

# Review of **Pharmacy Remuneration and Regulation** Interim Report

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June 2017



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## STRATEGIC VISION AND INTENT

This Interim Report presents the findings and options for reform arising from the Review of Pharmacy Remuneration and Regulation (the Review). The issues in this report are complex, with the potential to impact significantly on community pharmacy. The Independent Expert Panel conducting the Review (the Panel) has decided to present options rather than draft recommendations in this Interim Report. The Panel is still considering these options and not all members agree with all options.

The vision underpinning the Panel's Interim Report is for an integrated and sustainable community pharmacy sector, which is adaptive to the inevitable changes in health care given Australia's ageing population, rapid advances in technology and ongoing Pharmaceutical Benefits Scheme (PBS) reform.

The Panel has determined its strategic vision and considered options for constructive pharmacy reform by anticipating the future requirements of community pharmacy in Australia.

The Panel considered what the sector will need to look like to be able to respond to the changing needs of the community and the growing demands on the public funding of the health system.

It is known that, with the rise of chronic conditions such as obesity, asthma, hypertension and diabetes, there will be a need for a greater focus on integrated, rather than episodic, care. It is also known that, while the Australian Government has a role to play, the pharmacy sector must take a shared responsibility for its own future if the system is to remain sustainable.

The key aspect of the Terms of Reference for this Review is consumer access – the safe, efficient and effective distribution of medicines listed on the PBS to Australians who need them, regardless of location – consistent with the National Medicines Policy (NMP).

The Panel therefore recognises that consumer access to PBS medicines in the community is part of a broader healthcare system framework and that options must be closely aligned with the objectives of the NMP.

The role of the supply chain for medicines, from manufacturers to consumers, through community pharmacy is to enable and ensure safe, timely, affordable and reliable supply of PBS medicines. Community pharmacy acts as an agent of the Australian Government and provides a key link in the distribution of PBS medicines.

As an agent of the Australian Government, community pharmacy can only be effective if it is appropriately remunerated and provided with appropriate incentives. The Australian Government and the public require the community pharmacy sector to operate efficiently and sustainably to ensure the best value from taxpayer and patient contributions.

The Panel has therefore focused closely on the requirement of a flexible framework for community pharmacy remuneration and regulation, which is:

- consistent with a forward-looking, twenty-year time frame
- allows and encourages innovation in community pharmacy
- is adaptable to the changing needs of the Australian public and the broader healthcare system.

These requirements have underpinned options presented in this report by the Panel.

The Panel noted that, while Australia's pharmaceutical supply chain has strengths, like any system there is always room to build and improve capabilities, ensuring efficiencies, responsiveness and sustainability.

The Panel recognises the key role of the Australian Government's funding in the pharmaceutical supply chain. The Panel considers, and the majority of stakeholders expect, that with such significant funding there should be a requirement for robust, inclusive scrutiny and transparency in community pharmacy.

There have been significant changes in the supply of medicines over the past twenty years and, from submissions received, the Panel expects this to continue and accelerate over the next twenty years.

In a highly dynamic environment, the Panel believes approaches favouring specific models of community pharmacy will be fraught and have therefore been avoided.

The Panel recognises that regulation presents costs to the public, the government and the participants in the medicine supply chain. Regulation must be sufficient but not excessive and must underpin sustainable consumer access.

Some areas of this Interim Report detailing the community pharmacy arrangement do not present options. Options have been deliberately left out because the Panel has not found compelling evidence for change.

Options presented by the Panel for feedback and consideration represent the Panel's desire to seek comments on alternatives to the current arrangements across a specific topic or area of regulation or remuneration.

The Panel has worked to ensure that the issues associated with pharmacy remuneration and regulation are properly scrutinised in this Interim Report, consistent with a commitment that no new matters will be introduced for the final report.

The Panel would like to thank all those who have already provided their time, support and submissions to this review process.

The Panel believes that this will ultimately deliver a final report to government which supports appropriate change, consolidation and new arrangements. These new arrangements will secure value and maximise opportunities for the community pharmacy sector and the Australian public.

## EXECUTIVE SUMMARY

The Panel has consulted extensively with respect to the Terms of Reference for this important Review. The Terms of Reference are very broad, necessitating wide-ranging considerations by the Panel.<sup>1</sup>

This Interim Report presents the Panel's key findings and a series of options – or possible reform paths – for stakeholders to consider.

In essence, this Interim Report continues the conversation flowing from the release of the Review of Pharmacy Remuneration and Regulation Discussion Paper in July 2016, which resulted in more than 500 submissions to the Review.

The options for reform presented throughout this report have consolidated issues raised within the submissions and other feedback as well as primary evidence gathered from work specifically commissioned by the Review.

The report and its options capture a broad range of thoughts and ideas surrounding reform but do not discuss specific issues of implementation. Although this review has not been concerned with the specifics of implementation, the Panel welcomes and encourages further submissions that provide additional insight into such matters where considered appropriate.

This Review is primarily consumer focused and, while the viability and sustainability of an effective community pharmacy network is a key consideration, the Panel has also sought to identify services and programs that are of benefit and the consumer ultimately values.

It is important that consumers can easily access information about the services offered

by community pharmacies. The Panel presents options to improve consumers' access to information. This is an important step toward improving services and the equity of medicine access.

Consumers self-select the pharmacy model that best suits their needs. This should continue to ensure a viable and vibrant pharmacy network. However, consumers also need, and expect, consistent minimum levels of service from all community pharmacies.

This includes community pharmacy providing consumers with professional advice on complementary medicines. To avoid potential harm, or the confusion between the efficacies of different types of medicines, pharmacists need to be easily accessible to give needed advice when consumers choose a complementary or pharmacy-only medicine.

The Panel considers that the implementation of technology and mechanisms to support the use of electronic prescriptions and electronic medical records is overdue. While recognising that governments and industry are working to implement technology enablers, the first step needs to be about timely recognition of an electronic script as a valid prescription record for legislative and Pharmaceutical Benefits Scheme (PBS) purposes.

The Panel has noted some good practices and initiatives across the broader health sector in this regard, including improved communication and synergies between hospital and community pharmacies. Nevertheless, there still remain significant opportunities to improve services and reduce medicine-related risks for patients moving between healthcare settings.

The Panel's strategic vision is the continued development of an innovative, sustainable community pharmacy network that is

<sup>1</sup> See Appendix B, Review Terms of Reference.

adaptive to the inevitable changes occurring in health care.

Emphasis must therefore be on remuneration which rewards efficient pharmacy operations while enabling appropriate payment for providing all consumers with equitable access to PBS medicines, consistent with the National Medicines Policy. Remuneration based on the efficient costs of dispensing within a best-practice pharmacy is appropriate and ensures a fair and equitable use of government funds while safeguarding the variety of business models that exist today.

These efficient costs are tied to the delivery of core services by the pharmacist for the supply of PBS medicines and related services as needed by the consumer. In order to establish an appropriate level of remuneration for community pharmacy, government needs information about the costs of these core services. At present, these costs and their associated value are difficult to determine, as the accounting information required to inform decision-making at this level is not being made available to government. Increased transparency in the use of these public funds is therefore strongly supported by the Panel.

Few, if any, submissions to the Review approved of all aspects of the current location rules. The Review notes the 2014 National Commission of Audit and the Competition Policy Review (the Harper Review) in 2015, which recommended the removal of these rules. Options for the removal and/or replacement of the location rules are presented in this Interim Report.

In a federation like Australia, there will often be variation in rules across the country. However, the variations in relevant legislation between states and territories are causing undue administrative burden for pharmacists

and confusion for some consumers, especially those travelling between jurisdictions.

Improving regulatory arrangements will help to ensure nationally consistent services for all consumers, better align services with consumer access, and increase innovation in community pharmacy while reducing barriers to entry.

While advances in medicines are always welcomed, the escalating cost of their listing on the PBS could serve to compromise current supply arrangements. For example, the increasing prevalence of high-cost medicines listed on the PBS, and their associated terms of trade, has challenged the ability of many community pharmacies to supply these medicines. The Panel considers that the risks to pharmacies in supplying high-cost medicines may be better managed by placing an upper limit on wholesale payments made by community pharmacists.

The remuneration and regulation for the wholesale supply of PBS medicines can also be improved. The options presented by the Panel remove unnecessary regulation and focus medicine distribution on the suppliers, who have the strongest incentives to ensure that consumers can access their medicines. The options will improve the effectiveness and accountability for the public funds used to support wholesaling and establish clear base-level terms of trade for community pharmacy.

The Panel notes that successive Community Pharmacy Agreements (CPA) have led to important improvements in the engagement of community pharmacy. But they have also limited improvement in some areas. The CPA remains an appropriate mechanism to discuss and agree on the delivery of PBS medicines through community pharmacy. However, all the parties responsible for the major

components of that delivery need to be represented as signatories to the agreement.

This is currently not the case, and the Panel considers that future agreements should be extended to include broader sector and consumer health representation.

The Panel notes the many bodies which have claimed to be representative of pharmacy and/or pharmacists across the country. These bodies have challenged the notion that community pharmacy models currently operating in Australia are all represented appropriately, in CPA negotiations to date, to ensure integration and coordination across the pharmacy profession.

National policy includes the integration and financing of community pharmacy as a primary health focus on patient outcomes delivered through safe and effective pharmaceutical care.

Across the broader health policy and systems management, there is a need for wider presence of community pharmacy input and, conversely, a wider representation of pharmacy and consumer leadership is required.

The Panel notes that community pharmacy in the longer term will necessarily be led across various private and professional bodies with various agendas, and the challenge for government will be to coordinate agreements with a number of representatives to ensure that public access and health priorities are managed effectively.

The Panel also considers that the CPA is not the right mechanism to negotiate and agree on programs and services that are not directly related to the delivery of PBS medicines. Such services are more appropriately agreed separately between the government and the

relevant key stakeholders and funded on their own merits and evidence base. For example, the Panel has noted that pharmacies provide many valuable programs and services that are either not funded or underfunded, and the Panel considers these merit separate negotiation and agreement outside the CPA.

Ensuring that Aboriginal and Torres Strait Islander people have timely and affordable access to PBS medicines and medication management support services remains a priority that underpins the desire to improve access and affordability in remote locations.

The Panel recognises the benefits of programs such as the Closing the Gap PBS Co-Payment Measure. However, such programs need to be properly integrated to ensure that the program benefits follow the individual, regardless of where their prescription is written or dispensed. The Panel also considers that the ability for an Aboriginal Health Service to employ pharmacists and operate a pharmacy should be trialled to see if it improves services and outcomes for Indigenous Australians.

This Interim Report further presents options for consideration in relation to:

- current complexities and administrative inefficiencies with the section 100 Highly Specialised Medicines program
- fees paid by the government for the compounding of chemotherapy medicines which meet minimum safety and quality standards
- use of mechanisms such as machine dispensing to improve access to medicines and related advice in remote communities.

The Panel re-emphasises that the options and alternatives presented in this Interim Report



are not designed to address potential implementation issues. They are options for reform. The Panel notes that the Australian Government's 2017–18 Budget contained a range of decisions that affect elements of this Review. These decisions impact upon a number of community pharmacy programs and the pharmacy location rules.

The Interim Report presents options to replace or modify the pharmacy location rules. However, given the Government's recent commitment to continue the current location rules, the Panel considers that its options to replace the current location rules are no longer immediately relevant to this Review. While they are included in the Interim Report for the sake of transparency around the Panel's consideration of the issue, they will not be presented in the Final Report.

However, the Panel will continue to consider the options presented to modify the location rules that have been put forward on the assumption that the current location rules will be retained.

The Panel therefore welcomes further discussion through the submission of new evidence and additional insights in relation to what community pharmacy should look like in the future. This will be important for informing the Panel's recommendations to be presented in the Review's final report.

## 1. THE CASE FOR CHANGE

Community pharmacy in Australia faces considerable challenges which threaten the viability of traditional pharmacy operating models, constraining the ability of pharmacists to deliver quality health outcomes. Stakeholders have noted in their submissions or in discussions with the Panel examples of sustained financial, regulatory and patient care pressures exerted on the sector. These pressures have led to pharmacy closures, skilled pharmacists exiting the industry and consumer expectations going unmet.

This highlights the need for improvement and reform within the sector, to better position community pharmacy to adapt to inevitable change and to secure its long-term sustainability as a valued community resource.

### 1.1. THE AUSTRALIAN HEALTHCARE SYSTEM

The broader health sector is undergoing a period of change which has influenced the environment that community pharmacy operates within. The impacts of such headwinds in the health system are likely to become more profound in the future and will continue to challenge the delivery and funding of pharmacy services.

#### TIGHTENING FISCAL CONDITIONS

Prevailing economic conditions in Australia and the focus of successive governments on budget repair have increased funding pressures in the health sector. This is likely to

further drive change in health policy and investment.<sup>2</sup>

According to the Australian Institute of Health and Welfare (AIHW), health expenditure has grown steadily from year to year. However, this growth has outpaced overall gross domestic product (GDP) over the decade from 2003–04 to 2013–14, with the average health expenditure rising 2.2 per cent higher than growth in GDP.<sup>3</sup>

Health expenditure in the future is widely expected to rise owing to increased demand for services from an ageing population, rising consumer expectations, more expensive technologies and pharmaceuticals, and a growing burden of chronic conditions.<sup>4</sup> However, in recent years, government contributions to the health system have slowed, and in some areas expenditure has declined.<sup>5</sup>

As the funding envelope becomes more constrained and the demand for health services continues to grow, government will seek to maximise the return on investment in the health system through increased productivity and efficiency in the delivery of services. The focus of funding in the health system will be on services that deliver the best patient health outcomes and value for money. It is prudent in such economic conditions that government remuneration for community pharmacy is considered in a similar light.

<sup>2</sup> Department of Health, *Annual report 2015–16*, page 4.

<sup>3</sup> Australian Institute of Health and Welfare, [Australia's health system](#) (2017).

<sup>4</sup> Department of the Prime Minister and Cabinet, *Reform of the Federation White Paper: Issues paper* (2014).

<sup>5</sup> Australian Institute of Health and Welfare, [Australia's health system](#) (2017).

## ONGOING REFORMS

Successive governments have highlighted the need to reform and modernise Australia's healthcare system, ensuring its long-term viability. Recently, key parts of the health system have come under close scrutiny, encouraging sustainable change surrounding the delivery of health outcomes. This includes reform in the areas of primary health care, mental health programs and services, the Pharmaceutical Benefits Scheme (PBS), aged care, public hospital funding and digital health.

These reforms have sought to develop a health system that is more patient-centred and effective for consumers, to drive more efficient and effective use of public funding and to provide the system with the capacity to respond to future challenges.<sup>6</sup>

Community pharmacy is not immune to such scrutiny. Through this Review it has undergone a similar level of examination to determine what is required to align pharmacy with the broader reforms being implemented in the healthcare system. Careful consideration has been given by the Panel to how community pharmacy can support or build upon the structural changes recommended by other inquiries, as part of a more integrated and coordinated system.

## CHANGING PATIENT AND MEDICATION PROFILES

There are a number of external drivers that are likely to influence the characteristics of the patient cohort served by community pharmacy as well as the nature and scope of pharmacy services. This presents considerable

opportunities for growth for community pharmacy over the next five to ten years.

These factors include the following:

- The population in Australia is ageing. The proportion of the population aged 50 years and older expected to increase and drive growth in pharmaceutical consumption.
- The prevalence of chronic diseases is rising, and there is a need for greater monitoring and management of long-term conditions by health professionals.
- Rising health consciousness and changing community attitudes to health care in Australia is expected to contribute to growth in consumer healthcare products and use of complementary medicines.<sup>7</sup>
- Funding for the PBS is expected to rise in 2017–2018<sup>8</sup> as the volume of medicines dispensed continues to trend upwards.<sup>9</sup>
- PBS medicines expenditure through hospitals has also increased significantly, and in the future it may exceed expenditure through community pharmacy.<sup>10</sup>
- The development of new specialist-driven therapies and hyper-specific or personalised medicines and biologics is expected to increase the reliance on specialist dispensing services and medicine advice.<sup>11</sup>
- Delisting of medicines from 'Prescription Only' (Schedule 4) to 'Pharmacist Only' and 'Pharmacy Only' (Schedules 2 and 3) is predicted to increase the reliance on

<sup>7</sup> IBISWorld Industry Report C1841, *Pharmaceutical product manufacturing in Australia* (November 2016).

<sup>8</sup> The Treasury, Budget Measures, *Budget Paper No. 2 2016–17* (May 2016), page 114.

<sup>9</sup> Department of Health data.

<sup>10</sup> The increase is on the basis of cost, not volume.

<sup>11</sup> IBISWorld Industry Report C1841, *Pharmaceutical product manufacturing in Australia* (November 2016).

<sup>6</sup> Department of Health, *Annual report 2015–16*, page 4.

the professional advice role of pharmacists to ensure their quality use.

## ACCOUNTABILITY AND TRANSPARENCY IN THE EXPENDITURE OF FUNDS

There is an ever-increasing obligation placed on government to demonstrate accountability and transparency in the use of taxpayer funds. The Department of Health must maintain the ability to effectively discharge its accountability obligations to the Australian Parliament and the public with respect to funds administered by government entities and third parties.

This principle was emphasised by a recent Australian National Audit Office (ANAO) performance audit<sup>12</sup> which was critical of the department's capacity to satisfy accountability requirements and protect the government's interests. Similar criticisms have been put to the Panel, indicating that current funding arrangements for pharmacy are out of step with requirements for transparency and accountability of government agreements, particularly when involving billions of taxpayer dollars.<sup>13</sup> Community expectations over the acquittal of public funds are likely to rise as budget pressures increase.

Given such criticisms, it is essential that remuneration provided to community pharmacy be transparent and allow appropriate scrutiny to determine value for money in the achievement of health outcomes.

<sup>12</sup> ANAO, *Administration of the Fifth Community Pharmacy Agreement*, No. 25, 2014–2015.

<sup>13</sup> The Productivity Commission, *Efficiency in health: Productivity Commission research paper* (April 2015), acknowledges the value of information and transparency to consumers, governments and the health industry itself.

## 1.2. PHARMACY LANDSCAPE

The community pharmacy sector has experienced significant changes with a number of converging issues impacting on the nature and performance of traditional community pharmacies. These internal drivers of change are expected to intensify in the short term and will continue to apply pressure to those parts of the sector that fail to adapt to shifts in the pharmacy landscape.

### INCREASING COMPETITION

The continued growth of the 'big box' discounter model has profoundly influenced the pharmacy landscape. Over the past five years, the proliferation of warehouse-style pharmacies, with aggressive pricing strategies and everyday low prices, has eroded the profit margins and revenue streams of traditional pharmacy models.<sup>14</sup>

IBIS World has suggested:

"This development is forecast to continue over the next five years, with big-box retailers expected to account for an increasing share of both pharmacy numbers and the volume of pharmaceuticals dispensed."<sup>15</sup>

Retail banner groups have also driven competition within the sector. The growth of upstream pharmaceutical wholesaler brands and the recent consolidation of retail groups, such as the Terry White and Chemmart merger, have supported this trend.

The rise of discounters and banner groups has correlated with the decline of non-aligned pharmacies – a trend projected to continue. Over the past five years, several pharmacies

<sup>14</sup> IBISWorld Industry Report G4271a, *Pharmacies in Australia* (November 2016), page 8.

<sup>15</sup> IBISWorld Industry Report G4271a, *Pharmacies in Australia* (November 2016), page 18.

have exited the industry, with others consolidating, leaving approximately 2700 non-aligned pharmacies in operation.<sup>16</sup>

The community pharmacy landscape as of November 2016 is illustrated in **Figure 1**<sup>17</sup> below.

**Figure 1: Major groups in community pharmacy**



Community pharmacy faces increasing competition with respect to non-scheduled medicines, complementary medicines and related healthcare items from retail operators such as supermarkets, niche health and beauty retailers and discount department stores. Competitive pressures are forecast to intensify in the near term, threatening industry growth and adversely impacting on the profitability of front-of-store sales.<sup>18</sup>

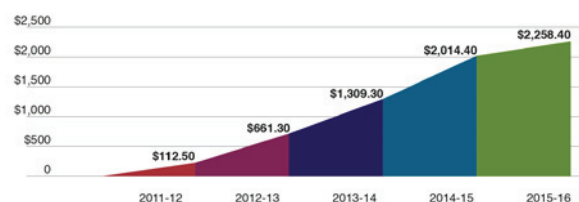
The Review considers that price disclosure reforms implemented by government are appropriate for increasing the transparency of real market prices for medicines and have clearly led to better value for money in the use of public funds. Nevertheless, the Panel is conscious of the significant impact of price disclosure policies on the profitability and operating arrangements on pharmacies. The impact of price disclosure is reflected in **Figure 2** below.

<sup>16</sup> IBISWorld Industry Report G4271a, *Pharmacies in Australia* (November 2016), page 18.

<sup>17</sup> Source: IBISWorld Report Industry Report G4271a, *Pharmacies in Australia* (2016).

<sup>18</sup> IBISWorld Industry Report G4271a, *Pharmacies in Australia* (November 2016), page 6.

**Figure 2: Price disclosure savings (\$millions)<sup>19</sup>**



Ongoing price disclosure cycles have resulted in the price deflation of PBS medicines over the past five years and have reduced growth in dispensing revenue – historically a key contributor to net profit in pharmacy.<sup>20</sup>

Consultations and submissions to the Review suggested that price disclosure is a significant source of anxiety for pharmacy owners and pharmaceutical wholesalers, as it has threatened the viability of some operators within the sector.<sup>21</sup> These pricing pressures are expected to continue as part of the reforms introduced in 2015 under the government's PBS Access and Sustainability Package reforms.

Price disclosure policy has influenced the inventory management practices of pharmacies. The Panel noted a reluctance of many pharmacies to maintain supplies of certain medicines close to price disclosure reduction days, lessening their exposure to price deflation. If not properly managed this could lead to significant supply disruption for some consumers.

<sup>19</sup> Source: RSM, *Financial analysis of pharmacy regulations and remuneration arrangements*, March 2017.

<sup>20</sup> IBISWorld Industry Report G4271a, *Pharmacies in Australia* (November 2016), page 6.

<sup>21</sup> For example, the Pharmacy Guild of Australia, Submission No. 486; Terry White Chemists, Submission No. 478; National Pharmaceutical Services Australia, Submission No. 482; Ventura Health, Submission No. 353; Kevin Li, Submission No. 270; and Simon O'Halloran, Submission No. 339.

An increasing number of pharmacies have looked to pursue alternative business models which diversify revenue streams and reduce their reliance on falling dispensary profit margins. Growing the front-of-store business and sales of non-prescription medicines, as well as introducing fee-for-service professional services in the areas of preventive health and primary care, has received increased focus.

It has been put to the Panel that the sustained impact of price disclosure reforms on pharmaceutical wholesalers has also led to some wholesalers reducing the discounts or trading terms traditionally offered to community pharmacy. This exerts further pressure on pharmacy profit margins.

## TECHNOLOGY

Technological disruption in the pharmacy sector has presented a number of challenges and opportunities for pharmacy.

The use of robotic dispensing systems has increased in recent times as pharmacies search for greater dispensing efficiencies amid diminishing profit margins. This includes the introduction of medication dispensing systems, packaging and labelling systems, storage and retrieval systems, compounding systems and tabletop counters.<sup>22</sup> These systems have the potential to improve patient outcomes by shifting resources to consumer interaction and advice.

These technological advances have affected the pharmacy workforce. Robotic dispensing systems challenge the traditional role of pharmacy technicians, as they can arguably dispense medications in a more timely, accurate and cost-effective manner, also

performing other functions such as sorting and managing stock.

The emergence of online pharmacies increases competition, putting pressure on traditional brick and mortar operators. Many retail groups and individual pharmacies have compensated for this by developing their own websites and e-commerce platforms.

A growing number of pharmacies are also filling prescriptions online and implementing electronic prescription reminder systems (e.g. to order repeat prescriptions for patients).

## CHANGING ROLE OF PHARMACISTS

As the pharmacy landscape in Australia has evolved, so too has the role of pharmacists. The pharmacy profession is in the midst of a transition from a product supply focus to a service focus. This trend is occurring both internationally and domestically. Recognition of the clinical knowledge held by pharmacists has resulted in an increase in the number of medicine-related services available in community pharmacy. In addition, there have been moves to embed pharmacists into primary healthcare teams.

In Scotland, the Cabinet Secretary for Health, Wellbeing and Sport announced in June 2015 that primary care funding would be used to recruit pharmacists to work in general practice.<sup>23</sup> This was to help improve patient medication management and free up GPs to support patients with complex conditions. In the United Kingdom, pharmacists have been able to complete additional certification to gain prescribing rights since 2006, with pharmacist prescribing being implemented to help address the GP workforce shortage.

<sup>22</sup> IBISWorld Industry Report G4271a, *Pharmacies in Australia* (November 2016), page 30.

<sup>23</sup> Scottish Government, [Primary care investment](#), 25 June 2015.



In Australia, there have been moves to expand the scope of pharmacy practice – for example, the Australian Medical Association’s proposal to employ non-dispensing pharmacists in medical practices, as part of a multidisciplinary healthcare team.<sup>24</sup>

The National Health Workforce Dataset<sup>25</sup> shows that the number of independent pharmacist consultants has increased by 6 per cent since 2013. This dataset also found that early career pharmacists were more likely to be working in Aboriginal Health Services (AHS) and Community Health Care Services, compared with other pharmacists. This suggests that there is an appetite for change within the profession, particularly among young pharmacists.

## YOUNG PHARMACISTS

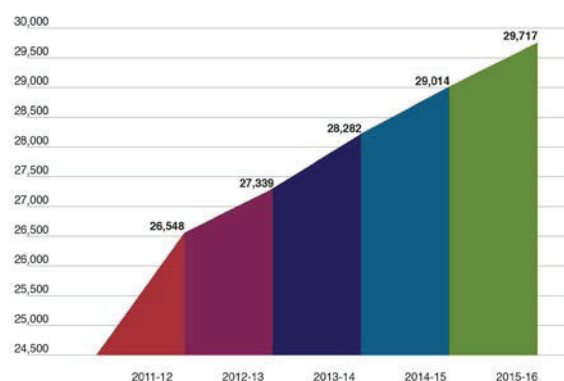
Young pharmacists represent a substantial proportion of the Australian community pharmacy workforce whose successful engagement will influence the future directions of the profession. As at 30 June 2016, pharmacists aged below 35 years represented 48.44 per cent of all registered pharmacists in Australia, with the largest age bracket being 25 to 29 years (21.10 per cent).<sup>26</sup>

Some have contended that there is an oversupply of pharmacy graduates in Australia, particularly in urban areas, which has threatened the viability of the workforce, depressed wages and heightened competition for pharmacy roles.<sup>27</sup> There were 1496 new

pharmacist registrants in 2015, with 1.7 new registrants for every pharmacist who did not renew their registration in 2014, suggesting that the pharmacy workforce is growing.<sup>28</sup> In addition, there were 7280 registered pharmacy students in 2015–16.<sup>29</sup>

**Figure 3** below illustrates the extent of growth in the overall pharmacy workforce in the period 2011–12 through to 2015–16, indicating steady year-on-year growth of approximately 2–3 per cent.

**Figure 3: Growth in number of registered pharmacists**



Source: Pharmacy Board of Australia

However, others argue that there is no longer an oversupply of pharmacists, with possibly the exception of some metropolitan areas. A recent survey of new higher education graduates, taken around four months after the completion of their qualifications, showed that 95.6 per cent of pharmacy graduates were in full-time employment in 2015.<sup>30</sup> A further 1.8 per cent of pharmacy graduates were seeking full-time employment while

<sup>24</sup> Australian Medical Association, Submission No. 45, page 2.

<sup>25</sup> Department of Health, [The national health workforce dataset pharmacy 2015](#).

<sup>26</sup> Pharmacy Board of Australia, *2015/16 Annual report summary*, page 10.

<sup>27</sup> Ian Carr, community pharmacy owner, Submission No. 394; Umer Khatta, community pharmacist, Submission

No. 395; and Anvin Javanmard, community pharmacy owner, Submission No. 396.

<sup>28</sup> Department of Health, [The national health workforce dataset pharmacy 2015](#).

<sup>29</sup> Pharmacy Board of Australia, *2015/16 Annual Report Summary*, page 8.

<sup>30</sup> Graduate Careers Australia, [GradStats employment and salary outcomes of recent higher education graduates](#) (December 2015).

working part-time or on a casual basis. Only 2.6 per cent of recently graduated pharmacists were not working (either full-time or part-time) four months after the completion of their qualifications, suggesting that pharmacy graduates have the second-highest rate of employment across all fields of education surveyed. The Panel has not received conclusive evidence to suggest an oversupply or undersupply of pharmacy graduates. However, the Panel notes that this remains an area of contention within the sector.

A consistent theme from the Review's public forums was that low wages are currently paid to employee pharmacists, particularly those early in their careers. Hourly rates of \$25 were regularly quoted to the Panel by young pharmacists. This issue was further emphasised in submissions to the Review, including the following submission:

"The reason I left the profession, and what I hope you will consider as a matter of great importance in this review, is that the conditions for an employee pharmacist are disgraceful ... studying a very demanding subject matter for five years to make the same money you can make without any skills at ALDI or working at a pub ... If the minimum wage for a pharmacist is not lifted, there will be a mass exodus of bright young pharmacists who will flock to better careers, and the Australian public will be much worse off for it."<sup>31</sup>

In this respect, the Pharmaceutical Society of Australia (PSA) has previously noted that pharmacist wages are the single largest issue facing the profession.<sup>32</sup>

Further, a 2016 survey highlighted that the average starting salary for a graduate pharmacist was \$40 937 per annum four months after finishing their degree.<sup>33</sup> This indicated that, in Australia, pharmacy graduates had the lowest starting salary of all industries requiring higher education training.

The Panel notes that low wages are a key concern for several parts of the community pharmacy sector and that this issue is likely to increase in significance following the February 2017 Fair Work Commission penalty rates case decision. This will mean that some employee pharmacists will receive reduced Sunday and public holiday penalty rates and also highlights the tension between pharmacists operating as both retailers and health professionals. In this regard, the Panel notes that no other health profession was considered in scope of the Fair Work Commission's review of awards in the retail sector.<sup>34</sup>

Young pharmacists also face significant challenges when considering pharmacy ownership. The Panel received firsthand accounts from young pharmacists of the large financial risk they are forced to accept to enter the tightly controlled pharmacy market. The high cost of buying into a pharmacy under the current regulations requires substantial capital costs that are beyond the means of many within the profession.

Several submissions by young pharmacists cited concerns regarding the perception of the profession given media commentary which has painted pharmacists as salespeople or as 'peddlers of snake oil'.<sup>35</sup> They also

<sup>31</sup> Employee pharmacist, Submission No. 20.

<sup>32</sup> Lance Emerson, Chief Executive Officer, Pharmaceutical Society of Australia, speaking at PSA16.

<sup>33</sup> The Good Universities Guide 2016, pages 148–149.

<sup>34</sup> Fair Work Commission, [AM2014/305 Penalty rates case](#).

<sup>35</sup> Phoung Po, community pharmacist, Submission No. 295.



mentioned a general lack of career satisfaction, being unable to spend time with customers due to workload pressures and keeping up with professional development requirements as challenges facing the profession.<sup>36</sup>

There is fear that these, along with other factors mentioned earlier, are creating an atmosphere of discontent within parts of the profession that may lead to pharmacists leaving the sector. The sentiment is captured in Submission 370 from community pharmacist Kevin Li:

“Nowadays I work in a corporate environment with the odd weekend in pharmacy. My story is very common, where some of my current colleagues are ex-community pharmacists that have left community pharmacy with little intention of coming back. Furthermore, there are those who have moved on by completing degrees in more lucrative industries and others who remain in community pharmacy who are looking for a way out ... the common perception is that there is little incentive to remain in the community pharmacy environment.”<sup>37</sup>

A recent online poll of pharmacists found that 33 per cent of respondents indicated that they plan to leave the profession.<sup>38</sup> This follows a similar poll conducted in 2016, where 61 per cent of respondents answered ‘yes’ to the question, “Are you considering leaving the profession”, with a further 21 per cent answering ‘maybe’.<sup>39</sup>

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<sup>36</sup> Ivonne Kusumah, community pharmacy owner, Submission No. 99; Hilde de Smet, community pharmacist, Submission No. 130; and Professional Pharmacists Australia, Submission No. 314.

<sup>37</sup> Kevin Li, community pharmacist, Submission No. 370, page 1.

<sup>38</sup> AJP, [Poll: Professional goals in the new year, 6 January 2017](#) (6 January 2017).

<sup>39</sup> AJP, [Pharmacists want to run away](#) (21 April 2016).

## 2. CONSUMER ACCESS AND EXPERIENCE

### 2.1. AN ACCESSIBLE PHARMACY SECTOR

Consumer access to medicines and pharmacy services forms part of the Terms of Reference and is a key focus of the Review. In developing its recommendations, the Panel is seeking to ensure that community pharmacy remains an accessible health destination for consumers.

The concept of ‘access’ as it relates to medicines and pharmacy services is multidimensional. While the physical location of a pharmacy is important, as is a consumer’s travel distance, there are multiple factors that impact on accessibility.

Whereas the National Medicines Policy (NMP) does not define the concept of ‘accessibility’, it does refer to timely access, affordability, care that is responsive to people’s needs, quality use, and cost-effectiveness for the community.

The Sixth Community Pharmacy Agreement (6CPA) was negotiated in the context of the government’s Pharmaceutical Benefits Scheme (PBS) Access and Sustainability Package, although in this instance ‘access’ refers to supporting access to new medicines through their listing on the PBS and the consequent sustainability measures to contain costs at their most efficient level.<sup>40</sup>

The Pharmacy Guild of Australia (the Guild), in its submission to the Review, discussed the accessibility of pharmacies, noting that:

“The issue of access by patients to PBS medicines and pharmacy services is not only limited to opening hours but also covers such things as the location of pharmacies, number of pharmacists and the breadth and reach of pharmacy services.”<sup>41</sup>

The Panel considers that an accessible network requires consumer choice involving different business models tailored to customer demands, not just a pharmacy in an appropriate location.

For the purposes of this Review, the Panel has adopted a broader and more inclusive definition of the concept of access as used by the World Health Organization.<sup>42</sup>

The World Health Organization recognises access as having three key dimensions:

- *Physical accessibility:* This is understood as the availability of quality pharmaceutical services (good health services) within reasonable reach of those who need them and of opening hours, appointment systems and other aspects of service organisation and delivery that allow people to obtain the services when they need them.
- *Financial affordability:* This is a measure of people’s ability to pay for services without financial hardship. It takes into account not only the price of the health services but also indirect and opportunity costs (e.g. the costs of transportation to and from facilities and of taking time away from work). Affordability is influenced by the

<sup>40</sup> The Australian Government and the Guild recognise that the purpose of the Package is to ensure longer-term access to, and sustainability of, the PBS (refer to the [Sixth Community Pharmacy Agreement](#)).

<sup>41</sup> The Pharmacy Guild of Australia, Submission No. 486, page 70.

<sup>42</sup> D. Evans, J. Hsu & T. Boerma, [Universal coverage and universal health access](#), *Bulletin of the World Health Organization*, vol. 91 (2013).

wider health financing system and by household income.

- *Acceptability*: This captures people's willingness to seek services. Acceptability is low when patients perceive services to be ineffective or when social and cultural factors such as language or the age, sex, ethnicity or religion of the health provider discourages them from seeking services.

By adopting this broader definition, the Panel seeks to have an accessible pharmacy sector in Australia. This requires pharmacies to be located close to people, with extended opening hours (where appropriate) and services that are designed to meet particular community and demographic requirements, including social and cultural needs.

The firm RSM were engaged as financial advisors for the Review. They have assisted the Panel in understanding the economics that underpin the pharmacy sector and community pharmacy practice. This includes an analysis of the arrangements in place and how the current pharmacy remuneration and regulation arrangements affect equity of access to medicines and related services (i.e. 'physical' access).

RSM has developed a Geospatial Information System (GIS) model that provides information on:

- the location of and PBS revenue received by each pharmacy
- the socio-economic status and location of the surrounding population of Australians that each pharmacy serves.

