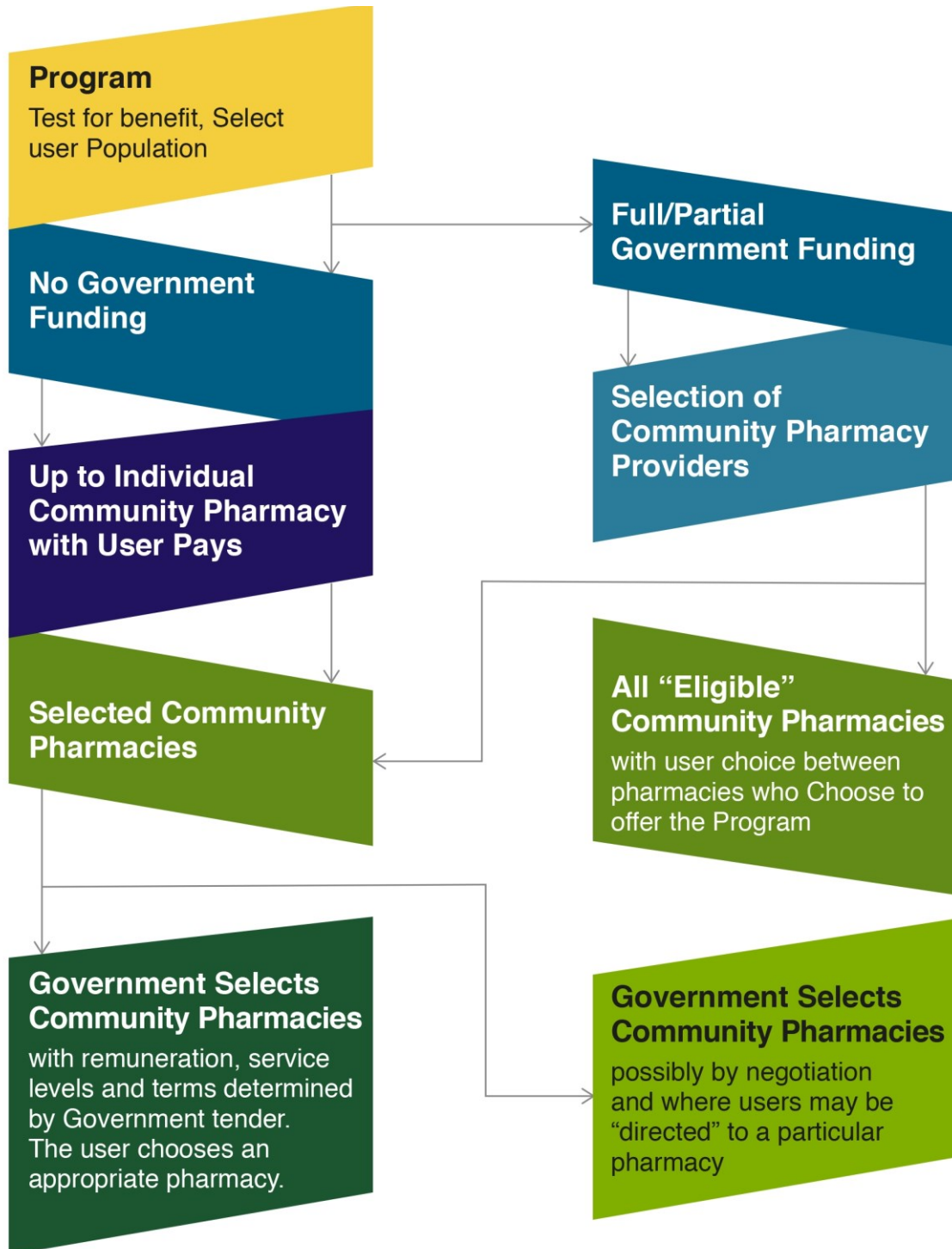
The Panel considers that there is a need for advocacy and leadership within the pharmacy profession to demonstrate the need for such services, to secure appropriate funding and to develop effective data collection and evaluation mechanisms to be able to demonstrate value and outcomes.

As previously considered in this report (see Chapter 8: Future Community Pharmacy Agreements), the Panel is concerned that funding under successive CPAs has grown beyond the core services expected to be provided from a community pharmacy. The Panel recommends that these be considered outside future CPAs and appropriately funded according to their own merits.

There is value in continuing to support and fund community pharmacy programs. Enforcing a systematic approach would be the best way to achieve this as underpinned by the principles recommended below and in line with the approach described in Figure 9.

¹³⁶ Australian Private Hospital Association, Interim Report Submission No. 191, Page 7.

FIGURE 9: AN APPROACH TO THE DETERMINATION OF COMMUNITY PHARMACY PROGRAMS



RECOMMENDATION 9-1: COMMUNITY PHARMACY PROGRAMS—KEY PRINCIPLES

The range of programs offered by community pharmacy should be underpinned by the following principles:

- a. Programs should be based on evidence of clinical and cost effectiveness and the health benefits they provide to the community.
- b. Programs may or may not involve the Australian Government paying for some or all the costs of the service to some or all patients.
- c. Programs may in some cases be offered on the basis of each community pharmacy choosing whether or not to offer the program (with all community pharmacies being eligible to offer the program). In other cases, the program will only be available (with Australian Government payment) through pharmacies/pharmacists that are selected by the Australian Government (e.g. through a tender process or as a result of negotiation between the Australian Government and the relevant pharmacies or pharmacists or their representatives).
- d. For some programs, the Australian Government remuneration for the program will be channelled through the users of the program (or their representatives) so that users will decide which community pharmacies (or pharmacists) to use to deliver the program.
- e. Adequate funding for the above needs to be found outside PBS expenditure. It is important that similar services are funded in the same way to ensure a level playing field across primary health. For example, this means that, where pharmacist administration of drugs or vaccines by injection is authorised, a pharmacist should be able to expect to receive the same level of remuneration for a vaccination as a doctor or nurse.

9.2. LEVERAGING PHARMACY AND PHARMACIST CAPABILITY

Significant opportunities exist to better use community pharmacy and pharmacist programs and services in improving the health of Australians.

As discussed in Chapter 8 (Future Community Pharmacy Agreements), the Panel notes that the government will provide \$825 million over three years, from 2017–18, to community pharmacies to support and improve Australians' access to medicines, under the *Improving Access to Medicines—support for community pharmacies* measure. This includes \$600 million through the 6CPA to continue existing community pharmacy programs and to enable pharmacists to deliver new and expanded medication management services for Australians that need additional assistance to manage their medications.

The following pharmacy programs have been redesigned to support the collection of information to assist with assessment of the effectiveness of these services:

- DAAs;
- Staged Supply;
- Meds Checks;
- Diabetes Meds Checks;
- Home Medicines Review program; and
- Pharmacy Trial programs.

The Panel also notes that all other 6CPA Programs will continue from 1 July 2017 in their current format pending the outcomes of program evaluations.

The following are therefore merely examples of the significant opportunities that the Panel believes exist for the better use of community pharmacy and pharmacist programs and services in improving the health of Australians, including issues that the Panel has observed in relation to their operation.

Dose Administration Aids

A DAA allows individual medicine doses to be organised according to the patient’s dose schedule. They have been defined as a mechanism that assists the patient with their medication management, and it has been suggested that the provision of DAAs reduce medication errors whilst improving adherence.

The government has recognised the value of DAAs and initially remunerated pharmacists through the Pharmacy Practice Incentives Program (PPIP). The Panel notes that for the 2017–18 financial year the government has changed this, and is providing funding of \$100 million through the 6CPA to continue the provision of DAAs through DAA service providers.¹³⁷

However, all DAA service providers will be allocated an individual cap based on previous DAA service volumes recorded and claimed under the PPIP program. As noted by the PSA:

“Encouragingly, additional funding has been allocated for the DAA program, with pharmacies receiving \$6 per patient per week ... PSA also welcomed the announcement that from February 2018, pharmacists will also be remunerated for patient registration and data collection. However even through PSA has welcomed the funding announcement, we still have concerns regarding the proposed capping of DAA services per pharmacy as this may lead to some patients who would benefit from DAAs missing out on the service ...”¹³⁸

As foreshadowed in Chapter 5 (Community Pharmacy Remuneration by Government), data received from pharmacists on community pharmacy remuneration will facilitate the effective assessment of DAA remuneration.

While the provision and use of DAAs has been proven to be an effective tool for improving a user’s medication management and their clinical status, the Panel has seen a range of DAA models during its consultation. Differences in these models invariably affect the quality and usefulness of the device.¹³⁹

¹³⁷ Department of Health, Dose Administration Aids—Program Rules, (July 2017).

¹³⁸ Pharmaceutical Society of Australia, Interim Report Submission No. 183, page 32.

¹³⁹ University of Queensland Therapeutic Research Unit, Effectiveness and Cost Effectiveness of Dose Administration Aids (DAAs), (2004).

Some facilities utilised high quality models involving machine packing and robust checking, with manual packing as a backup. The Panel also observed what they consider was the packaging of DAAs with insufficient quality control and the potential for increased risks in medicine misadventure by patients.

In order to improve the overall effectiveness of the device and to reduce the likelihood of medicine misadventure, the Panel recommends a set of minimum standards that can ensure consistent quality control over the preparation of these aids. In this respect, the Panel notes the suggestion of AHPRA:

“In developing any enforceable minimum standards for the supply by pharmacists of medicines in dose administration containers consideration should be given to the existing guidance and practice standards (Pharmaceutical Society of Australia professional practice standards, the Quality Care Pharmacy Program and Pharmacy Board of Australia guidelines).