As illustrated in **Figure 4** below, the results of this analysis demonstrate that:

- The distribution of pharmacies across Australia reflects the population distribution. The largest numbers of pharmacies tend to be located in cities, where most of Australia's population lives.
- The distribution of pharmacies within and around Australia's major cities broadly reflects the population distribution as well as areas of greatest socio-economic disadvantage, which are indicated in dark red. Sydney has been used to as an example to demonstrate this breakdown in **Figure 5**.<sup>43</sup>

A more complete overview of equity in terms of an Australian's physical access to the medicines they need is provided in **Figure 6**.<sup>44</sup> This shows the straight-line distance residents in different regions of Australia live from their nearest pharmacy. In summary:

- The residents of Australia's major cities have to travel the least distance to visit their nearest pharmacy, regardless of the socio-economic status of the regional areas in which they live.
- The further Australians live from a major city, the further they have to travel to visit their nearest pharmacy. Even residents from regions with an average socio-economic index of disadvantage (i.e. a SEIFA<sup>45</sup> score of around 1000) have to travel

<sup>43</sup> Source: RSM, *Financial analysis of pharmacy regulations and remuneration arrangements* (March 2017), page 24.

<sup>44</sup> Source: RSM, *Financial analysis of pharmacy regulations and remuneration arrangements* (March 2017), page 25.

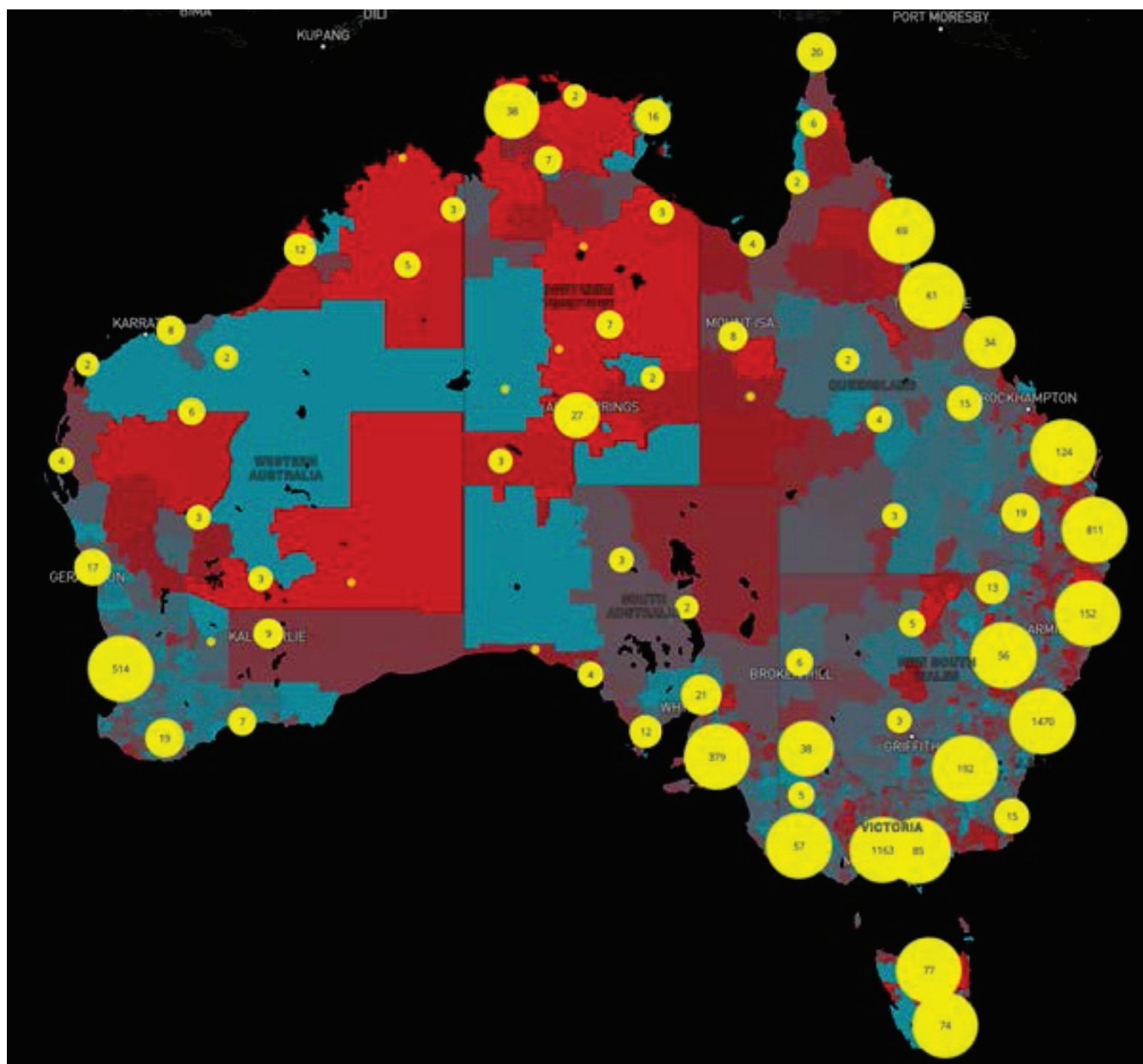
<sup>45</sup> SEIFA refers to the *Socio-economic indexes for areas* that have been developed by the Australian Bureau of Statistics to rate areas in Australia according to their relative socio-economic advantage or disadvantage.

significant distances to visit their nearest pharmacy if they live outside of a major city.

- Residents in very remote regions of Australia have to travel the longest distances to visit their nearest pharmacy. Residents from remote regions with the greatest levels of socio-economic disadvantage (i.e. those with the lowest SEIFA scores) have to travel significant distances to visit their nearest pharmacies.

The differences in access highlighted by the GIS model will underpin a number of options in this Report. In particular, differences in options for location rules between urban and non-urban Australia are discussed in Chapter 5 (The Regulation of Pharmacy for Medicine Supply).

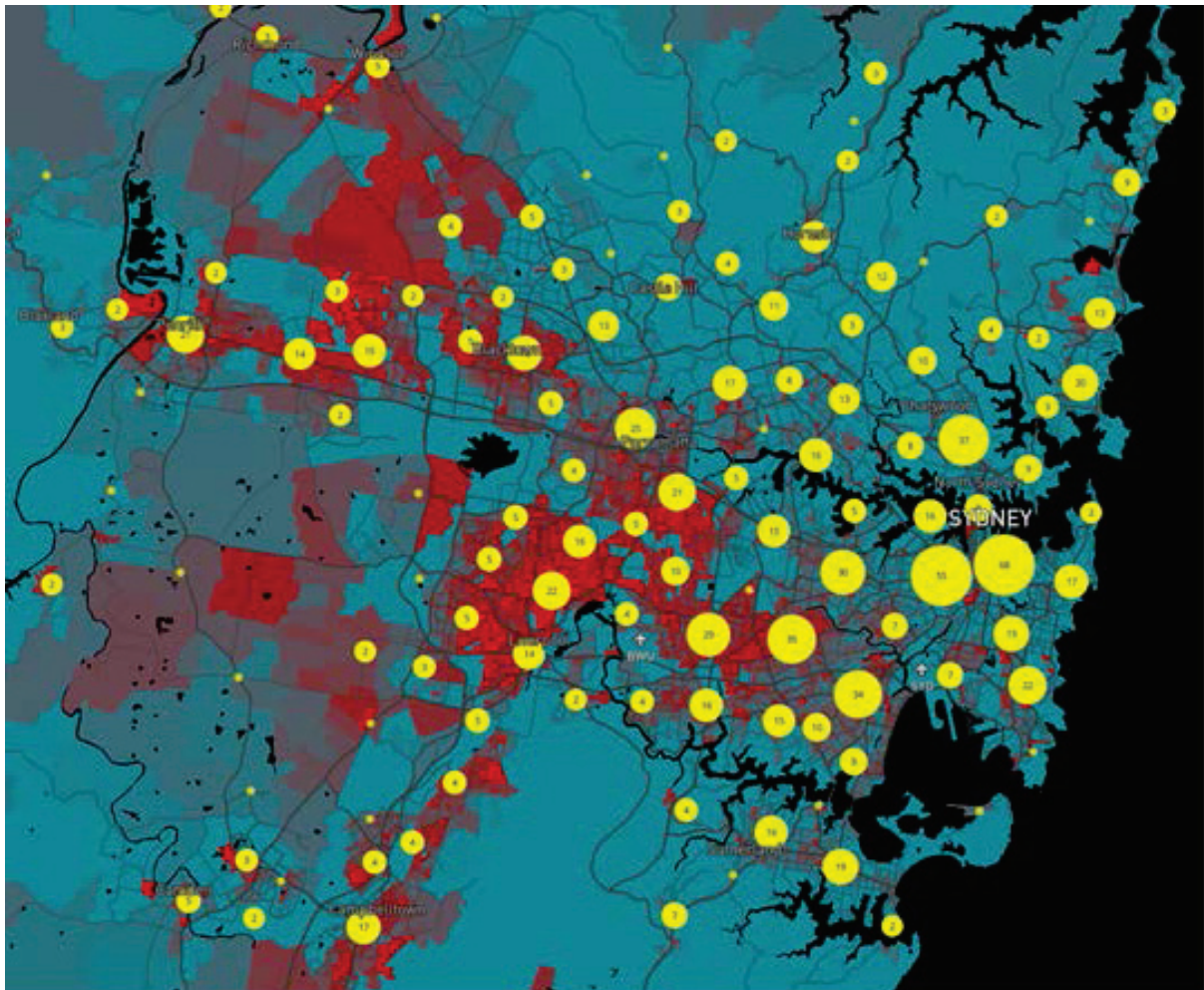
**Figure 4: Distribution of pharmacies across Australia**



**Note:** The areas in red indicate areas of greater socio-economic disadvantage. The yellow circles indicate the number of pharmacies in the relevant area as represented by the size of the circle.



**Figure 5: Distribution of pharmacies across regional areas of Sydney**



**Note:** The areas in red indicate areas of greater socio-economic disadvantage. The yellow circles indicate the number of pharmacies in the relevant area as represented by the size of the circle.

**Figure 6: Distances that different socio-economic groups travel to visit their nearest pharmacy (by regional area)**



**Note:** Lower SEIFA scores represent areas with greater levels of socio-economic disadvantage.

## 2.2. DIVERSITY OF PHARMACY DELIVERY MODELS AND CONSUMER CHOICE

Feedback provided to the Panel clearly shows that consumers recognise and value the range of different pharmacy models operating in Australia.

The Panel therefore considers it inappropriate to be specific about a one-size-fits-all business delivery model for community pharmacy.

Maximising the ability of consumers to ‘self-select’ the retail model that best suits them (traditional, discount or online) is a key factor underpinning this Review.

## 2.3. PRICING VARIATIONS

*The variation in pricing for medicines due to pharmacy pricing discretion creates consumer confusion.*

## DISCUSSION

PBS-listed medicines dispensed by community pharmacies are subject to a patient co-payment (currently \$6.30 for concession card holders and \$38.80 for general patients). The co-payments are indexed annually in line with increases in the Consumer Price Index (CPI).

Co-payments are generally used in health care and other government-supported services to provide a price signal for consumers. This acts as an incentive to moderate the use of the service and minimise wastage while also ensuring that consumers make a contribution towards the cost of the relevant service. In the case of the PBS, consumer contributions allow the government to spread the funds available for medicines further. This means that Australians can access a broader group of PBS-listed medicines by making a contribution when having a medicine dispensed.

A co-payment may mean that some consumers have difficulty accessing medicines when needed. To help ensure that the delivery of medicines is equitable, the government has established a PBS Safety Net that limits the total amount of the co-payment made by a consumer on an annual basis. The PBS Safety Net is discussed in more detail at Section 2.5 below.

Pharmacies currently have discretion to charge consumers any price up to the co-payment. The dispensed price (Commonwealth price) of a medication includes the approved price to pharmacist from the wholesaler plus the dispensing and Administration, Handling and Infrastructure (AHI) fees which provide remuneration for the community pharmacy. This is demonstrated in **Figure 7** below.

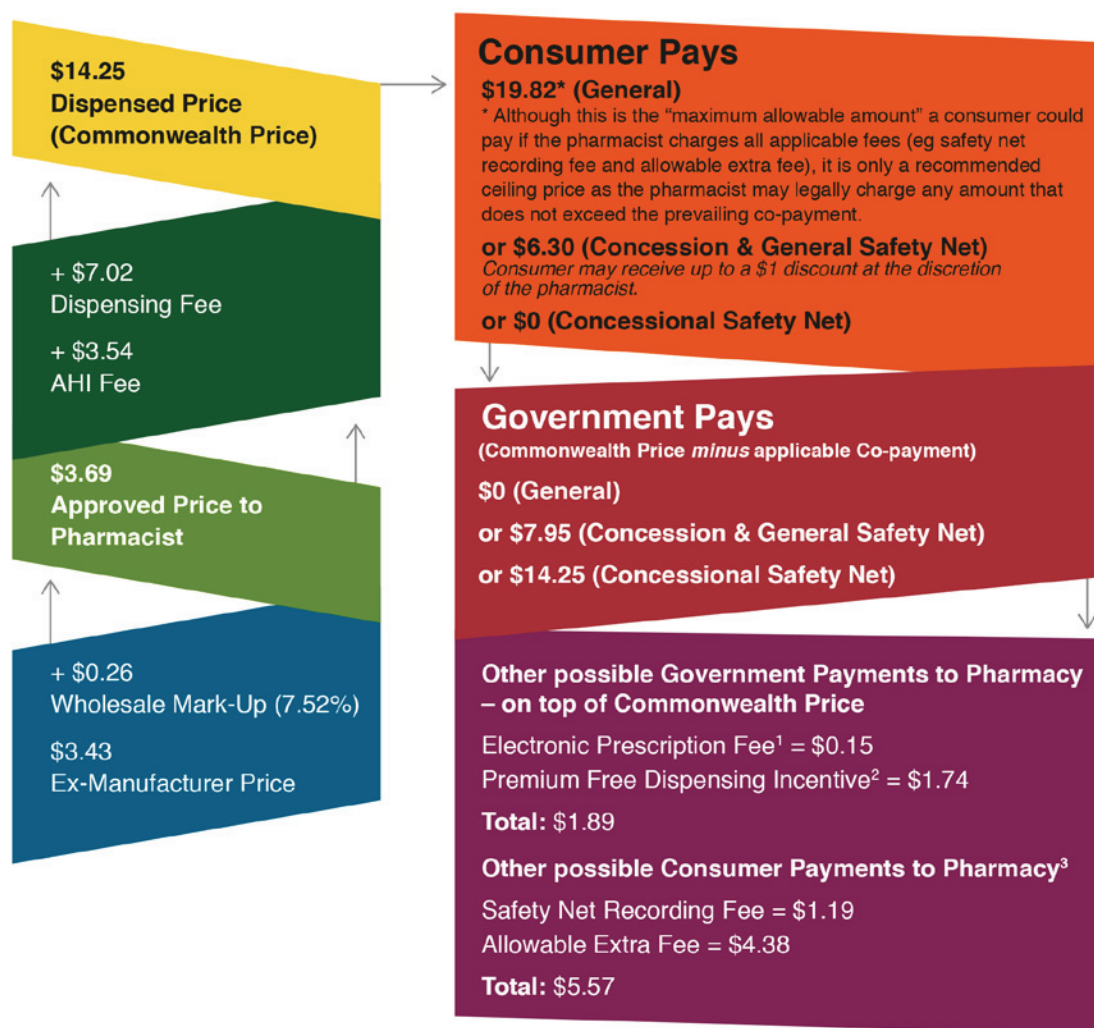
There are some additional fees which may also be applied depending on the type of medication (e.g. Dangerous Drug Fee).

Where the dispensed price is below the general patient co-payment, the pharmacy may choose to charge an additional Safety Net Recording Fee of \$1.19 for ready prepared items or \$1.55 for extemporaneously prepared items, and an Additional Allowable Fee of up to \$4.38, so long as the total amount charged does not exceed the patient co-payment.

This Additional Allowable Fee is a recommended amount, as the pharmacist can legally charge any amount so long as it does not exceed the co-payment. The Safety Net Recording Fee counts towards the Safety Net Threshold, but the Additional Allowable Fee does not.



Figure 7: Pharmacy remuneration (under co-payment) – 40mg Atorvastatin (May 2017)

**Notes:**

8215J Atorvastatin, 40mg, 30 tablets, 5 repeats (benchmark priced brand): [www.pbs.gov.au](http://www.pbs.gov.au) (May 2017).

1. The \$0.15 Electronic Prescription Fee only applies for each prescription dispensed electronically.
2. The \$1.74 Premium Free Dispensing Incentive only applies for each substitutable brand dispensed without a premium and attracting a government subsidy (i.e. priced above relevant patient co-payment).
3. The Safety Net Recording Fee of \$1.19 and the Allowable Extra Fee of \$4.38 is a discretionary charge and pharmacist are only permitted to apply these fees where the PBS dispensed price is below the general patient contribution of \$38.80. The allowable extra fee is not a government-initiated fee.

The discretion that pharmacies have in pricing medications, subject only to the patient co-payment, means that prices for the same medication often vary significantly between different pharmacies.

Some pharmacies choose to discount medications below the dispensed price, and some pharmacies charge above the Additional Allowable Fee (while not going over the co-payment).

**Table 1**<sup>46</sup> displays the different prices that general non-Safety Net patients paid per pack for the top ten PBS medicines (ranked by script volume) in September 2016 for under co-payment scripts. These differences in prices come from two main sources:

- differences in the quantity of medicines that medical practitioners prescribe per authority script (i.e. the number of packs of medicine per script)
- differences in the prices that pharmacies charge for each of those packs of medicine.

After adjusting the observed differences in the quantities of packs dispensed per script, it is apparent that at least 96 per cent of the price variations set out in **Table 1** is due to differences in the prices charged by pharmacies per pack of medicine.

These differences in price have unintended effects on both the equity of access for different consumers to different types of medicines and the efficient use of those medicines.

As indicated in **Table 2**, not all Australians benefit from the different prices that pharmacies charge for medicines which are below the relevant patient co-payment.

For example, analysis by RSM shows that consumers who purchase their medicines from pharmacies in urban regions of Australia (i.e. PhARIA 1) receive a nominal rate of assistance of 9 per cent as a result of the different prices charged by pharmacies (i.e. their prices are 9 per cent lower than the recommended consumer contribution).<sup>47</sup>

By contrast, consumers who purchase their medicines from pharmacies in the more remote regions of Australia (i.e. PhARIA 3 to PhARIA 6) actually have to pay more for their medicines than the dispensed price (i.e. they receive negative nominal rates of assistance). Indeed, the more remote the location of the pharmacy, the greater the extent to which consumers have to pay prices that exceed the dispensed price (i.e. the nominal rates of assistance provided to consumers become even more negative).<sup>48</sup>

The major beneficiaries of current variations in the prices that pharmacies charge are those consumers who purchase their medicines from small and medium pharmacies located in urban regions of Australia (i.e. PhARIA 1), since those pharmacies provide consumers with the highest nominal rates of assistance.

As indicated in **Table 3**, general under co-payment consumers who purchase their medicines from small and medium pharmacies located in urban regions of Australia (i.e. PhARIA 1) receive nominal rates of assistance of 13 per cent and 18 per cent

<sup>46</sup> Source: RSM, *Financial analysis of pharmacy regulations and remuneration arrangements* (March 2017), page 122.

<sup>47</sup> RSM, *Financial analysis of pharmacy regulations and remuneration arrangements* (March 2017), page 42.

<sup>48</sup> RSM, *Financial analysis of pharmacy regulations and remuneration arrangements* (March 2017), page 42.

respectively as a result of the variations in prices charged by those pharmacies.<sup>49</sup>

Feedback to the Panel has indicated that consumers generally have a poor understanding of the reasons for variation in pricing between pharmacies. Hall & Partners' consumer research, commissioned by the Review, found:

- Most consumers want to know what price will be charged in advance of a prescription being filled and be able to see the government's contribution to the price. The majority also want to pay the same consumer contribution (and co-payment) for the same medicine across all pharmacies.
- There is little consumer understanding of reasons for variations in medicine prices between pharmacies. Consumers expect that subsidised medicines will be the same price for concession and non-concession cardholders, regardless of where they are purchased.
- The lack of consumer understanding is fuelled by the inconsistent and widely varying general co-payment amounts for PBS-listed medications.

An organisation representing consumers with HIV submitted:

"Consumers with HIV have little understanding of price variation (either general patient co-payment or concessional co-payment amounts) for dispensed medicines when these vary between different medicines and between different community and hospital pharmacies. While consumers generally understand that generic branded medicines cost less than branded medicines, the availability or non-

availability of generics and the difference in price for supply of these medicines, is generally not explained to consumers by the pharmacist or pharmacy staff and can lead to higher out of pocket expenditure for medicines and consumer confusion about pricing and price variation between different medicines and different pharmacies.

PLHIV [people living with HIV] with multi-morbidity often require multiple prescriptions dispensed at the same time. Discounting and price variation on specific medications further adds to customer confusion ..."<sup>50</sup>

As medicines are not normal items of commerce, it makes little if any sense for the government to allow this significant variation in pricing across different pharmacies for the same medications.

The government subsidises PBS medicines and should determine the dispensed price to support sustainable, efficient and equitable access to medicines across Australia, consistent with the NMP. The Panel considers that it is not appropriate for community pharmacies to be able to charge any amount above the dispensed price, being subject only to the patient co-payment.

Community pharmacies that increase the amount a consumer pays above the dispensed price likely raise the pharmacy's profits. However, this undermines the objective of equitable access to medicines.

The Panel therefore considers it inappropriate to allow community pharmacies discretion to raise the price paid by any consumer above the relevant dispensed price. It is also unnecessary to allow pharmacists to add optional additional charges to the price paid by consumers.

<sup>49</sup> RSM, *Financial analysis of pharmacy regulations and remuneration arrangements* (March 2017), page 42.

<sup>50</sup> Positive Life NSW, Submission No. 321. Sentiments also echoed in Submission No. 503.

A similar argument can be made for reduced pricing. If a community pharmacy lowers the price that it charges a consumer for a PBS medicine then it lowers its own profit. But, whether the decision is made for reasons of equity or competition, the pharmacist is undermining the balance of equity, funding and incentives embodied in the PBS and medicine distribution system.

As the Guild noted in its submission:

“the PBS co-payment discount is not consistent with the Federal Government’s NMP in which costs and savings between partners are shared, access processes are simple and streamlined, cost-shifting minimised and perverse incentives avoided. Discounting the PBS co-payment commoditises the PBS, devalues the clinical role of the pharmacist, undermines the purpose of having a consistently applied price signal and most importantly, is contrary to the concept of universality of the PBS in which all Australians can access subsidised PBS medicines at the same price irrespective of where they live. The Guild has a particular concern with discounting PBS prescriptions for medicines that may be subject to abuse or misuse (e.g. opiates, stimulants, hypnotics).”<sup>51</sup>

It is also inappropriate to allow community pharmacies discretion to lower the price paid by any consumer below the level that represents the approved price to pharmacy plus dispensing fees.

The removal of pricing discretion may appear to be inconsistent with standard retail competition, but PBS medicines are not provided through normal retail mechanisms. The government subsidises the distribution of these medicines and, where the medicine price is above the relevant patient co-payment, it directly remunerates the

community pharmacist for the dispensing services provided.

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 price and profits go down then the pharmacy is, in effect, passing on some of its government-determined dispensing remuneration to the consumer. But the remuneration for dispensing is set by government to appropriately remunerate community pharmacies for the dispensing services and no more. If these dispensing payments are too high then the government should reduce them.

The Panel notes that the removal of pricing discretion under the PBS may not limit all pricing variations between pharmacies, as some pharmacies may opt to offer consumers a private sale (i.e. where relevant prescriptions would not contribute towards the patient’s Safety Net). The Panel does not believe, at this stage, it is appropriate to limit this type of sale.

Further, the Panel notes that the introduction of an automatic electronic recording system for the PBS Safety Net (discussed later in this report) would remove the need for a Safety Net Recording Fee.

<sup>51</sup> The Pharmacy Guild of Australia, Submission No. 486, page 88.

#### **OPTION 2-1: PRICING VARIATIONS**

The payment made by any particular consumer for a PBS-listed medicine should be the co-payment set by the government for that consumer or the dispensed price for that medicine, whichever is the lower. A community pharmacy should have no discretion to either raise or lower this price.

**Table 1: Differences in the prices that general non-Safety Net consumers pay for the top ten medicines for under co-payment scripts (September 2016)**

PBS item code	Medicine name	Dispensed Price at Maximum Quantity (DPMQ)	No. of scripts ('000s)	Average price paid by consumer per pack	Standard deviation of price paid by consumer per pack
01215Y	PARACETAMOL + CODEINE	\$11.36	86	\$11.41	\$4.78
01394J	LEVONORGESTREL + ETHINYLOESTRADIOL	\$18.28	101	\$16.08	\$5.24
01889K	AMOXYCILLIN	\$11.89	176	\$12.01	\$4.88
03119E	CEPHALEXIN	\$12.13	158	\$12.66	\$4.95
08008L	PANTOPRAZOLE	\$14.05	99	\$11.81	\$4.99
08215J	ATORVASTATIN	\$15.85	74	\$13.06	\$5.99
08254K	AMOXYCILLIN + CLAVULANIC ACID	\$13.33	186	\$13.66	\$5.45
08600P	ESOMEPRAZOLE	\$24.09	112	\$21.00	\$6.30
08700X	ESCITALOPRAM	\$13.50	74	\$12.46	\$5.80
09043Y	ROSUVASTATIN	\$21.39	202	\$17.22	\$6.46

**Notes:**

1. Top 10 medicines ranked by script volume.
2. Only community pharmacies included.
3. Excludes any price differences due to special patient contributions, therapeutic group premiums and brand premiums.
4. Excludes chemotherapy medicines.

**Table 2: Effect of price variations on the nominal rates of assistance provided to consumers by pharmacy location (excluding premiums)**

PhARIA	Accumulated recommended consumer contribution*	Accumulated price variation**	Nominal rate of assistance to consumers (arising from price variations)***
1	\$1 063 669 635	-\$94 080 686	9%
2	\$34 769 640	\$192 196	-1%
3	\$45 443 307	\$5 851 184	-13%
4	\$14 932 988	\$2 606 211	-17%
5	\$16 820 761	\$3 917 202	-23%
6	\$7 561 046	\$2 368 720	-31%

**Notes:**

- \* Equals the sum of the Commonwealth dispensed price for scripts filled.
  - \*\* Excludes price differences caused by brand premiums, therapeutic group premiums, special patient contributions and the \$1 discount.
  - \*\*\* Positive nominal rates of assistance indicate the patients paid less than the dispensed price and vice versa for the negative nominal rate of assistance.
1. Only pharmacies with approval number as at March 2015 are included.
  2. Price variation and PBS Patient Contribution are extracted from PBS data from 1 January 2016 to 31 December 2016.
  3. Chemotherapy medicines are excluded.
  4. Includes general non-Safety-Net under co-payment patients only.
  5. The data may contain minor unadjusted price variations that are not attributable to pricing discretion at pharmacy level.

**Table 3: Effect of price variations on the nominal rates of assistance provided to consumers by pharmacy type and location (excluding premiums)**

PhARIA	Type of pharmacy				
	Micro	Small	Medium	Large	Very large
1	-6%	13%	18%	-10%	8%
2	-12%	2%	–	–	–
3	-17%	-12%	–	–	–
4	-18%	-18%	–	–	–
5	-23%	-26%	–	–	–
6	-32%	-31%	–	–	–

**Notes:**

- \* Excludes price differences caused by brand premiums, therapeutic group premiums, special patient contributions and the \$1 discount.
  - \*\* Positive nominal rates of assistance indicate the patients paid less than the dispensed price and vice versa for the negative nominal rate of assistance.
1. Pharmacies have been classified into the various categories of pharmacies using their PBS revenue, with the assumption that this comprises 80% of their revenue.
  2. Includes general non-Safety-Net under co-payment patients only.
  3. The data may contain minor unadjusted price variations that are not attributable to pricing discretion at pharmacy level.

## 2.4. THE \$1 DISCOUNT

*The \$1 discount has not led to appropriate outcomes for consumers.*

### DISCUSSION

The \$1 discount on patient co-payments for PBS scripts was introduced as part of the 6CPA and became operational on 1 January 2016. The \$1 discount is optional, allowing pharmacies to choose whether or not they reduce the price payable by consumers to access their medicines.

The primary intention behind the policy was to increase competition amongst pharmacies while also providing savings for consumers on the cost of medicines. The policy was expected to save the government \$373 million in funding over the five years of the 6CPA.

The savings were expected to be generated as fewer consumers would reach their safety net threshold for PBS medicines.

The \$1 discount policy has been criticised by the Guild, individual pharmacy owners and pharmacists for several reasons, including:

- “[It] 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.”<sup>52</sup>
- It encourages consumers to ‘shop around for price’, commoditising medicine.
- The discount has a significant effect on pharmacy turnover, while

providing little financial benefit to patients.

- Many pharmacies indicated in their submissions that they had to implement the discount to remain competitive, but as a result they also had to reduce opening hours and staff levels, thereby affecting service levels.
- It can be confusing for patients, and takes up a significant amount of the pharmacists’ time explaining the policy, especially in relation to:
  - how it affects the safety net (i.e. taking longer to reach the threshold)
  - why they have to pay more at some pharmacies than others
  - why some pharmacies have not passed on the discount.
- The discount is most likely to be applied by pharmacies in areas with direct competition, meaning rural and remote communities are likely to continue to pay the higher payment.

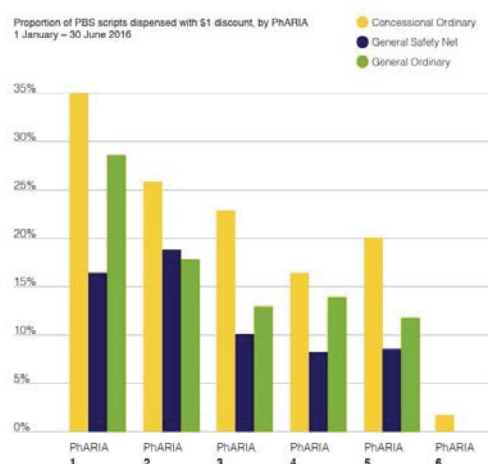
The Panel broadly agrees with the Guild’s argument. Data available to the Panel shows the application of the \$1 discount as highly variable. As indicated in **Figure 8**<sup>53</sup>, pharmacies located in urban regions of Australia (i.e. PhARIA 1) discount the highest proportions of the scripts they dispense, whereas the more remote a pharmacy is, the lower the proportion of the scripts that it discounts.

<sup>52</sup> Pharmacy Guild of Australia, Submission No. 486, page 88.

<sup>53</sup> Source: RSM, *Financial analysis of pharmacy regulations and remuneration arrangements* (March 2017).



**Figure 8: Proportion of \$1 discount scripts dispensed by PhARIA 1 January – 30 June 2016**



This suggests that the \$1 discount is having the unintended effect of reducing the overall equity of access to affordable medicines. Rather than improving the equity of access to affordable medicines for residents in the more remote regions of Australia, the policy is in effect further improving access for residents in metropolitan areas.

While it might be argued that the policy has been effective in increasing competition between community pharmacies, at least in some parts of Australia, this view is at best confused.

The \$1 discount may make competition between community pharmacies in certain regions more transparent. 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.

However, having varying levels of competition in community pharmacy in different parts of Australia creates issues of equity. The \$1 discount simply highlights and possibly exacerbates these inequities. It does not fix them. In the opinion of the Panel, the appropriate way to deal with the inequities created by differential and, in some areas, inadequate competition is through the redesign of the pharmacy location rules that restrict competition in some regions of Australia.

It is undeniable that the \$1 discount policy has saved some consumers up to \$1 in their co-payment for medicines. However, the policy is clearly inequitable given its discretionary application. Further, it undermines the principle that the co-payment is set by the government to balance the level of government funding, with consumer incentives and equity of medicine access.

**Table 4**<sup>54</sup> illustrates the categories of consumers that derive the greatest benefit from the application of the \$1 discount. In particular, it indicates that consumers subject to the concessional co-payment receive the greatest benefit from the \$1 discount.

It might also be argued that the introduction of the \$1 discount has reduced government expenditure on medicines. The Panel does not believe that this is an appropriate way to reduce government expenditure on PBS medicines.

The savings are 'indirect', via reduced safety net payments. The savings come about due to some consumers (but not others) paying up to \$1 less than the co-payment determined appropriate by the government and the

<sup>54</sup> RSM, *Financial analysis of pharmacy regulations and remuneration arrangements* (March 2017), page 45.

relevant pharmacist receiving up to \$1 less in remuneration than the amount determined by the government as appropriate remuneration to the pharmacist for dispensing.

If the government believes that the reduced remuneration to pharmacists for dispensing is appropriate then it could save substantially more expenditure by directly reducing the dispensing fees for all community pharmacists, holding co-payments constant.

The \$1 discount has provided some evidence that the existing government remuneration for dispensing may be too high given that some community pharmacies are effectively able to forego up to \$1 of this remuneration. This raises issues surrounding the level of government remuneration for dispensing, which is discussed further in Chapter 4.

An indication of the potential cumulative effect of removing the \$1 discount, as well as the ability of pharmacies to charge different prices for the medicines they supply, is provided in Table 4.<sup>55</sup> This suggests that overall:

- general under co-payment patients receive the greatest net savings from differences in the prices that pharmacies charge for their medicines
- General Safety Net patients pay more for their medicines as a result of variations in the prices that pharmacies charge for their medicines. They experience a negative net saving as a result of price variations
- concessional patients receive the greatest benefit from the \$1 discount

- general under co-payment patients receive the greatest gain from the combined effect of differences in the prices that pharmacies charge consumers and the \$1 discount.

The removal of both price variations and the \$1 discount has the potential to improve the overall equity of access to affordable medicines across Australia by removing the additional benefits that residents of metropolitan regions of Australia derive from the current discounts.

#### **OPTION 2-2: \$1 DISCOUNT**

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

<sup>55</sup> RSM, *Financial analysis of pharmacy regulations and remuneration arrangements* (March 2017), page 45.

**Table 4: Combined effect of price variations and the \$1 discount on the prices paid by consumers**

Consumer type	Variation in actual price paid from Commonwealth dispensed price or co-payment (whichever applies)*		Net saving to consumers from price variation**	Sum of \$1 discount	Total consumer gain/loss from price variation and \$1 discount
	Sum of positive variation	Sum of negative variation			
Concessional Safety Net	\$0	\$0	\$0	\$0	\$0
Concessional	\$1 959 664	-\$3 687,005	\$1 727,341	\$48 178 138	\$49 905 479
General Safety Net	\$81 053	-\$5 502	-\$75 551	\$501 024	\$425 473
General (over co-payment)	\$291 157	-\$1 728 403	\$1 437 246	\$3 288 724	\$4 724 970
General (under co-payment)	\$143 238 137	-\$241 123 864	\$97 885 727	\$0	\$97 885 727
<b>Total</b>	<b>\$145 570 011</b>	<b>-\$246 544 774</b>	<b>\$100 974 763</b>	<b>\$51 966 886</b>	<b>\$152 941 649</b>

**Notes:**

- \* Excludes price differences caused by brand premiums, therapeutic group premiums, special patient contributions and the \$1 discount. Positive variation means the patients paid more than the dispensed price or co-payment, and negative price variation means the patients paid less.
- \*\* Negative saving means that patients paid more than they would have paid in the absence of price variation.
1. Negative price variation and positive dollar discount means patients have paid less.
  2. Negative price variation comes in the form of discount on the dispensed price and does not include the \$1 discount.
  3. Chemotherapy medicines are excluded.
  4. Discussions around costs or savings to patients if pricing variation or the \$1 discount is removed assumes that pricing will be kept at current dispensed price or co-payment levels and all else being held equal.
  5. Although price variations are not expected for concessional, General Safety Net and general over co-payment scripts, some variations were found that are likely to be due to quantity variations at script level rather than pharmacy discretionary pricing. These observations do not alter the results of the analysis.

## 2.5. PBS SAFETY NET

*The current PBS Safety Net system is not transparent and is difficult for consumers to document and understand. The lack of transparency and understanding also results in the Safety Net not being utilised to the extent possible, which disadvantages the more vulnerable consumers.*

### DISCUSSION

The purpose of the PBS Safety Net system in Australia is to protect individual consumers and families who require a large amount of prescription medications.<sup>56</sup>

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

Most significantly, the current PBS Safety Net system relies on consumers or their chosen pharmacist maintaining a manual record of expenditure on PBS or Repatriation Pharmaceutical Benefits Scheme items on a designated form. This is an outdated system that 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 was overly cumbersome – in particular, for disadvantaged patients with literacy issues, patients with culturally and linguistically diverse backgrounds, homeless patients and other vulnerable groups.

The lack of an automated system is in contrast to the Medicare Safety Net system, which the

Department of Human Services uses to automatically record consumers' out-of-pocket medical expenses. Many stakeholders, including consumers and consumer groups, pharmacy owners and other healthcare providers, commented that consumers found the PBS Safety Net complicated and that many consumers are paying more for their PBS scripts than they should be because they have not registered or kept the required records to demonstrate their eligibility for the Safety Net. There was also strong support among stakeholders for the introduction of an automated PBS Safety Net recording system, which is expected to improve and simplify access for consumers while reducing the administrative burden for pharmacies.

The Health Care Consumers Association commented in their submission to the Review:

“The purpose of the PBS Safety Net is to protect patients and their families who require a large number of PBS items (reference in Discussion Paper p47), providing financial support for consumers who reach a certain threshold of out-of-pocket payments for PBS medicines. However, unlike the Medicare Safety Net, access to the PBS Safety Net is not automatically calculated and relies on a complicated system of manual data collection that primarily relies on the knowledge and health literacy of the consumer. In essence, this equates to a great disparity in accessing the PBS Safety Net.”<sup>57</sup>

Catholic Health Australia stated:

“There are significant potential gains for consumers if PBS Online was electronically linked with calculations of safety net values.

- Currently consumers are required to keep records of all their PBS scripts in a calendar

<sup>56</sup> For further details of how the Safety Net operates, see pages 47–48 of the Discussion Paper.

<sup>57</sup> Health Care Consumers Association, Submission No. 248, page 4.

year by collecting stickers on a Prescription Record Form. Once they have reached the Safety Net limit they may apply to have a Safety Net card issued at a Pharmacy and it is only after this time that they are entitled to PBS scripts at a cheaper rate.

- Often consumers are unclear, unable or do not understand how to keep track of their Safety Net records, particularly when prescriptions are filled at multiple pharmacies.
- In the current system pharmacists are unable to ascertain a consumer's PBS Safety Net status if they do not carry their Safety Net Card or Prescription Record Form with them.”<sup>58</sup>

A pharmacy owner explained some of the issues they experienced with the Safety Net and how it might be improved:

“The Safety Net would be a reasonable measure if the Government took true responsibility for it (instead of hiving off responsibility for administration and all financial risk to Community Pharmacy) and did the things necessary to make it workable. To make it workable it requires a system of unique patient identification (UPI) and determination of what constitutes a family, accompanied by electronic tracking of entitlements. It lacks these things at the moment as *[sic]* is a diabolical nightmare for community pharmacy as a result. For example, earlier this month we took almost 3 hours to determine one family's entitlement (husband and wife). The patient told us that the two previous pharmacies had taken 90 minutes and 2 hours respectively to assess their SN entitlement. This is not unusual and it isn't surprising that some consumers are incapable of managing their own entitlement and that some pharmacies simply avoid doing it – we have had examples of consumers who have actually

qualified for a Safety Net 20 or more prescriptions before coming to my pharmacy.”<sup>59</sup>

The Panel agrees that the introduction of an automated recording system for the PBS Safety Net is essential. This 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. In particular, 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.

Another issue around the current Safety Net system relates to how it is structured over a twelve-month calendar year. Under the current system, consumers pay their standard co-payment (general or concessional) until they reach their relevant Safety Net limit. Those consumers are then able to access their medicines at a significantly reduced price (general patients) or for free. Consumers' spending on medications is concentrated in that initial period before the Safety Net is reached, which may cause financial difficulties for them during that time and even deter them from accessing their prescribed medications (see Positive Life NSW's comment below).

Many stakeholders emphasised the need for a system that worked to spread patient contributions more evenly over the twelve-month period and/or provided additional support for those patients with multiple chronic conditions for whom reaching the Safety Net is a given.

<sup>58</sup> Catholic Health Australia, Submission No. 348.

<sup>59</sup> Peter Crothers, community pharmacy owner, Submission No. 392.

The Health Care Consumers Association stated:

“Another issue with the PBS Safety Net is that the threshold for out-of-pocket costs can be up to \$1,475.70 per calendar year, which may still present a barrier for access to the safety net concession card, as there is currently no mechanism by which to spread the costs of PBS medicines more evenly throughout the year (particularly relevant to consumers with chronic and complex conditions who often have ongoing medication requirements).

To address consumer access, particularly for those consumers on low incomes, where cost is a significant barrier to the quality use of medicines, we suggest that consideration be given to a strategy for some consumers where a subsidy is spread over a 12 month period. Such a system would provide up-front financial assistance and relieve the undue stress on consumers of large out-of-pocket expenses on PBS medicines. This could be a real improvement on the current PBS Safety Net arrangements for consumers with chronic and complex conditions who need a range of medicines on an ongoing basis.”<sup>60</sup>

Positive Life NSW stated:

“We consider that the PBS Safety Net does not provide sufficient assistance to people with HIV and multi-morbidity, who are living on low incomes and not subject to measures to reduce out-of-pocket expenditure for medicines (such as in NSW). It can typically take many months before the Safety Net threshold is reached for these individuals, which can mean that some struggle to start or maintain treatment, because they are financially unable to sustain several months of co-payments until the safety net threshold is reached.

We consider that the PBS Safety Net should support access to the quality use of PBS medicines in Australia and that the

Safety Net threshold should be adjusted so that out-of-pocket costs for Australians with multiple chronic and complex health conditions are contained. There has been discussion amongst consumer groups over many years that the Australian Government should give serious consideration to implementing a Chronic and Complex Conditions Health Care Card. Eligibility for the card could be restricted to individuals with multiple chronic and complex health conditions and be income dependent. Eligibility could also be dependent on the number of diagnosed chronic health conditions.”<sup>61</sup>

An example of a safety net system designed to spread consumer costs over a twelve-month period is found in Quebec, Canada:<sup>62</sup>

“In Quebec a patient in the public medicine plan will pay a monthly set fee when they first purchase medicines for that month, this is called ‘the deductible’ and is set at \$18.85. The patient must also pay co-insurance which is 34.50% of the price of the prescription, minus the deductible. The co-insurance and deductible paid by the patient is called the patient’s contribution.

The government will then pay the difference between the prescription price and the patient contribution. There is also a maximum monthly and annual amount – if a person reaches either then the government will pay for all remaining prescriptions.”<sup>63</sup>

The Panel considers that a system which works to spread patient contributions more evenly over the twelve-month period would provide better protection for consumers. This should be further investigated by government.

Another issue with the PBS Safety Net that was presented to the Panel related to

<sup>60</sup> Health Care Consumers Association. Submission No. 248, page 4.

<sup>61</sup> Submission No. 321, page 6.

<sup>62</sup> Deloitte Access Economics, *Remuneration and regulation of community pharmacy: Literature review* (November 2016), page 19.

<sup>63</sup> Régie de l’assurance maladie Québec, 2016.



methadone and other treatments for opioid dependence. These treatments fall under section 100 of the *National Health Act 1953* (Cth), with differing government funding arrangements applying across different jurisdictions. Payments made by consumers to access opioid dependence treatments do not count towards the PBS Safety Net. Several pharmacy owners, consumer groups and other stakeholders have also raised concerns about this.

The submission from Harm Reduction Victoria (HRV) (a representative body for people who use or have used illicit drugs) and the Pharmacotherapy, Advocacy, Mediation and Support (PAMS) Service, who work with MATOD (Medication Assisted Treatment of Opioid Dependence) service providers and clients, stated:

“It is HRV/PAMS view that this ongoing situation represents a fundamental human rights and health equity issue for MATOD consumers in Australia that should be addressed as a matter of urgency. According to the World Health Organisation (WHO) “the enjoyment of the highest attainable standard of health is a fundamental right of every human being” (WHO, 2015). The ‘right to health’ also contains entitlements to ensure essential medicines are accessible and affordable to key populations – these ‘essential medicines’ specifically include methadone and buprenorphine which were added to the WHO Model List of Essential Medicines in 2005 (WHO, 2015).

Further, Australia is also a signatory to a number of international conventions including the Universal Declaration of Human Rights (Article 25) and the International Covenant on Economic, Social & Cultural Rights (Article 12) that together, provide not only for an adequate standard of health and wellbeing for all people but also for non-discriminatory access to affordable health care (UNOHCHR, 2008). As noted in research conducted by the Pharmacy Guild of Australia, with only 17% of

MATOD consumers on wages, “most illicit opioid users are poorly placed to pay any significant amounts towards the costs of their treatment” (Feyer et al, 2008). On this basis, it is reasonable to argue that the basic health and human rights of the majority of MATOD consumers (protected at international and domestic law) are not being met, and there is an urgent need to address the inherent structural inequities and discrimination associated with high MATOD dispensing fees.”<sup>64</sup>

The Section 100 Opiate Dependence Treatment programs are administered by state and territory governments and are therefore separate from general PBS arrangements. 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. However, the Panel finds that this system unfairly discriminates against patients requiring opiate dependence treatment, and should be rectified.

### OPTION 2-3: PBS SAFETY NET

In relation to the PBS Safety Net, the government should:

- a. require the PBS Safety Net to be managed electronically for consumers. This expectation 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 patient’s progress towards the PBS Safety Net is collated, including information on any gaps in how it is calculated
- d. investigate and implement an appropriate system which allows

<sup>64</sup> Harm Reduction Victoria, Submission No. 345, page 3.

payments for opiate dependence treatments to count towards the PBS Safety Net.

## 2.6. LABELLING

*The label is a vital part of the supply of PBS medicines. It is relied on by patients and health professionals for the proper identification, dosage, categorisations and monitoring of medicines.*

## DISCUSSION

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.<sup>65</sup>

The selection of a medicine, whether by a pharmacist, nurse, doctor or consumer, requires the user to read the label, identify the medicine and, if applicable, prepare to administer the product. 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. Barcodes on original packaging have helped significantly in this regard.

The pharmacist's requirements in respect to labelling dispensed medicines are specified in legislation and enforced in the jurisdiction in which a pharmacist practices.<sup>66</sup>

The Pharmacy Board of Australia (PBA) is the national board for the pharmacy industry. While its primary role is to protect the public,

it is also responsible for regulating practitioners and students as well as having other professional functions.

The PBA has implemented guidelines for the dispensing of medicines under section 39 of the national law enforced in each state and territory.

The guidelines focus on the safe dispensing and labelling of medicines, including compounded medicines. Non-compliance with these guidelines or the relevant dispensing practice standards may result in a notification to the PBA, which ensures appropriate action is taken under national law.

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

To minimise the geographic, cultural and financial barriers inhibiting Aboriginal and Torres Strait Islander peoples' access, special arrangements exist under the provision of section 100 of the *National Health Act 1953*. These arrangements provision the supply of PBS medicines to clients of eligible remote area Aboriginal Health Services (AHSs).

Under these arrangements, clients of an approved remote area AHS are able to receive PBS medicines from the AHS without the need for a normal PBS prescription form and without charge.

Remote area AHSs typically enter into a commercial arrangement with a pharmacy to supply PBS medicines in bulk, which the AHS then stores and dispenses directly to eligible clients at the time of consultation with a qualified health professional.

Clients of the 162 AHS clinics, including Aboriginal community controlled AHSs and

<sup>65</sup> Therapeutic Goods Administration, *Regulation Impact Statement: General requirements for labels for medicines* (2015), page 7.

<sup>66</sup> Pharmacy Board of Australia, *Guidelines for dispensing of medicines* (September 2015), page 7.



remote services operated by the states and territories, benefit from improved PBS access through these remote dispensing arrangements.

However, in the provision of bulk supplies, the Panel has been made aware of concerns that medicine labels are not being supplied as required. The following submission illustrates the problem:

“It is recognised that labelling and recording of dispensing (or supply) of medicines by nurses or ATSIPs is not optimal. Computer systems are not available that are able to both prescribe and dispense a medication, even though some systems in place in remote AHS have been developed with the remote context in mind, and where prescribing and dispensing occurs frequently in the same place.

For labelling, some health services have purchased a standalone dispensing program that does not ‘talk to’ the medical records system, but mostly relies on a series of Word documents scaled down to print on a medicine label. The person labelling the medicine opens the document, makes appropriate changes to dose and patient’s name and prints. This is subject to error, not to mention lack of privacy, as labels get saved with patients’ names and dosages on it which then has to be changed when the next person opens the file. There are also some AHS that still rely on handwritten labels (or none at all).”<sup>67</sup>

Irrespective of the dispensing system being used, 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.<sup>68</sup>

The Panel does not consider that the legislative and professional requirements for the labelling of PBS medicines should vary 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.

As noted later in this report (refer to Section 9.1, Section 100 RAAHS Program), a number of initiatives have been recently announced by the 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, patients are properly identified (so that the medicine is dispensed to the person for whom it is intended<sup>69</sup>) and that an appropriate label for the dispensed medicine is generated.

#### OPTION 2-4: LABELLING

All PBS medicines provided to patients should be appropriately labelled and dispensed. Where there is a system in place that involves ‘remote’ dispensing or ‘bulk supply’ then this system will require appropriate monitoring to ensure the quality of medicine supply.

<sup>67</sup> Fran Vaughan, consultant pharmacist, Submission No. 402.

<sup>68</sup> Fran Vaughan, consultant pharmacist, Submission No. 402.

<sup>69</sup> “If uncertain, the pharmacy would contact the clinic to ensure patient details were updated”: Pharmacy Guild of Australia Submission on *Equitable access to dispensing services for patients of Remote Area Aboriginal Health Services (RAAHS): Supply of medicines under the section 100 RAAHS* (2016).

## 2.7. CONSUMER INFORMATION ON PHARMACY SERVICES

*Information about pharmacy services is inconsistent and inadequate to support sufficient consumer awareness and choice.*

### DISCUSSION

Many consumers are not aware of what they are entitled to from community pharmacies. This ranges from consumers not being aware of:

- the range and types of services being offered by community pharmacies
- the different types of medicines and the mechanisms in place for accessing them
- the various medicine-related education programs available to reduce medication risks.

The range and types of services being offered by individual pharmacies can vary quite significantly. A small number of pharmacies may only be engaged in dispensing prescription medicines, while others may have various involvement in supplying broader health-related services such as medication reviews, blood pressure monitoring, diabetes services, flu vaccination, smoking cessation, sleep apnoea and weight management.

The Panel has observed some leading pharmacies that have tailored their patient services to meet the specific cultural and demographic needs of their local communities. This included pharmacies employing multilingual staff to better engage with consumers with culturally and linguistically diverse backgrounds and supplying tailored dose administration aids

and delivery services as well as pharmacies specialising in wound care management when other health professionals were not offering a similar service in the area.

Pharmacies supply a broad range of medicines from a broad range of categories, providing for basic treatments to more complex medication. They can also supply a diverse range of complementary medicines. The availability and diversity of medicines can also result in medication risks to certain patients, particularly if they are not aware of possible side effects, certain medicine interactions or the lifestyle changes required for certain medicines.

Some pharmacies also offer specialist programs and services such as treatments for opioid dependency and the provision of fit-packs. Promotion of these specialist services is often limited owing to the need to maintain patient privacy.

Despite the breadth of services provided by community pharmacies, many consumers are unaware of even the basic services or opening hours offered by particular pharmacies. This information is particularly important for consumers who seek to access pharmacy services outside of their normal locality.

The poor understanding of pharmacy services by consumers has been evidenced in a number of submissions provided to the Review:

“Many consumers do not understand the distinction between the various kinds of over the counter medicines and the different requirements there are for assessing them and this causes some confusion and discontent.”<sup>70</sup>

<sup>70</sup> Consumers Health Forum of Australia, Submission No. 483, page 12.

“Consumer surveys consistently report a lack of public awareness and understanding of the patient services available through community pharmacies.”<sup>71</sup>

Given the diversity of pharmacy models and services available, the Panel is keen to ensure that consumers are provided with an acceptable minimum set of information to help them understand the location, opening hours and patient services being offered by a particular pharmacy. This will aid in improving individual consumer choice while also enhancing broader public awareness of the value of community pharmacy.

The Panel considers that this would be best achieved through the provision of a ‘pharmacy atlas’ for consumers. This would cover the discrete and essential services offered by pharmacies, including consumer rights and expectations associated with those services.

While strongly in favour of the ‘pharmacy atlas’, the Panel acknowledges that there will be some challenges associated with implementation. This includes ensuring that information such as pharmacy name, location and opening hours are kept up to date. This also applies to supplies of certain products and services that may or may not be available when required by a patient.

The Panel is aware of the Australian Government’s Health Direct website and the Guild’s Find a Pharmacy service in addition to many pharmacy websites which provide details of opening hours and services provided. However, the Panel notes that none of these provides a comprehensive and up-to-date register of key patient information.

<sup>71</sup> Pharmacy Guild of Australia, Submission No. 486, page 10.

## OPTION 2-5: PHARMACY ATLAS

There should be an easily accessible and searchable ‘atlas’ of all community pharmacies in Australia that provides key patient information, including the services and programs offered by that 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).

## 2.8. CONSUMER MEDICINES INFORMATION

*While Consumer Medicines Information (CMI) leaflets are generally available, there are variances in how these are provided to consumers. Some consumers may be unaware of the availability of a CMI and there is a risk that these may not be provided, which could impact on quality of care.*

### DISCUSSION

The CMI is a document that contains information on the safe and effective use of a prescription or specified 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.<sup>72</sup>

A CMI includes:

<sup>72</sup> Therapeutic Goods Administration, [Consumer Medicines Information \(CMI\)](#) (29 July 2014).

- the name of the medicine
- the names of the active and inactive ingredients
- the dosage of the medicine
- what the medicine is used for and how it works
- warnings and precautions, such as when the medicine should not be taken
- interactions the medicine might have with food or other medicines
- how to use the medicine properly
- side effects
- what to do in case of an overdose
- how to store the medicine properly
- name and address of the sponsor
- the date the CMI was last updated.

CMI documents may not be available for every product. Sponsors are required to provide CMIs prior to new prescription medicines and specified over-the-counter medicines being released onto the market.

Therapeutic Goods Administration (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 Pharmaceutical Society of Australia (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 valuable tool for the provision of medicines information, and pharmacists are strongly

advised not to withhold the provision of a CMI<sup>73</sup>.

The Panel notes that consumers are not always aware of the availability of a CMI or, indeed, being offered a CMI as part of the dispensing process.<sup>74</sup> This could result in medication misadventure and loss in quality of care.

Addressing this risk requires a strengthening of the information dissemination system to improve consumer awareness and understanding of CMIs as well as strengthening dispensing controls to ensure that consumers receive the CMI as appropriate.

It would also be useful 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 pharmacy profession to improve consumer awareness of a CMI, including through mobile phone applications.<sup>75</sup>

## OPTION 2-6: CONSUMER MEDICINES INFORMATION

### A Consumer Medicines Information (CMI)

<sup>73</sup> Pharmaceutical Society of Australia, *Consumer medicine information and the pharmacist – Guidelines for pharmacists* (January 2007).

<sup>74</sup> Health Care Consumer Association, Submission No. 248.

<sup>75</sup> Mypharmacylink and Medadvisor now include an automatic link to the CMI. Various other methods of electronic delivery direct to the patient's phone are under consideration. Guildlink also provide the CMI in regular print, large print, audio and braille.

leaflet should be offered and made available to consumers with all prescriptions dispensed in accordance with Pharmaceutical Society of Australia (PSA) guidelines. The PSA guidelines and the distribution of CMLs to consumers need to be audited and enforced to ensure compliance.

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

## 2.9. THE BENEFITS OF AN ELECTRONIC HEALTH RECORD FOR CONSUMERS

*The current paper-based system of prescriptions used in Australia is outdated. It inhibits the creation of a universal medication record for Australians, creates excessive administration, is less convenient for consumers and presents significant challenges in meeting the standard required for quality use of medicines.*

### DISCUSSION

Australia's current paper-based prescription model requires that pharmacists sight the paper script when dispensing.

The Panel considers that the time is right for the current paper-based system of prescriptions to be replaced by electronic prescriptions. Quality use of medicines would be greatly improved with electronic prescriptions and an electronic medication record.

The first step will be the recognition by government of an electronic prescription record as a valid legal record. This would allow the move to a paper optional system,

which will better support the use of an electronic medication record and harvest the benefits that would flow from a complete record of medications being available to prescribers and dispensers.

Although an electronic prescription system does exist in Australia, with approximately 35 per cent of scripts uploaded to the system, the paper script is still considered the legal record.

The limitations of the current barcode-reliant electronic prescription model and the lack of a universal, consistent record of dispensed medicines (linked into patients' electronic health records) is concerning.

There is support among pharmacies and pharmacists to move towards a paperless system:

*"Over 64% of pharmacists believe paper optional prescriptions could help prevent prescription fraud and misadventure and 55% see paperless scripts as the next obvious step."*<sup>76</sup>

## ELECTRONIC PRESCRIPTIONS IN AUSTRALIA

Electronic Transfer of Prescriptions (ETP) in Australia involves an electronic system known as a Prescription Exchange Service (PES). There are currently two PES systems operating in Australia – eRx Script Exchange and MediSecure.

Pharmacies and prescribers may be connected to one or both PES systems. When a prescriber writes a prescription, the electronic copy of the prescription is encrypted and uploaded to a PES. A pharmacy is able to 'pull down' and decrypt the

<sup>76</sup> Fred IT, Submission No. 317, referring to eRx Script Exchange 2015 Pharmacy Survey Report.

prescription from the PES by scanning a barcode on the paper prescription. This information then automatically populates the pharmacy dispensing system, including patient details and the statutory required prescription information.

The consumer therefore still has to present the paper script to the pharmacy to collect their medications.

The intended benefits of the system are as follows:

- The risk of transcription errors is greatly reduced, reducing the likelihood of preventable adverse medication events.
- Time and workflow efficiencies occur for pharmacists, as they do not need to manually enter prescription information into their dispensing system.
- Messaging and coordination between prescribers and pharmacists is improved due to health providers having ubiquitous access to the same medicine record. This will greatly reduce the confusion during transitions of care settings and better enable the safer use of medicines.
- The electronic prescription and electronic medicine record may require additional checking and analysis before the health professional makes a decision, and this could increase the accountability of the professions.

During the consultation process for this Review, the Panel has received positive feedback relating to the electronic prescription scheme to date, noting in particular that the Electronic Prescription Fee (combined with electronic Practice Incentives

Program requirements for GPs) appears to have increased the level of uptake. There was also broad support for moving e-prescriptions to the next level – i.e. through removing the requirement for paper scripts.

In their submission to the Review, the Guild stated:

“As part of the broader integration of community pharmacy into the health system, it is vital that dispensing and medicine-related community pharmacy services are incorporated into the e-health system with community pharmacies receiving financial incentives that reflect the value of their work uploading and maintaining medicine profiles in the MyHealth Record.”<sup>77</sup>

Fred IT, the owner of the eRx Script Exchange service, considered that:

“The move to paperless prescriptions (initially as paper optional prescriptions) is seen as the most logical and value adding development of the ETP concept. There are several aspects to enabling paperless prescriptions, including technology development, security and privacy, legislation and public policy, change management and behavioural change, and stakeholder management.”<sup>78</sup>

Fred IT considers that a move to paper optional prescriptions is technically within reach, provided that the electronic prescription can act as the legal prescription. The benefits of this would include:

- increased consumer convenience by enabling consumers to use whichever option is most useful for them
- reduced wastage and inefficiency, such as reduced retyping of data and the replacement of lost prescriptions

<sup>77</sup> The Pharmacy Guild of Australia, Submission No. 486, page 13.

<sup>78</sup> Fred IT, Submission No. 317, page 5.



- increased quality use of medicines and a reduction in the risk of medication errors (i.e. allowing patients to use their mobile device to manage all their prescriptions, reducing lost prescriptions, and providing support services such as prompting patients to renew prescriptions at the right time, thereby improving medication adherence)
- over time, as electronic prescriptions become standard, a reduction in the risk of fraud whilst enabling the failsafe monitoring of issues such as prescription shopping.

The Priceline Pharmacy Brand Advisory Committee stated:

“Our collective view is that paperless prescriptions are a more efficient dispensing process and that eRx has proven to be stable, reliable and maintains patient privacy.

It provides the opportunity for less administration time and therefore more time to develop the pharmacist–patient engagement level.

This type of evolution is important in taking advantage of technology to improve patient experience and access.”<sup>79</sup>

The issues that have been identified relating to the current system include:

- lack of uptake from non-GP prescribers (e.g. hospital doctors) who have no incentive to connect to and upload information to a prescription exchange service

- uptake by GPs at the point of prescribing.<sup>80</sup>

The submission from MediSecure states:

“Medicine prescribing in hospitals and by specialists are not captured as there is no incentive for the hospital prescriber to be connected to and upload information to a PES, and therefore in an effective capture mechanism for the myHR. As there is no demand for electronic capture, the associated software vendors have no desire to perform the integration activity required. To capture all prescribing information an incentive should be created for hospitals and specialists either through financial reward or requirement to be able to prescribe.”<sup>81</sup>

Several stakeholders indicated to the Panel that uptake could be further increased at the pharmacy level by providing some direct remuneration to pharmacies above the current 15 cent Electronic Prescription Fee that is passed on to the software companies, leaving the exercise ‘cost neutral’ for pharmacies.

MediSecure commented in their submission:

“Some pharmacies refuse to use ETP as they believe that there are little efficiency benefits in scanning and see administration involved with the reconciliation of bills between the PBS and both PES as a major issue ...”<sup>82</sup>

Pharmacists needing a paper script can sometimes be disadvantaged when required to dispense appropriate medicine on verbal or electronic advice from a relevant medical specialist. This often leaves the pharmacist ‘chasing up’ the paper prescription at a later date in order to be remunerated. This occurs

<sup>79</sup> Priceline Pharmacy Brand Advisory Committee, Submission No. 116, page 3.

<sup>80</sup> Noting that current arrangements require medical practitioners to upload 50 per cent of their prescriptions to a PES in order to receive ePIP.

<sup>81</sup> MediSecure, Submission No. 329.

<sup>82</sup> MediSecure, Submission No. 329.



regularly in the case of chemotherapy compounding.

## OVERSEAS EXPERIENCE

Examples of e-prescription systems that have successfully been introduced, with near universal uptake and linkage into a comprehensive electronic health records, are seen in the following case studies:<sup>83</sup>

### Norway

The National Health Network provides efficient and secure electronic exchange of patient information between all relevant parties within the health and social services sector including pharmacists. While the system is fragmented, almost all GPs use electronic patient records and transmit prescription electronically to pharmacies.

In Norway, the e-prescription program was introduced on 18 October 2011 and has since been gradually rolled out throughout the country. By 2013, almost 90 per cent of municipalities had implemented e-prescription systems. Approximately 80 per cent of the total reimbursed prescription claims were electronic in 2013. A personalised web service named 'Mine resepter' provides citizens with an overview of their valid e-prescriptions.

### Sweden

Electronic prescribing in Sweden is well advanced; it has both a long history of use and a national system with a common infrastructure for transmission and storage. The world's first e-prescription from prescriber to pharmacist was transmitted in Sweden in 1983. Nearly all Swedish prescriptions are e-prescriptions; more than 90 per cent of prescriptions are dispensed from e-prescriptions.

### Canada

Canada has had a system called Pharmanet since 1995 that requires compulsory recording of every

prescription medicine. In over 20 years of experience, Pharmanet has demonstrated very few problems. The system is managed through the Canadian Pharmacy Board and College of Surgeons (Medical Board) in a practical and effective manner without too much unnecessary administration."<sup>84</sup>

Another example provided to the Panel was that of Finland:

"The Finnish model for delivering medication to a patient who accesses the healthcare system is evidence that paperless prescribing is effective.

The Finnish government implemented an entirely digital route for the prescribing and authorisation of medication provision for its citizens.

Finland instigated a National Prescription Centre to hold all prescription information for 30 months from the time of prescribing."<sup>85</sup>

The *kanta.fi* website lists the difference experienced by patients in Finland moving from paper to electronically recognised prescriptions:

"The biggest difference from paper prescriptions is that patients can pick up their medicines with their Kela card from any pharmacy. The prescription itself is stored in the Prescription Centre, where it is always kept safe. You can get a summary of all your electronic prescriptions, showing all their details in one place."<sup>86</sup>

## ELECTRONIC PRESCRIBING CAN REDUCE PATIENT RISK

A study of e-prescribing in the USA found that using electronic health records to electronically communicate prescription data between GPs and pharmacies nearly halved the risk of dispensing errors when compared

<sup>83</sup> These are extracts from Deloitte Access Economics, *Remuneration and regulation of community pharmacy: Literature review* (November 2016).

<sup>84</sup> British Colombia, [PharmaNet](#).

<sup>85</sup> MediSecure, Submission No. 329, page 5.

<sup>86</sup> Kanta Fi [Notices](#).

with printing the prescription and giving it to the patient.

Hospitals in the United States are heavily involved in dispensing prescription medicine to in-patients. A trial of a computerised prescriber order entry system for improving efficiency and reducing errors in medicine orders in hospitals found that the system resulted in an 8.9 per cent decrease in errors compared with paper-based medicine.<sup>87</sup>

## POTENTIAL TO IMPROVE EQUITY OF ACCESS

Electronic prescribing, as evident in overseas examples, removes the administrative burden associated with patients having to provide a paper script. This has the potential to facilitate increased supply of PBS medicine through online pharmacies, leading to greater equity of access to affordable medicines. This would be particularly beneficial for less mobile consumers and those residing in more remote regions of Australia, who would otherwise have to travel relatively long distances to visit their nearest pharmacy.

Some indication of the potential savings that consumers could derive from purchasing their medicines online rather than incurring the additional costs associated with visiting the pharmacy in person are provided in the simple example below.

Consider the case of a consumer who would otherwise have to travel 100 kilometres (i.e. 50 kilometres each way) to visit the nearest pharmacy to have a script filled. Their ability to order their medicines online would save them around:

- \$28 in road transport costs (i.e. for a 100-kilometre round trip that costs \$0.28 per kilometre)
- \$15 in travel time (i.e. assuming an average speed of 100 kilometres per hour)
- \$2.50 in time waiting for the script to be filled (i.e. assuming a wait time of 10 minutes that has an opportunity cost of \$15 per hour of private time).

These total savings of \$45.50 would be offset by the:

- opportunity cost of the time that the consumer spends ordering the medicine online, which is assumed to be around \$2.50 (it is assumed for the purposes of this simple example that the consumer spends 10 minutes of their private time, which has an opportunity cost of \$15 per hour)
- shipping costs charged by the online pharmacy for the delivery of the medicine, which are assumed to be \$8.95
- opportunity cost of having to wait for the medicines to be delivered by the online pharmacy. For the purposes of this simple example, it is assumed that these costs are zero (e.g. it is assumed that these medicines are not urgent and little value is lost having to wait for the delivery of these medicines).

In this case, the consumer would save around \$34.05 for each script they purchase online, which is around 88 per cent of the price they have to pay for that medicine (assuming that they pay the general co-payment of \$38.80 for that medicine).

## CONCLUSION

<sup>87</sup> Referenced in Deloitte Access Economics, *Remuneration and regulation of community pharmacy: Literature review* (November 2016), page 38.

The Panel considers the implementation of a fully ('paperless') electronic prescription system in Australia should be a high priority. Under this system, the electronic record would become the legal record.

All prescribers would be required to upload prescriptions to the e-prescription service, and pharmacists would be required to access the electronic record before dispensing.

The e-prescription system should be linked to an automatic electronic medicine record that can be accessed by all appropriate professionals, including hospital prescribers, medical specialists and pharmacists (more details below). The system should be updated in real time to ensure continuity of care and the avoidance of medical misadventure.

Prescribers and pharmacists should receive appropriate incentives to cover costs associated with the introduction of the new system. There will also need to be an appropriate 'transition' to electronic prescriptions – for example, a suitable period of time where paper and electronic prescriptions operate as parallel systems.

#### **OPTION 2-7: ELECTRONIC PRESCRIPTIONS**

The 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 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 patient who is seeking to fill a PBS prescription.

## **ELECTRONIC RECORD KEEPING**

*Australia lacks an integrated and effective universal health record system. This reduces consumer access to best-practice care and continuity of care between providers.*

## **DISCUSSION**

Australia's electronic health record system is known as MyHealth Record. It is an opt-in system requiring patients to register (though trials were run in some areas of Australia in 2016 introducing an opt-out system).<sup>88</sup>

For prescription information to be stored on the MyHealth Record system, prescribers or pharmacists must be registered and set up for MyHealth Record (including having met the relevant prerequisites). They must also be using clinical software that has functionality to produce and send records to the MyHealth Record system.

The fragmented, 'opt-in' nature of the current system means that there is no comprehensive record of a patient's medicines that can be accessed by GPs, specialists and other healthcare professionals at the time of prescribing or community pharmacists at the time of dispensing. Similarly, there is no record for health professionals to refer to at the time of admission to hospital or at discharge.

This contributes to medicine wastage as well as increased hospital readmissions due to medicine misuse. Importantly, it also increases the risk of medicine interactions that can harm patients, as prescribers and community pharmacists do not have a

<sup>88</sup> Refer to detail provided at Australian Digital Health Agency, [My Health Record News](#), issue 1 (February 2016).

complete record of a patient's medicines. They instead have to rely on the patient 'remembering' their medicines both when prescribing and when dispensing.

The literature review of medication safety in Australia, undertaken by the Australian Commission on Safety and Quality Use of Medicines, noted that:

"Medication histories taken at the time of admission to hospital are still a point of vulnerability for medication error, particularly where there is no routine practice of medication reconciliation. In studies where initial medication histories were compared with reconciled histories, high levels of error with medication histories at admission were observed where medication reconciliation was not undertaken. Two studies showed that between 60% and 80% of patients were noted to have a discrepancy with their medication history and their reconciled history, while three studies reported error rates ranging from 1 to 2.5 per patient on the initial history. Omission of therapy was the most common discrepancy, accounting for between 40% and 60% of errors. One study found that medication histories were less likely to be accurate if the patients presenting to emergency departments had not brought in their own medicines."<sup>89</sup>

This is an unacceptable margin of error. The Panel considers a universal, comprehensive electronic medicines record is the only solution to ensure accurate information is available for healthcare providers and to support appropriate quality of care for patients.

Submissions to the Review generally indicated support for a universal, easily accessible electronic health record system. Pharmacy groups and owners called for remuneration

for pharmacies to support the system. The current system was reported as 'incomplete', 'unreliable' and slowing down dispensing software (especially in rural areas with poor internet connection).

The Panel notes that the Digital Health Agency (DHA) is working towards a system of automatic uploads to MyHealth Record, including improved compatibility with general practice software and dispensing software, and the ability to generate up-to-date medication lists from uploaded data.

The DHA advised that annually in Australia there are approximately two million medication misadventures and 230 000 hospital admissions for misadventure that cost Australia \$1.2 billion, with some 10 000 deaths.

The DHA considers that the implementation of nationally consistent and comprehensive health technology enablers, such as electronic medication records and related communication mechanisms, can have a significant impact on reducing medication misadventure risks.

The Panel fully supports these aims and believes they should be a high priority for the government in the near future.

In relation to the MyHealth Record system, take-up as of March 2017 was as follows:

- 4 662 170 consumers registered, or 19% of Australia's population
- 1296 retail pharmacies, or 24% of community pharmacies
- 1 912 056 dispense documents.

Overall, Australia lacks an integrated and effective electronic health record system through which all health professionals (including community pharmacies and hospitals) can access comprehensive patient

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<sup>89</sup> Australian Commission on Safety and Quality in Health Care, [Literature review: Medication safety in Australia](#) (August 2013).

health information, including medicine records. The current system is lagging behind comparable overseas health systems and is affecting consumer access to best-practice care and continuity of care between different providers.<sup>90</sup>

It is the Panel's preference that the e-prescription system described above and universal medicine record forms part of the MyHealth Record system, which includes patients' broader medical history. If MyHealth Record is not likely to achieve universality in the near future, the Panel believes that an appropriate universal electronic medicine record should be introduced in the short term, which could later be linked into MyHealth Record.