Enhancing quality use of medicines by consumers and delivering improved patient safety/health outcomes should be appropriately funded given the widespread benefits to the public and the health care system.”¹⁴⁰

The Panel agrees that Standard 15 of the *Professional Practice Standards*¹⁴¹ adequately covers the provision of DAA services. This standard, together with the associated practice guidance material developed by the PSA, has value in application more broadly as a national standard and should be enforceable in its application. This links to the need to develop a set of minimum standards outlined in Recommendation 4-1 (Community Pharmacy—Minimum Services).

RECOMMENDATION 9-2: DOSE ADMINISTRATION AIDS—STANDARDS

The Australian Government should establish clear, enforceable minimum standards for the supply of medicines by community pharmacies through dose administration aids. There should also be appropriate data for the evaluation of payments provided to community pharmacies for the dispensing of medicines using dose administration aids (in recognition that this tends to be a higher cost activity than dispensing in manufacturer’s packaging).

Home MedicineS Reviews

HMRs have been designed to enhance the quality use of medicines and reduce the number of adverse medicine events. They assist consumers to better manage and understand their medicines through a medication review conducted by an accredited pharmacist in the patient’s home.

Currently, each approved service provider may conduct and claim up to a total of twenty HMR services in any calendar month. This cap applies to both the organisation that is submitting the claim and the individual Accredited Pharmacist who completes the service.

There should not be a ‘cap’ placed on HMR services, because the size of such a cap is arbitrary and non-responsive to the varying needs of different communities or the varying business models adopted by different pharmacists.

¹⁴⁰ Australian Health Practitioner Regulation Agency, Interim Report Submission No. 197, page 9.

¹⁴¹ Pharmaceutical Society of Australia, Professional Practice Standard, Version 5—Section 15, page 84, (2017).

As such, the cap limits the ability of HMRs to contribute to the prevention of patient hospitalisations and readmissions to hospital and improvement in the quality use of medicines. It also prevents the expansion of a proven and effective way of delivering medication management services for high risk patients who need additional assistance.

The Panel agrees with the PSA and other stakeholders that the cap has had negative consequences for populations with high requirements for medicine management, such as some Indigenous communities.

The cap was introduced on 1 March 2014 following a \$4.2 million cost overrun on the annual review budget, funded through the 5CPA, triggering claims that some pharmacists were ‘rorting the system’. There had also been reports that some pharmacists had been performing high numbers of HMRs, and pharmacy groups were encouraging owners to carry out high numbers of MedsChecks to the detriment of both consumers and the profession.

The Panel considers that there should be regular auditing of HMRs to confirm that objectives relating to quality and compliance with required criteria are being met.

The program should be based on the clinical needs of patients and focused on patient outcomes. The Panel contends that the program would be better funded via the MBS, with the government setting the remuneration rate for different HMRs. The government should also set the required MBS referral criteria to ensure these services are appropriately targeted and represent value for money.

The Panel notes that the HMR program is continuing unchanged from 1 July 2017, but a review of the current MBS item 900 eligibility criteria is to be undertaken. Potential changes to patient eligibility criteria, the inclusion of two new in-pharmacy follow-up services and criteria to increase access to the service for Aboriginal and Torres Strait Islander patients are anticipated to commence in early 2018.

RECOMMENDATION 9-3: HOME MEDICINES REVIEWS—REMOVAL OF CAPS

The Australian Government should abolish ‘caps’ on Home Medicines Reviews and fund the program through the Medicare Benefits Schedule. The Australian Government should set the Medicare Benefits Schedule referral criteria to ensure these services are appropriately targeted and represent value for money.

The Australian Government should conduct regular audits of Home Medicines Reviews for quality and compliance with required criteria.

Pharmacy Support for Residential Aged Care Facilities

Polypharmacy is common among older people, who are more likely to be taking multiple medicines. The majority of residents of Residential Aged Care Facilities (RACFs) have long-term therapy for chronic conditions. Medications for cardiovascular, diabetes, dementia musculoskeletal, and mental health require regular ongoing supply for the elderly patient. As the medication regimens become more complex, the workload can be significant. Older people are also at higher risk of experiencing side effects from their medicines, and difficulties with vision, hearing, memory or cognitive functions that can make managing medicines safely more challenging.

Residents in RACFs are also at greater risk than the general population to the more severe complications of annual influenza. The Panel notes that:

- this year (2017) has been called the worst flu season on record and that NSW Health’s latest Influenza Surveillance Report (for example) shows that around 250,000 flu tests have been conducted in New South Wales to 1 September 2017 compared with 149,000 over the same period last year and just 16,000 flu tests over the same period in 2010; and
- a decreased rate of vaccinations has probably contributed to the influenza outbreak in RACFs.

The Panel notes that it has been reported by Painaustralia that as many as one in two residents of RACFs are undertreated for chronic pain and, in too many cases, residents of RACFs are subject to inappropriate use of chemical and physical restraint. Instead, they should be having their pain investigated. The Panel agrees with Painaustralia that pharmacists could, and should, be a key part of this investigation process, whether in RACFs or in the community.

As stated by Painaustralia in their September 2016 submission to the Panel:

“Chronic pain affects one in five Australians and one in three people over the age of 65. At a total cost to the community of \$34 Billion including \$7 billion in health care costs and \$11 billion in productivity—it is one of the most costly health conditions and the major cause of forced retirements from the workplace.

Pain is the most common reason people seek medical help—with one in five GP consultations involving a person with chronic pain. In pharmacy, analgesics are the most commonly requested over the counter medications.

Despite the prevalence of chronic pain and the human and economic cost, there is a major shortage of pain services, with long wait times at public pain clinics and very limited access to best practice multidisciplinary services in primary care.”¹⁴²

Working as a pharmacist in RACFs may involve carefully preparing and packing medicines, as well as conducting Residential Medication Management Reviews (RMMRs) that can be delivered as part of a healthcare team or as an independent accredited pharmacist.

RMMRs are designed to enhance the quality use of medicines for consumers in approved government-funded RACFs by assisting consumers and their carers to better manage their medicines. The program also supports activities that are designed to improve quality use of medicines across approved government-funded RACFs through the QUM component of the program.

A RMMR is a service provided to a permanent resident of a government-funded RACFs including those in flexible care arrangements (transitional care facilities), who are not eligible for a HMR. In order to identify, resolve and prevent medication-related problems, information about the resident’s medicine is collated, a comprehensive assessment is undertaken and a report is provided to the resident’s GP.

¹⁴² Painaustralia, Discussion Paper Submission No. 223, page 2.

The QUM service is a separate service provided by a registered or accredited pharmacist and focuses on improving practices and procedures as they relate to the quality use of medicines in a residential care facility.

Current funding limits the ability for an accredited pharmacist to have a regular on-site consultative presence at RACFs, without being dependent on carrying out RMMRs to meet the associated costs.

The Panel considers that there should be provision of professional pharmacy programs by non-retail consultant pharmacists in RACFs, as well as the support provided by retail community pharmacies for DAAs.

The Panel believes that, if pharmacists are able to work in RACFs on a dedicated basis as part of an effective multidisciplinary team, the management of resident's treatment could be greatly improved. The timeliness of intervention to prevent medical interactions, clarity of medication orders and supply, and a reduced workload for medical practitioners, are likely to be some of the benefits that would be gained.

These RACF pharmacists should be actively engaged with their PHNs to facilitate links with GPs, allied health professionals and retail community pharmacy services (including the provision of DAAs) in their area to assist a person with chronic pain (for example) and ensure their continuity of care.

RECOMMENDATION 9-4: PHARMACY SUPPORT FOR RESIDENTIAL AGED CARE FACILITIES

The Australian Government should explore the provision of dedicated consulting or employee pharmacists in residential aged care facilities to deliver professional pharmacy programs.

These residential aged care facilities pharmacists should be actively engaged with their Primary Health Networks to facilitate links with general practitioners, allied health professionals and community pharmacy services (including the provision of dose administration aids) in their area to assist a person with chronic pain (for example) and ensure their continuity care.

Support for Expanded Pharmacy Services Identified by THE Pharmacy Trial Program

The Panel notes that, under the 6CPA, \$50 million has been allocated for the Pharmacy Trial Program (PTP), which is designed to trial new and expanded community pharmacy programs that seek to improve clinical outcomes for consumers by extending the role of pharmacists in the delivery of primary healthcare services through community pharmacy.

The Panel also notes that approximately \$10 million over three years has been allocated for PTP Tranche 1 and that the government has agreed to fund trials in the following areas:

- pharmacy-based screening and referral for diabetes;
- improved medication management for Aboriginal and Torres Strait Islander people through pharmacist advice and culturally appropriate services; and
- improved continuity in the management of patients' medications when they are discharged from hospital.

Trials undertaken under the PTP need to reflect the centrality of community pharmacy as a key point of accessible care for consumers. However, the involvement of pharmacy can potentially take a number of forms, including where the community pharmacy is a participant in a broader care model.

The Panel also notes that the grant opportunity for the PTP Tranche 2 closed on 15 December 2016, with the resubmittal process closing on 1 March 2017. It is understood that the assessment process for this grant opportunity is currently underway and an outcome will be advised to all applicants in due course.

The PTP is still in an early stage of implementation and it is too early to determine whether the trials will be successful in meeting evidence of comparative clinical and cost effectiveness as required by Medical Services Advisory Committee (MSAC). However, the Panel supports the objectives of the program to extend the funded roles of pharmacists in the delivery of primary healthcare services.