All prescribers should be required to record any prescriptions that they issue on the electronic medicine record. Pharmacists should similarly be required to record any medications that they dispense on the electronic medicine record. This should also include a vaccines register. The system should be updated in real time to ensure continuity of care and the avoidance of medical misadventure.

The Panel is aware of opposition to the implementation of a fully electronic system relating to privacy and data security concerns. The Panel notes that, in moving towards a universal and comprehensive electronic prescription and medication record system, it is imperative that the highest standard of privacy and data security be maintained.

<sup>90</sup> A Recent OECD report, *New health technologies: Managing access, value and sustainability* (2017) rates Australia as "medium for technical and operational readiness" and "low for data governance readiness" when compared to the other OECD countries (page 214).

## KEY INITIATIVES TO IMPROVE ELECTRONIC MEDICAL RECORDS DATA AND INFORMATION IN AUSTRALIA

The Panel notes that governments across Australia understand the importance of technology enablers in improving health outcomes for consumers and have implemented a range of initiatives to harvest these opportunities.

### *Digital Health Agency*

The DHA was formed in 2016 as a successor to the National E-Health Transition Authority. As noted above, the DHA's aim is to drive Australia's digital health strategy at a national level.

For example, the DHA's Medical Safety Program was established in January 2017 to engage with consumers and clinicians in enhancing medicine management use and capability with the MyHealth Record system.

This is being achieved through:

- completing an environmental scan of all digital activities that support access to safer medicines
- identifying existing agency projects that should be governed by the Medical Safety Program
- driving an evidence-based, sector-wide digital health road map, including benefits realisation, to monitor progress of adoption and outcomes.

### *New South Wales eMeds implementation*

The Panel notes that New South Wales is currently strengthening its data and information capability to improve quality of care as follows:

“NSW Health is currently implementing Electronic Medications Management (eMeds) across the system. By improving access to data and information, the eMeds program supports professional collaboration and better coordinated care. It aims to reduce medication errors, adverse drug events, average length of stay, and improve the patient experience. Doctors, nurses and pharmacists are supported in medicines reconciliation, prescribing, dispensing and administration with clinical decision support tools, while communicating information to other providers and patients on discharge from hospital. This system builds on NSW Health’s Electronic Medical Record (eMR) to provide functionality to manage medications more efficiently, effectively and safely. The eMeds program also includes upgrades to the existing pharmacy system, development of interfaces and systems to manage medication data standards, and the implementation of antimicrobial stewardship systems.

NSW Health recommends that funding should be made available to encourage the development of similar tools which can be used by community pharmacists and other healthcare providers to make prospective changes to care, in order to improve health outcomes.”<sup>91</sup>

The eMeds program is continuing to be rolled out to hospitals and facilities in New South Wales and is successfully enabling the integration of systems and processes that enhance patient safety.<sup>92</sup>

#### *Queensland Digital Health Strategy*

The Queensland Government has also embarked on a comprehensive program to:

“[D]evelop a digital health system that offers integrated services with timely, secure and reliable access to patient

information across both public and private care providers.”<sup>93</sup>

The Queensland strategy recognises that:

“Information is central to improving integrated care for Queensland patients in the community. Queensland Health needs to easily, accurately and comprehensively share patient and clinical information with the HHS [hospital and health services], across regional boundaries with relevant healthcare providers.

Improved data integrity, assurance and access will better support the fair and equitable distribution of services in a close to home model ... Patients are demanding more participatory, informed decisions in their care journey. They require access to referral pathways, scheduling information across the continuum of care, and ability to select their healthcare providers and the services as part of their treatment plan.”<sup>94</sup>

## OVERSEAS EXAMPLE – ELECTRONIC RECORD KEEPING

Denmark provides an example of an effective electronic record keeping system:<sup>95</sup>

“Technology is used at all levels of the health system as part of a national strategy supported by the Danish Health Data Authority. Each region uses its own electronic patient record system for hospitals, with adherence to national standards for compatibility. Danish GPs were ranked first in an assessment of overall implementation of EHRs in 2014. All citizens in Denmark have a unique electronic personal identifier, which is used in all public registries, including health databases. A shared medical

<sup>91</sup> NSW Health, Submission No. 494, page 9.

<sup>92</sup> New South Wales Government, [eHealth](#).

<sup>93</sup> Queensland Government, *21<sup>st</sup> century healthcare – eHealth investment strategy* (2015), page 3.

<sup>94</sup> Queensland Government, *21<sup>st</sup> century healthcare – eHealth investment strategy* (2015), page 15.

<sup>95</sup> Deloitte Access Economics, *Remuneration and regulation of community pharmacy: Literature review* (November 2016).



card—accessible by all relevant health professionals—has been implemented. It contains encoded information about each patient’s prescriptions and medicine use.”

#### **OPTION 2-8: ELECTRONIC MEDICATIONS RECORD**

The electronic personal medications record should cover all Australians and ensure appropriate access by, and links between, community pharmacy, hospitals and all doctors. This record should also include a vaccines register.

#### **MANAGING RISKS ASSOCIATED WITH ‘CHANNELLING’ PRESCRIPTIONS**

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

#### **DISCUSSION**

The Panel is aware of concerns relating to ‘script channelling’, whereby prescribers direct electronic prescriptions to particular pharmacies based on existing relationships or inappropriate incentives. The Fred IT submission to the Review noted that 59.5 per cent of pharmacists saw ‘script channelling’ as a concern in moving to a paperless prescription system.<sup>96</sup>

Fred IT also stated:

“Through the existence of strong legislation to regulate, monitor and police such practices, the certification of all participating systems and the comprehensive compliance reporting and

monitoring of all activities aided by the technology platform deployed, we are confident that such issues will be appropriately addressed.”<sup>97</sup>

The Panel agrees that these risks can be managed through legislation and appropriate monitoring.

The electronic prescription system should not require that a prescription is directed when it is ‘written’. Rather, it should allow consumers to fill the script after leaving a medical practice, in a secure and verifiable way, at the community pharmacy of their choice if this is the consumer’s preference.

The Panel believes that the electronic prescription system should also allow a consumer to ‘direct’ the prescription so that the consumer can easily access the medicines from the community or online pharmacy of their choice. The purpose of this would be to:

- reduce waiting times by allowing pharmacists to download and arrange the medications to be dispensed before the consumer arrives at the pharmacy
- support the use of online pharmacies, as the consumer could ask the prescriber to forward the script to an online pharmacy for delivery to the consumer.

An appropriate system should also be put in place to assist and educate consumers about their rights, ensuring inappropriate behaviour by prescribers does not occur.

<sup>96</sup> Fred IT, Submission No. 317, page 3.

<sup>97</sup> Fred IT, Submission No. 317, page 12.



**OPTION 2-9: ELECTRONIC PRESCRIPTIONS – CONSUMER CHOICE**

The choice of where a consumer has an electronic prescription dispensed should remain a decision for that consumer. The consumer may request that the electronic prescription 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 may not direct an electronic prescription to a particular community pharmacy for dispensing. This will require appropriate oversight and enforcement by professional bodies.

**2.10. MANAGING MEDICINE RISKS ASSOCIATED WITH HOSPITAL DISCHARGE AND READMISSION**

*The lack of a robust framework for the management of medicines between hospitals and community pharmacies creates risks for patients on discharge.*

**DISCUSSION**

The need for consistent and effective discharge planning for patients leaving hospital is a well-recognised issue within the Australian health system.

Effective discharge planning, including communication back to a patient's primary care provider, is necessary to support continuity of care and patient safety. The effective planning, supply and reconciliation of patients' medications forms part of this broader issue.<sup>98</sup>

<sup>98</sup> See, for example, E. Cummings et al., *Discharge, referral and admission: A structured evidence-based*

Submissions to the Review and broader research indicate that the situation is particularly complex for patients transitioning between hospitals and aged care facilities as well as for elderly patients returning to their own homes.

Patients are often prescribed new medications upon discharge, and hospital policies and practices around supplying these medicines appear to be inconsistent. Some patients are not receiving education and information about their new medications. In some cases, new medicines are not reconciled against existing medications.

One study that documented medicine-related problems post-discharge for cardiology patients found a significant number of medication related problems:

"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."<sup>99</sup>

*literature review*, eHealth Services Research Group, University of Tasmania (on behalf of the Australian Commission on Safety and Quality in Health Care and the New South Wales Department of Health) (2010).

<sup>99</sup> L. Roughead et al., *Literature review: Medication safety in Australia* (on behalf of Australian Commission on Safety and Quality in Health Care) (2013).

Many community pharmacists have indicated that the burden falls on them to ensure patients have access to the medications they require upon discharge and to follow up and check missing information or inconsistencies on discharge records.

The Literature Review of Medication Safety in Australia<sup>100</sup> also identified specific issues with medications upon the transition of patients to aged care facilities:

“Further insight into problems with transition into aged care is provided by a study assessing transition from a 400 bed acute care hospital or discharge from an 80 bed sub-acute aged care hospital to residential aged care. The Melbourne study was conducted over a three month period in 2009. Eligible patients were those who had an overnight inpatient stay in hospital. For those transitioning to an aged care facility for the first time, the hospital provided all prescribed medicines. However, for those returning to a facility that was their usual place of residence, only new or changed medicines were provided ... In all, 202 patients discharged to 90 residential care facilities were included. Eighteen percent of patients experienced a missed or significantly delayed dose of their medicine within 24 hours of discharge. In 93% of cases the medicine dose was completely missed and in the majority of cases this was for regularly scheduled medicines. Twelve percent of missed doses were considered high risk and 53% moderate risk. Medication charts were not written or updated in time for the first dose for 62% of patients and medicines were not suitably packed for 38% ... Patients who missed doses were more likely to represent to the hospital within seven days of discharge, although

this could not be directly attributed to missed doses.”<sup>101</sup>

Although there are some examples of effective collaboration between hospitals and community pharmacies, the Panel considers that there is a significant opportunity to improve these processes for the benefit of patients.

In their submission to the Review, NSW Health advocated an increased role for hospital pharmacists to strengthen the hospital discharge process:

“[T]here is an opportunity to strengthen the process of discharge from hospital to an aged care facility, by increasing the role of public hospital pharmacy within this process.

Currently, the communication pathway between the hospital, the consumer’s General Practitioner, the aged care facility and the facility’s pharmacy supplier is complex, and holds substantial risk when considering how changes to medicines are communicated and implemented in this transition.”<sup>102</sup>

However, as detailed in Chapter 8 (Health Programs Offered by Community Pharmacy), community pharmacies often play a valuable role in coordinating the discharge process for patients. Community pharmacy staff in particular are often familiar with patients and their requirements, able to check discrepancies in hospital discharge papers and communicate changes in medication regimes back to GPs and other healthcare providers.

One hospital pharmacist emphasised in their submission the valuable role that community pharmacists play:

<sup>100</sup> L. Roughead et al., *Literature review: Medication safety in Australia* (on behalf of Australian Commission on Safety and Quality in Health Care) (2013).

<sup>101</sup> L. Roughead et al., *Literature review: Medication safety in Australia* (on behalf of Australian Commission on Safety and Quality in Health Care) (2013).

<sup>102</sup> NSW Health, Submission No. 494, pages 7 & 8.

“I have encountered countless scenarios where the community pharmacy has taken on significant continuity of care responsibilities for these patients in a prompt and responsible manner. One good example is in the preparation of dosage administration aids in line with discharging requirements to ensure ongoing medication needs are met in a timely and efficient manner. These patients represent some of the most vulnerable people within our community. Often there is great familiarity by the community pharmacy, of the patient in question and their personal scenario and specific care requirements addressed whether it be with a sensitivity to their family, home environment, or greater health situation.

These critical services by community pharmacy have furthermore alleviated the burden of discharge medication management on myself and my colleagues and allowed us more time to focus our energies and expertise on acutely unwell patients.”<sup>103</sup>

The Panel is not in a position to recommend one specific approach over another, but it is clear that consistent policies and procedures are required to ensure patients have the medications they require after discharge. Appropriate communication back to regular primary care providers, including GPs and community pharmacies, is also essential.

The Panel has heard reports of the difficulties that arise for community pharmacies in tracking down discharge records. One community pharmacy owner commented:

“Commonly, patients are discharged from hospital and [the] pharmacist spends a great deal of unremunerated time follow[ing] up discharge records. The statistics on patient misadventure after hospitalisation is un-Australian and is directly a result of archaic communication

from hospitals to other health care professionals.”<sup>104</sup>

The introduction of a universal and comprehensive medication record accessible by all relevant health professionals will support improvements in discharge planning around medications.

The introduction of a direct referral pathway for pharmacist medication reviews will also support improved outcomes for patients.

The Panel recognises that in many cases the patient’s community pharmacy will be best placed to supply and reconcile new medications. Communication and planning is required between the hospital and pharmacy to ensure that the pharmacy is able to do this. The Panel is aware of issues arising for patients and community pharmacies when patients are discharged late in the afternoon or over the weekend.

Where appropriate, hospital pharmacies should provide a ‘discharge pack’ with a sufficient 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 these cases, it may be appropriate for hospital pharmacies to provide a ‘discharge pack’ containing around three to four days of the patient’s medications or as appropriate.

One community pharmacist who supported the use of ‘discharge packs’ in rural communities explained:

“In Tamworth my experience is with the Friday afternoon clear-out of wards, particularly cardiac wards. The specialist has visited all patients and agreed to the

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<sup>103</sup> Marijana Putnikovic, clinical hospital pharmacist, Submission No. 217.

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<sup>104</sup> Feras Karem, community pharmacy owner, Submission No. 359.

discharge. He/she has delegated the role of the paper-work to the intern.

By the time they get to the prescription paperwork, the lowest priority in their eyes, for cardiac patients they produce a six item prescription.

The patient presents at the pharmacy, usually pale and wearing the wrist band. As this was not a planned trip to hospital and they have just lost a week's work and are now worried about their future, money is always an issue.

When presented with the above prescriptions and a bill for between \$75 and \$100, they are almost ready for another emergency trip after a new heart attack.”<sup>105</sup>

#### **OPTION 2-10: MANAGING MEDICINE RISKS FOR PATIENTS UPON DISCHARGE**

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. 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.

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<sup>105</sup> Patrick Mahony, community pharmacy owner, Submission No. 77.

### 3. THE ROLE OF COMMUNITY PHARMACY IN MEDICINE SUPPLY

#### 3.1. THE ROLE OF COMMUNITY PHARMACY

*There are certain minimum services that all community pharmacies should provide in order to meet consumer and government expectations about the level of consistency that is required from a national pharmacy network.*

#### DISCUSSION

The Panel views the integral role of community pharmacy as akin to an ‘agent’ of government in relation to the dispensing of Pharmaceutical Benefits Scheme (PBS) medicines.

This is consistent with the view of the Pharmacy Guild of Australia (the Guild) of the role of community pharmacy:

“pharmacies are explicitly tasked to deliver Quality Use of medicines related health outcomes to patients through the professional dispensing of PBS and RPBS medicines and related services, working effectively as agents of the federal government.”<sup>106</sup>

As an agent of government, the key role of community pharmacy is the dispensing of PBS medicines and the delivery of medicine-related services to promote quality use of medicines.

The Panel also recognises that the broader role of pharmacies in the primary healthcare system includes:

- dispensing or selling ‘pharmacy only’ medicines (Schedule 2 and Schedule 3) and non-PBS or private prescriptions
- providing advice across a range of healthcare services
- supplying, selling and advising on other health-related products.

#### KEY PRODUCTS AND SERVICES PROVIDED BY COMMUNITY PHARMACIES

Currently, the range of products and services offered by community pharmacies varies depending largely upon the location or local market in which the pharmacy operates.

Pharmacies located in shopping strips or medical centres traditionally tend to derive a greater proportion of their income from the dispensing of medicines, while pharmacies located in shopping centres may have a greater emphasis on front-of-store retail sales.<sup>107</sup>

The level and range of professional services offered by community pharmacy can similarly vary, from a customer-oriented approach concentrating on high-volume medicines dispensing and front-of-house (non-medicine) sales to a more patient-centred approach offering specialised medicines management and adherence services, advice and consulting, including medicines reconciliation and health checks, wound management and vaccination programs.

While the Panel notes that it is important for pharmacies to be able to supply products and provide services that best meet local needs, it also considers that a ‘minimum level’ of

<sup>106</sup> Pharmacy Guild of Australia, Submission No. 486, page 8.

<sup>107</sup> IBISWorld Industry Report G427/a, *Pharmacies in Australia*, page 12.

products and services should be provided by all pharmacies that dispense PBS medicines.

As an agent of government that is funded to fill a particular role, it is logical that pharmacies will be required to meet certain obligations expected by the Australian community.

## DEFINING THE MINIMUM PRODUCTS THAT SHOULD BE AVAILABLE FROM COMMUNITY PHARMACIES

Community pharmacies act as agents of the government to dispense PBS medicines in a safe and secure way. They are paid for this service.

It is the opinion of the Panel that the government, on behalf of consumers, should establish clear minimum standards for the range of products that a community pharmacy is required to supply.

It should not be up to an individual pharmacy to decide which PBS medicines it supplies. The Panel has heard reports of some pharmacies refusing to supply certain medicines (generally high-cost medicines) for various reasons.

It is the understanding of the Panel that all PBS-approved community pharmacies should supply all PBS medicines.

Where generic versions of a particular medicine are listed, the pharmacy should be required to supply at least one medicine containing the relevant active ingredient. That should be established as part of its 'contract' with government, such that an approval to supply PBS medicines comes with a responsibility to supply all PBS medicines.

The Panel notes that some pharmacies have to date faced difficulties in ordering and supplying higher cost medicines due to cash-

flow issues and the current delay in reimbursement of GST. Two examples from submissions to the Review follow:

"[W]e are able to supply those expensive, currently non PBS drugs for Hepatitis C (eg Harvoni) and HIV that many of our competitors literally refuse to order in for their customers simply due to the expense involved. I have lost count of the number of customers who have been sent to us by other local pharmacies to order these items for them as they would not do so. In fact only last week we had a local gentleman who came in requesting whether we were able to get his anti HIV medication. Up until this point he had had to travel to Brisbane – quite a trek from Hervey Bay – each time as no other pharmacy in the area would order them in for him."<sup>108</sup>

"Our experience at my pharmacy is that the GST component of these high cost medicines can place a significant cashflow burden on smaller pharmacies. In our particular catchment, many other pharmacies refused to dispense scripts for these medications because of it. In our case, the GST paid on the items that then had to be later claimed back on our Business Activity Statements exceeded our nett profit every month since the listing of the directly acting Antivirals to treat Hepatitis C infections. In one month, our BAS refund was almost at the level of our Gross Profit from trading."<sup>109</sup>

This issue would be greatly reduced by the Panel's suggested option for the introduction of a new maximum payment by pharmacies to wholesalers (see Option 6-2).

In addition to the supply of PBS medicines, part of the service of a community pharmacy involves the supply of particular products that are used with medicines and required to

<sup>108</sup> Matt Hughes, community pharmacy owner, Submission No. 203.

<sup>109</sup> Anvin Javanmard, community pharmacy owner, Submission No. 396.



ensure the quality use of medicines (e.g. syringes and asthma spacers).

A minimum schedule of these products that all community pharmacies should be required to supply as part of their PBS approval should be established. The schedule should be established by government, working with appropriate stakeholders.

### DEFINING THE MINIMUM SERVICES THAT SHOULD BE PROVIDED BY COMMUNITY PHARMACIES

In relation to the services that all community pharmacies should provide, the Panel contends that a minimum level of services is encompassed within a quality dispensing process.

The Pharmacy Board of Australia has *Guidelines for dispensing of medicines* developed under section 39 of the Health Practitioner Regulation National Law (2010). The Pharmacy Board website specifies the board's guidelines and policies which:

"... help clarify the Board's views and expectations on a range of issues. Codes and guidelines are approved by the Pharmacy Board of Australia and may be used as evidence of what constitutes appropriate professional conduct or practice for pharmacy in proceedings under the National Law of a co-regulatory jurisdiction against a health practitioner."<sup>110</sup>

These guidelines are a bare minimum set of standards for dispensing. Deviation from these standards could constitute professional misconduct.

<sup>110</sup> Pharmacy Board of Australia, [Codes, guidelines and policies](#).

The guidelines list areas that are required for safe dispensing and good pharmaceutical services and include:<sup>111</sup>

- ensuring dispensing of the prescription is consistent with the safety of the patient
- managing requests for dispensing multiple repeat prescriptions at one time
- managing facsimile and scanned prescriptions
- managing internet, mail order and other indirect supply of medicines
- extemporaneous dispensing (compounding)
- maintaining appropriate incident records
- labelling of dispensed medications
- counselling patients about prescribed medications
- ensuring patients' privacy and confidentiality and complying with relevant standards and legislation
- dealing with, and minimising the risk of, dispensing errors and near misses
- managing workloads
- utilising dispensing assistants / dispensary technicians appropriately
- returning unwanted medicines.

The Pharmaceutical Society of Australia (PSA) *Professional practice standards* set out a similar comprehensive list of requirements for dispensing.<sup>112</sup>

The Panel considers that an appropriate minimum schedule of services can be derived from the above professional standards and guidelines for dispensing. This schedule would

<sup>111</sup> For an in-depth description, refer to Pharmacy Board of Australia, [Codes, guidelines and policies](#).

<sup>112</sup> Refer to Pharmaceutical Society of Australia, [Professional practice standards](#), ver. 4 (2010), Standard 5.



not only set the minimum services that all community pharmacists should provide but also feed into the calculation of appropriate remuneration for dispensing services, which is dealt with in Chapter 4.

The Panel also contends that those services that do not fall under the dispensing process should be considered a separate service or program. Remuneration for these programs is discussed in Chapter 8 (Health Programs Offered by Community Pharmacy).

The Panel is aware that the distinction between dispensing-related services and ‘add-on’ additional pharmacy services may not always be clear cut and may in fact sit along a continuum. As discussed later in the report, the pharmacy profession requires vision and leadership to establish clear evidence of the need for such services; secure, appropriate funding; and the development of effective data collection and evaluation mechanisms.

The Panel also notes that dose administration aids (DAAs), clinical interventions and Medschecks are essential services that the Panel would expect every pharmacy to provide and that should be remunerated appropriately (see Chapter 8 (Health Programs Offered by Community Pharmacy) for more information).

## CONCLUSION

In summary, the government should establish a minimum set of products and service requirements that must be met by all community pharmacies that dispense PBS medicines. These requirements should cover safe and effective dispensing and the service requirements of a community pharmacy.

Some of these requirements already exist. However, it is desirable that they are regularly revisited and set as a standard for each

community pharmacy before that community pharmacy can receive any government remuneration for dispensing. It may 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 medicine in private with a pharmacist.

It is not the intention of this Panel to try and fully formulate the set of minimum requirements. That is a job for a separate group of specialists, including community pharmacists themselves.

The Panel also notes that these minimum requirements will require appropriate enforcement and oversight from professional bodies and/or government agencies.

### OPTION 3-1: COMMUNITY PHARMACIES – MINIMUM SERVICES

The government should establish a process to determine the set of minimum requirements that a community pharmacy must meet in order to receive remuneration for dispensing. The government should initiate procedures to enforce these requirements and to have them updated at regular intervals. These requirements should be promoted by being incorporated within the Community Pharmacy Service Charter.

### 3.2. THE PHARMACY RETAIL ENVIRONMENT

*There is a significant degree of variability in the models of community pharmacy in operation in Australia. While the diversity in these models is valued by consumers, there are some operations that do not meet expectations of a 'full-service' community pharmacy. If not properly managed, the community pharmacy retail environment may detract from the range and quality of medicine services being provided to some consumers.*

#### DISCUSSION

Although it is operating in a primarily retail setting, the community pharmacy sector cannot be categorised as simply retail.

Community pharmacies are recognised as an important healthcare destination by the majority of consumers and, when dispensing PBS medicines, community pharmacies are acting as agents of government. Ideally, the environment within a community pharmacy should more consistently recognise this and must clearly be differentiated from a standard retail environment.

It has been put to the Panel during consultations that some models of community pharmacy operating today do not reflect a healthcare environment and that this impacts negatively on consumers' perception of, and trust in, community pharmacists.

Hall and Partners' in-depth consumer consultation found that:

"Clinic-style pharmacies attract more support from the public than from pharmacists. This research showed that the Australian public has an appetite for a pharmacy environment that reflects a more clinical focus. The current typical

set-up of the community pharmacy environment impacts the clinical trust placed by consumers in pharmacists, as well as their willingness to accept extra services provided by them. Consequently, across all the service scenarios tested in the survey, a dispensing or clinic style pharmacy was the most preferred choice. A clinic-like pharmacy with private consultation rooms is favoured for accessing a specialised program or service and for discussing a health issue with a pharmacist, while a dispensing pharmacy with less focus on retail is most commonly favoured for filling both a repeat script and an initial script."<sup>113</sup>

The Guild noted in its submission that:

"Consumer surveys consistently report a lack of public awareness and understanding of the patient services available through community pharmacies."<sup>114</sup>

The Guild therefore recommended that:

"[The government should fund] an ongoing campaign to raise public awareness of the role of community pharmacy as a trusted health destination, and the availability of pharmacy services."<sup>115</sup>

The Panel considers that there need be no limits set on the level of retail products provided through community pharmacy; there should be agreement on the types of non-medicine-related health services provided and a clear understanding of the benefits to accessing these services through community pharmacy.

<sup>113</sup> Hall and Partners Open Mind, qualitative and quantitative consumer research (2016).

<sup>114</sup> Pharmacy Guild of Australia, Submission No. 486, page 10.

<sup>115</sup> Pharmacy Guild of Australia, Submission No. 486, page 15.

### 3.3. COMPLEMENTARY MEDICINES

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

#### DISCUSSION

The Review's consultation process has clearly demonstrated that consumers expect access to complementary medicines in their local pharmacy.

It is also clear that consumers value pharmacist advice to support their selection and use of complementary medicines. Research undertaken by Hall & Partners concluded:

"The inclusion of complementary medicines and treatments (primarily thought of as vitamin and mineral supplements) in pharmacies attracts majority support among Australian consumers, most of whom want to access these products in pharmacy. This result is unsurprising given the current Australian health climate that reflects a widespread belief in complementary medicines or treatments as a part of managing one's health, based on the influence of doctors, health experts, spokespeople, media and word of mouth. Consumers rely on pharmacists to help them understand whether certain complementary medicines are safe to take with their pharmaceutical medicine."<sup>116</sup>

Community pharmacy owners expressed similar views in the submissions to the Review. They were overwhelmingly supportive of complementary medicines continuing to be sold in community pharmacy,

<sup>116</sup> Hall and Partners Open Mind, qualitative and quantitative consumer research, 2016.

as patients have the opportunity to seek advice from, or be referred to, a pharmacist.

This includes advice on the evidence base relating to the product, advice on whether the product is appropriate for that patient, advice on potential adverse reactions with other medications and referral to a general practitioner where appropriate.

There was also a strong focus on the importance of quality advice being available for consumers, as demonstrated by the following submission:

"Complementary medicines will continue to be sold whether or not they are ranged in pharmacy. However the pharmacy is a controlled environment where advice can be easily obtained.

While most complementary medicines are safe there are some that can have adverse consequences if taken with the wrong prescription medicines. The pharmacy is the right place for consumers to determine how to best use complementary medicines from trained healthcare professionals."<sup>117</sup>

Many pharmacy owners and pharmacists emphasised their support for the consumer's right to choose when it comes to managing their health needs. This includes the use of complementary medicines alongside traditional pharmacy medicines.

A submission from Move Muscle, Bone & Joint Health<sup>118</sup> explained that many consumers expect their pharmacist to play a supporting role in when obtaining complementary medicines:

<sup>117</sup> Priceline Pharmacy Brand Advisory, Submission No. 116, page 9.

<sup>118</sup> Move Muscle, Bone & Joint Health, Submission No. 205, incorporating material from H. Sabanovic, B. Harris, O. Clavisi & L. Bywaters, 'Attitudes towards opioids among patients prescribed medications in Victoria' in MOVE Muscle, Bone & Joint Health, *Consumer attitudes to pain medication* (July 2016).

“the use of complementary medicines in conjunction with pharmaceutical compounds is very common for muscle, bone and joint conditions. Further, many people using complementary medicines do not discuss this with their doctors. Sabanovic et al found that people with chronic pain often used a combination of prescribed, off the shelf and complementary medications to manage their pain.

Pharmacy has an opportunity to bring together patients’ experiences and preferences, to discuss possible interactions and to provide advice. As there are significant poly-pharmacy risks between prescribed, off the shelf and complementary medications, prohibiting businesses from providing the range of options is counterintuitive.”<sup>119</sup>

In general, stakeholders put forward the view that pharmacists perform a valuable role in advising consumers on complementary medicines. However, there is some concern relating to the sale of products with a limited evidence base, or none at all, alongside prescription and other scheduled medicines.

The Hall & Partners’ consumer research noted:

“The presence of these products within the pharmacy environment does, to some extent, allow complementary medicines to borrow some of the clinical trust placed in the pharmacy. However, this research finds no evidence to support the view that their presence in turn negatively impacts clinical trust in the pharmacist. If pharmacies are to supply complementary medicines, this brings with it a consumer expectation these products have been selected for their health benefits and that staff will be able to provide related product advice –

especially about possible interactions or side effects.”<sup>120</sup>

However, Dieticians Association Australia contradicted these assertions, suggesting:

“it is confusing for patients if non-evidence based therapies are sold alongside prescription medicines. It is reasonable to expect that pharmacists manage any conflicts of interest and provide evidence based advice to consumers, but it is difficult to see how this can be realised in a retail environment in which evidence based and non-evidence based products are collocated.”<sup>121</sup>

The Panel agrees with the above comments and remains concerned that the sale of complementary medicines alongside other medicines may mislead consumers. It therefore concludes that complementary medicines should be held in a separate area within community pharmacies, where customers can easily access a pharmacist for appropriate advice.

## THE THERAPEUTIC GOODS ADMINISTRATION APPROVAL PROCESS

The Panel notes that complementary medicines encompass a wide range of products generally considered useful for health maintenance and enhancement. This extends to a range of products with a history of use based on cultural and traditional values.

The Panel also noted that the current Therapeutic Goods Administration (TGA) pre-market approval process for the listing of complementary medicines on the Australian

<sup>119</sup> Move Muscle, Bone & Joint Health, Submission No. 205, incorporating material from H. Sabanovic, B. Harris, O. Clavisi & L. Bywaters, ‘Attitudes towards opioids among patients prescribed medications in Victoria’ in MOVE Muscle, Bone & Joint Health, *Consumer attitudes to pain medication* (July 2016).

<sup>120</sup> Hall and Partners Open Mind, qualitative and quantitative consumer research, 2016.

<sup>121</sup> Dieticians Association Australia, Submission No. 72 page 3.

Register of Therapeutic Goods (ARTG) is based on assessment of a lower level of evidence than that for registered medicines.

Complementary medicines listed on the ARTG are subject to specific requirements relating to the level of therapeutic claim made for each product, the ingredients which it may contain and the facilities and standard to which the product is manufactured. The Panel also notes that no assessment of efficacy is made as part of the TGA listing process.

Although the sponsor (or manufacturer) of a complementary medicine is required to hold evidence of the efficacy of that product for its approved indication, this evidence is not assessed by the TGA prior to listing on the ARTG.

The Panel considers that limited consumer understanding of the TGA approval process for complementary medicines coupled with the availability of these products through community pharmacy can give rise to unsubstantiated expectations of the efficacy or medical benefits offered by these products.

The Panel notes that the recent *Review of medicines and medical devices regulation* (2015) made a range of recommendations relating to the regulation of complementary medicines. It was suggested that two further reviews be undertaken to potentially streamline the regulatory framework for low-risk products and increase consumer access to the products. Significantly, the TGA's February 2017 public consultation paper, *Reforms to the regulatory framework for complementary medicines: Assessment pathways*, notes that:

"A critical issue in the use of listed complementary medicines is to ensure that they are suitable for self-selection by consumers and that the information

provided with the medicine supports consumer health decisions."<sup>122</sup>

Clearly, community pharmacists can play a valuable role in advising consumers on the potential health benefits or dangers of using complementary medicines. The Panel remains concerned that consumers may be misled about the value of complementary medicines in the absence of appropriate evidence-based advice at the point of sale.

In this context, the TGA's actual role in the approval process for complementary medicines may be misunderstood by consumers, who may be likely to believe that that role is much broader than what occurs.

The Panel therefore considers that community pharmacies should provide consumers with information on any limitations noted by the TGA over the medical efficacy of these products. This could be achieved through the provision of appropriate signage near the sale of these products which clearly informs on the relevant TGA limitation.

### OPTION 3-2: COMPLEMENTARY MEDICINES – SUPPLY FROM PHARMACIES

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
- b. provide appropriate information to consumers on the extent of, or limitations to, the Therapeutic Goods Administration (TGA) role in the approval of complementary medicines. This could be achieved

<sup>122</sup> Department of Health, Therapeutic Goods Administration, Consultation: Reforms to the Regulatory Framework for Complementary Medicines: Assessment Pathways (February 2017).

through the provision of appropriate signage (in the area in which these products are sold) that clearly references any limitations on the medical efficacy of these products noted by the TGA.

### 3.4. PHARMACY ONLY AND PHARMACIST ONLY MEDICINES (SCHEDULE 2 AND SCHEDULE 3 MEDICINES)

*Complementary medicines pose a risk to consumers when they are not clearly separated from Pharmacy Only and Pharmacist Only (Schedule 2 and Schedule 3) medicines.*

#### DISCUSSION

Controls on the availability and use of medicines in 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.

Medicines available from community pharmacy are classified to include the following:

- *Prescription Only (Schedule 4) Medicines:* The use or supply of these medicines is only permissible on the order of a person authorised by state or territory legislation to prescribe, and they are available from a pharmacist upon presentation of a prescription.
- *Pharmacist Only (Schedule 3) Medicines:* For safe use, these medicines require professional advice, they but are available from a pharmacist without a prescription.

- *Pharmacy Only (Schedule 2) Medicines:* The safe use of these medicines may require advice from a pharmacist, and they are available from a pharmacy.

The Panel notes that, whereas the supply of Pharmacist Only and Prescription Only medicines in community pharmacies must be from behind the counter and involve interaction with a pharmacist, Pharmacy Only medicines may not be provided with consistent recourse to professional advice when this would be of benefit to the consumer.

When the availability of this advice is not obvious, there would appear to be little from a consumer's perspective to distinguish the availability of Pharmacy Only medicines from unscheduled medicines, including complementary medicines otherwise available from supermarkets, groceries or convenience stores.

#### EVIDENCE FROM SUBMISSIONS (REINFORCING THE DISTINCTION BETWEEN SCHEDULE 2 AND COMPLEMENTARY MEDICINES)

The Panel notes that certain jurisdictions including Queensland, Western Australia and South Australia, place specific requirements on the storage of Schedule 2 (Pharmacy Only) medicines for retail supply:

- In Queensland, all Schedule 2 medicines must be stored in a place that is not accessible to the public (*Drugs and Poisons Regulations 1966* – Chapter 4, Part 6, reg. 284(2)).
- Similarly, Western Australia requires that Schedule 2 medicines be stored to only be accessible by an employee of the pharmacy (*Medicines and*



*Poisons Regulation 2016* – Division 2, reg. 86(2)(b)).

In South Australia, Schedule 2 medicines may only be made accessible to the public when stored in accordance with specific shelf height and packaging requirements (*Poisons Regulation 2011* – Part 3, reg. 27(b)(i)).

Regarding the supply of complementary medicines in community pharmacy, the Panel sees further benefit in clearly separating access to Pharmacy Only and Pharmacist Only (Schedule 2 and Schedule 3) medicines from complementary medicines so that, from the consumer’s perspective, the potential health benefits and risks associated with use of these products are clear.

### **OPTION 3-3: PLACEMENT OF PHARMACY ONLY AND PHARMACIST ONLY (SCHEDULE 2 AND SCHEDULE 3) MEDICINES WITHIN A PHARMACY**

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

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

## **3.5. HOMEOPATHIC PRODUCTS**

*There are unacceptable risks where community pharmacies are allowed to sell homeopathic products.*

### **DISCUSSION**

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.

In 2015 the National Health and Medical Research Council (NHMRC) conducted an assessment of the evidence of efficacy of homeopathy and concluded:

“Based on the assessment of the evidence of effectiveness of homeopathy, NHMRC concludes that there are no health conditions for which there is reliable evidence that homeopathy is effective.

Homeopathy should not be used to treat health conditions that are chronic, serious, or could become serious. 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.”<sup>123</sup>

The general consensus as demonstrated by submissions to the Review and the Panel’s face-to-face consultations is that homeopathy and homeopathic products do not belong in community pharmacies. The majority of pharmacists and other stakeholders argued that these products lack any evidence base and have sufficient evidence of non-efficacy to preclude their ethical sale in community pharmacies.

This is supported by the public positions of professional pharmacy bodies – for example,

<sup>123</sup> National Health and Medical Research Council, *Statement on homeopathy* (March 2015).



the PSA, whose Position Statement on Complementary Medicine states:

“PSA does not support the sale of homeopathy products in pharmacy.”<sup>124</sup>

The only defence put to the Panel regarding homeopathy was that it was harmless and able to be used as a placebo in certain circumstances. The Panel does not believe that this argument is sufficient to justify the continued sale of these products in pharmacies that supply PBS medicines.

In particular, the Panel notes that the supply of homeopathic products through pharmacies is not benign but, rather, risks creating a perception of reliability and efficacy in the mind of the consumer based on the status of the pharmacy as a healthcare provider. This may encourage patients to choose a homeopathic product over a conventional medicine with robust evidence of efficacy, which creates a risk of harm to the patient’s health.

#### **OPTION 3-4: SALE OF HOMEOPATHIC PRODUCTS**

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.

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<sup>124</sup> Pharmaceutical Society of Australia, *Complementary medicines: Position statement* (September 2015).

## 4. COMMUNITY PHARMACY REMUNERATION BY GOVERNMENT

### 4.1. INTRODUCTION

A pharmacy is a complex business, and the Panel has seen a wide range of different business models for community pharmacy in its Australia-wide investigation. It has seen examples of high-quality business practices, but it has also seen examples of very poor business practices.

Appropriate remuneration for community pharmacy does not mean that any community pharmacy, regardless of the efficiency of its operations, should make a profit. Rather, the focus must be on remuneration that ensures an efficient pharmacy is appropriately remunerated when consumer access to medicines is consistent with the National Medicines Policy (NMP).

The Panel considers that a reduction in revenue, by itself, does not imply that community pharmacists are being under-remunerated for dispensing and other services.

To make that inference would be to confuse a change with a 'level'. The job of the Panel is to consider the appropriate level of remuneration – for example, for dispensing. The level is based on the appropriate amount that the government and consumers, together, should pay to community pharmacy to efficiently remunerate them for the services that they provide.

In contrast, a fall in revenue or profit (a change) by itself provides no information about whether or not the level of compensation is excessive, appropriate or inadequate.

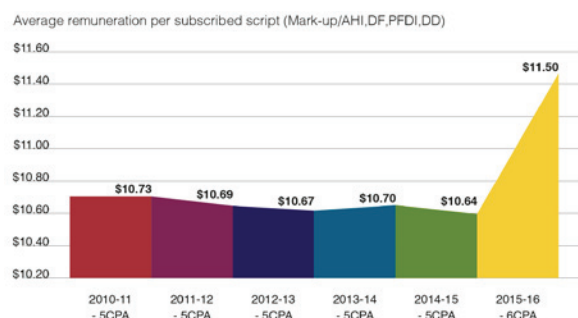
Similarly, information that highlights that some community pharmacies are finding the operating environment tough, while at the same time other community pharmacies appear to be thriving and expanding, by itself provides little information on the adequacy of compensation.

The Panel also notes that, where there have been instances of 'failure' of a pharmacy in the past, this has generally not resulted in a disruption to the network, as either the pharmacy has been restructured and continued to trade (possibly under new ownership) or the approval number has been used by a replacement pharmacy.

In considering pharmacy remuneration, the Panel also wishes to draw attention to the strong links between the operations of community pharmacy and the Pharmaceutical Benefits Scheme (PBS), where community pharmacists perform their role as agents of the government, distributing PBS medicines safely and securely to consumers throughout Australia.

For most community pharmacies, the provision of scheduled medicines provides the majority of their revenue and profit. Thus the remuneration for dispensing and, more broadly, the PBS is intimately tied to the financial viability of most community pharmacies.

**Figure 9** presents the average pharmacy remuneration per subsidised script paid by government from 2010–11 to 2015–16. The average remuneration in 2015–16, the first year of the Sixth Community Pharmacy Agreement (6CPA), increased to \$11.50 per script. This compares to an average remuneration of \$10.69 over the Fifth Community Pharmacy Agreement (5CPA).

**Figure 9: Average pharmacy remuneration per script<sup>125</sup>**

Pharmacy remuneration cannot be considered in isolation, as it directly influences the profits of community pharmacies.

Remuneration for dispensing also interacts closely with the impact of location rules, the degree of competition and the incentives for entry and innovation in community pharmacy.

These linkages are highlighted in the discussion on location rules, as there are strong connections between remuneration and the state ownership rules for community pharmacy.

## 4.2. SOURCES AND TRANSPARENCY OF PHARMACY REMUNERATION

*The extent and quality of data and information is currently not adequate to inform decisions and determinations about the costs related to an efficient dispensing service.*

### DISCUSSION

As noted elsewhere in this report, community pharmacies draw some of their funding from a range of federal, state and territory government programs.

Examples of state and territory funding include funding for Indigenous health pharmacy services, opioid replacement therapy and the syringe exchange program.

While this funding has to be accounted for, there is no statistical information on how significant these funding sources are to pharmacy or what their costs to combined governments are.

At present, there is little transparency or coordination for this funding. This presents challenges when attempting to derive quality information for decision-making.

The Panel commissioned a financial survey of a cross-section of Australian pharmacies with the intention of developing a comprehensive financial analysis of the sector.

This was to assist the Panel in developing options that appropriately reflected the challenges and opportunities faced by the breadth of Australian pharmacies.

It would have also provided individual pharmacy owners and pharmacists with an opportunity to present their particular point of view whilst helping inform the Panel's deliberations.

The pharmacy survey was designed to be answered online by community pharmacists and was significantly promoted. Despite these attempts, the Panel has been very disappointed with the level of engagement with the survey. The low level of response from pharmacists across the country has created difficulties for the review process.

The Panel is aware that some pharmacy groups and the Pharmacy Guild of Australia (the Guild) have discouraged members from participating in the survey.

<sup>125</sup> This calculation is based on remuneration to pharmacy for the elements set out in the 6CPA (dispensing fee, AHI, Premium Free Dispensing Incentive and dangerous drug fee). Source: Department of Health.

This Review was jointly established by the Guild and the Australian Government under 6CPA. As part of the 6CPA the Guild committed to provide, “its full support” to the Review, including “taking all reasonable steps to ensure that its members provide such information within their possession or control as requested”.<sup>126</sup>

Despite these commitments and both correspondence from the Department of Health and a face-to-face meeting between the Panel and senior executive members of the Guild, the Guild refused to support the survey.

In particular, the Guild recommended that “Guild members should be wary about participating in this survey”.<sup>127</sup>

The Panel is concerned that, despite the pharmacy sector receiving a significant amount of government funding, there is a general reluctance by the sector to provide this Review and, more generally, the Australian Government with the information required to ensure accountability and transparency for the public money that is being used to remunerate community pharmacy.

The Panel can only consider its options on the basis of information available to it. Given the lack of primary information about community pharmacies from the survey, the Panel has had to place more weight on secondary information available to it from other sources.

The Panel considers that there is a lack of transparency in the community pharmacy sector relating to the services they provide in

return for government funding. This is troubling from the perspective of public accountability. Further, it may create long-term issues for the community pharmacy sector, as it will be unclear what level of remuneration is needed to maintain a viable and effective pharmacy network.

#### **OPTION 4-1: ACCOUNTING INFORMATION**

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

- a. determine a set of accounting principles that will apply for community pharmacies in order to provide the relevant information needed to determine the best-practice benchmark cost of a dispense (as these terms are defined in this report)
- b. require community pharmacy (as a condition of being approved to dispense PBS medicines) to provide the necessary accounting information to inform consideration in the development of each Community Pharmacy Agreement (including as a basis for the determination of a best-practice pharmacy). The relevant accounting information should be provided for each financial year and no later than 31 December of the following financial year (beginning with 31 December 2018)
- c. designate a body within the government (although potentially an existing independent statutory authority with the relevant expertise such as the Pharmaceutical Benefits Remuneration Tribunal or, more broadly, the Australian Competition and Consumer Commission) to provide a recommendation to the government on the best-practice benchmark cost of a dispense as required over time by the

<sup>126</sup> Department of Health, Sixth Community Pharmacy Agreement, page 21.

<sup>127</sup> Review of Pharmacy Remuneration and Regulation, *Pharmacy financial survey: A clarification from the Review Panel* (December 2016).

government. The first such advice is to be provided as soon as practical and certainly before the end of 2019. The timing of later determinations will depend on the process used in the future by the government to set the remuneration for dispensing PBS medicines.

- d. the information and advice submitted to the government should form the basis for the average remuneration for a 'dispense' to community pharmacy in the future and certainly from the expiration of the Sixth Community Pharmacy Agreement. The provision of appropriate accounting information should be an ongoing requirement to support the development of each Community Pharmacy Agreement.

### 4.3. REMUNERATION FOR DISPENSING SERVICES

*The government should set the same remuneration for dispensing for all community pharmacies, regardless of a specific pharmacy business model.*

#### DISCUSSION

Community pharmacies provide a range of medicine-related services and primary health services. These include the dispensing of PBS medicines, the provision of medicine advice on Schedule 2 and Schedule 3 medicines, the preparation of dose administration aids to assist consumers to manage their medicines and the preparation of health programs such as diabetes management and blood pressure monitoring along with many more. Examples

of dispensing services are illustrated in **Figure 10**.<sup>128</sup>

In some situations, consumers pay directly for the relevant service. In other cases, the pharmacy 'cross-subsidises' the service from other activities.

Pharmacists receive remuneration for the dispensing and sale of PBS medicines from three broad sources:

- consumer co-payments
- government payments
- revenue derived from any difference between the amount a pharmacy pays for a medicine and the reimbursement to the pharmacy from the government for that medicine.

The first two of these sources are together 'remuneration for dispensing'. Any additional revenue received by pharmacies due to a mismatch between the government payment for a medicine and the price the pharmacist pays for that medicine is being dealt with through the current price disclosure policy.

Remuneration (including any relevant consumer co-payment) is meant to appropriately remunerate the community pharmacy for the costs of dispensing. However, these costs can be defined in different ways. They may also differ significantly between different community pharmacies. Before appropriate remuneration levels for dispensing can be discussed, the following should be considered:

- Should every dispense receive the same government remuneration or should they be differentiated?

<sup>128</sup> Source: Review of Pharmacy Remuneration and Regulation Discussion Paper (July 2016), page 44.

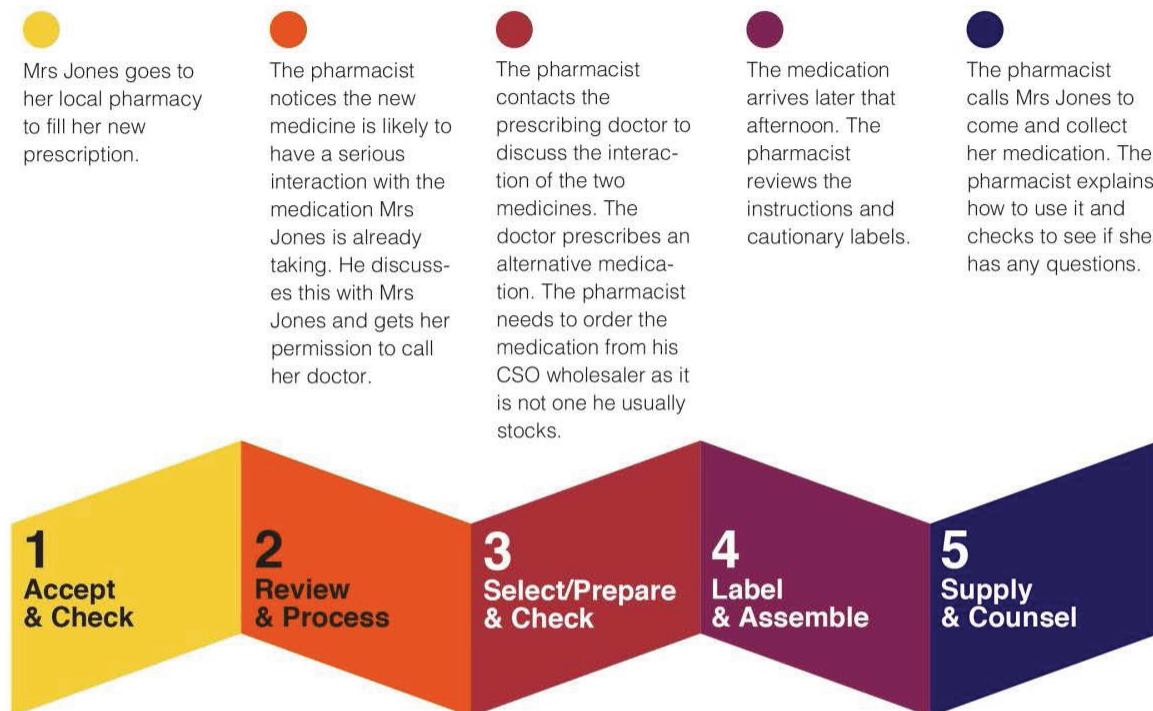
- What benchmark community pharmacy should be used for the calculation of the remuneration for dispensing?
- Which are the most relevant costs in determining the appropriate remuneration for dispensing?



**Figure 10: Examples of dispensing services provided by community pharmacies**

### Patient Scenario 1:

#### Medication Complication



### Patient Scenario 2:

#### Referral Back to GP



## DIFFERENTIAL DISPENSING FEES

We will first consider the issue of differential dispensing fees. It is clear from the submissions provided and discussions with community pharmacists that the time and effort involved in dispensing a medicine can vary greatly. While there may be an average cost, there is not a systematic way to characterise dispensing according to differences in cost.

The Review of Pharmacy Remuneration and Regulation Discussion Paper questioned whether it was possible to systematically distinguish between the costs of an ‘initial’ dispense for a patient and the costs of a ‘repeat’ dispense.

From the information received, the Panel considers that any attempt to distinguish a differential dispensing fee on the basis of whether the dispense is an ‘initial’ or ‘repeat’ would be fraught.

The Panel has therefore concluded that the same ‘formula’ for dispensing should be applied to all dispensed medicines. That formula should be cost based, as discussed below.

## THE BENCHMARK PHARMACY

*Pharmacy remuneration is a complex area of policy and practice involving diverse delivery models and settings. This necessitates the use of a benchmark pharmacy model as a basis to establish cost-efficient remuneration choices.*

Submissions to the Review have made it clear that there is no single community pharmacy model. Different consumers value differing features in community pharmacies.

Differentiation should be encouraged to allow greater choice to consumers. Community pharmacies should be encouraged to adopt

business models that suit their customer demographics. This is particularly the case when the population of customers is sufficiently large to support multiple pharmacies. In such situations, pharmacies should be able to operate different business models to actively appeal to different groups of customers. In so doing, the pharmacies will be better able to serve all customers than if they had the same business model.

As discussed in the location rules section of Chapter 5, excessive geographic clustering has been extensively flagged in both submissions and in previous debates on community pharmacy. However, in the opinion of the Panel, ‘excessive business model clustering’ would also lead to poor outcomes for consumers.

In this regard, the Panel is concerned that data provided by the Treasury suggests that the current pharmacy regulations and remuneration arrangements have facilitated the development of a large number of very small pharmacies:

- Fifty-eight per cent of all pharmacies have a turnover of less than \$2 million per annum.
- Ninety-six per cent of all pharmacies have an annual turnover of less than \$10 million.

In order to encourage pharmacies to continue to innovate and differentiate, the remuneration for dispensing should be ‘business model neutral’. Pharmacies that are able to better serve the particular needs and preferences of their customers should not be penalised for their success through reduced dispensing remuneration. Such a system would discourage innovation and lead to a poor outcome for consumers.

## THE ADVANTAGES OF A BUSINESS MODEL NEUTRAL APPROACH

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.

This 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.

Some of the options in this Interim Report place limitations upon the structures of community pharmacy and the location of medicines in order to improve clarity and safety for consumers.

### 4.4. BASIS OF EFFICIENT DISPENSING COST/REMUNERATION

*Remuneration should be based on the efficient costs of dispensing within a best-practice pharmacy.*

## DISCUSSION

Even though there will be uniform minimum requirements, the Panel expects significant overall differences between pharmacies to continue. However, the remuneration for dispensing should be based on the costs for dispensing of an *efficient* pharmacy.

The ‘efficient business’ benchmark is the standard used in a variety of regulatory contexts. For example, the National Electricity Objective, which underpins the regulation of Australia’s electricity networks, promotes the

efficient investment in and operation and use of electricity services for the long-term interest of consumers. Section 7A of the National Electricity Law captures this objective, requiring network operators be given a reasonable opportunity to recover at least the efficient costs.

Australia’s National Gas Law has similar objectives, ensuring efficient benchmarks are used by regulators.<sup>129</sup>

In the current context an ‘efficient pharmacy’ benchmark helps to ensure that neither the government nor consumers are paying more than is appropriate for the dispensing of medicines.

The benchmark would fully reward an efficient community pharmacy for all the economic costs associated with dispensing. This would relate government remuneration and the cost of dispensing whilst separating them from the other retail functions that a pharmacy may engage in. The efficient pharmacy model will be independent of the broader business model adopted by a community pharmacy for its non-dispensing operations.

Using an ‘efficient pharmacy’ benchmark for the remuneration of dispensing also provides appropriate incentives for each community pharmacy. The remuneration for dispensing will provide each community pharmacy with a strong signal about its performance in dispensing relative to other community

<sup>129</sup> The cost of service regulation model (described as the “Building Block” method) has become the mainstream model for Australian regulators. The objective of the building block model is to provide regulated entities the opportunity to recover efficiently incurred operating and capital costs over the long term (c.f. Australian Competition and Consumer Commission (ACCC), *Submission to the NBN non-commercial services funding options consultation paper* (5 July 2015), page 4.

pharmacies. If a community pharmacy is not operating its dispensary efficiently then it has strong incentives to improve its performance.

#### **OPTION 4-2: REMUNERATION TO BE BASED ON EFFICIENT COSTS OF DISPENSING**

The remuneration for dispensing paid by government and consumer co-payments to community pharmacy should be based on the costs of dispensing for an efficient pharmacy.

### **4.5. COST ESTIMATES FOR AN EFFICIENT DISPENSING SERVICE**

If an 'efficient pharmacy' benchmark is to be used to determine pharmacy remuneration for dispensing then, in order to estimate the efficient costs of dispensing, it will be necessary to implement the same rigorous 'building block' method that is used to determine the efficient costs of supplying other regulated essential services.

As outlined in **Figure 11**<sup>130</sup>, the 'building block' approach to estimating efficient costs would involve identifying:

- types and quantities of medicines and related services that the pharmacy would be required to provide on behalf of the government
- types and quantities of inputs and capital equipment that the pharmacy would have to purchase in order to supply those medicines and related services
- efficient costs of those inputs and capital (i.e. the efficient cost of capital, which provides the pharmacy with a return on their investment as

well as a return of any capital used up in the production process)

- total efficient costs of dispensing medicines per script, which is equal to the sum of the efficient operating and capital costs per script.

This is not the approach that has been used to date to determine the remuneration provided to pharmacies for supplying medicines and related services on behalf of the government.

Although pharmacies are currently paid different fees for supplying different types of medicines and related services, those fees have not been estimated using information on the efficient costs of supplying those medicines and related services. Rather, those fees are more a reflection of historical precedent, as modified by successive rounds of negotiation between the Guild and the government.

At this point in time, there is relatively little information available on the efficient costs of a pharmacy in supplying medicines on behalf of the government. In this regard, the Review considered information provided by Mr Bruce Annabel (a pharmacy industry consultant) which identifies the costs incurred by a best-practice pharmacy. This was supplemented with financial information pertaining to the average revenue and costs that pharmacies actually derive and incur from supplying all of the goods and services they sell.

This information included:

- data provided by the Treasury, which provides the most comprehensive, consistently derived and independent data on total revenues and expenses derived and incurred by pharmacies for 2013–14
- PBS data on the amount of remuneration that each pharmacy

<sup>130</sup> Source: RSM, *Financial analysis of pharmacy regulations and remuneration arrangements* (March 2017), page 49.

received from the government and consumers as well as the cost of the pharmaceuticals they purchase (valued using ex-manufacturer prices rather than actual prices paid)

- data from a major Australian bank that provides information on the value of capital that pharmacies of different sizes typically invest in their businesses
- Pharmacy Guild Digest survey data on independent pharmacy operations in Australia for the 2014–15 financial year, which presents financial data obtained from a sample of 313 pharmacies weighted according to their prescription volumes
- Medici Capital Pty Ltd survey data, which provides financial information for a sample of 205 pharmacies across Australia in the 2016 financial year and 371 pharmacies in the 2015 financial year
- data sourced from benchmarking.com.au, which provides financial benchmarking data for the 2016 financial year on pharmacies, obtained from a sample of 132 pharmacies
- data sourced from the financial survey conducted by the Review, which provides financial data for the pharmacies that responded to the pharmacy survey.

In order to help the Review to make the best possible use of these existing data sources, RSM has:

- presented data on a more consistent basis using a common profit and loss statement format, which is set out in **Table 5**. This expresses each of the key items of revenue and expenditure as a percentage of total turnover

- indicated the extent to which each of the cost and revenue items differ across the various data sources (i.e. by presenting the maximum and minimum values found in that data).

Since there are significant differences between the size, financial performance and taxable status of pharmacies, RSM has classified pharmacies into a number of different categories based on their:

- turnover, with the identification of five different pharmacy sizes, including:
  - ‘micro’ pharmacies, which have an annual turnover of less than \$2 million (57.9 per cent of all pharmacies)
  - ‘small’ pharmacies, which have an annual turnover between \$2 million and less than \$10 million (37.80 per cent of all pharmacies)
  - ‘medium’ pharmacies, which have an annual turnover between \$10 million and less than \$20 million (0.5 per cent of all pharmacies)
  - ‘large’ pharmacies, which have an annual turnover between \$20 million and less than \$40 million (3.7 per cent of all pharmacies)
  - ‘very large’ pharmacies, which have an annual turnover of \$40 million or more (0.1 per cent of all pharmacies).<sup>131</sup>
- profitability (i.e. profitable or not profitable)
- taxable status (i.e. taxable or not taxable).

<sup>131</sup> RSM, *Financial analysis of pharmacy regulations and remuneration arrangements* (March 2017), page 54.

As illustrated in **Table 5**<sup>132</sup>, there is significant variation in revenues and costs across each of these different types of pharmacies (as indicated by the maximum and minimum values).

In particular, the estimated average cost per dispense varies across the different types of pharmacies from \$6.66 to \$12.33.<sup>133</sup>

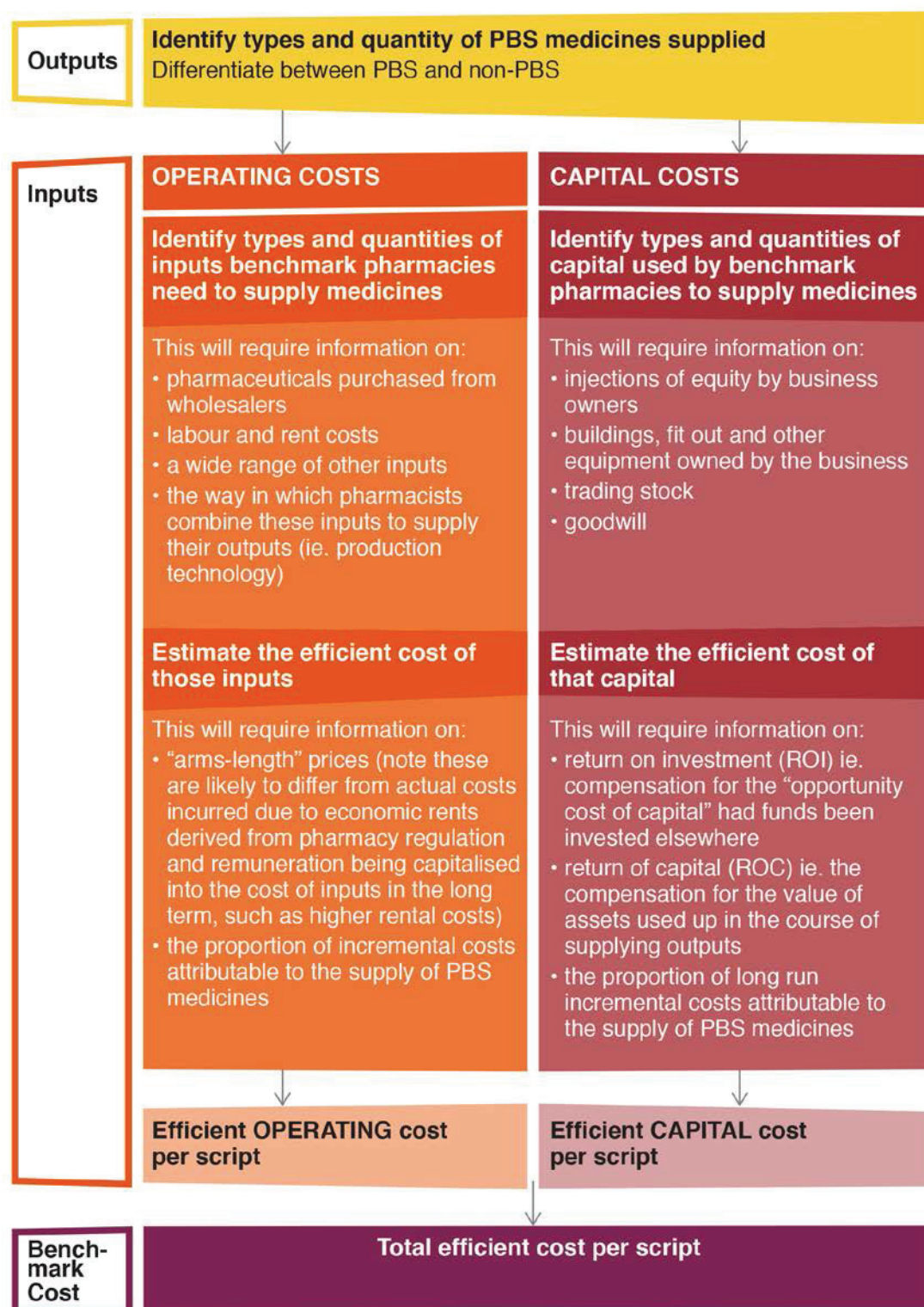
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<sup>132</sup> Source: RSM, *Financial analysis of pharmacy regulations and remuneration arrangements* (March 2017), page 53.

<sup>133</sup> The analysis in section 4.5 is based on information from RSM, *Financial analysis of pharmacy regulations and remuneration arrangements* (March 2017).



**Figure 11: Illustration of the ‘building block’ approach to estimating efficient pharmacy cost of dispensing**



**Table 5: Summary of pharmacy financial information available**

Item	Micro (\$0–\$2m)		Small (\$2–\$10m)		Medium (\$10–\$20m)		Large (\$20–\$40m)		Very large (\$40m+)	
	Range min	Range max	Range min	Range max	Range min	Range max	Range min	Range max	Range min	Range max
<b>SALES</b>	55%	67%	58%	64%	66%	80%	86%	87%	88%	88%
COST OF GOODS SOLD										
GROSS MARGIN	33%	45%	36%	41%	20%	34%	13%	14%	12%	12%
<b>Less owners salary</b>	8%	18%	1%	3%	1%	1%	1%	1%	0.4%	0.4%
TOTAL EXPENSES (aos*)	26%	57%	27%	44%	14%	36%	6%	7%	5%	5%
NET PROFIT/LOSS (aos*)	–21%	13%	–4%	9%	–2%	6%	–7%	7%	2%	2%
EBITDA (aos*)	–17%	16%	–1%	14%	0%	8%	–5%	9%	4%	4%
<b>SALES ANALYSIS</b>	66%	77%	61%	77%	–	–	–	–	–	–
Prescriptions										
Other Sales	23%	27%	30%	39%	–	–	–	–	–	–
<b>STATISTICS</b>	10.00	28.03	10.00	28.03	10.00	28.03	10.00	28.03	–	–
DISPENSING REVENUE PER SCRIPT										
COST PER DISPENSE	5.96	11.12	5.96	11.12	–	–	–	–	–	–
COST PER DISPENSE (INCLUDING RETURN ON CAPITAL)**	6.66	12.33	6.66	12.33	6.66	12.33	6.66	12.33	6.66	12.33
NET ASSETS	85%	85%	79%	85%	79%	79%	59%	59%	50%	50%

**Notes:**

\* AOS: After owners' salary.

\*\* Includes \$0.10 for working capital and a 10% margin to allow for a return on capital.

1. Blank fields indicate areas where no data was available.
2. Excludes data from financial survey responses due to range extremities.

RSM has used these data sources to conduct a financial analysis looking into the effects that the current regulations and remuneration arrangements have on these different types of pharmacies.

The analysis indicates that:

- The current pharmacy regulations and remuneration arrangements are not enabling pharmacies to earn ‘economic rents’.<sup>134</sup> Treasury data shows:
  - 15 per cent of all pharmacies are not earning taxable profits
  - profitability increases in line with the pharmacy’s size
  - the most profitable pharmacies are only earning normal rates of return on their investments.
- Current remuneration arrangements have the potential to unintentionally provide higher levels of assistance (i.e. a higher ‘effective rate of assistance’) to those pharmacies that add the least value to their inputs and are the least efficient at performing those activities. This is because the current arrangements pay pharmacies the same fee for performing a range of different value-adding activities.

To illustrate this last point, **Table 6**<sup>135</sup> presents a hypothetical example demonstrating how

<sup>134</sup> According to RSM, the return that profitable pharmacies are earning ranges up to 15 per cent. Thus, any ‘economic rents’ tend to have been capitalised into the price of a pharmacy, or the rents charged for ‘scarce’ sites that meet the location rules: RSM, *Financial analysis of pharmacy regulations and remuneration arrangements* (March 2017), pages 54–68.

<sup>135</sup> Source: RSM, *Financial analysis of pharmacy regulations and remuneration arrangements* (March 2017), page 62.

the current pharmacy remuneration arrangements may have an adverse effect on the equity with which pharmacies are remunerated if pharmacists are paid the same fee of \$11.50 per script for performing a range of different dispensing activities. In this example, Activities 1 to 9 each represent notional tasks in the dispensing process, with each dispense requiring a different level of effort by the pharmacist. Specifically, Activities 1 to 9 range from:

- relatively high economic value-adding activities, such as Activity 1, which involves the pharmacist adding the greatest economic value to the cost of the medicines and other inputs they use (e.g. dispensing activities that require the pharmacist to perform more complex and time-consuming tasks, including consultation with the prescriber and the provision of more complex advice to the patient on the appropriate use of the medicines)
- through to relatively low economic value-adding activities, such as Activity 9, which involves the pharmacist adding the lowest amount of economic value to the cost of the medicines and other inputs they use (e.g. dispensing activities such as labelling pre-packaged medicines, which may require less skill by the pharmacist compared to the more complex dispensing activities).

This theoretical example indicates that the payment of a single fee would under-remunerate those pharmacies that on average perform greater value-adding activities (i.e. Activity 1 tasks). The smallest, and potentially least efficient and profitable, pharmacies may receive the highest effective rates of assistance.

**Table 6** also demonstrates the effects of implementing a single flat \$10 dispensing fee. This \$10 flat fee is an illustrative figure drawn from the 2015–2016 median dispensing fee. In this scenario, the \$10 flat fee would replace the following different fees:

- Dispensing Fee
- Administration, Handling and Infrastructure (AHI) fee (three-tiered)
- Premium Free Dispensing Incentive (PFDI)
- Dangerous Drug Fee (Schedule 8, or drugs of addiction)
- Electronic Prescription Fee
- Container Fee
- Wastage Amount
- Water Fee.

It might seem that such a proposed reform is more likely to reduce, rather than improve, the economic efficiency with which those different types of medicines are supplied (i.e. reduce, rather than increase, production efficiency). This would be the case if the current fees charged for the provision of different types of medicines accurately reflected the actual efficient long-run marginal costs of supplying those medicines.

Considerable uncertainty currently surrounds the actual efficient long-run marginal costs associated with supplying the different types of medicines that are currently supplied by pharmacies on behalf of the government. The current fees that are paid by the government to pharmacies are more a reflection of historical precedent, as amended by numerous rounds of negotiation between the government and the Guild. They are not the result of a rigorous process of analysis designed to accurately estimate the efficient marginal costs of supplying those medicines.

Consequently:

- It is highly unlikely that the fees government currently pays pharmacies for the different types of medicines will accurately reflect the efficient long-run marginal costs of supplying those medicines. Although it is possible that some of the fees paid to some pharmacies might accurately reflect the efficient marginal costs of supplying medicines, it is more likely that most of those fees will differ from the efficient marginal costs of supplying those medicines on behalf of the government.
- The economic cost arising from differences between the fees that pharmacists are paid to supply medicines on behalf of the government and the actual efficient marginal costs of performing those activities will be many times higher than the economic benefits that the nation would derive if those differences did not exist (i.e. since the deadweight costs arising from those unintended differences increase with the square of the magnitude of those differences).

This means that, rather than reducing production efficiency, the implementation of a flat fee for dispensing has the potential to improve production efficiency by reducing unintended differences in the effective rates of assistance provided to different types of pharmacies. Specifically, as indicated in **Table 7**<sup>136</sup>, prior to the introduction of an illustrative \$10 flat fee, the effective rates of assistance

<sup>136</sup> Source: RSM, *Financial analysis of pharmacy regulations and remuneration arrangements* (March 2017), page 90.

afforded pharmacies range from –17.3 per cent to 26.8 per cent.

By contrast, after the introduction of the \$10 flat dispensing fee, the effective rates of assistance would range from –30.4 per cent to 6.7 per cent.

**Table 7** indicates that the implementation of a \$10 flat dispensing fee would reduce the economic costs of funding the pharmacy remuneration arrangements by approximately \$1.9 billion over the period 2015–16 to 2019–20.

As RSM notes, these economic cost savings are greater than the fiscal cost savings outlined above since they take into account the opportunity cost of each dollar spent by the government (which is assumed to be a real rate of return of 7 per cent) as well as the economic cost of raising revenue through the tax system (which is assumed to be 20 per cent of the amount of revenue raised).<sup>137</sup>

#### **OPTION 4-3: BENCHMARK FOR AN EFFICIENT DISPENSE**

On the basis of the information that has been made available to the Panel, and given the data limitations, the Panel considers that the current benchmark for a best-practice dispense be set within a range of \$9.00 to \$11.50. This should be reflected in the average remuneration paid to a pharmacy for a dispense.

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<sup>137</sup> Concepts such as the Effective Rate of Assistance (ERA) have been based on models developed by OECD and the former Australian Industry Commission.