The Panel notes that it is likely that more funding will be needed to be found beyond the \$600 million that has been set aside to support recommendations by MSAC, about which new programs and services should continue to be funded after trials conclude, based on assessment of their clinical and cost effectiveness. This funding should be found outside of the PBS.

RECOMMENDATION 9-5: SUPPORT FOR EXPANDED PHARMACY SERVICES IDENTIFIED BY PHARMACY TRIAL PROGRAM

The Australian Government should continue to support pharmacy programs that have been successful in meeting evidence of comparative clinical value and cost effectiveness as required by Medical Services Advisory Committee. Funding for programs that demonstrate these requirements should continue on the basis of merit and not be dependent on the outcomes of any other consideration, such as an agreement on pharmacy remuneration.

10. CHEMOTHERAPY COMPOUNDING

10.1. CHEMOTHERAPY COMPOUNDING STANDARDS

The current standards for the compounding of chemotherapy medicines in community pharmacy and other facilities appear to be overly complex. The oversight currently includes legislation, codes and guidelines. The overlap and inconsistency of these across Australia do not provide clear rules or guidance for compounders.

The legislative standards that sterile compounding pharmacies must meet vary across jurisdictions. In addition, best practice professional standards may vary between practice settings. While compounding facilities must meet the PBA and SHPA guidelines for the preparation of sterile medicines, the additional standards applied to chemotherapy preparations are complex and layered, referencing state, territory and Commonwealth legislation as well as industry codes, guidelines and pharmaceutical standards. This complexity places an administrative burden upon the compounding facilities that are subject to current reimbursement arrangements under the PBS. The PBA has noted concerns in this regard:

“Compounding of sterile injectable medicines (which includes relevant chemotherapy preparations) poses significant risks to the public if the requirements of relevant legislation, guidelines and practice standards are not strictly adhered to throughout the compounding and supply process.”¹⁴³

In both the United States of America and Canada, all compounding facilities are subject to uniform minimum standards in regards to personnel, policies and procedures and general maintenance logs. As the PBA has noted in its current compounding standards, Compounding of Sterile Injectable Materials, there are a large number of regulations, codes and guidelines that are needed to be met to ensure safe compounding practices.¹⁴⁴ These standards also reference regulatory authorities, PSA professional practice standards, SHPA guidelines and occupational health and safety standards.

This was noted by other organisations such as SHPA, which advised that:

“SHPA is aware that the Pharmacy Board of Australia is developing Guidelines on Compounding of Medicines to cover the Compounding of Sterile Injectable Medicines (unpublished), and this should be included in uniform minimum standards for all compounding premises.”¹⁴⁵

Conversely, the submission from Icon Group disagrees with the Panel’s findings, noting:

“there is clear, unambiguous guidance for sterile medicinal compounders via:

1. Current Good Manufacturing Practice (i.e. cGMP); and
2. The PIC/s and TGA implementation of cGMP.

The only acceptable minimum standard for the manufacture of sterile medicines for wide-spread distribution, as recognised by the TGA, FDA and other international regulatory bodies, is cGMP. No other acceptable standard exists. No other standard is required to be developed.”¹⁴⁶

¹⁴³ Pharmacy Board of Australia, Interim Report Submission No. 197, page 13.

¹⁴⁴ Pharmacy Board of Australia, Compounding of Sterile Injectable Medicines (2017).

¹⁴⁵ Society of Hospital Pharmacists Australia, Interim Report Submission No. 194, page 37.

¹⁴⁶ Icon Group, Interim Report Submission No. 92, page 5.

Icon also identifies that, for non-TGA-licensed compounders, standards vary based on state and territory legislation and are open to self-adoption. For these compounders there are a number of state-based self-regulating systems in place that drive further inconsistency in chemotherapy compounding practice. The Panel recommends that these inconsistencies should be addressed through uniform minimum national standards for both TGA-licensed and non-TGA-licensed facilities involved in the sterile compounding of chemotherapy preparations.

The TGA Licensed Chemotherapy Compounders of Australia (TLCCA) also agreed that:

“beyond the cGMP there are no defined minimum standards for chemotherapy compounding.”¹⁴⁷

TLCCA also noted that while the Interim Report pressed for the development of minimum standards, there was little consideration of the need for these standards to be auditable by an independent body, or for someone to oversee the minimum standards to ensure compliance. This is an integral requirement for the implementation of minimum standards and to ensure they are met.

The Panel agrees with the TLCCA that the current Good Manufacturing Practice (GMP) is an appropriate standard due to its global implementation and rigorous framework. However, the inclusion of PBA compounding standards allows for tailoring to the Australian operating environment. This would also assist in aligning non-TGA facilities with TGA standards, providing that suitable arrangements are included for monitoring, compliance and performance in relation to the approved standards.

RECOMMENDATION 10-1: CHEMOTHERAPY COMPOUNDING—UNIFORM MINIMUM STANDARDS

There should be a clear and uniform minimum set of national standards for all approved chemotherapy compounding facilities. These minimum standards should:

- a. be developed based upon current Good Manufacturing Practice and the Pharmacy Board of Australia compounding standards, therefore ensuring all Therapeutic Goods Administration licensed facilities will meet the minimum standards;
- b. not require that a compounding facility be Therapeutic Goods Administration licensed to meet minimum requirements;
- c. reflect the various settings that are appropriate for the preparation of chemotherapy medicines, including ‘urgent’ preparations in a hospital or community pharmacy setting; and
- d. detail specific and measurable requirements that will be audited to maintain approval to operate as a chemotherapy compounding facility.

The Pharmacy Board of Australia, or appropriate regulatory body, should be adequately resourced to monitor compliance with these national standards.

10.2. CHEMOTHERAPY COMPOUNDING—PAYMENTS

The rationale for differential payments for compounding of chemotherapy preparations is not substantiated on the basis of patient risks or health outcomes for

¹⁴⁷ TGA Licensed Chemotherapy Compounders of Australia, Interim Report Submission No. 193, page 9.

medicines that must meet an appropriate level of quality, whether prepared at a facility that is Therapeutic Goods Administration licensed or not licensed.

Chemotherapy compounding is the preparation and supply of chemotherapy medicines. It is a highly specialised area within pharmacy practice. Less than fifty pharmacies supply 70 per cent of all chemotherapy compounding in Australia. To assist with the costs of these medicines, prices are subsidised under the PBS.

The government recognises that chemotherapy compounding requires specialised preparation methods. Fees are therefore paid to participating pharmacists in accordance with the Efficient Funding of Chemotherapy (EFC) measure. For community pharmacies these fees include:

- ready-prepared dispensing fee (\$7.02);
- preparation fee (\$83.22);
- distribution fee (\$25.92); and
- diluent fee (\$5.14).

Public hospital pharmacies authorised to supply PBS-subsided medicines are paid on a similar basis however, they are not currently eligible for the distribution or diluent fees.

As part of the PBS Access and Sustainability Package, the Chemotherapy Compounding Payment Scheme (CCPS) was introduced by the government as a revised payment arrangement for compounding fees that related to eligible EFC PBS claims. The scheme established a two-tier fee structure consisting of \$40 per eligible PBS claim for compounding and an additional \$20 for facilities that hold a TGA licence.

From the submissions received, there was a strong view that no therapeutic difference exists between products that are produced by a TGA-licensed facility and those produced by a non-TGA-licensed facility. This was noted in the SHPA submission:

“SHPA supports the harmonising of equitable payments for chemotherapy at the level of current remuneration received by TGA licensed supply sources. SHPA is confident that Australians being treated with chemotherapy in public or private hospitals receive highly effective chemotherapy medicines regardless of the TGA licensing of their originating facility. According to our members there is no therapeutic difference in chemotherapy medicines provided by TGA licensed compounders and non-TGA licensed compounders. There is no difference in efficacy or effectiveness, and both will achieve the same clinical and patient outcomes.”¹⁴⁸

There were submissions that had opposing arguments. Some respondent’s suggested that there are differences between the qualities of a licensed TGA facility when compared with a non-licensed TGA facility, and remuneration should be different. For example, TLCCA stated:

“While some non-TGA compounding facilities may contend that products are ‘identical’, this is not the view of many private and public hospitals which have mandated a TGA licence as the minimum requirement to participate in tender processes. This behaviour demonstrates that the users of compounded products do not support the view that there is no difference between non-TGA and TGA licensed products.”¹⁴⁹

¹⁴⁸ Society of Hospital Pharmacists of Australia, Interim Report Submission No. 183, page 37.

¹⁴⁹ Licenced Chemotherapy Compounders of Australia (Baxter Healthcare), Interim Report Submission No. 193, page 5.

Facilities that hold a TGA licence contended that they had gone through greater effort and costs to acquire and maintain the license, and they should be remunerated an additional \$20 to acknowledge the extra cost. The Panel is not satisfied of there being sufficient evidence to demonstrate the value of those additional costs or whether they should be valued at \$20 per claim.

Furthermore, the Panel does not consider that medicines compounded in a TGA-licensed facility are any safer than those compounded in a non-licensed facility. There was no evidence provided to the Panel to refute this, including from the TGA. If TGA-licensed facilities were remunerated, it would imply that there is a difference in quality or safety, which is not the case. The Panel instead considers that appropriate standards should be in place for chemotherapy preparations produced in any relevant facility, to ensure that these preparations meet a required level of quality, with minimum risks to patient harm.