**Table 6: Illustration of how paying pharmacies the same fee for performing different types of activities unintentionally provides the highest effective rates of assistance to the least efficient pharmacies that add the least value to their inputs**

ACTIVITY									
	Activity 1	Activity 2	Activity 3	Activity 4	Activity 5	Activity 6	Activity 7	Activity 8	Activity 9
<b>UNASSISTED VALUE OF OUTPUTS, INPUTS AND VALUE ADDED</b>									
Cost of medicine to pharmacy	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00
Cost of other inputs	\$2.00	\$2.00	\$2.00	\$2.00	\$2.00	\$2.00	\$2.00	\$2.00	\$2.00
Unassisted value added by dispensing	\$11.50	\$11.00	\$10.50	\$10.00	\$9.51	\$9.00	\$8.50	\$8.00	\$7.50
Unassisted value of output (UVO)	\$113.50	\$113.00	\$112.50	\$112.00	\$111.51	\$111.00	\$110.50	\$110.00	\$109.50
Government remuneration for cost of medicine	\$61.20	\$61.20	\$61.20	\$61.20	\$61.20	\$61.20	\$61.20	\$61.20	\$61.20
Co-payment by consumer	\$38.80	\$38.80	\$38.80	\$38.80	\$38.80	\$38.80	\$38.80	\$38.80	\$38.80
Financial profit (loss)	-\$13.50	-\$13.00	-\$12.50	-\$12.00	-\$11.51	-\$11.00	-\$10.50	-\$10.00	-\$9.50
<b>ASSISTED VALUE OF OUTPUTS, INPUTS AND VALUE ADDED</b>									
Cost of medicine to pharmacy	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00
Cost of other inputs	\$2.00	\$2.00	\$2.00	\$2.00	\$2.00	\$2.00	\$2.00	\$2.00	\$2.00
Unassisted value added by dispensing (UVA)	\$11.50	\$11.00	\$10.50	\$10.00	\$9.51	\$9.00	\$8.50	\$8.00	\$7.50
Government remuneration for cost of medicine	\$61.20	\$61.20	\$61.20	\$61.20	\$61.20	\$61.20	\$61.20	\$61.20	\$61.20
Co-payment by consumer	\$38.80	\$38.80	\$38.80	\$38.80	\$38.80	\$38.80	\$38.80	\$38.80	\$38.80
Dispensing fee from Government	\$11.50	\$11.50	\$11.50	\$11.50	\$11.50	\$11.50	\$11.50	\$11.50	\$11.50
Assisted value added by dispensing (AVA)	\$9.50	\$9.50	\$9.50	\$9.50	\$9.50	\$9.50	\$9.50	\$9.50	\$9.50
Assisted value of output (AVO)	\$111.50	\$111.50	\$111.50	\$111.50	\$111.50	\$111.50	\$111.50	\$111.50	\$111.50
Financial gain (loss) (AVA - UVA)	-\$2.00	-\$1.50	-\$1.00	-\$0.50	\$0.01	\$0.50	\$1.00	\$1.50	\$2.00
<b>EFFECTIVE RATE OF ASSISTANCE PROVIDED TO DISPENSING ACTIVITY (ERA)</b>									
ERA with a \$11.51 dispensing fee (AVA-UVA)/UVA	-17.3%	-13.5%	-9.4%	-4.9%	0.00%	5.67%	11.88%	18.88%	26.8%
ERA with a \$10.00 dispensing fee (AVA-UVA)/UVA	-30.4%	-27.3%	-23.8%	-20.0%	-15.9%	-11.1%	-5.9%	0.0%	6.7%



**Notes:**

1. The content of this table is hypothetical and is used to illustrate the effect that paying a single flat fee for dispensing may have on the equity of pharmacy remuneration.
2. All values in this table are notional except the co-payment value of \$38.80.
3. Unassisted value added (UVA) is equal to the unassisted value of output (UVO) less the unassisted value of inputs (i.e. cost of medicine and other inputs).
4. Assisted value added (AVA) is equal to the assisted value of output (AVO) less the assisted value of inputs, which is assumed to be the same as the unassisted value of inputs.
5. Unassisted value of outputs (UVO) is the value of outputs before government subsidy.
6. Assisted value of outputs (AVO) is the value of outputs after government subsidy.
7. Activity 1 represents a high value adding activity, for example, a complex dispense.
8. Activity 9 represents a low value adding activity, such as a simple dispense.

**Table 7: Fiscal and economic cost savings from a \$10 flat fee per script**

Year	Fiscal cost savings	Economic cost savings		
		Opportunity cost (7%)	Deadweight cost (20%)	Total economic cost saving
2015–16	\$277 693 429	\$19 438 540	\$55 538 686	\$352 670 655
2016–17	\$290 328 480	\$20 322 994	\$58 065 696	\$368 717 170
2017–18	\$296 564 010	\$20 759 481	\$59 312 802	\$376 636 293
2018–19	\$303 674 132	\$21 257 189	\$60 734 826	\$385 666 148
2019–20	\$310 954 719	\$21 766 830	\$62 190 944	\$394,912 493
<b>TOTAL</b>	<b>\$1 479 214 770</b>	<b>\$103 545 034</b>	<b>\$295 842 954</b>	<b>\$1 878 602 758</b>

**Notes:**

1. A \$10 flat fee was selected for illustrative purposes with the proposed range as set out in Option 4-3.
2. Fiscal cost savings based on 2016 PBS data and excludes chemotherapy remuneration.

## 4.6. THE COSTS OF DISPENSING

*Remuneration for dispensing should be based on the incremental costs of dispensing rather than fully distributed or stand-alone costs.*

The remuneration for dispensing should be based on the efficient costs of dispensing. However, there are a range of different cost concepts that could be relevant.

### ECONOMIC OR ACCOUNTING COSTS

Accounting costs generally only include explicit costs. In contrast, economic costs include both explicit and implicit costs.<sup>138</sup> As a result, economic costs will always be at least as high as accounting costs.

For example, suppose a pharmacist owner spends some of their time working in the pharmacy dispensary but does not pay themselves a formal ‘wage’.

Further, suppose the pharmacist has funded part of the capital costs of the dispensary through his or her own savings rather than fully relying on borrowed funds. Neither the time that the pharmacist works in the dispensary nor the ‘foregone interest’ that the pharmacist could have earned by investing his or her savings elsewhere would be included as accounting costs.

In contrast, both of these are implicit costs and are included in economic costs. The pharmacist’s time is not ‘free’ simply because there is no explicit wage. And the self-provided funds are not ‘free’ because the pharmacist gives up the return that could

have been received by investing the funds elsewhere.

The economic costs cover all the efficient dispensing costs for a community pharmacy. In the opinion of the Panel, the remuneration for dispensing should be based on economic costs, not accounting costs.

### MULTIPLE PRODUCTS AND INCREMENTAL COSTS

For almost every community pharmacy, the dispensing of PBS medicines is only one of a range of services provided by the pharmacy. As such, community pharmacy is characterised by ‘joint production’.

A traditional accounting approach to costs involves ‘fully distributed cost’ modelling. Under this approach, any ‘shared costs’, including the cost of premises or the wages of employees who work both in the dispensary and elsewhere in the pharmacy, are allocated (or distributed) between dispensing and other tasks.

However, there is no agreed way to do this allocation. For example, the allocation of rental costs between dispensing and other services could be based on floor area. However, such an approach is almost always arbitrary and unclear. Is a consulting room that is sometimes used for medicine advice, but is also used for other health advice, part of the dispensary? How are shared areas for storing Schedule 2, Schedule 3 and prescription medicines allocated? Is the ‘front of counter’ space dispensary space or general shop space?

Two broad alternatives exist in economics for dealing with shared costs: standalone costs and incremental costs.

<sup>138</sup> Implicit costs are costs borne by a business but not recorded in financial accounts, such as the opportunity cost of equity finance.

The efficient standalone costs of dispensing would consider the costs of establishing and operating a ‘dispensary only’ pharmacy. However, it has been noted to the Panel that such a model of community pharmacy does not exist and probably would not be viable.<sup>139</sup>

In this sense, using standalone cost involves creating an unrealistic construct to evaluate the costs of dispensing.

The incremental costs of dispensing consider all the extra costs that a community pharmacy faces when it operates a dispensary compared with operating a pharmacy without a dispensary.

For example, if the operation of a dispensary requires the pharmacy to lease a larger floor space and employ additional staff (including additional pharmacists and pharmacy assistants) then the additional costs are part of the incremental costs of the dispensary.

Incremental costs have the benefit of being business model neutral. The dispensary is considered separately from the other retail activities in the community pharmacy, with the relevant analysis focusing on the additional costs required for an efficient dispensary rather than the allocation of costs that are shared over retail operations.

Further, incremental costs have the benefit of ensuring that the dispensary ‘pays its way’ without artificially creating a standalone dispensary model.

In practice, incremental costs often involve a cost allocation method for shared costs. However, because the analysis starts from the perspective of the ‘extra cost’ for a

dispensary, the allocations are often more straightforward and can often be externally benchmarked.

For example, floor space will often be used to determine the incremental rental cost for the dispensary. But the ambiguities compared to allocated cost are reduced. For example, if questioning the front of counter space, the incremental cost response is to ask what space would be required even if there were no dispensary and excluding that space. The remaining space is clearly incremental to the dispensary.

Similarly, if rental costs are not ‘linear’ in space, this can be taken into account through incremental cost (but not allocated cost). For example, if adding 20 per cent extra space to a pharmacy for the dispensary increases rent by more (or less) than 20 per cent, incremental cost can take this into account.

In the opinion of the Panel, the remuneration for dispensing should be based on the incremental costs of dispensing rather than fully distributed or standalone costs.

## LONG-RUN COSTS

Economic costs are often divided into long-run and short-run costs. Short-run costs do not include any inputs (such as capital costs) that are fixed in the short term. While short-run costs are relevant for some economic and business questions, they are not relevant for determining the long-term remuneration for dispensing.

In contrast, long-run costs include all costs, both fixed and variable. Having remuneration for dispensing based on long-run costs ensures that community pharmacies are

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<sup>139</sup> Full Service Pharmacy Group, Submission No. 145.

remunerated for all dispensing costs and, if efficient, will be viable in both the short and the long term. In the opinion of the Panel the remuneration for dispensing should be based on the long-run costs of dispensing.

## REMUNERATION PER DISPENSE

The remuneration for dispensing is currently based on the number of prescriptions dispensed by a pharmacy. In other words, a pharmacy is remunerated for each dispense rather than paid for simply having a dispensary.

Having a 'per dispense' payment provides strong and appropriate incentives for a community pharmacy. It means that community pharmacies will have an incentive to reach an appropriate level of scale in their operations and to reduce costs while providing appropriate service to consumers. In contrast, if a community pharmacy was paid a fixed amount just for having a dispensary, the pharmacy would have less incentive to grow and the likely result would be small pharmacies that would supply a number of dispenses below a minimum efficient level.

In the opinion of the Panel, the government remuneration for dispensing should continue to be based on a 'per dispense' basis without any upfront payment for simply having a dispensary.

## MEDICINE-SPECIFIC COSTS

Remuneration for dispensing should be based on the efficient, average, long-run incremental cost of a dispense in a community pharmacy. This cost will have elements that are independent of the specific medicine being dispensed.

For example, many of the labour costs associated with a dispense will, on average, be similar across pre-packaged medicines. These costs do not vary between medicines.

However, some medicines will involve more expensive storage or higher financial costs. Medicines that have a high price to the pharmacist can involve additional financing, inventory and risk costs compared to lower-priced medicines.

It is desirable to have a 'formula' for the remuneration of dispensing that recognises appropriate cost differences but is simple to administer and easy for the community pharmacy and the general public to understand. A simple formula will save on costs, facilitate transparency and help maintain public confidence in the medicine distribution system.

For these reasons the Panel considers that the remuneration for a dispense activity should consist of either a simple fixed 'per dispense' payment or a two-part tariff where remuneration involves both a fixed component and a component based on the 'cost' of medicine to the pharmacy.

The Panel believes that the simplicity and transparency of a simple fixed payment is preferred to a more complex remuneration formula. Further, the options in this report provide safeguards for both medicine supply and pharmacy viability under a simple dispense payment.

Given the requirement in Option 3-1 that pharmacies be obliged to provide all PBS medicines, community pharmacy will not be able to 'cherry-pick' by avoiding high-cost medicines. Further, given Option 6-2 (Supply of High-Cost Medicines), a pharmacy's exposure to funding costs for high-cost medicines will be limited.

**OPTION 4-4: REMUNERATION FOR DISPENSING – FORMULA**

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

**4.7. 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 and simplicity of government payments.*

**DISCUSSION**

Given the information available to the Panel, and assuming that the upper limit of the wholesale payment for a medicine is put in place, the dispensing fee should be a fixed amount in the range \$9 to \$11.50.

In comparison with PBS payments to state hospitals, the Panel noted that there appears to be a lack of consistency in the treatment of community pharmacy.

In the case of high-cost medicines, different payments are made to community pharmacies and to hospitals for dispensing the same medicine. The Panel did not see how this difference was justified on the information that it has available to it.

Similarly, the Panel noted that there is no equivalent to the price disclosure process for PBS payments to hospitals.

Although the Panel has not provided options to address this issue, it notes that:

- the growing share of PBS payments going to hospitals
- the lack of transparency of costs at the state hospital level
- the differences between approaches for regulation and remuneration between community pharmacies.

Depending on the government's approach to other options in this report, the following option is provided as a 're-framing' mechanism to protect community pharmacies from certain pressures in the medicine supply chain.

**OPTION 4-5: REMUNERATION LIMITS**

If the government does not place an upper limit on the wholesale payment for a community pharmacist then the 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 government, following the acceptance of Option 4-4.

**4.8. REMUNERATION – ALTERNATIVE SERVICE CHANNELS**

*Government is currently paying different amounts through different mechanisms for the same service supplied by different primary health professionals.*

**DISCUSSION**

The option presented below is based on the fact that currently the government pays different amounts through different

mechanisms for the same service supplied by different primary health professionals.

For example, the government pays different amounts to GPs, nurses and pharmacists to deliver the same flu vaccination. In the view of the Panel, this makes no sense. So long as the service delivery satisfies the set minimum standard, the government should be paying remuneration for a particular health outcome, regardless of what health professional delivers the outcome.

The Panel noted a number of positive experiences in relation to the delivery of flu vaccinations by community pharmacies:

“Our pharmacy offered Flu vaccinations this year and delivered over 300 to our community. We vaccinated many truck drivers and port workers who would have never have thought to walk into a doctor’s surgery.”<sup>140</sup>

“We have seen the recent implementation of flu vaccination services by Pharmacists achieve great success, due to ease of accessibility and cost ... this type of service is ideally suited to the walk-in, walk-out business style of a pharmacy.”<sup>141</sup>

“A national online survey participated by 7076 patients who used the service this year found that 10% had not had a Flu vaccination prior ... and that 95% would also consider having their vaccination again next year through CW.”<sup>142</sup>

“In the 2016 flu season, our pharmacists administered over 4500 flu vaccinations. In Queensland, our pharmacists are vaccinating against measles and whooping cough. To date, pharmacist-led immunisation services in pharmacy have been wholly patient-funded.”<sup>143</sup>

Delivery should 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 Home Medicines Review (HMR) is clearly a place-based service and needs to be provided in the home or other appropriate location.

There should be no requirement for all community pharmacies to provide all program services. In fact, the opposite is preferred, where pharmacies can determine which programs to offer based on demand and the local demographics and health needs.

The payment for programs should be based on the delivery of a service to a patient, regardless of whether this is in a community pharmacy or another appropriate setting (e.g. medical clinic).

There may be exceptions where the payment relates to the location, most obviously for travel to a HMR. HMRs are discussed separately in Chapter 8 (Health Programs Offered by Community Pharmacy).

Specific advanced training, supported by robust 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.

<sup>140</sup> Anthony Vass, community pharmacist, Submission No. 361.

<sup>141</sup> Fiona Gardner, pharmacy owner, Pinjarra, Submission No. 403.

<sup>142</sup> Michael Youssef, Managing Partner, Chemist Warehouse, Submission No. 243.

<sup>143</sup> Good Price Pharmacy, Submission No. 352.

#### **OPTION 4-6: REMUNERATION FOR OTHER SERVICES**

Government should require that if the same service is offered through alternative primary



health outlets then the same government payment should be applied to that service, regardless of the specific primary health professional involved.

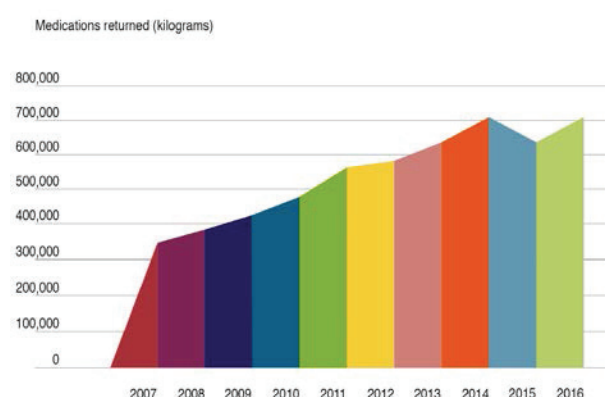
#### 4.9. COST OF PBS MEDICINES – SHRINKAGE/WASTAGE

*There is evidence of significant wastage of PBS medicines.*

#### DISCUSSION

There is evidence of considerable wastage of PBS medicines. For example the Return Unwanted Medicines (RUM) project reported the collection and disposal of more than 5452 tons of medicines returned over a 10-year period. This is demonstrated in **Figure 12**.<sup>144</sup>

**Figure 12: RUM results 2007–2016**



The National Return and Disposal of Unwanted Medicines Project Audit conducted in late 2013 reported the following:<sup>145</sup>

<sup>144</sup> This represents the number of unwanted and out-of-date medicines collected by community pharmacies from consumers and reported to the National Return & Disposal of Unwanted Medicines Limited: Return Unwanted Medicines (The RUM Project), *Collections* (2016–17).

<sup>145</sup> Monash University & The RUM Project, *The National Return and Disposal of Unwanted Medicines: Final report* (December 2013), pages 8 & 9.

- Approximately 540 tonnes (i.e. 540 000 kilos) of medicines were returned that year, with an estimated cost to government of \$2.05 million.
- Consumers predominantly returned scheduled medicines (85.4 per cent) – 80.9 per cent (Schedule 4), 9.1 per cent (Schedule 2), 7.8 per cent (Schedule 3) and 2.3 per cent (Schedule 8).
- Almost half of the returned medicines had not expired.
- The majority of medicines (68 per cent) belonged to five therapeutic classes (cardiovascular (17.9 per cent), nervous system (17.5 per cent), alimentary tract (15.7 per cent), respiratory (8.8 per cent) and anti-infective (8.1 per cent)). This correlated well with PBS dispensing data.
- The report considered that it was important to do further work to determine the reasons why consumers return medicines.
- The large number of unexpired medicines (and related risks arising) warrants communication of these findings with prescribers and other healthcare professionals.

The Panel notes that the audit has provided valuable insights into the types and quantities of medicines being discarded by the Australian community.

While the Panel has not provided any additional options to address the issue of medicine wastage, it supports the need for future research in this area as foreshadowed in the National Return and Disposal of

Unwanted Medicines Project final report.<sup>146</sup> In particular:

- why consumers return non-expired medicines
- why there are low rates of return for non-scheduled medicines (when compared to the rate of return for scheduled medicines).

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<sup>146</sup> Monash University & The RUM Project, *The National Return and Disposal of Unwanted Medicines (NatRUM) Project Audit*, Final Report (December 2013), page 41.

## 5. THE REGULATION OF PHARMACY FOR MEDICINE SUPPLY

### 5.1. A VIABLE NETWORK OF COMMUNITY PHARMACIES

The Panel considers that, while individual community pharmacies are important, it is the viability of the overall network of pharmacies that provides the most value to the government and the public.

This does not mean that the Panel has less regard for the important work that individual pharmacies do in serving their own communities.

However, the factors affecting the viability of individual pharmacies are highly variable and at times unique to that pharmacy or pharmacy group. The Panel has therefore tended to concentrate its focus on the viability of the pharmacy network as a whole, and its concerns in relation to the network are reflected in this report.

The Panel has no evidence that the network of community pharmacies is inadequate. The starting point for this Review is that the network is good, but this does not mean that it cannot be improved.

The Panel has seen pressure points in the network, including arrangements that do not represent appropriate government policy.

The Panel is also concerned with the sustainability of an effective community pharmacy network that demonstrates innovation and positive change and is not constrained by unnecessary regulation.

### 5.2. REFORMS TO PHARMACY LOCATION RULES

*Certain aspects of the pharmacy location rules are limiting competition and are unnecessary in some areas.*

#### DISCUSSION

***Given the Government's recent commitment in the 2017–18 Budget to continue the current pharmacy location rules, the Panel considers that options 5-1, 5-2 and 5-3 are no longer immediately relevant to this Review. They have been presented but will not be considered further by the Panel. However, the Panel will continue to consider options to modify the location rules that have been put forward on the assumption that the current location rules will be retained.***

The location rules for community pharmacy in Australia limit the potential for new pharmacies to open or for existing pharmacies to relocate. There are questions about the effects of these rules, with competing claims made that they either increase or decrease consumer access.

Any discussion of the merits, or otherwise, of the pharmacy location rules is likely to be complex. The following analysis covers:

- the purpose of the pharmacy location rules
- the economic theory underpinning entry and location of retail outlets
- approaches to regulating outlet numbers and locations
- whether or not there is any evidence of an 'entry' problem in Australia
- the costs of the location rules.

A detailed analysis of the economics of location rules and pharmacy access is

provided at Appendix D (Understanding Location Models).

## THE PURPOSE OF THE PHARMACY LOCATION RULES

The existing regulatory framework for community pharmacies aims to support the achievement of the objectives under the National Medicines Policy (NMP).

The pharmacy location rules were originally designed as a regulatory mechanism to:

- ensure that the distribution of community pharmacies broadly reflects the requirements for the Australian population
- limit the costs of maintaining the pharmacy network (as a means of distributing Pharmaceutical Benefits Scheme (PBS) subsidised medicines)
- reinforce service quality requirements
- encourage investment in community pharmacy infrastructure and facilities.

The pharmacy location rules are divided into two general types:

- those that apply to the relocation of an existing pharmacy
- those for the establishment of a new pharmacy.<sup>147</sup>

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.

It is important to note that, while the location rules determine where a pharmacy operated

by an approved pharmacist can be located, they do not impose restrictions on who can own a pharmacy.

## RELEVANT ECONOMIC THEORY

The economic theory around the entry and location of competing retail outlets is well developed and uncontroversial. It provides important results that can assist in understanding the pharmacy location rules and the interaction between these rules and other parts of the regulation and remuneration of community pharmacy in Australia.

According to economic theory, the operation of a free market for retail outlets can lead to the following:

- *For a fixed number of retail outlets:* Those outlets can be located either 'too close' or 'too distant' from an economic perspective. However, there are strong incentives for outlets to locate in a way that minimises average customer access costs, particularly when new outlets can threaten to enter the market.
- *For a variable number of retail outlets (i.e. entry by any outlet that believes that it is profitable to do so):* There may be too few outlets but, if there are fixed costs of entry and 'economic rents' (i.e. if incumbent outlets make operating profits that exceed their fixed costs), there may be economically excessive entry. The gain in customer access from increased entry is more than offset by the costs of establishing and operating extra outlets.

<sup>147</sup> National Health (Australian Community Pharmacy Authority Rules), *Determination 2011* (PB65 of 2011), where Schedule 1 of this Act divides applications to the authority into these two groups.

- The examination of the location and number of retail outlets, and any price control, cannot be analysed separately.

These three conclusions from economic theory are critical to this Review.

For community pharmacy in Australia, government funds provide a substantial part of most pharmacies' revenue and profit. In particular, many community pharmacies earn a substantial share of their revenue and profit from dispensing of PBS medicines. From a consumer and social perspective:

- On a region-by-region basis, government payments to community pharmacy are too high if this results in excessive entry in a region or too low if there are insufficient entrants in a particular region (economic welfare will be improved with improved customer access in that region if government lowers or raises these payments respectively).
- If government sets the level of pharmacy remuneration so that the number of pharmacies in a region is at the appropriate level for overall consumer access then it is likely that these pharmacies will distribute themselves over the region over time approximately in the ratio with the distribution of customer demand. This is particularly the case when the government does not prevent entry of a new pharmacy that can compete against and potentially 'displace' an existing pharmacy.

Together, these implications mean that, while the distribution of pharmacies in a region may not be 'perfect', if there is an issue of too many or too few pharmacies overall then this

should be dealt with by a change in government remuneration for pharmacies.

It is possible that some sort of 'location rules' or government process to locate pharmacies in a region could improve access for some consumers (while lowering access for others). However, the existing pharmacy location rules, which are based on arbitrary distances and proxies for consumer 'traffic flow', are unlikely to improve customer access compared with allowing pharmacies to make their own location decisions, subject to the threat of entry.

Indeed, existing location rules may reduce consumer access both by limiting the number of pharmacies in recognised high traffic flow areas and preventing pharmacies from locating in areas that may have a higher traffic flow than that measured by the proxies used in the rules. Further, by removing the threat of entry, the location rules themselves can provide incentives for pharmacies to cluster.

### IS THERE ANY EVIDENCE OF AN 'ENTRY' PROBLEM IN AUSTRALIA?

There can be either excessive or insufficient entry of community pharmacy in a region depending on the level of 'economic rents'<sup>148</sup> or the gap (if any) between operating profits and fixed establishment costs.

It can be argued that the 'overall' number of community pharmacies in Australia is appropriate, particularly at the national level.<sup>149</sup>

<sup>148</sup> Economic rents can arise if there are moderate levels of retail competition or when there is a price regulation and the regulated prices are above the average operating costs for each retail outlet (e.g. when the operating profit of an outlet exceeds the fixed costs of establishing the outlet).

<sup>149</sup> Pharmacy Guild of Australia, Submission No. 486, advises that, overall, there is reasonable access to

In terms of pharmacies per head of population, Australia appears to be in line with many other OECD countries.

However, there may still be issues of excessive or ‘repressed’ entry or insufficient entry at a local or regional level. This may be reflected by either:

- too many pharmacies in some regions and too few pharmacies in other regions
- pharmacies seeking to enter and establish in some areas but being prevented by the entry restrictions, which reflects that government is allowing overcompensation for incumbent pharmacies in these areas, leaving them with economic rents paid either directly by users or indirectly by taxpayers.

There is evidence available to the Review that indicates pharmacies may not be appropriately distributed in some locations. For example, a submission from Chemist Warehouse<sup>150</sup> presents a list of fifty-two areas where it would like to establish a pharmacy. Similarly, the Ingham Family Medical Centre<sup>151</sup> also noted their failed attempt to enter and provide pharmacy services in Ingham, Queensland.

Furthermore, the National Rural Health Alliance considers that:

“There is evidence of probable lower levels of access to pharmaceuticals for people living outside major cities, but the publicly available recent data are

insufficient to clearly quantify the extent. The Alliance would strongly suggest that the Government carefully investigate the levels of access to pharmaceuticals and to professional advice and review of pharmaceuticals for people living in rural and remote areas.”<sup>152</sup>

It is therefore possible that there are issues of too few pharmacies being present in some regional and remote areas.

For remuneration, it follows from the economic analysis that, if the overall number of pharmacies is appropriate but there are economic rents accruing to these incumbent pharmacies, there will be attempted entry by new pharmacies.

This attempted entry may be unsuccessful due to the pharmacy location rules (as in the Ingham Family Medical Centre example) and would tend to signify excessive government remuneration to the existing pharmacies.

There is further evidence of economic rents accruing to some pharmacies. Such rents will be part of the ‘goodwill’ of a community pharmacy when it is sold or when a new owner buys into the business. It can be difficult to separate out the part of ‘goodwill’ that is associated with economic rent and the part relating to standard non-monetised business assets.

However, under an earlier version of the pharmacy location rules, Terry White Chemists noted that:

“the focus on relocation promoted the practice of pharmacists trading in approvals and in the period leading up to October 2011, it was common practice for approvals to be bought and sold for up to \$500,000 and sometimes more.”<sup>153</sup>

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community pharmacies in Australia (e.g. capital cities: the average resident is less than one kilometre from the nearest pharmacy, while 97 per cent of consumers are no further than two kilometres from a pharmacy; and outside capitals: residents are just 6.4 kilometres from the nearest pharmacy, with 65 per cent having a pharmacy within two and a half kilometres).

<sup>150</sup> Chemist Warehouse, Submission No. 218.

<sup>151</sup> Ingham Family Medical Centre, Submission No. 313.

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<sup>152</sup> National Rural Health Alliance, Submission No. 484, page 3.

<sup>153</sup> Terry White Chemists, Submission No. 458, page 14.



There is also evidence of economic rents accruing to pharmacies in shopping centres, albeit that the shopping centre owners may, in turn, be able to seize taxpayer-funded rents.

For example, Sunil Narula notes:

“When a Pharmacist in such a new suburb establishes a new pharmacy, the process is, in general, put to tender by a developer and the Pharmacist that ‘bids the highest’ gains the right to open in this new suburb. Once established there is little or no chance of any other pharmacist having the ability to open under the current pharmacy location rules. The end result is that the ‘highest bidder’ must now get a return on the investment he or she makes and by inference this results in higher prices to the patients that have no option in this suburb but to shop in this pharmacy.”<sup>154</sup>

It should be noted that the presence of economic rents does not necessarily imply that existing pharmacy owners are gaining the benefits of these rents. As the shopping centre example shows, these rents may be able to be seized by landlords.

If there is potential for excessive entry, driven by economic rents accruing to community pharmacies, then an appropriate approach is to change government remuneration to community pharmacies to ensure that efficient community pharmacies are only earning a fair commercial return.

The Panel considers that its options on remuneration for dispensing, presented earlier, provide the basis for fair and equitable remuneration for community pharmacy that will eliminate any issues of excessive entry.

The potential for economic rents to have been transferred raises issues about transition if

the government reduces remuneration to existing pharmacies in order to eliminate these rents. The cost of this policy change may fall on parties who do not benefit from the rents.

As submission number 1 indicates, pharmacy owners can draw on significant loans to buy into existing practices, suggested in the vicinity of \$2 million. To the degree that the price the owner paid for a share of the pharmacy includes economic rents then the seller gained the expected future value of these rents through the purchase price. Eliminating the rents will clearly harm the new owner.

However, such harm must be balanced against the ongoing harm to taxpayers if there is excessive government remuneration to community pharmacies. These taxpayer funds could be reallocated to socially valuable alternative uses.

### IS THERE ANY EVIDENCE THAT THE LOCATION RULES (UNDESIRABLY) CHANGE THE DISTRIBUTION OF PHARMACIES?

RSM’s geospatial analysis, briefly illustrated in **Figure 13**, completes an investigation of PBS data on the place of residence of the consumer (or patient) accessing PBS medicines, the location of the medical practitioner who prescribes those medicines, and the location of that pharmacy that supplies those medicines.<sup>155</sup> The investigation confirms the following trends:

- Of the 54 per cent of scripts dispensed by pharmacies located in the same postcode as the consumer resides:

<sup>154</sup> Submission No. 472, page 3.

<sup>155</sup> RSM, *Financial analysis of pharmacy regulations and remuneration arrangements* (March 2017), page 28.

- 34 per cent of total scripts are prescribed by medical practitioners and dispensed by pharmacies in the same postcode as the consumer resides
- 20 per cent of total scripts are dispensed by pharmacies in the same postcode as the consumer is located but are prescribed by medical practitioners in another postcode.
- Forty-five per cent of all scripts are dispensed by pharmacies in another postcode. Only 10 per cent of the people who travel to another postcode to have their script dispensed come from a postcode in which there is no pharmacy.
- Twenty-nine per cent of all scripts are filled by pharmacies located in a postcode that differs from the postcode where the consumer resides and the postcode where the medical practitioner that prescribes the required medicine:
  - 25 per cent of these scripts dispensed require the consumer to travel up to 4.7 kilometres to visit the pharmacy.
  - 50 per cent of these scripts require the consumer to travel up to 9.8 kilometres to visit the pharmacy.
  - 75 per cent of these scripts require the consumer to travel up to 26.5 kilometres to visit the pharmacy.
- Seventeen per cent of all scripts are prescribed by medical practitioners who are located in the same postcode as the location of the pharmacy that dispense that script but in a different

postcode from where the consumer resides.

Economic theory indicates that, in the absence of location rules, the distribution of community pharmacies will be approximately consistent with the distribution of population.

The distribution may vary for a number of reasons. If there are particular communities with a high demand for medicines then it would be expected that more pharmacies would serve these communities. If there are areas of concentrated foot-traffic that differ from the residential population density (e.g. CBD areas where individuals who live in other areas find it convenient to buy medicines) then it would be expected that a 'cluster' of pharmacies would form in these areas.

It should also be noted that the distribution of these pharmacies may not be 'optimal' from a social perspective. In particular, areas of 'thin' population may have no pharmacy even though, as a society, we would like to see people in these areas able to access medicines.

The submissions to the Review provide both formal and informal evidence relating to the distribution of pharmacies.

Chemist Warehouse has provided evidence of the distribution of pharmacies per head of population around Australia, which shows that there is significant variation, even in urban areas.<sup>156</sup>

"South Perth has the highest number of people per pharmacy at 32% above the national average ... whereas Central and Eastern Sydney has the least number of

<sup>156</sup> Chemist Warehouse, Submission No. 218A (includes analysis from Deloitte Access Economics).

people per pharmacy at 23% below the national average.”<sup>157</sup>

Chemist Warehouse also provided evidence of clustering of pharmacies in Blacktown, a suburb of Sydney.<sup>158</sup>

The Panel has heard accounts of the current location rules being open to gaming in some circumstances. For example, an owner-pharmacist notes that the current location rules can lead to clustering and underserved areas.<sup>159</sup> The submission discusses how two community pharmacies were relocated from Invermay to the centre of Launceston:

“[B]oth [were] within 200m of another pharmacy and [left] Invermay without a pharmacy”.

If the existing location rules were providing appropriate access to consumers, compared to the alternative of pharmacies choosing their locations, then it would be expected that the rules would be supported by consumers. After all, the objective is consumer benefit. However, the Consumers Health Forum of Australia (CHF) recommends the opposite, as it has advocated for the removal of location rules to allow new pharmacies to be established by competition for the benefit of consumers.<sup>160</sup>

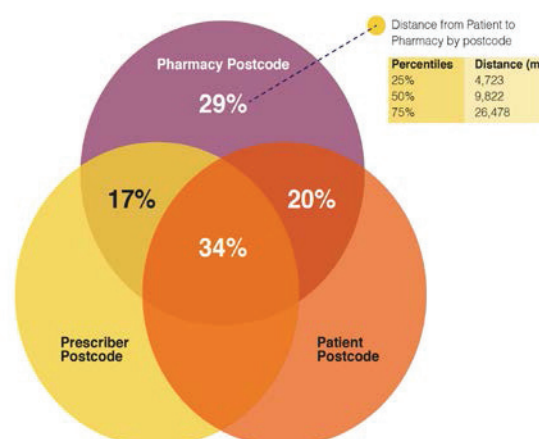
<sup>157</sup> Chemist Warehouse, Submission No. 218/218A, page 21.

<sup>158</sup> Chemist Warehouse, Submission No. 218/218A, page 25.

<sup>159</sup> Owner pharmacist, Submission No. 505, paragraph 10.

<sup>160</sup> Consumers Health Forum of Australia, Submission No. 483, page 10.

**Figure 13: Proportion of PBS scripts dispensed relative to prescriber and patient location**



A more detailed breakdown of the relative consumer, prescriber and pharmacy location for different categories of consumers (e.g. general and concessional consumers) is provided in **Table 8**. The results of this analysis are broadly consistent with those outlined above:

- Concessional consumers tend to have their scripts prescribed by medical practitioners, and dispensed by pharmacies, that are located in the same postcode in which they reside, which may reflect their lower regional mobility. For example:
  - concessional Safety Net consumers tend to have the highest proportion (i.e. 40 per cent) of their prescriptions prescribed by medical practitioners and dispensed by pharmacies that are located in the same postcode in which they reside
  - concessional consumers who have not reached the Safety Net (i.e. ‘concessional non-Safety Net’ consumers) have a slightly lower

proportion of their scripts (i.e. 37 per cent) prescribed and dispensed by medical practitioners and pharmacies located in the same postcode in which they reside.

- Non-concessional consumers who are not eligible for the annual Safety Net tend to have lower proportions of their scripts prescribed and dispensed by medical practitioners and pharmacies that are located in the same postcode as they reside, which may reflect their greater regional mobility and hence lower generalised costs of visiting those more remote pharmacies. For example:
  - general Safety Net consumers have a slightly lower proportion of their scripts (i.e. 32 per cent) prescribed and dispensed by medical practitioners and pharmacies located in the same postcode as they reside
  - general non-Safety Net over co-payment consumers have the lowest proportion of their scripts (i.e. 23 per cent) prescribed and dispensed by medical practitioners and pharmacies located in the same postcode as they reside.

**Table 8: Location of consumer, prescriber and pharmacy (by consumer category)**

Patient type	Number of scripts	Percentage of total scripts	Location of consumer, prescriber and pharmacy			
			Consumer and pharmacy in same postcode	Prescriber and pharmacy in same postcode	Consumer, prescriber and pharmacy in same postcode	Consumer, prescriber and pharmacy in different postcodes
Concessional non-Safety Net	145 061 002	49%	58%	53%	37%	26%
Concessional Safety Net	43 712 612	15%	63%	53%	40%	24%
General non-Safety Net (over co-payment)	14 486 038	5%	45%	41%	23%	37%
General non-Safety Net (under co-payment)	80 762 096	27%	46%	47%	28%	34%
General Safety Net	3 192 802	1%	58%	46%	32%	28%
RPBS non-Safety Net	7 408 118	2%	59%	53%	39%	27%
PRBS Safety Net	2 936 671	1%	47%	53%	31%	31%
Prescriber Bag	382 285	0%	0%	72%	0%	28%
ALL	297 941 624	100%	55%	51%	34%	29%

**Note:** Includes community pharmacy and hospital pharmacy data for 2015–16.

## THE COST OF THE CURRENT PHARMACY LOCATION RULES

The current pharmacy location rules have both observable and hidden costs. The observable costs are reflected in the costs of administering the existing system<sup>161</sup> and the reduced consumer access that potentially occurs when an application for a pharmacy approval is not approved due to the application of the location rules.

The hidden costs of the location rules reflect reduced consumer access to community pharmacy, which arises because of the pharmacies that are never developed as a result of the rules. These are difficult to measure because generally no application is made to the Australian Community Pharmacy Authority (ACPA) for the establishment of a community pharmacy if the rules are unlikely to be met.

The ‘hidden’ costs can be proxied in two ways. First, because the location rules have changed over time, there are examples of existing community pharmacies that improve consumer access that would not be allowed to be established under current rules.

For example, the Panel visited a pharmacy in Gympie which was located well outside the city centre. The pharmacy provided accessibility to consumers due to its close proximity to a number of other ‘destination’ retail outlets and appeared to be thriving. However, the Panel understands that the current locations rules would not allow the

establishment of a pharmacy in such a location. In particular, the requirements under rule 130, which demand there be a nearby supermarket, would not be met. Under current location rules a regional community’s access to pharmacy are reduced as a clear cost of the rules.

Secondly, an indicator of the hidden costs can be reflected in the views of community pharmacists, particularly young and innovative pharmacists, who are unable to ‘take a risk’ and start a pharmacy because of the rules. The Australian Journal of Pharmacy (AJP) recently hosted a discussion on whether the location rules should continue and provided the following insights into the hidden costs of the rules:<sup>162</sup>

“Not all pharmacists seek to own their own business. Those pharmacists that do wish to run their own show face significant hurdles primarily in the form of location rules. Location rules drive the astronomical value of pharmacies, inflate retail costs per square metre, create geographical regions of same owner monopoly and prevent true innovation due to the safety net of market share.”

“National interest should come first before personal interest. Why should a pharmacist be deprived of his or her right to open up a new pharmacy by putting in place rules that in a way prohibits and favours only existing owners.”

“Location rules can allow poorly run businesses to survive and some to prosper. If a business cannot stand without restraint of trade protection it is doing something wrong.”

“Why should a pharmacy business remain anticompetitive. If current owners are not making enough money then I can ask any one in Your CBD to find a pharmacy that is on sale without a huge premium.”<sup>163</sup>

<sup>161</sup> These administration costs (as estimated by the Department of Health) range between \$2 million and \$3 million per annum. They include Department of Human Services costs, as well as Department of Health costs, the legal costs for the Administrative Appeals Tribunal (AAT) and Federal Court challenges, and the costs for meetings of the Australian Community Pharmacy Authority (ACPA).

<sup>162</sup> AJP, [Should location rules be abolished?](#) (17 January 2017).

<sup>163</sup> AJP, [Should location rules be abolished](#) (17 January 2017).



In many sectors of the economy, including health, innovation starts with younger practitioners who are willing and able to operate at the frontier of their discipline. This is reflected in community pharmacy by recent winners of the Pharmacy Guild of Australia (the Guild) ‘Pharmacy of the Year’ awards. In general, the finalists and winners have been young pharmacists who are innovating and improving consumer health through their pharmacies.

During its national consultations, the Panel met with several recent nominees and winners of the ‘Pharmacy of the Year’ awards. These pharmacists are inspirational, and the Panel was excited by their energy and innovation. Unfortunately, by restricting young pharmacists, the location rules more broadly harm innovation in community pharmacy as well as reducing consumer access.

## SUMMARY

A number of submissions concluded that the current pharmacy location rules are not fit-for-purpose and may be limiting equitable and affordable access in some areas.

Rather than try to modify the existing rules, the Panel has considered that it is more appropriate to remove the existing rules and, if required, replace them with a different, simpler system that directly deals with the issues of consumer access.

### OPTION 5-1: PHARMACY LOCATION RULES – REMOVAL AND REPLACEMENT

The government should remove the location rules for community pharmacies. It should replace the location rules with one of the alternatives presented below.

## PHARMACY DISTRIBUTION AND THE REMOVAL OF THE PHARMACY LOCATION RULES IN URBAN AREAS

The issue of consumer access to medicines will be different in urban and other areas. In particular, the information available to the Panel strongly indicates that removal of the location rules with appropriate behavioural regulation to remove any economic rents and protect against excessive entry will lead to a desirable distribution of community pharmacies.

While this discussion follows from both the economic theory outlined above and the application of this theory to the submissions received by the Panel, it would be useful if there were direct analysis based on the distribution of outlets that would be chosen by pharmacies in the absence of the location rules.

The Panel notes that such an analysis was carried out by M. Waterson prior to the introduction of the location rules for community pharmacies in metropolitan Melbourne using data collected in 1979–80 covering fifty statistical retail areas.<sup>164</sup>

Waterson’s analysis focused on the actual distribution of pharmacies to calibrate a location model for pharmacy distribution. He then considered the optimal distribution of pharmacies to trade off consumer access costs and economies of scale in pharmacy.

Waterson’s analysis provides a guide to whether the distribution of pharmacies across metropolitan Melbourne, with behavioural second-best regulation, is significantly different from the distribution that allows an

<sup>164</sup> M. Waterson, ‘Retail pharmacy in Melbourne: Actual and optimal densities’, *The Journal of Industrial Economics*, vol. 41 (1993), pages 403–419.

efficient level of community pharmacy while also minimising consumer access costs.

Waterson concludes that:

- [While] he “cannot obtain a complete answer to the question of whether there are too many pharmacies ... the model suggests that the market-determined number of pharmacies would be socially excessive in the absence of any regulation”.<sup>165</sup>
- When comparing the actual distribution of pharmacies with the optimal distribution, assuming “that price setting under the PBS was carried out in such a way as to create the right total number of pharmacies in this area as a whole”, Waterson notes that the optimal and actual distributions are “extremely close”.<sup>166</sup>

These empirical results for metropolitan Melbourne are consistent with the economic theory referred to above.

While the Waterson paper provides only one piece of evidence, it comprises a set of valuable independent and empirical peer-reviewed research that focuses on the distribution of community pharmacies in the absence of location rules but with appropriate remuneration levels. It is also based on Australian data. In this sense, it provides input that is directly relevant for one of the key issues of concern for this Review.

Given the information available to it, including economic theory, the Waterson analysis and the information provided by submissions, the

Panel recommends that the current location rules be replaced in urban areas by one of the three options presented below.

### 5.3. PHARMACY LOCATION RULES – ALTERNATIVES FOR URBAN LOCATIONS

#### OPTION 5-2: URBAN LOCATION RULES

##### ALTERNATIVE 1:

The government should undertake an analysis (as per Option 4-2) to determine and implement efficient remuneration for the dispensing of PBS medicines. Following the implementation of efficient remuneration and a suitable transition period (no later than 31 December 2020), the government should remove any restrictions to limit the ability of any qualified pharmacist or pharmacists to establish a pharmacy to dispense PBS medicines at any location in urban areas.

##### ALTERNATIVE 2:

The government should replace the location rules in urban areas in two stages:

1. For the first five years, the government should:
  - a. establish an independent statutory authority (the Pharmacy Location Board (PLB)) of five members, at least two of whom are persons who have been, but are no longer, engaged either directly or indirectly in community pharmacy. No PLB member may be a current pharmacy owner. Any pharmacist wishing to establish a new pharmacy in an urban location would be required to apply to the PLB for a provider number. The PLB would assess all such applications and engage in relevant consultation as it sees fit. The PLB would issue a provider number if (and only if) in the opinion of the PLB, this would materially improve consumer access

<sup>165</sup> M. Waterson ‘Retail pharmacy in Melbourne: Actual and optimal densities’, *The Journal of Industrial Economics*, vol. 41 (1993), page 417.

<sup>166</sup> M. Waterson ‘Retail pharmacy in Melbourne: Actual and optimal densities’, *The Journal of Industrial Economics*, vol. 41 (1993), page 417.

- to PBS medicines
  - b. undertake an analysis (as per Option 4-2 above) to determine and implement efficient remuneration for the dispensing of PBS medicines.
2. Prior to the end of the five-year period, the government should assess whether the PLB is required in urban areas or whether consumer access to PBS medicines would be appropriately served by removing any remaining restrictions that limit the ability of any qualified pharmacist or pharmacists to establish a pharmacy to dispense PBS medicines at any location in urban areas.

### ALTERNATIVE 3:

New pharmacy location rules should be introduced based on existing rules. This includes:

- a. retention of the prohibition within the location rules relating to the co-location of approved pharmacies in supermarkets
- b. the establishment by the Department of Health and the Guild of a joint working group with the aim of identifying and addressing any anomalies that have arisen over time, to ensure the location rules remain responsive to the evolving needs of the community.

## THE REPLACEMENT OF THE PHARMACY LOCATION RULES IN OTHER LOCATIONS

Outside urban areas (roughly outside PhARIA 1<sup>167</sup> regions) both the economic theory and the information available to the Panel suggest that the situation is complex. There appear to

<sup>167</sup> PhARIA Category 1 is categorised as Highly Accessible – with relatively unrestricted accessibility to a wide range of goods, services and opportunities for social interaction.

be regions outside city areas where the location rules are acting as a barrier to entry and limiting consumer access and choice.

However, in other non-urban areas, there is a lack of pharmacies, and the government has found it necessary to support the operation of pharmacies in such areas through the application of a subsidy – the Rural Pharmacy Maintenance Allowance (RPMA).

The Panel considers that the existing pharmacy location rules do not appropriately address these issues of consumer access.

There are 909 (16 per cent) pharmacies in regions PhARIA 2 to 6 in Australia. While this is a considerable number of pharmacies, the Panel considers that the government can significantly improve on the current location rules based approach to consumer access by moving to a process which directly addresses consumer access.

## 5.4. PHARMACY LOCATION RULES – ALTERNATIVES FOR NON-URBAN LOCATIONS

### OPTION 5-3: NON-URBAN LOCATION RULES

#### ALTERNATIVE 1:

The government should replace the pharmacy location rules in non-urban areas by establishing an independent statutory authority (the Pharmacy Location Board (PLB)) of five members, at least two of whom are persons who have been, but are no longer, engaged either directly or indirectly in community pharmacy. No PLB member may be a current pharmacy owner. Any pharmacist wishing to establish a new pharmacy in a non-urban location would be required to apply to the PLB for a provider number. The PLB would assess all such applications and engage in

relevant consultation as it sees fit. The PLB would issue a provider number if (and only if), in the opinion of the PLB, this would materially improve consumer access to PBS medicines.

The PLB would also work with the local Primary Health Network (PHN) in any relevant region to determine areas where there is a lack of appropriate pharmacy services and work with the PHN to initiate a tender to seek options by pharmacists to provide the identified services. The government would appropriately fund PHNs and the PLB to carry out these tenders and, where relevant, to provide any subsidy determined through the tender process.

#### **ALTERNATIVE 2:**

New pharmacy location rules should be introduced based on existing rules. This includes:

- a. retention of the prohibition within the location rules relating to the co-location of approved pharmacies in supermarkets
- b. the establishment by the Department of Health and the Guild of a joint working group with the aim of identifying and addressing any anomalies that have arisen over time, to ensure the location rules remain responsive to the evolving needs of the community.

### **5.5. REFORMS IF THE LOCATION RULES ARE RETAINED IN SOME PARTS OF AUSTRALIA**

*The policy in respect of pharmacy location rules is unclear. This results in different interpretations of their purpose and intent and reduces the ability to monitor performance and the achievement of outcomes.*

For the reasons discussed above, the Panel has recommended the removal of the existing pharmacy location rules.

The Panel recognises, however, that the government may not accept all of its recommendations. The purpose of this section is to ensure that the government has appropriate policy options if it decides not to remove the location rules in at least some parts of Australia.

For example, the objective of the location rules in the current environment is not sufficiently clear. This needs to be clarified and articulated as an appropriate and critical part of the policy rationale for retention. The inclusion of the evidence required to demonstrate achievement of this objective should also form part of the policy statement.

#### **OPTION 5-4: PHARMACY LOCATION RULES – POLICY OBJECTIVE**

If the government retains the pharmacy location rules (or some version of these rules) following the end of the Sixth Community Pharmacy Agreement then the policy objective of these rules should be clearly stated and the rules modified to ensure that the desired outcomes are achieved over the medium term.

The objective of the pharmacy location rules should be to assist the Australian consumer to ensure equitable and affordable access to medicines for all Australians, consistent with the National Medicines Policy, with evidence to demonstrate the achievement of this objective.

## 5.6. OVERLAPPING OWNERSHIP AND LOCATION OF PHARMACIES

*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.*

### DISCUSSION

A key principle in economics is that cross-ownership of otherwise competitive outlets will reduce competition and harm consumers. This can be reflected in a variety of ways – higher prices to consumers, less variety for consumers, lower-quality service (e.g. reduced opening hours) or increased travel costs for consumers who wish to access independent outlets.

The harms created by cross-ownership will be intensified if there are fewer alternatives and if there are significant barriers to entry such as the barriers created by the location rules for community pharmacy in Australia.<sup>168</sup>

It is also recognised that cross-ownership of some potential competitors also reduces the competitive pressure on other non-integrated competitors.<sup>169</sup> Cross-ownership mutes or eliminates competition by changing the incentives of the relevant outlets.

For example, in the absence of cross-ownership, two pharmacists in a particular location are forced to compete. The incentive

to differentiate can be strong, and either pharmacy may choose to offer a more personalised service, longer opening hours, a more expansive range of products, better medicines advice or lower prices to better serve the customer and gain extra revenue from them. This will improve the profitability and viability of the pharmacy.

There is also the issue that when one pharmacy gains custom the other loses. In this situation, a dollar of additional revenue flowing to one pharmacy (due to it better meeting the needs of a customer) means that a dollar less revenue is potentially available to the competing pharmacy.

In contrast, suppose there is cross-ownership and one pharmacy buys a stake in its competitive rival. This would change the incentives for that pharmacist-owner. The 'one-way' cross-ownership means that the cross-owner has less interest in keeping all of their customers.

After all, when a customer chooses the rival pharmacy, some of the profits from that 'lost customer' will flow back through the cross-ownership share. If the same pharmacist owned both pharmacies in full then the pharmacist would be indifferent as to the pharmacy chosen by the customer. The pharmacist would get the revenue one way or another.

Cross-ownership therefore mutes (and potentially eliminates) the incentive to compete. Customers become fully or partially 'captive' to the pharmacist-owners and, at worst, the revenue from a customer who chooses the rival pharmacy is only partially lost.

The harm created by cross-ownership is reflected in the *Competition and Consumer Act 2010* (Cth). Section 50 of this Act makes it

<sup>168</sup> M. Motta, *Competition policy: Theory and practice* (2004), pages 335–336.

<sup>169</sup> M. Motta, *Competition policy: Theory and practice* (2004), page 234.

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”.

It should be noted that cross-ownership can harm competition and consumers even if there is no joint control of the relevant businesses or even if the cross-ownership share(s) are relatively small.<sup>170</sup>

For example, the Chemist Warehouse submission notes the problems created by monopolisation:

“The problem is most evident in regional towns where there are a small number of pharmacies, often owned by the one pharmacist or same group of pharmacists.”<sup>171</sup>

The Central Australian Aboriginal Congress Aboriginal Corporation provides an explicit example of the aggregation of ownership in Alice Springs:

“Congress has the additional concern about a pharmacy monopoly in Alice Springs which creates a significant barrier to access of pharmaceuticals. The current ownership of the four pharmacies in Alice Springs, in accordance with both the ABN & ASIC register, indicate that a single group of pharmacists are co-owners of all the pharmacies in town. It is argued that the monopoly situation is contributing to increased pricing for the general population of Alice Springs and having a public pharmacy not owned by one group will improve competition and pricing and therefore improve access by breaking the monopoly.”<sup>172</sup>

Issues of concentrated ownership have also been noted in situations where entry of a new pharmacy has been prevented by the location rules.

Sunil Narula discusses the inability to open a new pharmacy in Karratha:

“the 2 local Pharmacies (which are operated by the same Pharmacy owner) have a monopoly on the city. There is an incentive therefore for the incumbent Pharmacy owner to not sell to another Pharmacist and a direct incentive to raise prices to the public and make pharmaceuticals less affordable.”<sup>173</sup>

While the existence and potential problems of overlapping ownership have been discussed, the Pharmaceutical Society of Australia (PSA) argued that overlapping ownership may not restrict consumer choice:

“PSA is aware of proprietors owning two pharmacies that operate significantly different business models – providing consumer choice.”<sup>174</sup>

In the opinion of the Panel, ‘mediated’ choice by a pharmacy owner is a pretence. The same owner or group of owners will not compete against themselves. They may create a façade of competition and choice, but actual competition, mediated by consumer preferences, will be modest to non-existent.

By limiting new entry, the pharmacy location rules promote and protect anti-competitive cross-ownership. If the rules are retained in some areas of Australia then they should be modified to avoid this (possibly unintended) consequence.

<sup>170</sup> See, for example, D. O’Brien & S. Salop, ‘Competitive effects of partial ownership: Financial interest and corporate control’, *Antitrust Law Journal*, vol. 67 (2000), pages 559–614.

<sup>171</sup> Chemist Warehouse, Submission No. 218, page 27.

<sup>172</sup> Central Australian Aboriginal Congress Aboriginal Corporation, Submission No. 487, page 4.

<sup>173</sup> Sunil Narula, community pharmacy owner, Submission No. 472.

<sup>174</sup> Pharmaceutical Society of Australia. Submission No. 481, page 14.



**OPTION 5-5: PHARMACY LOCATION RULES – OWNERSHIP AND LOCATION**

In areas where pharmacy location rules are maintained, any group of two or more pharmacies, each of which are located within 1.5 kilometres of another pharmacy in the group, that have an overlapping ownership should be considered to be a single pharmacy for the application of the location rules.

The nominal 'location' of this single pharmacy would be the location of the pharmacy within the group that had the smallest turnover (in terms of the number of Pharmaceutical Benefits Scheme scripts dispensed) in 2016.

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.

It is also considered that this option should be implemented five years after this Review to allow an appropriate time frame for transition.

The oversight of this option should be undertaken by the Australian Competition and Consumer Commission.

**5.7. PHARMACY LOCATION RULES AND SUPERMARKETS**

*The current broad restriction on the co-location of pharmacies and supermarkets may be limiting business models that would benefit both consumers and pharmacists.*

**DISCUSSION**

The Panel is conscious that the removal of pharmacy location rules could enable pharmacies to be directly integrated into

supermarkets. With limited exceptions, state and territory legislation also disallows the location of a pharmacy within a supermarket.

For these reasons, the Panel sought to better understand the objective of the current requirements through the presentation of the following question in the Review of Pharmacy Remuneration and Regulation Discussion Paper:

“Recognising that restrictions on co-location of pharmacies and supermarkets exist under state and territory legislation, would the removal of this restriction from the pharmacy location rules be desirable or undesirable?”<sup>175</sup>

A number of alternative views on the merits or otherwise of retaining the current restrictions were submitted to the Review and are explored below.

The New South Wales Government considers that there is a public benefit in retaining the current restrictions:

“The consistent position of the NSW Government for some time has been to support ownership rules that limit pharmacy ownership to registered pharmacists. This position has not changed. NSW legislation disallows the location of a pharmacy within a supermarket, or directly accessible from a supermarket. The NSW Government has no plans to change these restrictions.”<sup>176</sup>

Both the Guild and the PSA are in favour of retaining the current restrictions:

“It is not in the interest of the community that a pharmacy be located in a premise inappropriate for the dispensing of medicines. The Guild strongly believes that the prohibition within the location Rules in relation to the co-location of

<sup>175</sup> Review of Pharmacy Remuneration and Regulation Discussion Paper (July 2016), page 32.

<sup>176</sup> NSW Health, Submission No. 494, page 10.

approved pharmacies in supermarkets should be retained.”<sup>177</sup>

“PSA supports the retention of state and territory legislative restrictions on the co-location of pharmacies and supermarkets. The physical setting and atmosphere of supermarkets are not regarded as places where consumers seek personal health care advice PSA believes [this] will impede the pharmacist–consumer interaction and potentially impact on public safety and the quality use of medicines (QUM).”<sup>178</sup>

The reasons for maintaining the current restrictions tend to be grounded in the notion that community pharmacies are not merely another retail service but a crucial part of the health system which provides services on behalf of government.

Proponents for retention (such as the Guild and the PSA) therefore contend that it is in the public interest to ensure that community pharmacies perform well (as there is a reduced cost to achieving the objectives of the health system) and to avoid poor performance (as there would be a greater cost to the health system).<sup>179</sup>

The Guild considers that deregulation would provide poor outcomes from two perspectives:

- Consumers currently place a high degree of trust in their local pharmacy, as well as valuing travel distance. This trust does not extend to supermarkets, and consumers would, in aggregate, be materially worse off if supermarkets became the predominant owners of pharmacies. This loss in welfare is likely to be

particularly pronounced for older and disadvantaged consumers.

- Large-scale entry of supermarkets into community pharmacy would through vertical integration represent a significant shift in the bargaining power relative to the pharmacy sector, with attendant costs and risks for taxpayers.<sup>180</sup>

The PSA has presented similar reasons for retention, including the following:

- Supermarkets do not provide a suitable environment for consumer-centred care, promotion of health literacy, opportunistic interventions, interdisciplinary collaboration or effective operation of the healthcare team.
- The environment which highlights ‘price and convenience’ will impede the pharmacist–consumer interaction and “potentially impact on public safety and the quality use of medicines (QUM)”.
- It has potential for “consumers to develop the notion that potent, scheduled medicines are safe enough to be located in an unregulated environment” and can “serve to undermine the extensive rigor underpinning the extensive regulatory and scheduling requirements that these products are subject to”.<sup>181</sup>

## OVERSEAS EXPERIENCE

A number of overseas countries, such as the United Kingdom and the United States, have deregulated ownership and location rules. Both the supporters of the current restrictions on ownership and location and the proponents for their removal have referred to

<sup>177</sup> Pharmacy Guild of Australia, Submission No. 486, page 60.

<sup>178</sup> Pharmaceutical Society of Australia, Submission No. 481, page 15.

<sup>179</sup> These points have been adapted from Pharmacy Guild of Australia, Submission No. 486, page 40.

<sup>180</sup> Pharmacy Guild of Australia, Submission No. 486, page 57.

<sup>181</sup> Pharmaceutical Society of Australia, Submission No. 481.

overseas experience in justifying their alternative points of view.

The Panel has also commissioned a study of overseas experience in this area which indicates that evidence both for and against co-location deregulation is inconclusive. This is because the varying national healthcare frameworks in operation make the evaluation of deregulation outcomes difficult to compare in the Australian context.

In New Zealand, regulations allow non-pharmacists or companies to have a significant commercial interest in pharmacies, although these rules restrict non-pharmacists to being minority partners. The Woolworths Group's New Zealand Countdown supermarkets has fifteen in-store pharmacies which are operated by registered pharmacy companies.

## CONSUMER FEEDBACK

The Panel also commissioned a survey on consumer attitudes to reviewing the overlapping ownership and location of pharmacies.

The survey asked a sample of consumers whether they would like to access pharmacy medicine dispensing services from within their local supermarket. Sixty-six per cent of responses showed that there is little current consumer support for supermarkets as pharmacy outlets. The feedback also showed that placing pharmacies inside supermarkets is also not a popular solution to consumer access issues. The responses are displayed in **Table 9**.

**Table 9: Consumer survey results in response to the question, "I would like to be able to access pharmacy medicine dispensing services within my local supermarket"**

Agree	Disagree	Neutral	Don't know
15%	66%	17%	2%

Overall, while the convenience of a pharmacy inside a supermarket was seen as an advantage, the majority of consumers had concerns about the quality and turnover of staff, the privacy of the environment and quality of service they would receive at a supermarket pharmacy.

Extended opening hours at existing pharmacies, better stock management and a greater number of pharmacies in particular areas were seen by consumers as better solutions for improving consumer access to medicines. Some consumers also identified the need for better links between doctors and pharmacists as a possible way to resolve their pharmacy access issues.

## CONCLUSION

Despite the current restrictions, the Panel has observed that many supermarket chains have continued to expand their health offerings into complementary medicines and vitamins in response to the growing demand for these products.

As consumers continue to purchase these non-scheduled products from supermarkets, they will be able to form their own views about convenience, price and advice.

The Panel also observed two instances where pharmacies were operating a supermarket.

For example, Superpharmacy-Plus, located in Stafford, Queensland, also operates an IGA Express supermarket on its premises that

supplies groceries and general merchandise to consumers. The Panel observed that the model was providing a good level of service to its customers and, in some respects, was better able to integrate pharmacy services with their retail offering by aligning food products with health campaigns and medicine advice.

The Panel therefore considers that there is no reasonable rationale for maintaining the current co-location restrictions, provided that scheduled medicines are dispensed in accordance with existing legislative and professional obligations. As such, any unintended consequences would be mitigated by requiring that dispensing of these medicines continues to be performed in accordance with the relevant code of conduct and standards issued by the relevant professional pharmacy bodies.

This also recognises that pharmacists cannot stimulate demand for prescription medicines and will continue to oversee the dispensing and supply of medicines, whether these are sold in supermarkets or community pharmacies.

Options 3-1, 5-1, 5-2 and 5-3 in this report have been proposed to address pharmacy access and location issues. The Panel has therefore presented no additional options to address the co-location issue.

## 5.8. PHARMACY ACCESS AND OPENING HOURS

*In urban Australia, there are pharmacies currently operating with extended hours (from around 7 am to 11 pm); however, consumers often lack information about these pharmacies and they are not evenly spread through urban areas.*

## DISCUSSION

The Panel considers that there is no need for it to recommend on extra opening hours in any areas. The above finding reflects the information it has received on urban Australia.

Opening hours outside urban areas were briefly discussed, but at present there are no options provided in this report. Rather, it is subsumed under the above option (refer to Option 5-3) on the pharmacy location rules for non-urban areas. In other words, if particular areas where opening hours or other issues of access are determined then these should be dealt with through a tender process for pharmacies.

The Panel also considered the issue of hospital pharmacies being able to operate as community pharmacies. We noted that there was no consistent view presented on this matter and that no additional option by us is required.

### OPTION 5-6: INFORMATION ON PHARMACY OPENING HOURS

The Pharmacy Atlas (Option 2-5) should include information on pharmacy opening hours.

### OPTION 5-7: 24-HOUR PHARMACY INFORMATION AND RELATED SERVICES

The government should investigate the feasibility of a 24-hour telephone and or internet 'pharmacy hotline' to provide medicine information to consumers Australia-wide.

## 5.9. THE RURAL PHARMACY MAINTENANCE ALLOWANCE

*There are a number of anomalies in the administration of RPMA payments that serve to reduce the effectiveness of the program.*

### DISCUSSION

The efficient remuneration for dispensing for community pharmacy may not lead to an appropriate level of access to medicines for Australians living outside urban areas. This can reflect both cost differences and lower population densities. The non-urban recommendation presented above (refer to Option 5-3: Pharmacy Location Rules – Non-Urban Areas) deals with this problem through the replacement of the location rules with an explicit contracting approach.

Under existing pharmacy location rules, the Rural Pharmacy Maintenance Allowance (RPMA) is used to encourage increased access to community pharmacy in non-urban areas.

Information available to the Review, however, suggests that the current operation of the RPMA is flawed.

In particular, there appear to be situations where multiple community pharmacies in a location are all receiving the RPMA even though this is not needed for consumer access. Further, there appear to be ‘gaps’ in the distribution of community pharmacies around Australia, and the RPMA, as a one-size-fits-all approach, appears unable to fill these gaps.

The RPMA is currently calculated on the basis of PhARIA location and script volume. An alternative approach would be to allocate the RPMA using a combination of parameters to

reflect the community serviced by that community pharmacy.

A useful example of such a model has been provided by the Society of Hospital Pharmacists of Australia (SHPA). It involves using:

- population estimates (the same as those used to identify PHNs)
- an adjustment for location for three groups: outer regional, remote and very remote as defined by the Independent Hospital Pricing Authority. The Independent Hospital Pricing Authority uses the following adjustment values for these categories: metropolitan and inner regional, 100 per cent; outer regional, 107 per cent; remote, 115 per cent; and very remote, 121 per cent
- an adjustment for socio-economic factors based on Socio-Economic Statistics within the specific PHN.<sup>182</sup>

### OPTION 5-8: RURAL PHARMACY MAINTENANCE ALLOWANCE

In situations where there is more than one pharmacy within a 10-kilometre area that is receiving the Rural Pharmacy Maintenance Allowance (RPMA), the government should:

- a. only make payments to a single pharmacy in the area
- b. ensure that the pharmacy that receives the RPMA is based on the programs offered by that pharmacy, including services, opening hours and location (centrality and ease of access)
- c. ensure that the selection process is transparent.

<sup>182</sup> Society of Hospital Pharmacists of Australia, Submission No. 497, page 19.

## 5.10. VARIATIONS AMONG STATE AND TERRITORY REGULATORY ARRANGEMENTS RELATING TO COMMUNITY PHARMACY

*The community pharmacy sector is subject to a complex array of regulations made by state and territory governments as well as the Australian Government.*

Across the jurisdictions there are significant differences in the structure of legislative and regulatory schemes containing the rules that affect day-to-day operations of pharmacies. Some legislative schemes have been in place for over half a century (with subordinate regulations introduced more recently) and other schemes have been overhauled and replaced in the last decade.

The types of regulatory bodies involved are also very different between jurisdictions. Legislative research and comparison in this area is therefore a complex task and would likely cause difficulties for pharmacists that operate businesses across multiple jurisdictions as well as for consumers who travel across state and territory borders.

There has been some progress towards achieving uniformity across jurisdictions in certain areas of regulation – for example, through recommendations contained in the (Commonwealth) Poisons Standard itself.

These recommendations relate to access and control of drugs and poisons and have been incorporated into relevant legislative instruments of each state and territory jurisdiction.

The National Registration and Accreditation Scheme for health professionals, introduced in 2010, has improved uniformity across

jurisdictions and allowed registrants to practise in all states and territories.

The national scheme has replaced the previous state and territory based registration systems for fourteen categories of health professionals, including pharmacists, who must now be registered with the national Pharmacy Board of Australia in order to practise.

The national scheme also appears to have improved uniformity in regulations applying to the advertising of pharmacy services across jurisdictions.

Despite these changes, there still exists significant variation in regulations applying to community pharmacy across state and territory jurisdictions – in particular, regulations relating to pharmacy premises, pharmacy ownership, medicines distribution and storage, and the prescription and dispensing of restricted medicines.

Examples of these differences are explored below.

### REGULATION OF PHARMACY PREMISES

The approval and regulation of pharmacy premises is the responsibility of each state and territory jurisdiction.

There are requirements in each state and territory as to the physical premises in which a pharmacy operates and, in some jurisdictions, premises must be officially approved by the relevant regulatory body.

In some cases, these regulations can be quite broad, while in other cases they are narrowly prescribed, such as when they relate to issues such as square meterage, public access, security, lighting, dispensary bench space et



cetera. This variability can impact on pharmacy practice and consumer experience.

In New South Wales, for example, pharmacy registration and approval of pharmacy premises is managed by the Pharmacy Council of New South Wales.

In Queensland, regulatory requirements relating to pharmacy are managed directly by the Queensland Department of Health. In contrast to New South Wales, there does not appear to be any requirement for pharmacy premises to be registered or approved.

In Tasmania, pharmacy premises are required to be registered with the Tasmanian Pharmacy Authority, which also has an approval process for pharmacy premises.<sup>183</sup>

Premise-related requirements are also found within state and territory poisons and drug legislation.

## REGULATION OF MEDICINES DISTRIBUTION AND STORAGE

The *Therapeutic Goods Act 1989* (Cth) and Poisons Standard aim to create a national scheme and a framework for the states and territories to adopt to control availability and access to medicines and poisons across Australia. The Poisons Standard contains decisions relating to the scheduling of poisons and medicines for inclusion in the relevant legislation in the states and territories as well as recommendations about other controls on drugs and poisons. However, the regulation of medicines supply is still governed by individual states and territories, with each jurisdiction's legislation and regulations providing requirements for the supply, prescribing and handling of medicines.

The Review of Drugs, Poisons and Controlled Substances Legislation (Galbally Review) in 2000, and the response from the Australian Health Ministers' Advisory Council Working Group in 2003, both recommended the adoption of uniformity in medicines legislation. Some amendments were made to individual state and territory drugs and poisons legislation to accommodate the national registration scheme; however, there remain many differences between jurisdictions.

One example of jurisdictional differences in regulation is the storage requirements for Schedule 2 poisons.

The rules that apply in different jurisdictions are set out in **Table 10** below, which is based on a similar table contained in the Guild's *Full final report: Consumer perceptions on supply of and access to pharmacy medications*, 2008.

This table has been updated to reflect identified changes in legislation since that date.

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<sup>183</sup> Tasmanian Pharmacy Authority, *Pharmacy guidelines*, Version 3.0 (2013), cII 5–6.

**Table 10: State/territory poisons regulations – storage requirements**

State or territory	Schedule 2 poisons regulation – storage requirements
<b>Australian Capital Territory</b>	Sale by medical practitioner, pharmacists, veterinary surgeons and poisons licence holders. In pharmacy, if available for retail sale, store not more than 4 metres from and in sight of dispensary, and otherwise, so that public access to medicine is restricted.
<b>New South Wales</b>	Available without prescription from pharmacists or poisons licence holders only. Storage in shop allowed if apart from food.
<b>Northern Territory</b>	Retail sale from pharmacy, or by holder of Poisons Licence from premises more than 40 kilometres by road from the nearest pharmacy.
<b>Queensland</b>	Supply to minors is limited to pharmacists on prescription, doctors, and some nurses; must be stored in a place that is not accessible to the public and apart from food.
<b>South Australia</b>	Available only from pharmacies and licensed medicines sellers (more than 25 kilometres from nearest pharmacy). Must be stored in an area of the retail premises to which the public is not permitted access or, if it is stored in a part of the premises to which the public is permitted access, it is stored not less than 1.2 metres above floor level or is enclosed in a child-resistant blister pack or is stored in a container that has a capacity of not less than 5 litres or is stored in a container that has

a gross weight of not less than 5 kilograms.

<b>Tasmania</b>	Sale from pharmacies, doctors, dentists, veterinary surgeons and limited list from licensed country stores. Store out of public access in country stores. In pharmacies, store on level shelves on wall or partition separating dispensary from rest of store, or not more than 4 metres from and in sight of dispensary, or in manner, as otherwise approved, that allows close supervision from dispensary.
<b>Victoria</b>	Sale by pharmacy; limited selection for sale by licensed general dealers.
<b>Western Australia</b>	Sale by pharmacies or specially licensed country stores. If storing for retail sale, store so that can only be accessed by owner of business or employee, and such that contamination of food/drink is precluded.

Another example of jurisdictional difference is the strict storage requirements for Schedule 8 medicines. The regulations relating to the cabinets/safes that must be used vary from jurisdiction to jurisdiction.

Regulations generally relate to the construction material, mounting/fixing method, thickness and fit of doors, and type of lock and hinges.<sup>184</sup>

Some prescribe a minimum weight and/or that safes are bolted to a concrete floor.<sup>185</sup> In some jurisdictions, Schedule 8 medicines can

<sup>184</sup> See, for example, *Drugs, Poisons and Controlled Substances Regulations 2006* (Vic), reg. 35; and *Poisons and Therapeutic Goods Regulation 2008* (NSW), reg. 76.