RECOMMENDATION 10-2: CHEMOTHERAPY COMPOUNDING—PAYMENTS

There should be a no difference in the remuneration paid by the Australian Government for the compounding of chemotherapy medicines in any facility that meets the minimum quality and safety standards. In particular, there should be no additional payment for medicines prepared in a facility that meets or exceeds the minimum standards.

10.3. CHEMOTHERAPY COMPOUNDING—PRACTICE MODELS

There are a number of good practice chemotherapy compounding models that can be leveraged to improve access to existing compounding arrangements.

There are a variety of chemotherapy compounding settings and facilities operating in Australia. Not all of these are utilised across every Australian health service. Some facilities operate more efficiently than others and can be used to further guide improved access to compounded chemotherapy medicines.

For example, in New South Wales there is a well-developed practice model in place for nuclear medicine. In maintaining its own medical cyclotron on-site, the Royal Prince Alfred Hospital provides centralised access for other public hospitals across New South Wales to radiopharmaceuticals for use in Positron Emission Tomography (PET).

There are a number of good practice chemotherapy compounding models that could be leveraged to improve access to existing compounding arrangements, provided that this could be achieved without an increased risk of patient harm. This is further reiterated by SHPA:

“Depending on existing arrangements greater distribution of medicines prepared onsite can be beneficial; however care must be taken to ensure compliance with guidelines. Consultation between interested organisations would be necessary to trade possibilities are optimised in this highly restricted area.”¹⁵⁰

However, it is noted by the Australian Private Hospitals Association that:

¹⁵⁰ Society of Hospital Pharmacists of Australia, Interim Report Submission No. 194, page 38.

“Consideration should also be given to allowing such models in the private sector particularly noting that there are a number of major providers of integrated cancer care in the private sector and that the private sector also plays a significant role in delivery of cancer services to regional centres.”¹⁵¹

Private hospitals, public hospitals and other healthcare facilities may already have the ability to take part in the trading of medicines prepared on-site. As such, they could provide best practice references for improving access to chemotherapy medicines.

RECOMMENDATION 10-3: CHEMOTHERAPY COMPOUNDING—PRACTICE MODELS

Existing practice models in place in public hospitals for limited trade of medicines prepared on-site should be considered for providing greater access to chemotherapy arrangements.

¹⁵¹ Australian Private Hospitals Association, Interim Report Submission No. 191, page 8.

11. HOSPITAL PHARMACIES

11.1. MANAGING MEDICINE RISKS FOR PATIENTS

Hospital discharge processes lack a robust framework to support communication between a patient’s hospital, primary care provider and community pharmacy. This can make medicine management difficult while creating risk for the patient.

The likelihood of a patient receiving education about new medication, or the reconciling of new medicines against existing medications, is dependent upon the discharge policies and practices in effect at the place of treatment. This is due to an inconsistent discharge framework—a recognised issue within the Australian health system.

The transition for patients leaving hospital and returning to community care is well understood as a significant risk period for continuity of care resulting in poor patient outcomes.

The Panel supports greater liaison between hospitals and community pharmacies to enable an optimal transition of care for patients returning home from hospital or moving into residential services.

In Option 2-10 of the Interim Report, the Panel commented that hospitals should work closely with community pharmacies to ensure patients have access to the medicines they require upon discharge. Consistent policies and procedures are required to ensure each patient has access to the medicines they require, relevant education, and information relating to their medications. This may involve the hospital providing a ‘discharge pack’ with an appropriate level of patient medication to allow the patient to safely access a community pharmacy, and their community health practitioner, without running short of medication.

In its response to the Interim Report, SHPA noted that:

- “current Public Hospital Pharmaceutical Reforms arrangements (Pharmaceutical Reforms) where hospitals in participating states and territories commit to provide patients with access to a month’s worth of medicines upon discharge with appropriate counselling and clinical review”¹⁵² (i.e. to ensure patients receive either a thirty-day supply of PBS medicines or, after review by a clinical pharmacist, a prescription for thirty days of medicines, to be filled at a convenient community pharmacy); and
- the current ‘inconsistency’ it observed with regard to ‘discharge packs’ reflects the lack of participation of some states and territories in the Pharmaceutical Reforms arrangements, rather than any explicit public hospital pharmacy discharge practice.¹⁵³

Prior to the Pharmaceutical Reforms, hospitals typically supplied two to seven days of discharge medicines. This was not sufficient to enable an optimal transition of care for some patients returning home or moving into residential services. This contributed to poor patient outcomes and increased re-hospitalisations.

¹⁵² Society of Hospital Pharmacies Australia, Interim Report Submission No. 194, page. 14.

¹⁵³ Ibid.

New South Wales and the Australian Capital Territory are the only jurisdictions that do not participate in the Pharmaceutical Reforms—patients receiving care at public hospitals in their jurisdiction therefore cannot access PBS funded medicines under the reform arrangements. However, access to the PBS HSD Program is available under section 100, which is separate from the Pharmaceutical Reforms.

SHPA notes that feedback from its members has shown an ongoing concern regarding the inherent risks of re-hospitalisations in New South Wales and the Australian Capital Territory where ‘7-day supply’ remains a common occurrence. Patients living in these jurisdictions would receive safer, better quality care, if the New South Wales and the Australian Capital Territory governments were to sign up to the Pharmaceutical Reforms as a matter of priority. The Panel, like SHPA, supports consistency in public hospital pharmacy discharge practice and processes in order to maintain equity and uniformity for all Australian patients.

While acknowledging SHPA’s position, the Panel also notes that the Pharmaceutical Reform Agreement is just one mechanism available to jurisdictions to address continuity of patient care to medicine supply. In this sense, there is nothing to stop jurisdictions from implementing their own measures to improve quality of care for patients transitioning between hospitals and the community.

The Panel, like SHPA, supports consistency in public hospital pharmacy discharge practices and processes in order to maintain equity and uniformity for all Australian patients. The Australian Government should make all efforts to enable this to occur.

While the Panel has seen examples of effective collaboration between hospitals and community pharmacies, the Panel believes there is significant opportunity to improve upon this area for the overall benefit of patients.

One study that documented medicine-related problems post-discharge for cardiology patients found:

“No medicine-related problems were recorded for five patients, while 398 medicine-related problems were identified among the remaining 71 patients. The average number of medicine-related problems was 5.6 per patient. Uncertainty regarding the aim of the medicine accounted for 32% of the identified problems, medicine interactions accounted for 22% and adverse drug reactions accounted for 15%. Under-use of medicines accounted for 12% of problems. There were differences in medicines listed on the discharge summaries, GP referral forms and home medicines review reports. However, the average time between when these documents were written was not reported so the import of these differences is unclear.”¹⁵⁴

In its submissions to the Interim Report, both the PSA and the National Pharmacies Friendly Society Medical Association (NPFMSMA) expressed support for the development of consistent policies for discharge and transition framework. For example, the PSA believed that the post-discharge transition period warranted more attention, suggesting:

¹⁵⁴ L. Roughead et al., Literature review: Medication safety in Australia (on behalf of Australian Commission on Safety and Quality in Health Care) (2013).

“Medication related admissions account for 20–30% of all hospital admissions for people over 65 ... [The] PSA would recommend that the Panel focus on discharge interventions for which evidence exists: those that involve a pharmacist. For example medicines reconciliation, post discharge [HMR] and pharmacists in transitional care management/liason pharmacists ...”¹⁵⁵

The Panel considers that the introduction of a universal and comprehensive medication record accessible to all relevant health professionals could considerably improve how hospitals and pharmacists manage and communicate a patient’s discharge and transition back into the community. Coupling this record with a clear framework and communication channel for the discharge process could also considerably improve the patient’s health outcomes.

RECOMMENDATION 11-1: MANAGING PATIENT MEDICINE RISKS ON DISCHARGE FROM HOSPITAL

Hospitals should work closely with community pharmacies to ensure patients have access to the medicines they require upon discharge. Consistent policies and procedures are required to ensure each patient has access to the medicines they require as well as appropriate education and information relating to their medications.

The Australian Government should also increase national consistency in public hospital discharge practices, including the supply of medicines on discharge.

11.2. LEVERAGING COMMUNITY PHARMACY AND HOSPITAL PHARMACY CAPABILITY AND SERVICES

The focus of this Review was primarily on the community pharmacy settings. However, the Panel also acknowledges the significant role that both Primary Health Networks and Health Care Homes and hospital pharmacists play in ensuring Australians have appropriate and convenient access to medicines and related services.

Primary Health Networks and Health Care Homes

The Panel is aware that the government has introduced new initiatives—PHNs and HCH—that create an integrated, team-based approach to improving the coordination of patient care at the community level. Pharmacists are intended to have a key role in these new care models, including optimising medication regimens, increasing medicines safety and facilitating appropriate transitional care to improve the health outcomes for patients with chronic and complex conditions.

On July 2015, following an independent review, the government established PHNs. This was pursuant to a recommendation that more capacity is required to reduce fragmentation of care by integrating and coordinating health services, supporting the role of general practice and leveraging and administering health program funding.

PHNs were therefore established with the key objectives of increasing efficiency and effectiveness of medical services for patients, particularly those at risk of poor health outcomes, and improving coordination of care. This should ensure patients receive the right care in the right place at the right time.

¹⁵⁵ Pharmaceutical Society of Australia, Submission No. 183, page 14.

The Panel also notes that PHNs are well placed to:

- optimise, and improve, effective shared healthcare responsibilities for patients living in rural and remote communities that have significant services and infrastructure related challenges; and
- improve transitional care—to have pharmacists play a more integral part of people’s experience of Australia’s healthcare system, whether in the community, or in hospitals, or during a patient’s transition between the two, or in RACFs.

While PHNs were established during the time of this Review and have not been operating long enough to be evaluated effectively, the Panel acknowledges their potential future value in driving more integrated healthcare in Australia. This includes the important role of a PHN in addressing patient related risks as they transition between healthcare facilities and providers.

It is a matter for government to decide where pharmacy sits within the PHN collaborative primary healthcare arrangements. It is important however, that as the pharmacy role is defined, PHNs update their guidelines and other relevant documents, in consultation with relevant pharmacists and peak bodies, to ensure that community pharmacies and independent pharmacists are identified and represented as key stakeholders.

The Panel has also noted that a central element of the HCH trials is a tailored and shared care plan for patients. The 10 PHNs that are conducting the HCH trials will support GP-led care teams that will use an expanded staffing model in which pharmacists, nurses and other allied health providers assume greater care management roles to ensure that eligible patients receive the highest quality support.

The HCH shared care plans for patients should include a plan to manage their medication needs and, where clinically relevant, teams should work collaboratively with the patient’s pharmacy to ensure provision of necessary medication support. Integrating pharmacists within the HCH team has the potential to reduce the use of multiple medicines and medication-related hospital admissions/readmissions, leading to a reduction of overall primary care expenditure and savings to the broader health sector.

Hospitals

The Panel recognises that improved transitional care is a complex area that deserves equal consideration by both the hospital and community pharmacy workforces. The non-community pharmacy setting cannot be ignored if Australia is to achieve a greater focus on integrated, rather than episodic, care. Pharmacy is an essential element of both primary and acute healthcare and is a shared responsibility that requires greater liaison if the healthcare system is to remain sustainable.

This is a view that is supported by SHPA, which is keen to ensure that:

“policy and remuneration planning for community pharmacies supports greater liaison with hospital pharmacies for the benefit of patients, rather than being limited to non-collaborative dispensing or patient counselling.”¹⁵⁶

As noted earlier in this Report, a universal medication record would facilitate liaison and communications between hospitals and community pharmacy. There are also opportunities to use technology solutions to increase transparency and collaboration in clinical decision-making—for example, with non-admitted patients undergoing chemotherapy treatment.

The Panel also notes that, from 1 January 2017, the contribution rate for PBS medicines for general patients as outpatients at public hospitals in most states and territories in Australia is \$31.00—as opposed to the usual maximum cost for a pharmaceutical benefit item at a community pharmacy, which is \$38.80 for general patients.

In public hospitals from 1 January 2017:

- all concessional patients pay a maximum of \$6.30—except in South Australia, where Department of Veterans’ Affairs (DVA) card holders are treated as general patients, and in New South Wales, where DVA White Card holders are treated as general patients; and
- in states participating in the PBS Public Hospital Pharmaceutical Reforms, patients pay the Safety Net value of an item when it is listed in the PBS and a maximum of \$38.80 for items not listed in the schedule.

The Panel made every effort to find out the reason for these price differences—that is, what consumers pay for their medicines in hospitals and as outpatients as opposed to what they pay in the community—but it had no success.

In addition, a medicine that is available to a consumer in the hospital may not be the same brand as available at their community pharmacy. This can create confusion to the consumer and potentially lead to medicine mismanagement.

As noted by SHPA and others, the adoption of the PBS Public Hospital Pharmaceutical Reforms in all states and territories (with the exception of New South Wales and the Australian Capital Territory) has enabled patients being discharged from public hospitals to be provided with access to a one-month supply of PBS medicines subsidised by the government.

Despite recent moves by the New South Wales Government, access to medicines for Australians not living in participating PBS Public Hospital Pharmaceutical Reform jurisdictions remains a challenge, with seven-day supply and invoices a common occurrence. The Panel agrees with SHPA and considers that New South Wales and the Australian Capital Territory patients would receive safer, better quality care if these governments made signing up to the PBS reforms a matter of priority.

The issues with transitional care highlighted above show that Australia has a disjointed, fragmented system of medicine management between the primary and acute care settings that creates undue problems in the timely access to affordable medicines and unnecessary confusion for consumers.

¹⁵⁶ Society of Hospital Pharmacists of Australia, Submission No. 194(b), page 7.

The Panel believes these discrepancies (barriers) need to be removed if we want to achieve better quality use of medicines and better continuity of care for consumers.

While these all remain important issues, the Panel notes that the government is currently reviewing the efficiency and effectiveness of the PBS in meeting the medication needs of patients of public and private hospitals in Australia and has therefore not provided any specific recommendations in this area.¹⁵⁷ It is noted that the findings of the PBS Pharmaceuticals in Hospitals Review are expected to be released later this year.

11.3. NEED FOR A COORDINATED VISION FOR PHARMACY

The Panel acknowledges that the government has introduced PHNs and HCH to create a team-based approach to improve patient care at the community level. It also recognised that there needs to be greater liaison between community pharmacies and hospitals to improve transitional care. A coordinated pharmacy vision for the broader primary care landscape across different settings is therefore needed if Australia is to achieve a greater focus on integrated rather than episodic care.

At present, it is still unclear what the government’s overall vision for pharmacy is within the broader primary healthcare system and if a continuum of pharmacy services and programs across different settings is to be achieved.

Given that there is no overall strategic vision, it is incumbent on the government, along with peak professional organisations, to lead this agenda. As stated by the PSA in its submission:

“[The vision should be to] ..have pharmacists deliver services tailored to consumer need, delivered at the right time, by the pharmacist with the right skill set in the right setting”.¹⁵⁸

Until pharmacist services are truly valued for the outcomes that they can deliver to consumers we will continue to have episodic rather than fully integrated care.

¹⁵⁷ Department of Health, Pharmaceutical Benefits Scheme (PBS) Pharmaceuticals in Hospitals Review, commenced in May 2017.

¹⁵⁸ Pharmaceutical Society of Australia, Interim Report Submission No. 183, page 4.

12. APPENDICES

The following appendices are included to provide supporting information and context to the Final Report:

- Appendix A: Abbreviations and Explanations
- Appendix B: Review Terms of Reference
- Appendix C: Stakeholder Engagement
- Appendix D: Cross-references to Interim Report
- Appendix E: Responses to the Interim Report

APPENDIX A: ABBREVIATIONS AND EXPLANATIONS

A description of the terms used in this Report is provided below.

TERM	DEFINITION
5CPA	The Fifth Community Pharmacy Agreement between the Commonwealth and the Guild dated 3 May 2010.
6CPA	The Sixth Community Pharmacy Agreement between the Commonwealth and the Guild dated 24 May 2015.
Act	The <i>National Health Act 1953</i> (Cth)
AHPRA	Australian Health Practitioner Regulation Agency
AHS	Aboriginal Health Service
APHA	Australian Private Hospitals Association
Approved Pharmacist	Has the meaning given in Part VII of the Act.
Approved Supplier	Has the meaning given in Part VII of the Act.
Closing the Gap (CTG) Program	Part of an Australian Government strategy that aims to reduce disadvantage among Aboriginal and Torres Strait Islander people with respect to life expectancy, child mortality, access to early childhood education, educational achievement and employment outcomes.
Community Pharmacy Agreements (CPAs)	The series of agreements between the Commonwealth and the Guild (since 1990).
Community Pharmacy Programs (CPPs)	Has the meaning given in clause 6 of the Sixth Community Pharmacy Agreement.
Community Service Obligation (CSO)	Arises when a government specifically requires a public enterprise to carry out activities relating to outputs or inputs which it would not elect to do on a commercial basis. Under these arrangements, payments are provided directly to eligible wholesalers (known as CSO Distributors) who supply the full range of PBS medicines to any pharmacy, usually within twenty-four hours, and that meet compliance requirements and service standards.

TERM	DEFINITION
CSOD	Community Service Obligation Distributors
Complementary medicine	Also known as ‘traditional’ or ‘alternative’ medicines. Complementary medicines include vitamin, mineral, herbal, aromatherapy and homeopathic products. They may be either listed or registered, depending on their ingredients and the claims made.
Consumers Health Forum of Australia (CHF)	Represents the interests of Australian healthcare consumers at a national level.
Determination	The determination in force from time to time under subsection 98B(1)(a) of the Act.
Dose Administration Aids (DAA)	A tamper-evident, adherence device developed to assist medication management for a consumer by having medicines divided into individual doses and arranged according to the dose schedule. It can be either a unit-dose pack (one single type of medicine per compartment) or a multi-dose pack (different types of medicines per compartment).
DVA	Department of Veterans’ Affairs
Efficient Funding of Chemotherapy (EFC)	Refers to PBS medications that are distributed under alternative arrangements provided for under section 100 of the Act.
FDA	Food and Drugs Association
GMP	Good Manufacturing Practice
Highly Specialised Drugs (HSDs)	Drugs that are used for the treatment of complex medical conditions that require ongoing specialised medical supervision. HSDs are subsidised through the PBS and administered under section 100 of the Act.
Home Medicines Review (HMR)	A comprehensive clinical review of a patient’s medicines, conducted in their home by an accredited pharmacist on referral from the patient’s general practitioner (GP). The patient may choose to be referred to their usual community pharmacy or an accredited pharmacist who meets the patient’s needs. The service involves cooperation between the GP, pharmacist, other health professionals and their patient (and, where appropriate, their carer).

TERM	DEFINITION
MSAC	Medical Services Advisory Committee
Medicare Benefits Schedule (MBS)	Contains a list of Medicare services subsidised by the Australian Government. The schedule is part of the wider Medicare Benefits Scheme managed by the Department of Health and administered by Department of Human Services.
NACCHO	National Aboriginal Community Controlled Health Organisation
National Medicines Policy (NMP)	A cooperative endeavour to bring about better health outcomes for all Australians, focusing especially on people’s access to, and wise use of, medicines. The term ‘medicine’ includes prescription and non-prescription medicines, including complementary healthcare products.
NPFSMA	National Pharmacies Friendly Society Medical Association
Panel	The three independent reviewers appointed to conduct the Review of Pharmacy Remuneration and Regulation.
PET	Positron Emission Tomography
Pharmaceutical Benefit	Has the meaning given in Part VII of the Act.
Pharmaceutical Benefits Scheme (PBS)	An Australian Government scheme that provides reliable, timely and affordable access to a wide range of medicines for all Australians.
Pharmaceutical Society of Australia (PSA)	The peak national professional pharmacy organisation representing Australia’s pharmacists. PSA’s core business is focused on practice improvement in pharmacy through the provision of continuing professional development and practice support.
Pharmacy Guild of Australia (the Guild)	The national peak body representing community pharmacy. It seeks to serve the interests of its members and to support community pharmacy in its role delivering quality health outcomes for all Australians.
Pharmacy Location Rules (the Rules)	The rules determined by the Minister under section 99L of the Act.
Pharmacy Practice	Supports pharmacies which provide medicines to consumers in

TERM	DEFINITION
Incentive Program PPIP	instalments, when directed by the prescriber, or packed into dose administration aids to assist with improving the quality use of medicines. Clinical interventions are also supported through an incentive payment to participating pharmacies.
PTP	Pharmacy Trial Program
PhARIA	The <i>Pharmacy Accessibility Remoteness Index of Australia</i> quantifies the degree of remoteness (both geographic and professional) of pharmacies for the purposes of administering the RPMA and other rural pharmacy allowances administered by the federal Department of Health. The PhARIA was designed specifically to aid in the equitable distribution of financial assistance to rural and remote pharmacies.
Polypharmacy	The use of five or more medicines, including prescribed, over-the-counter and complementary medicines, which may be a useful prompt for medicine review.
Primary Health Network (PHN)	Established with the key objectives of increasing the efficiency and effectiveness of medical services for patients (particularly those at risk of poor health outcomes) and improving the coordination of care arrangements.
Quality Care Pharmacy Program (QCPP)	Introduced by the Guild and PSA in 1997 as a quality assurance program for community pharmacy that provides support and guidance on professional health services and pharmacy business operations. By increasing the number of accredited pharmacies in Australia, QCPP aims to ensure that community pharmacies provide quality professional services and customer care.
Quality Use of Medicines (QUM)	Forms one of the central objectives of the NMP, as it involves selecting health management options wisely; choosing suitable medicines (if a medicine is considered necessary); and using medicines safely and effectively
RACFs	Residential Aged Care Facilities
Remote Area Aboriginal Health Services Program (RAAHS)	A special supply arrangement administered under section 100 of the Act. Under the program, patients receive their medicines from their local community pharmacy, enabling these PBS medicines to be provided to Aboriginal and Torres Strait Islander peoples, as they present to the RAAHS without the need for a normal prescription form and without being

TERM	DEFINITION
	charged. The program was implemented in 1999 to address the geographical, cultural and financial barriers that Aboriginal and Torres Strait Islander peoples living in remote areas face in accessing essential PBS medicines.
RMMR	Residential Medication Management Review
Repatriation Pharmaceutical Benefits Scheme (RPBS)	Established under the <i>Veteran’s Entitlements Act 1986</i> (Cth); <i>Military Rehabilitation and Compensation Act 2004</i> (Cth); and <i>Australian Participants in British Nuclear Tests (Treatment) Act 2006</i> (Cth).
Rural Pharmacy Maintenance Allowance (RPMA)	A monthly allowance paid to eligible proprietors of section 90 approved pharmacies in recognition of the additional financial burden of maintaining a pharmacy in rural and remote areas of Australia.
Safety Net	Reduces the cost of medicines for individuals and families once the PBS Safety Net threshold has been reached.
Society of Hospital Pharmacists of Australia (SHPA)	A professional association for pharmacists, pharmacist interns, pharmacy technicians and pharmacy students. It aims to support and provide professional development to its members and be an advocate for improved medicines management in policy and practice.
Therapeutic Goods Administration (TGA)	Australia’s regulatory authority for therapeutic goods and devices. The TGA conducts a range of assessments and monitoring activities to ensure that products are of an acceptable standard.
TLCCA	TGA Licensed Chemotherapy Compounders of Australia

APPENDIX B: REVIEW TERMS OF REFERENCE

Pharmacy and pharmacists play an important role in the delivery of primary health care in the Australian Community. As successive Community Pharmacy Agreements have seen increasing investment by Government in supporting pharmacy, the Review of Pharmacy Remuneration and Regulation (the Review) is intended to provide recommendations on future remuneration, regulation including pharmacy location rules, and other arrangements that apply to pharmacy and wholesalers for the dispensing of medicines and other services, including the preparation of infusions or injections for chemotherapy, provided under the Pharmaceutical Benefits Scheme (PBS), to ensure consumers have reliable and affordable access to medicines.

In consideration of the Commonwealth's roles and responsibilities in health, in the context of the Australian Government's Reform of Federation White Paper, the Review's recommendations are directed toward achieving arrangements which are transparently cost-effective for Government and consumers, financially sustainable, considerate of current and future expectations for the community pharmacy sector, and effective in delivering quality health outcomes and promoting access and quality use of medicines, in the context of Australia's National Medicines Policy (NMP) and the broader Australian Health sector.

The Review will provide a report to the Minister for Health by 1 May 2017.

In making its recommendations, the Review has considered:

PHARMACY REMUNERATION FOR DISPENSING

1. The appropriate level and structure of remuneration for community pharmacy for the dispensing of medicines under the PBS consistent with the NMP and its role in delivering health outcomes for patients, including consideration of:
 - a. the costs and cost drivers associated with dispensing;
 - b. market considerations, including likely growth and distribution of demand and community need, based on medicines listing projections and population and healthcare trends (in Australia and overseas);
 - c. funding models that could be used, including comparable overseas examples; and
 - d. different funding structures that may be appropriate for different business models for delivery of pharmaceutical services (including the preparation of chemotherapy infusions or injections) in different settings and how any new structures improve access to, affordability and quality use of medicines.

REGULATION

2. The appropriate regulation of pharmacy and pharmacy distribution, including the role of Pharmacy Location Rules in supporting access to medicines in Australia, including consideration of:
 - a. the costs and benefits of such structures, their consistency with current thinking for effective competition in a pharmacy environment and impacts on access and affordability for consumers and communities;

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- b. key components of such structures that are necessary to support access and quality use of medicines in the Australian population;
 - c. the role of government in the regulation of pharmacy and wholesalers; and
 - d. the impact of any recommendations for change on the community pharmacy sector and transitional arrangements that may be necessary to sustainably manage those impacts and how those recommendations improve access to, affordability and quality use of medicines.

WHOLESALE, LOGISTICS AND DISTRIBUTION ARRANGEMENTS

3. The appropriate level and structure of remuneration for wholesalers and pharmacies for wholesaling, logistics and distribution of medicines from manufacturer to community pharmacy, including consideration of:
 - a. regulatory requirements, standards and quality control to provide assurance of timely and reliable access and delivery;
 - b. the costs and cost drivers associated with timely supply consistent with the NMP, wholesaling, logistics and delivery;
 - c. the adequacy of funding to promote investment in supply chain infrastructure to meet future PBS supply and security needs; and
 - d. the relationships between manufacturer, wholesaler, distributor, delivery partner, pharmacy and government and how these impact consumer and community need.

ACCOUNTABILITY AND REGULATION

4. What regulatory arrangements are necessary to promote high standards of delivery and accountability amongst pharmacies, wholesalers, manufacturers and other entities receiving funding under the PBS, and the data required to monitor and assess these standards of delivery and community outcomes.

CONSUMER EXPERIENCE

5. The consumer experience, including:
 - a. consumer attitudes to the services expected from community pharmacy;
 - b. consumer expectations regarding access to and affordability of medicines; and
 - c. consumer priorities regarding access to and quality use of medicines.

APPENDIX C: STAKEHOLDER ENGAGEMENT

The Panel undertook a comprehensive approach to engaging with multiple stakeholders and interested parties through all stages of the Review process. This included a series of bilateral meetings, public forums, online webcasts, site visits and presentations that have been summarised below.

A: Bilateral meetings—December 2015 to March 2016

In the lead-up to the release of the Discussion Paper, a series of bilateral meetings were held with the following organisations and individuals:

Australian Friendly Society Pharmacies Association	Australian Medical Association	Medicines Australia	McCarthy's Pharmacy Samford Chemmart Pharmacy	Cominos Pharmacy Services
Consumers Health Forum of Australia	National Aboriginal Community Controlled Health Organisation	Health Care Consumers' Association	Charnwood Capital Chemist	Ramsay Health Care
The Pharmacy Guild of Australia	Australian Self Medication Industry Ltd	Leukaemia Foundation	Guidlink	Melanoma Patients Australia
Pharmaceutical Society of Australia	Generic and Biosimilar Medicines Association	Lymphoma Australia	Pitcher Pharmacy	Medici Capital
National Pharmaceutical Services Association	Australian Private Hospitals Association	National Seniors Australia	Baxter Healthcare	ICON Group
Sigma Pharmaceuticals Limited	Catholic Health Australia	Epic Pharmacy	Slade Pharmacy	Australian Pharmaceutical Industries
Symbion EBOS Group	Chronic Illness Alliance	Scott McGregor, ACPA	Pfizer Australia	Friendly Society Medical Association (National Pharmacies)
Alzheimer's Australia	Arthritis Australia	National Pharmacy Association, United Kingdom	Boehringer Ingelheim	Professional Pharmacists Australia
Friendly Pharmacy High Wycombe	Australian Federation of AIDS Organisations	Canadian Pharmacist Association	Terry White Group	Diabetes Australia
Society of Hospital Pharmacists of Australia	Prof Lloyd Sansom	Pharmaceutical Services Negotiating Committee, United Kingdom	NPS MedicineWise	Australian Injecting & Illicit Drug Users league
Chemist Warehouse	NSW Users	Pharmacy Guild of New Zealand	Mouhamad Zoghbi	Hepatitis Australia
Mt Hawthorn Community Pharmacy	DHL Supply Chain Australia	Department of Health – Stakeholders	AIDS Association	Cancer Voices Australia

B: Public forums—August 2016 to September 2016

Following the release of the Discussion Paper, 15 public forums were held at locations in each state and territory as well as an online live national webcast.

Perth (1 August 2016)	Hobart (10 August 2016)	Albury–Wodonga (17 August 2016)	Broome (29 August 2016)
Adelaide (2 August 2016)	Launceston (11 August 2016)	Cairns (22 August 2016)	Darwin (30 August 2016)
Broken Hill (4 August 2016)	Canberra (15 August 2016)	Brisbane (23 August 2016)	Alice Springs (1 September 2016)
Melbourne (9 August 2016)	Wagga Wagga (16 August 2016)	Sydney (25 August 2016)	Live national webcast (7 September 2016)

Forum location	Registrations by affiliation ¹⁵⁹				Total
	Consumer	Pharmacist	Wholesaler	Organisations	
Adelaide	5	62	3	9	79
Brisbane	6	91	8	23	128
Canberra	3	42	2	30	77
Albury–Wodonga	2	26	0	1	29
Alice Springs	1	5	0	2	8
Broken Hill	4	11	0	0	15
Cairns	5	10	1	1	17
Darwin	4	15	2	0	21
Hobart	4	22	1	0	27
Launceston	0	22	2	1	25
Melbourne	8	73	12	23	116
Perth	5	102	1	14	122
Sydney	2	88	3	23	116
Wagga Wagga	0	18	0	2	20
Broome	0	4	0	0	4
Webcast	1	33	0	23	57 ¹⁶⁰
Total	50	624	35	152	861

¹⁵⁹ People were given the option to pre-register their interest in attending each of the public forums. In almost all instances the number of actual attendees at the forums surpassed the number of registrants.

¹⁶⁰ While fifty-seven registrations were received for the webcast, the number of live unique logins was 362. This figure does not include groups of people viewing the webcast from each unique login.

C: Bilateral Meetings—August 2016 to September 2016

Bilateral consultations were held with the following individuals and organisations:

Pharmacy 777 Group	NAB Health	Winnunga Nimmityjah Aboriginal Health Service	Cape York Pharmacy	Slade Health	Broome Regional Aboriginal Medical Service
Western Australian Department of Health	Fred IT Group	The Pharmacy Guild	Torres Strait Island Pharmacy	Guildlink	NT Department of Health
SA Health	Australian Healthcare Associates (AHA)	Murrumbidgee PHN	Dose Aid	Ventura Health	Danila Dilba Health Service
Australian Pharmaceutical Council	Victorian Government Department of Health and Human Services	Chemist Warehouse	Sigma Members—Discount Drug Stores and Chemist King	Professional Pharmacists Australia	Pharmacy Guild NT
Nunyara Aboriginal Health Service	Tasmanian Government Department of Health and Human Services	Jim Cominos	Pharmaceutical Defence Limited (PDL)	Kimberley Pharmacy Services, Broome and Fitzroy Valley	Central Australian Aboriginal Congress
Pika Wiya Health Service Corporation	The Pharmacy Board of Australia	The Salvation Army	QLD Health	Kimberley Aboriginal Medical Service	Nganampa Health Council
Departmental officers	NSW Health	Professor Andrew Wilson	Consumers Health Forum of Australia	Western NSW PHN	Southern Cross Care, Broken Hill
Bruny Island Pharmacy	Dover Pharmacy, Tasmania				

C: Bilateral Meetings—June 2017

Following the release of the Interim Report, the Review Panel consulted with peak health consumer, pharmacy and industry bodies who were representative of participants in the pharmacy supply chain, including:

The Pharmacy Guild of Australia	Consumers Health Forum of Australia	Pharmaceutical Society of Australia	Professional Pharmacists Australia	Chemist Warehouse	National Pharmaceutical Services Association
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D: National consultation site visits

The Panel conducted site visits at the following pharmacies:

Friendlies Pharmacy High Wycombe	National Pharmacies Norwood	Crossroads Pharmacy	Broken Hill Base Hospital Pharmacy
Pharmacy 777 Nollamara	Port Augusta Hospital	Amcal Pharmacy (Broken Hill)	Temby's Day and Night Pharmacy (Outback Pharmacies)
CP Peoples Chemist (Outback Pharmacies)	Capital Chemist Charnwood	The Yarrabah Aboriginal Centre	Fullife Pharmacy (Gympie)
Shane Jackson Pharmacy	Tolland Capital Chemist	Atherton Amcal Pharmacy	Amcal Max (Gympie)
Amcal North Hobart	Michael O'Reilly Pharmacy	Wesley Hospital	Chemist Warehouse Gympie
Chemmart Pharmacy Sorell	Mobray Capital Chemist	EPIC Pharmacy	Fitzroy Crossing Hospital
Pharmacist Advice	Priceline Pharmacy Launceston Plaza	Superpharmacy Plus (Stafford)	United Chemists Palmerston
Kings Meadows Capital Chemist	Capital Chemist Charnwood	Alice Springs Pharmacy	United Chemists Alice Springs

E: Presentations

The Panel also presented at the following forums as part of the National Consultation Process:

Sigma Members Advisory Committee	Pharmacy WA Forum	Pharmacy Connect Conference
PSA16 Conference	Friendlies Conference 2016	Pharmacy Choice Presentations (three separate presentations were delivered)

APPENDIX D: CROSS-REFERENCES TO INTERIM REPORT

The Review's Interim Report serves as an important reference to this Report and should be referred to provide further context to the findings and recommendations. A copy of the Interim Report can be accessed from the Review website: <http://www.health.gov.au/pharmacyreview>

The following table provides a cross-reference to linkages between the individual sections in the two publications.

FINAL REPORT	INTERIM REPORT
2.1 Medicine Pricing Variations	2.3 Pricing Variations
2.2 The \$1 Discount	2.4 The \$1 Discount
2.3 PBS Safety Net	2.5 PBS Safety Net
2.4 Consumer Information on Pharmacy Services	2.7 Consumer Information on Pharmacy Services
2.5 Consumer Medicines Information	2.8 Consumer Medicines Information
2.6 Electronic Prescriptions	2.9 The Benefits of an Electronic Health Record for Consumers
2.7 A Universal Health Record	2.9 The Benefits of an Electronic Health Record for Consumers
2.8 Managing Risks Associated with 'Channelling' Prescriptions	2.9 The Benefits of an Electronic Health Record for Consumers
3.1 Section 100 Remote Area Aboriginal Health Services Program	2.9 The Benefits of an Electronic Health Record for Consumers
3.2 Pharmacy Ownership and Operation by Aboriginal Health Services	9.3 Pharmacy Ownership and Operations by Aboriginal Health Services
3.3 Patient Labelling in Bulk Supply	9.3 Pharmacy Ownership and Operations by Aboriginal Health Services
3.4 Machine Dispensing in Remote Regions of Australia	10.6 Machine Dispensing
4.1 Community Pharmacy—Minimum Services	3.1 The Role of Community Pharmacy
4.2 Complementary Medicines in Community Pharmacy	3.3 Complementary Medicines 3.4 Pharmacy Only and Pharmacist Only Medicines (Schedule 2 and Schedule 3 Medicines) 3.5 Homeopathic Medicines 5.11 Therapeutic Goods Administration Resourcing and Role in Monitoring Performance
4.3 Pharmacy Only and Pharmacist Only Medicines (Schedule 2 and Schedule 3 Medicines)	3.4 Pharmacy Only and Pharmacist Only Medicines (Schedule 2 and Schedule 3 Medicines)
4.4 Homeopathic Products in Community Pharmacy	3.5 Homeopathic Medicines
5.1 Community Pharmacy Accounting Information	4.2 Sources and Transparency of Pharmacy Remuneration 4.3 Remuneration for Dispensing Services

FINAL REPORT	INTERIM REPORT
5.2 The Benchmark For Best Practice Dispensing	4.3 Remuneration for Dispensing Services 4.4 Basis of Efficient Dispensing Cost/ Remuneration
5.3 Remuneration For Dispensing Services	4.6 The Costs of Dispensing
5.4 Structure of Remuneration For Dispensing	4.7 Structure of Remuneration for Dispensing
5.5 Remuneration—Alternative Service Channels	4.8 Remuneration—Alternative Services Channels
6.1 Reforms to Pharmacy Location Rules	5.2 Reforms to Pharmacy Location Rules
6.2 Co-location of Community Pharmacies with Supermarkets	5.7 Pharmacy Location Rules and Supermarkets
6.3 Concentration of Pharmacy Ownership	5.6 Overlapping Ownership and Location of Pharmacies
6.4 Transparency in Government Programs	5.12 Transparency in Government Programs
6.5 The Rural Pharmacy Maintenance Allowance	5.9 The Rural Pharmacy Maintenance Allowance
6.6 Harmonising Pharmacy Legislation	5.10 Variations Among State and Territory Regulatory Arrangements Relating to Community Pharmacy
6.7 Evaluating, Monitoring and Reporting on Regulation	5.13 Evaluating, Monitoring and Reporting on Regulation
6.8 Therapeutic Goods Administration Resourcing and Role in Monitoring Performance	5.11 Therapeutic Goods Administration Resourcing and Role in Monitoring Performance
7.1 Ensuring Timely Medicine Access Through Community Pharmacy	6.2 Ensuring Timely Medicine Access
7.2 Supporting Access to High-Cost Medicines Through Community Pharmacy	6.2 Ensuring Timely Medicine Access
7.3 Supporting Access to Highly Specialised Drugs Through Community Pharmacy	6.3 Procedures and Remuneration for the Supply of High-Cost Medicines
7.4 Limiting the PBS Listing of Generic Medicines	10.5 Tightening the Listing of Generic Medicine
8.1 The Community Pharmacy Agreement Process	7.1 The Community Pharmacy Agreement Process Appendix F: A History of the Community Pharmacy Agreements (1990-2015)
9.1 Community Pharmacy Programs—Key Principles	8.1 Leveraging Pharmacy and Pharmacist Capability
9.2 Leveraging Pharmacy and Pharmacist Capability	8.1 Leveraging Pharmacy and Pharmacist Capability
10.1 Chemotherapy Compounding Standards	10.3 Chemotherapy Compounding Standards
10.2 Chemotherapy Compounding—Payments	10.2 Chemotherapy Compounding—Payments
10.3 Chemotherapy Compounding—Practice Models	10.4 Chemotherapy Compounding Practice Models
10.4 Limiting the PBS Listing of Generic Medicines	10.5 Tightening the Listing of Generic Medicine
11.1 Managing Medicine Risks for Patients	2.10 Managing Medicine Risks Associated with Hospital Discharge and Readmission
11.2 Leveraging Community Pharmacy and Hospital Pharmacy Capability and Services	2.10 Managing Medicine Risks Associated with Hospital Discharge and Readmission Appendix G: Parallel Initiatives to Improve Primary

FINAL REPORT	INTERIM REPORT
Healthcare Services	

APPENDIX E: RESPONSES TO THE INTERIM REPORT

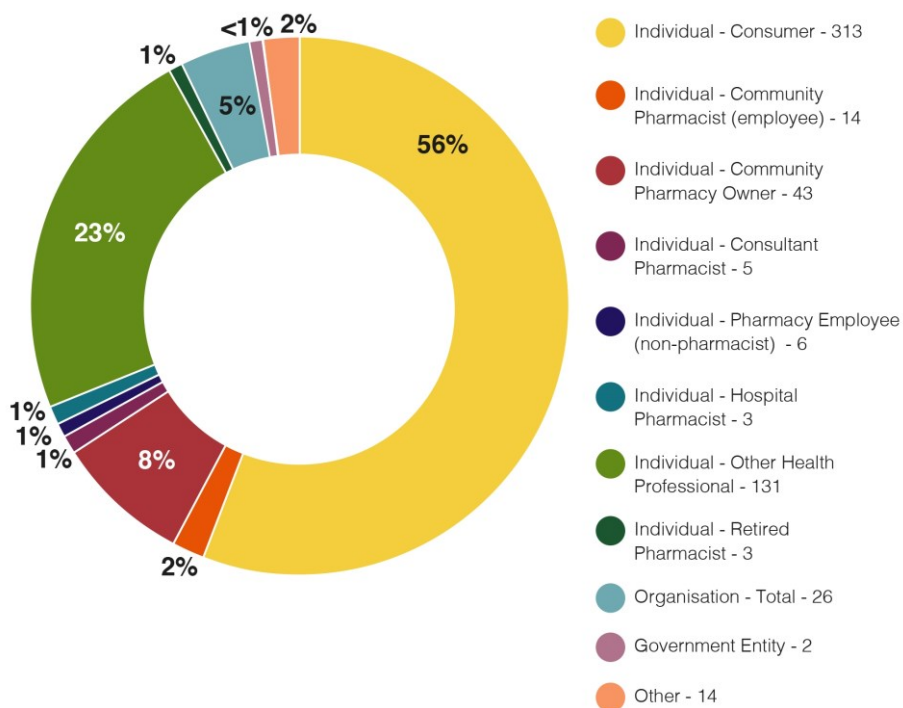
Following the release of the Review’s Interim Report in June 2017, the Panel sought feedback from interested parties on the proposed reform options through written submissions and responses to an online questionnaire. The information and commentary provided in the responses contributed to the Panel’s deliberations in formulating their final recommendations, together with submissions, consultations and commissioned research considered earlier in the Review.

In the interests of transparency, the number of responses and the level of support recorded for the reforms options are illustrated below. These figures represent an aggregate of both written submission and online questionnaire responses and do not contain options that did not receive any feedback.

The Panel is appreciative of the individuals and organisations that offered their feedback and insights on the reform options outlined in the Interim Report.

RESPONDENTS BY CATEGORY

The majority of responses to the Interim Report options were received from individual consumers (56 per cent) and other health professionals (23 per cent), as shown in the figure below. The Panel noted the relatively low interest from community pharmacy owners and employees towards the reform options, particularly given the potential impact on these stakeholders. These two groups represented only 10 per cent of all respondents.



NUMBER OF RESPONSES TO REFORM OPTIONS

The Panel received 197 written submissions in response to the Interim Report and 381 responses to the Interim Report online questionnaire. Proposed reform options relating to the sale of homeopathic products, complementary medicines, Pharmacy Location Rules in urban area, changes to the Community Service Obligation and minimum services for community pharmacies received the largest number of responses by stakeholders. This is demonstrated in the table below.



Level of support recorded for reform options

There was broadly a high level of support observed by respondents to the majority of the reform options contained in the Interim Report, as indicated in the table below. This included strong agreement for options relating to labelling, managing risks with hospital discharge, information on pharmacy opening hours, harmonising pharmacy legislation, transparency in pharmacy programs, standards for DAAs, medicines programs for indigenous Australians and chemotherapy compounding.

Respondents to the Interim Report generally disagreed with the proposed options for the sale of homeopathic products, the scope of Community Pharmacy Agreements for programs and services and Pharmacy Location Rules for urban areas.

Option	Agree	Disagree
2-1: Pricing variations	71%	29%
2-2: \$1 discount	67%	33%
2-3: PBS safety net	76%	24%
2-4: Labelling	95%	5%
2-5: Pharmacy atlas	80%	20%
2-6: Consumer medicines information	82%	18%
2-7: Electronic prescriptions	67%	33%
2-8: Electronic medications record	72%	28%
2-9: Electronic prescriptions	83%	17%
2-10: Managing medicine risks associated with hospital discharge and readmissions	94%	6%
3-1: Community pharmacies – minimum services	83%	17%
3-2: Complementary medicines	81%	19%
3-3: Placement of pharmacy only and pharmacist only medicines with a pharmacy	36%	64%
3-4: Sale of homeopathic products	14%	86%
4-1: Accounting information	47%	53%
4-2: Remuneration to be based on efficient costs of dispensing	53%	47%
4-3: Benchmark for an efficient dispense	43%	57%
4-4: Remuneration for dispensing - formula	54%	46%
4-5: Remunerations limits	55%	45%
4-6: Remuneration for other services	79%	21%
5-1: Location rules – removal and replacement	31%	69%
5-2: Location rules – alternative 1 for urban locations	30%	70%
5-2: Location rules – alternative 2 for urban locations	30%	70%
5-2: Location rules – alternative 3 for urban locations	67%	33%
5-3: Location rules – alternative 1 for non-urban locations	35%	65%
5-3: Location rules – alternative 2 for non-urban locations	63%	37%
5-4: Location rules – policy objective	74%	26%
5-5: Location rules – ownership and location	53%	47%
5-6: Information on pharmacy opening hours	87%	13%
5-7: 24 hour pharmacy information and related services	84%	16%
5-8: Rural pharmacy maintenance allowance	49%	51%
5-9: Harmonising pharmacy legislation	88%	12%
5-10: Transparency	89%	11%
5-11: Evaluation mechanisms	78%	22%
6-1: CSO removal, retention or replacement – alternative 1	61%	39%
6-1: CSO removal, retention or replacement – alternative 2	79%	21%
6-1: CSO removal, retention or replacement – alternative 3	65%	35%

Option	Agree	Disagree
7-1: Scope of CPA – dispensing	46%	54%
7-2: Scope of CPA - wholesaling	42%	58%
7-3: Scope of CPA – programs and services	27%	73%
7-4: Scope of CPA - participants	59%	41%
8-1: Dose administration aids - standards	90%	10%
8-2: Community pharmacy program – key principles	68%	32%
9-1: Access to medicines programs for indigenous Australians	90%	10%
9-2: Pharmacy ownership and operations by Aboriginal Health Services	74%	26%
10-1: section 100 specialised medicines	88%	12%
10-2: Chemotherapy compounding payments	75%	25%
10-3: Chemotherapy compounding – uniform minimum standards	88%	12%
10-4: Chemotherapy compounding – practice models	93%	7%
10-5: General medicine – listing arrangement	61%	39%
10-6: Machine dispensing	47%	53%



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