<sup>185</sup> For example, *Poisons Regulations 1965* (WA), Appendix M Cl 1.

be stored in a locked drawer or cupboard during the hours that the pharmacy is open.<sup>186</sup>

## PRESCRIBING AND DISPENSING OF SCHEDULED MEDICATIONS

There are also significant differences in rules that apply to the prescription and dispensing of scheduled medications between jurisdictions. In some jurisdictions, certain Schedule 4 and/or Schedule 8 prescription medications cannot be dispensed if the prescription comes from an interstate prescriber.<sup>187</sup>

In Queensland, changes were introduced in line with the new national registration scheme in 2010 such that pharmacists can dispense interstate prescriptions for Schedule 8 medicines. However, restrictions remain in place that prohibit the dispensing of interstate prescriptions for certain Schedule 3 and Schedule 4 medicines.<sup>188</sup> This is counterintuitive and leads to confusion for patients and pharmacists.

A study conducted on the Gold Coast by Griffith University in 2014<sup>189</sup> noted that variations in the categorisation and nomenclature of medicines between jurisdictions and variations in each jurisdiction's legislation relating to these categories present challenges for health practitioners. The study found that over 40 per cent of pharmacists surveyed were either

unsure of or incorrect in their understanding of whether they could legally dispense interstate scripts for certain prescription only (Schedule 4) medicines.

One research project recently published in the *Journal of Pharmacy Practice and Research*<sup>190</sup> further concluded:

“There is considerable variation in medicines legislation between jurisdictions which places patients and health practitioners at risk of harm. Despite more than a decade since the release of the Galbally Review, little progress has been made toward uniform medicines legislation. Inconsistencies in legislation that have the potential to harm patients need urgent attention.”<sup>191</sup>

The risks to patients included difficulties accessing medicines when travelling interstate:

“Patients may find the valid prescription they have for their usual S4 or S8 medicine/s is unable to be dispensed in another state or territory. This potential complication was identified in a 2011 report on pharmaceutical drug misuse in Australia. For example, patients with chronic pain conditions or carers of children diagnosed with attention-deficit hyperactivity disorder may take S8 prescriptions for regular opioid analgesics or psychostimulants on holidays, assuming they can be dispensed at any pharmacy in Australia.”<sup>192</sup>

A significant risk was also identified relating to access to non-prescription medicines:

<sup>186</sup> Tasmanian Pharmacy Authority, *Pharmacy guidelines*, Version 3.0 (2013), cl. 11.

<sup>187</sup> See, for example, Department of Health and Human Services Tasmania, Pharmacists' [‘ready reference’ for prescriptions](#) (September 2012).

<sup>188</sup> See *Health (Drugs and Poisons) Regulation 1996* (Qld), s. 193A(1)(b).

<sup>189</sup> N. Bernaitis, M. King & D. Hope, ‘Interstate dispensing: A case for uniform intuitive legislation’, *Journal of Law and Medicine*, vol. 22(1) (2014), pages 174–178.

<sup>190</sup> D. Hope, ‘Borderline health: Jurisdictional variation in Australian medicines legislation poses potential risks to patients and healthcare practitioners’, *Journal of Pharmacy Practice and Research* (2016), pages 201–208.

<sup>191</sup> D. Hope, ‘Borderline health: Jurisdictional variation in Australian medicines legislation poses potential risks to patients and healthcare practitioners’, *Journal of Pharmacy Practice and Research* (2016), pages 201–208.

<sup>192</sup> N. Bernaitis, M. King & D. Hope, ‘Interstate dispensing: A case for uniform intuitive legislation’, *Journal of Law and Medicine*, vol. 22(1) (2014), pages 174–178.

“Patients may also be refused access to non-prescription medicines. In Qld, requests for emergency contraception, adrenaline auto-injectors and other S2 or S3 medicines cannot be fulfilled to patients under 16 years of age. Age restrictions need to be supported by evidence that benefit is outweighed by harm and assessed in the context of other restrictions. In the case of emergency contraception, the World Health Organisation declares it safe for all women, including adolescents and a court ruling from the USA determined that age was not a valid reason for restricting the supply of emergency contraceptives.

Refusal to supply an S3 medicine can potentially cause patient and practitioner harm. This was exemplified by the 2013 death of a 14-year-old patient in Ireland with acute anaphylaxis, who was denied provision of an adrenaline auto-injector by a law-abiding pharmacist. While pharmacists are required to supply medicines in accordance with the law, in a similar life-threatening situation a Qld pharmacist would face a legal/ethical dilemma when considering the best interest of the patient.”<sup>193</sup>

## OTHER RULES APPLYING TO SCHEDULE 8 MEDICINES

There are also variations in jurisdictional regulations applying to the recording of Schedule 8 medicines and the destruction or disposal of Schedule 8 medicines.

## CONCLUSION

There still exists significant variation in regulatory requirements applying to pharmacy across state and territory jurisdictions. As discussed above, these differences can lead to confusion and potential risks to consumers and health practitioners. More broadly, variations in

legislation between jurisdictions may create hurdles and undue administrative burden for online pharmacies, which should have the ability to operate across state and territory borders.

The opportunity to move towards uniformity on these regulations, and the positive outcomes that uniformity would create for community pharmacy and consumers, needs further government investigation.

### OPTION 5-9: 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 federal 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 need to 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.

<sup>193</sup> N. Bernaitis, M. King & D. Hope, ‘Interstate dispensing: A case for uniform intuitive legislation’, *Journal of Law and Medicine*, vol. 22(1) (2014), pages 174–178.

## 5.11. THERAPEUTIC GOODS ADMINISTRATION RESOURCING AND ROLE IN MONITORING PERFORMANCE

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

### DISCUSSION

The Panel has noted that there are a number of compliance gaps when monitoring the quality use of medicines.

The panel notes that many of these issues and the role of the Therapeutic Goods Administration (TGA) in the regulation of therapeutic goods in Australia have been explored in the 2015 Expert Review of Medicines and Medical Devices Regulation.<sup>194</sup>

The government's September 2016 response to the Expert Review of Medicines and Medical Devices Regulation presents a strategic and systems-based approach to improving access to therapeutic goods for Australian consumers whilst 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 line with their risk profile – 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

- 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 powers being strengthened, whilst recognising the low-risk nature of complementary medicines.<sup>195</sup>

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

Option 3-2 above is designed to address any 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 option is specifically aimed at improving practices in community pharmacies and not towards the TGA's role as a regulator.

## 5.12. TRANSPARENCY IN GOVERNMENT PROGRAMS

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

### DISCUSSION

Most modern governments, including Australia's, recognise the importance of transparency, being able to demonstrate value in the expenditure of public moneys and

<sup>194</sup> 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).

<sup>195</sup> Department of Health, Therapeutic Goods Administration, *Australian Government response to the Review of Medicines and Medical Devices Regulation* (15 September 2016).

holding people and organisations accountable for their performance:

“Without transparency government accountability is not possible.”<sup>196</sup>

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

This gives rise to a community expectation that Australian 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 very high and there is a strong 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.

The Panel notes that, 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.

The Panel is seeking to strengthen the level of accounting information that should be provided to enable CPA decision-making (refer to Option 4-1). This type of information should be available as a normal course of managing public programs and not require

collection as a special or one-off exercise, as this Review has been tasked with.

The Community Service Obligation (CSO) also lacks transparency on the value achieved and is a key reason underpinning the Panel’s option to discontinue the program under its current settings (see Option 6-1).

In relation to remuneration and regulation, the Panel considers that, while it is clear that Australia has developed excellent capacity in the availability of community pharmacy services to consumers, it does not have sufficient information to demonstrate its 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 cannot persuade other stakeholders that it has the appropriate skills to deliver services in more integrated primary healthcare settings.

#### OPTION 5-10: TRANSPARENCY

It is important that, for each program that involves public funding, there is sufficient transparency as to the amount of funding provided by the government and the amount of funding provided by the recipient of the service.

<sup>196</sup> T. Andrews, *Towards true transparency*, Institute of Public Affairs (2015).



### 5.13. 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 community pharmacy network in Australia.*

#### DISCUSSION

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.”<sup>197</sup>

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.
- **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 the community pharmacy program demonstrates that it is able to meet these principles to a large degree, it is constrained by the lack of transparency referred to above as well the lack of established measures to evaluate the program's performance.

#### OPTION 5-11: EVALUATION MECHANISMS

The government should require the establishment of appropriate evaluation mechanisms to measure compliance and performance.

<sup>197</sup> Department of Finance, [Commonwealth Expenditure Review Principles](#).

## 6. THE DISTRIBUTION OF MEDICINES TO COMMUNITY PHARMACY

### 6.1. DISTRIBUTION OF PBS MEDICINES AS A GOVERNMENT PROGRAM

The Australian Government aims to ensure affordable and reliable access to a wide range of necessary medicines for all Australians through supporting the continued access and sustainability of the Pharmaceutical Benefits Scheme (PBS).

As an Australian Government program, the PBS primarily assumes responsibility for the cost of drugs to patients in the community setting. In contrast, the cost of medicines for patients in hospital is primarily the responsibility of each state and territory.

Providing the PBS has always represented fiscal challenges for the government, and the very high cost of new medications has increased scrutiny on the efficiency of the PBS and related government outlays.<sup>198</sup>

For example, the change in arrangements for chemotherapy drugs from section 85 to section 100 in 2011 resulted in a number of more expensive medicines being available on the PBS. This resulted in a significant increase in PBS expenditure on section 100 medicines over the last ten years.

### DISTRIBUTION ARRANGEMENTS UNDER THE NATIONAL HEALTH ACT 1953

Most medicines on the PBS are available under section 85 of the *National Health Act 1953* (Cth). In addition to this, some

medicines are distributed under alternative arrangements where these are considered more appropriate, which are provided for under section 100 of the *National Health Act*.

Several programs exist for the provision of medicines as pharmaceutical benefits in this way, including the Highly Specialised Drugs Program and the Efficient Funding of Chemotherapy (EFC) Program, both of which are available in private and public hospitals.

### THE NATIONAL MEDICINES POLICY

Australia's National Medicines Policy (NMP) represents an ongoing cooperative partnership between the Australian Government and state and territory governments, health educators, health practitioners, other healthcare providers and suppliers, the medicines industry and healthcare consumers.

The NMP is aimed at bringing better health outcomes for all Australians, with a focus on supporting timely access to the medicines that Australians need, at a cost individuals and the community can afford.

The NMP recognises that cost should not be a substantial barrier to people's access to the medicines they need and explicitly recognises the role of subsidies for medicines, within a framework of cost-effectiveness and rational use of medicines.

The NMP also recognises the primary position of the consumer at the centre of health policy.

### 6.2. ENSURING TIMELY MEDICINE ACCESS

*Current supply chain arrangements (terms of trade and supply conditions) involve unnecessary regulation, as well as Community Service Obligation (CSO) payments that appear unconnected with*

<sup>198</sup> Department of Health, [The Pharmaceutical Benefits Scheme](#) (1 January 2017).

*relevant distribution costs, and may be leading to wholesale margins that are higher than necessary for an effective and efficient supply chain.*

## DISCUSSION

The distribution of medicines through national and regional logistics networks is an integral part of supporting the NMP's objective of supporting timely access to the medicines that Australians need, at a cost individuals and the community can afford.<sup>199</sup>

Currently, this segment of the pharmaceutical supply chain is supported by government through the CSO funding pool arrangements that aim to ensure all Australians have access to the full range of PBS medicines via their community pharmacy, regardless of where they live and usually within 24 hours.

Pharmaceutical wholesalers who participate in CSO arrangements are eligible for a proportion (based on market share) of the \$195 million per annum CSO funding pool over the life of the Sixth Community Pharmacy Agreement (6CPA), which is in addition to the 7.52 per cent wholesale mark-up on the ex-manufacturer price of the medicine.

To receive funding under CSO arrangements, participating pharmaceutical wholesalers must meet service standards and compliance requirements set out in the CSO Deeds. More information on these requirements is available from the Department of Health's PBS website.<sup>200</sup> At the time of this report, there are currently five CSO Distributors (approved pharmaceutical wholesaling

companies under the CSO) of medicines eligible for CSO funding.

However, some suppliers have chosen to distribute their medicines directly to pharmacies through commercial logistics providers, completely bypassing the CSO Distributors, and without government funding. As such, this method of distribution is not required to meet any service standards set by government.

While the Panel has heard that there are issues with both regulated and non-regulated models of distribution, generally speaking medicines are being delivered into community pharmacy in an effective and timely manner.

As such, the Panel has found that in regard to the distribution of PBS medicines in Australia:

- there is no need for the government to regulate wholesaling as a separate 'segment' of the supply chain
- there is a need for more clarity in the specification of minimum requirements for delivery of medicines to community pharmacies around Australia
- there is a need to ensure that community pharmacists do not face significantly increased costs due to dealing with a large number of supply chains.

Currently, the timely distribution of PBS medicines to Australia's 5588 community pharmacies is ensured by the 7.52 per cent wholesale mark-up on the price of the medicine and the CSO funding pool. CSO Distributors provide PBS medicine wholesaling out of integrated facilities and as part of broader logistics supplying community pharmacies (and others) with a range of products.

<sup>199</sup> Department of Health, [National Medicine Policy Document](#) (2014).

<sup>200</sup> Department of Health, [The Pharmaceutical Benefits Scheme](#).

The evidence supporting the 7.52 per cent mark-up is ambiguous. It is hard to determine exactly what value the government is getting for this, particularly when this margin is being used by wholesalers to provide discounts to pharmacy customers to win market share.

In turn, this market share determines how the CSO funding pool is apportioned between the CSO Distributors.

The CSO Distributors consulted by the Panel stated that the remuneration provided through the CSO funding pool and wholesale mark-up (7.52 per cent) is insufficient to support the distribution of PBS medicines. They also noted that, if current remuneration does not increase, they would need to pass on additional costs to community pharmacy.

The Panel recognises that CSO Distributors are complex businesses, and supplying PBS medicines is only one part of their operations. An argument suggesting that all costs associated with these businesses' operations are also included with the distribution of PBS medicines ignores the revenue generated from non-PBS components of these businesses' operations.

For example, during a visit to a distribution centre operated by one CSO Distributor, the Panel observed orders being individually picked and packed for pharmacies. These orders included both PBS-listed medicines and front-of-store retail goods, all of which were being delivered in the same crate in the same courier van.

While efficiencies of this nature are to be expected in large-scale logistics and distribution businesses, it is difficult to gauge whether the current wholesale mark-up is sufficient or not.

As the Panel is unable to ascertain the PBS versus non-PBS mix cost of distribution on the basis of available data, it is difficult to verify the claims being made by the CSO Distributors.

Furthermore, many CSO Distributors are moving into other areas of the pharmaceutical supply chain, such as more vertically integrated models of pharmacy franchising and banner groups as well as supply and distribution of non-PBS product lines. This diversification is proving profitable as evidenced by the positive financial performance of these publicly listed companies.

However, when considering PBS wholesaling and distribution in isolation, commercial in confidence financial data provided to the Review by the National Pharmaceutical Services Association (NPSA) indicates that CSO Distributors are not earning economic rents.

It is important to note, however, that current wholesale pharmacy remuneration arrangements are not based on estimates of the efficient costs of purchasing, storing and distributing pharmaceuticals to pharmacies. Rather, like current remuneration arrangements for pharmacies, they are the result of historical precedent as amended by an ongoing process of negotiation. As a result, it is inevitable that such remuneration arrangements will over-remunerate wholesalers for some of the pharmaceuticals they supply and under-remunerate them for others.

For example, the current remuneration arrangements for wholesalers have the potential to:

- over-remunerate those wholesalers that purchase and store either high volumes of low-cost medicines or low

volumes of high-cost medicines and distribute those medicines relatively short distances to pharmacies (i.e. if it tends to provide relatively high effective rates of assistance to wholesalers that supply nearby pharmacies)

- under-remunerate those wholesalers that purchase, store and distribute to the more remote regions of Australia. That is, of course, the key reason why the CSO funding pool was created – to provide wholesalers with additional remuneration to cover the additional costs of delivering pharmaceuticals to those more remote communities.

The Panel has therefore been unable to determine whether 7.52 per cent is the ‘correct’ number.

## MODELS OF PHARMACEUTICAL WHOLESALING

Different models of wholesaling exist around the world. The literature review commissioned by the Panel<sup>201</sup> shows that those jurisdictions that do not have regulated wholesale mark-ups or prices tend to have lower wholesale mark-ups or prices than the regulated jurisdictions.

We also have different models of medicine delivery in Australia – for example, the direct to pharmacy model. Pfizer Direct involves the medicine supplier (Pfizer) organising the delivery of its medicines to community pharmacies using a third-party logistics provider (predominantly DHL). The Panel has heard that, in some remote parts of Australia, this model is significantly better than the delivery through the wholesaler, despite

neither DHL nor Pfizer receiving CSO payments. However, the Panel has also heard complaints about the Pfizer Direct delivery service and, as noted above, the Pfizer Direct model falls completely outside the government regulatory net.

From the Pfizer Direct model it is clear that the distribution of PBS-listed medicines can maintain a generally satisfactory standard without government regulation (i.e. the CSO). This standard could be improved by assuring timely access and placing the obligation to supply medicines to community pharmacy on parties other than pharmaceutical wholesalers. Provided there are requirements to ensure that medicines are delivered to community pharmacies in an appropriate time frame with appropriate terms and conditions, the responsibility can be placed on the medicine suppliers who are in the best position to control the supply of their medicines to community pharmacies.

Medicine suppliers have the strongest incentives to ensure that their products are delivered in a timely way to community pharmacies. This is how they generate their profits. The government could tighten incentives by placing delivery requirements on the medicine suppliers at the ‘point of listing’ on the PBS. It could be a requirement associated with listing to ensure delivery within the terms and conditions set by the government, and appropriate penalties may be designed to enforce compliance.

While current minimum CSO requirements such as the ‘24-hour rule’ generally ensure timely access, the Panel has heard this rule is not always being met. Furthermore, these rules can be relaxed between CSO Distributors and their pharmacy customers in exchange for more favourable prices. The Panel also notes that the terms and conditions for delivery to a

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<sup>201</sup> Deloitte Access Economics, *Review of pharmacy remuneration and regulation: Literature review* (November 2016).

community pharmacy are not covered under CSO arrangements and can be changed unilaterally by wholesalers in situations where it suits them to shift cost or risk onto the community pharmacy (e.g. for high-cost medicines).

This is not appropriate regulation. An improved system of supply should have clear and enforceable rules covering delivery times, terms and conditions. These do not have to be placed on the pharmaceutical wholesalers; rather, they can be placed on the medicine suppliers (who then have multiple unregulated wholesalers / logistics companies to choose from when servicing community pharmacies).

The Panel considers that the CSO therefore represents excessive and, when compared to the direct to pharmacy model, unnecessary regulation.

By not separately regulating pharmaceutical distribution, the government will reduce bureaucracy and can allow for significant innovation.

The medicine suppliers will negotiate with relevant logistics suppliers (such as the existing CSO Distributors), and the government will leave it up to the self-interest of these parties to come to an efficient solution at their own cost. So long as there is sufficient competition in the wholesaling/logistics function then this competition will ensure efficient delivery.

### CSO FUNDING POOL

The CSO funding pool provides financial support to distributors to supply PBS medicines and National Diabetes Services Scheme (NDSS) products to community pharmacies and NDSS Access Points across Australia within specified time frames (72

hours for high-volume PBS medicines; 24 hours for all other products), regardless of location. The objective of this arrangement is to ensure that all Australians have ongoing and timely access to their PBS medicines and NDSS products.

However, there are some postcodes which are exempt from the standard delivery time frames specified in the CSO Operational Guidelines. Due to their remoteness, access to these areas is not always possible within the time frame specified in the guidelines.

There are currently four national wholesalers and one state-based wholesaler participating in CSO arrangements. The number and locations of CSO distribution warehouses are illustrated in **Figure 14**<sup>202</sup> below.

**Figure 14: Locations of CSO distribution warehouses across Australia**



Like pharmacies, most wholesale distribution outlets are located in major population centres, with the largest numbers of outlets located in major capital cities. They must hold stock in their warehouses or distribution centres (that they will use to meet the CSO

<sup>202</sup> Source: RSM, *Financial analysis of pharmacy regulations and remuneration arrangements* (March 2017).



Service Standards) of at least one brand of every PBS medicine.

For multi-brand PBS medicines, CSO Distributors must hold stock of at least one innovator brand and one additional brand which is benchmark priced. CSO Distributors are also required to stock the full range of NDSS products for distribution to NDSS Access Points.

Approximately 300 million units of PBS medicines are delivered annually by CSO Distributors to community pharmacies and approximately 5.5 million units of NDSS product are distributed annually to NDSS Access Points.

## AUDIT AND COMPLIANCE OF THE CSO

Australian Healthcare Associates (referred to as the CSO Administration Agency (the Agency)) is an independent entity responsible for administering the CSO funding pool and monitoring the performance of CSO Distributors with regard to their contractual obligations, including CSO Compliance Requirements and CSO Service Standards.

The Agency has implemented various systems that are designed to ensure that CSO Distributors only claim for and are paid in respect of CSO claimable products.

The Agency conducts quarterly audits of all national CSO Distributors and biannual audits of the state-based CSO Distributors. For each audit, the Agency requests order information, invoices, credit notes and proof of delivery for a sample of products for a complete month.

The Agency reviews each of these documents to ensure that:

- for each product ordered, the total units listed on the invoices (less credit

returns) agree with the sales data provided to the Agency

- each product was delivered in the month claimed
- each customer listed on the invoice is a section 90 Approved Pharmacy (i.e. the delivery address and postcode matched the data provided by the Department of Health).

The Agency's processes have proven effective in identifying inaccurate data provided by CSO Distributors. To date, the Agency has recorded 176 breaches in relation to the provision of timely and accurate data and reports. For each of these breaches, any inaccurate data was corrected, where applicable, and the CSO Distributor was only paid for CSO claimable products to community pharmacies.

There is also a complaints and sanctions process in place for CSO Distributors if supply requirements are not met.

The Panel has noted the complexities in administering the CSO and have provided three options (see below), with Alternative 1 being its preferred option.

### OPTION 6-1: COMMUNITY SERVICE OBLIGATION REMOVAL, RETENTION OR REPLACEMENT

#### ALTERNATIVE 1:

The government should remove the Community Service Obligation (CSO), and suppliers of PBS-listed medicines should be placed under an obligation to ensure delivery to any community pharmacy in Australia within a specified period of time (generally 24 hours), with standard terms of trade offered to the pharmacy (such as four weeks for payment) using one or more of a specified

panel of wholesalers as follows:

- a. an initial Panel of around five wholesalers would be approved. It is expected that these will include the existing CSO Distributors
- b. the relevant terms of trade and other supply conditions may vary between medicines. For example, for high-cost medicines or medicines that have cold-chain supply requirements, the supply conditions may differ from those for low-cost medicines to ensure that there is not an unreasonable risk or cost placed on either community pharmacy or consumers
- c. a cap should be placed on the amount that a community pharmacy contributes to the cost of a medicine. This cap should be in the range of \$700 to \$1000.

#### **ALTERNATIVE 2:**

The government should retain the current CSO arrangements but ensure that all service standards, such as the 24-hour rule, are uniformly implemented.

#### **ALTERNATIVE 3:**

The government should conduct a separate review of the CSO to ensure current arrangements demonstrate value for money. A review would also present an opportunity to potentially streamline existing or remove unnecessary regulation. Such a review would require the full cooperation of the CSO Distributors, which would provide financial data and other relevant information to government.

### **6.3. PROCEDURES AND REMUNERATION FOR THE SUPPLY OF HIGH-COST MEDICINES**

*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.*

#### **DISCUSSION**

Increasingly, complex and expensive medicines are being listed on the PBS to be dispensed by community pharmacies. For example, the new hepatitis medicine Sovaldi was listed in 2016, with a price to pharmacy of \$19 367 plus GST.

The supply of this type of expensive medicine did not sit well within the existing medicine supply chain and pharmacy remuneration system, causing a number of issues for community pharmacies.

The time frame for community pharmacies to pay wholesalers for the medicine was in some cases shorter than the time frame for community pharmacy to be reimbursed by government, leaving community pharmacies significantly out of pocket.

Some wholesalers also had terms of trade (including credit caps) in place, which were not compatible with the supply of such high-cost medicines. This resulted in some pharmacies that ordered high-cost medicines quickly hitting their cap and not being able to order any other stock.

According to submissions received by the Review, it appears that the payment time frames and credit cap issues have been recently rectified, as wholesalers have modified trading terms accordingly.

However, a number of other issues around the supply of high-cost medicines are continuing.

In particular, the GST payable through the medicine supply chain is proving problematic. Pharmacies are required to pay GST on the purchase of high-cost medicines from wholesalers, but no GST is included in the reimbursement price from government. Pharmacies have to reclaim this GST amount at the end of month when they submit their Business Activity Statement (BAS), leaving them almost \$2000 out of pocket for each Sovaldi dispense during this time.

Chris Owen of Owen Pharmacy group explained:

“I have a pharmacy in Fortitude Valley in Brisbane which does 5 or 6 Hepatitis C medications a month. This is great for the local community, as the patients are not being stigmatized and have the comfort and convenience of my store to come into. The big issue for me is the cash flow implications and remuneration. I have to purchase the cost of several medium sized cars and receive than 0.3% of the total cost as gross profit. Not to mention the fact that I have to wait until the end of the month to submit my BAS statement and claim my GST refund. This is not only stressful and cash inhibiting, but this was brought onto the community pharmacy network well after the 6CPA was negotiated. These sorts of high cost medications weren’t even thought of when remuneration was being negotiated. It was a great policy but the implications and follow through weren’t completely thought through.”<sup>203</sup>

It was clear to the Panel during consultations that the financial risks and cash-flow issues associated with the dispensing of high-cost

medicines has been a significant area of concern for pharmacy owners.

Many pharmacy owners expressed concern over the risk of patients failing to return to pick up their high-cost medication after the pharmacy had ordered it. They advised that the cost of the medication then became a loss to the pharmacy, as these items are not able to be returned to the wholesaler or manufacturer.

Pharmacies also advised that they incur risks of stock being damaged or a script being lost. These risks were a concern not only for Hepatitis C medications, with a cost of \$19 367 plus GST, but also for many other medicines that cost upwards of \$1000:

“There are also costs of maintaining stock on hand, risks of products expiring, power failures affecting fridge lines and risks in the requirement to retain the paper prescription for payment. A \$70 profit margin on an item which costs thousands of dollars does not reflect this risk and I cannot think of any other industry that would accept such a low margin on a high cost item.”<sup>204</sup>

The Panel is aware that many pharmacies are unwilling to stock high-cost medicines due to the financial risks and potential cash-flow issues involved. One AJP poll demonstrated that 22 per cent of community pharmacy respondents were not stocking high-cost medicines due to cash-flow issues, with a further 8 per cent limiting their supply of such medicines for economic reasons and another 7 per cent considering limiting their supply.<sup>205</sup>

It is the view of the Panel that all PBS-licensed community pharmacies should be required to

<sup>203</sup> Chris Owen, Owen Pharmacy Group, Submission No. 58.

<sup>204</sup> Chad Arnold, community pharmacy owner, Submission No. 65.

<sup>205</sup> M. Haggan, *Large minority not supplying Hep C drugs: poll results*, *Australian Journal of Pharmacy* (8 July 2016).

supply all PBS-listed medicines. The government should put in place appropriate measures to address the financial risks and cash-flow issues described above so that the requirement to supply high-cost medicines does not place an unfair burden on community pharmacy.

It was put to the Panel by multiple stakeholders, including community pharmacy owners and commercial pharmacy groups, that a more appropriate payment system for the supply of high-cost drugs would be for the government to pay manufacturers directly for medicines above a certain price:

“We would propose that for these medicines, which are a very low proportion of the volume of prescriptions dispensed, that an alternative method for managing the supply chain is required.

Potentially the PBS payment could go directly to pharmaceutical wholesalers or the supplier directly, otherwise remuneration to pharmacies should be reflective of the risk we take in needing to change financing arrangements.

We believe that there is an argument that a review is required for any medicines on the PBS as \$100 or \$85 with a cost of more than \$1,000. Nor should there be any GST included in the cost of goods sold for these products.”<sup>206</sup>

Patrick Mahoney, an individual community pharmacy owner, echoed these sentiments:

“The introduction in 2016 of items with very high value has compounded the issue of managing the wholesaler distribution and the attached credit limits on said accounts. A solution is for a direct to manufacturer/distribution payment to cover bulk of the cost. Pharmacies have a fixed handling fee and wholesalers have a fixed handling fee for said items. Once the PBS authority prescription is dispensed and automatic payment is scheduled to

the approved pharmacy AND the manufacturer ... This scheme would take the risk out of distribution and could possibly reduce the overall cost of the PBS.”<sup>207</sup>

The Panel agrees that alternative payment options for high-cost medicines need to be investigated to avoid excessive costs to community pharmacy. For example, community pharmacy could pay up to \$1000 to wholesalers for any PBS-listed medicine, with the government paying the rest directly to the wholesaler.

The Panel also supports the introduction of standard terms of trade for all wholesaler medicine supply (refer to Option 6-1 above).

#### **OPTION 6-2: SUPPLY OF HIGH-COST MEDICINES**

In line with Option 6-1, patients should be able to receive high-cost medicines from the community pharmacy of their choice.

A cap should be placed on the amount that a community pharmacy contributes to the cost of a medicine. This cap should be in the range of \$700 to \$1000 so that all PBS-approved community pharmacies can supply all PBS medicines required by the public.

<sup>206</sup> Priceline Pharmacy Brand Advisory Committee, Submission No. 116.

<sup>207</sup> Patrick Mahoney, community pharmacy owner, Submission No. 77.

## 7. FUTURE COMMUNITY PHARMACY AGREEMENTS

### 7.1. THE COMMUNITY PHARMACY AGREEMENT PROCESS

*The Sixth Community Pharmacy Agreement (6CPA) process was not adequate, as reflected in the submissions to this review. The Australian National Audit Office (ANAO) was also critical of some of the processes in the Fifth Community Pharmacy Agreement (5CPA), which have been partially addressed in 6CPA.*<sup>208</sup>

#### DISCUSSION

Since 1990, the remuneration that pharmacists receive for dispensing Pharmaceutical Benefits Scheme (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 Pharmacy Guild of Australia (the Guild). The make-up of these agreements has evolved over time (see Appendix F, History of the Community Pharmacy Agreements).

The 6CPA recognises that community pharmacy is an integral part of the Australian healthcare system through its role in the delivery of PBS and related services. This includes a common interest in:

- promoting the sustainability, efficiency and cost-effectiveness of the PBS within the broader context of health reform

- ensuring that community resources are appropriately directed across the health system
- supporting the sustainability and viability of an effective community pharmacy sector.<sup>209</sup>

Successive agreements 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)).

Specifically, the current 6CPA provides funding of approximately \$18.9 billion in total to over 5500 community pharmacies, accredited pharmacists, public and private hospitals and pharmaceutical wholesalers.

The funding to community pharmacy in the 6CPA covers dispensing of PBS medicines as well as a range of healthcare programs delivered by community pharmacy and the Community Service Obligation (CSO) funding pool, which supports pharmaceutical wholesaling arrangements to community pharmacy.

The Panel notes that the Guild is the only signatory party to the agreement with the Australian Government, meaning that the negotiation of the Community Pharmacy Agreement (CPA) is only between the government and ‘pharmacy owners’.

However, the CPA agreements affect all community pharmacists, not simply pharmacy owners. In some cases, this is through funding determined by CPA. For example, some 6CPA funding flows directly to accredited pharmacists (e.g. those implementing the Home Medicines Review (HMR) service). More generally, however, the 6CPA process

<sup>208</sup> C.f. ANAO, *Administration of the Fifth Community Pharmacy Agreement*, Report No. 25 (2014–2015); and ANAO, *Community Pharmacy Agreement: Follow-on audit Report No. 9* (2016–2017).

<sup>209</sup> Sixth Community Pharmacy Agreement, May 2015 page 3.

determines a range of factors that directly impinge on the professional practice and livelihoods of all community pharmacists.

The CPA agreements also directly affect consumers of medicine. The agreements affect how and when consumers will be able to access key medicines.

During the 6CPA negotiations, the Minister and the Department of Health conducted a series of bilateral and multilateral consultations with a broad range of stakeholders with an interest in and affected by the outcomes of the 6CPA.

However, neither consumers nor the broad community pharmacy profession were represented as signatories to the 6CPA.

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

**National Pharmaceutical Services Australia**

“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.”<sup>210</sup>

**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.”<sup>211</sup>

## A BETTER FOCUSED CPA

It is the Panel’s view that the value of the CPA and its development is best maximised if it is focused more closely on the dispensing of medicines under PBS subsidy, including the pricing to consumers for such dispensing.

The CPA is not the right mechanism to attempt capture of more broadly based programs and services, or supply chain activities, as 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 will have flexibility to determine the most efficient ways in which to fund other non-PBS-related health services for the best outcomes for the broader community.

In refocusing the CPA, the Panel considers that it would be appropriate to continue to include the Guild in discussions. As already noted, the Guild represents the owners of

<sup>210</sup> National Pharmaceutical Services Australia, Submission No. 482.

<sup>211</sup> Consumers Health Forum of Australia, Submission No. 483.



community pharmacies that will act as government agents in the delivery of PBS medicines to consumers.

Other directly affected parties also need to be included in discussions. In particular, the Consumers Health Forum of Australia (CHF) (as the peak representative consumer body in Australia on health-related matters) and the Pharmaceutical Society of Australia (PSA) (as the peak representative body for pharmacists in Australia) should be included in CPA discussions and (if the process still leads to 'signatories') these bodies should also be signatories to the agreement.

The Panel considers that the role of a peak body is to represent the entire relevant-cohort. The Panel understands that Guild membership is open to all community pharmacy owners except the friendly society pharmacies (which are not owned by pharmacists).

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

If the government becomes aware that substantial groups of pharmacy owners do not see the Guild as an appropriate peak body to represent their interests then the government should consider alternative ways to have these owners participate in the CPA process.

Even if the parties directly participating in the CPA process did not change, the need for broad and clear consultation remains. At a minimum, future consultations should include the CHF, PSA, the National Aboriginal Community Controlled Health Organisation (NACCHO), Primary Healthcare Networks and others, including the Rural Health Alliance, the Australian Medical Association (AMA), the Generic Biosimilar Medicines Association (GBMA), NPS MedicineWise, the Royal

Australian College of General Practitioners (RACGP), organisations representing various disease cohorts/populations and manufacturers of medicines et cetera. These consultations should be organised by the Australian Government and attended by the aforementioned representative organisations.

Additionally, recent CPAs have introduced a variety of programs that are not directly related to the supply, distribution and quality use of medicines. In many cases, these medical programs involve community pharmacies but are 'primary health' programs and are not directly related to the supply of PBS medicines.

It should be recognised that, while such medical programs may be desirable, the CPA process is not the appropriate forum to determine these programs. Further, the Panel considers that, in many cases, the appropriate source of funding for medical programs that do not focus on medicine supply warrants broader consideration by government.

Recent CPAs have also set aspects of the government funding for medicine wholesalers. This is inappropriate. Wholesalers are not represented in the CPA discussions. The panel has presented a preferred alternative approach to wholesaling and medicine distribution in Chapter 6 (The Distribution of Medicines to Community Pharmacy).

**OPTION 7-1: 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.

**OPTION 7-4: COMMUNITY PHARMACY AGREEMENT PARTICIPANTS**

The parties invited to participate in future Community Pharmacy Agreements must include the Pharmacy Guild of Australia (as a representative of the majority of approved pharmacists), the Consumers Health Forum of Australia (as the peak representative consumer body in Australia on health-related matters) and the Pharmaceutical Society of Australia (as the peak representative body for pharmacists in Australia).

**OPTION 7-2: SCOPE OF COMMUNITY PHARMACY AGREEMENTS – WHOLESALING**

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

**OPTION 7-3: 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.

## 8. HEALTH PROGRAMS OFFERED BY COMMUNITY PHARMACY

### 8.1. LEVERAGING PHARMACY AND PHARMACIST CAPABILITY

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

#### DISCUSSION

Community pharmacy plays a vital role in the Australian healthcare system, not just in dispensing medicines and medicines advice but also as an accessible source of reliable healthcare advice and services. Community pharmacies are remunerated, whether in full or in part (there is a cap on some programs), to deliver a range of medicine-related services, including the following:

##### *Medication adherence programs:*

- dose administration aids (DAAs)
- staged supply.

##### *Medication management programs:*

- clinical interventions
- Home Medicines Reviews (HMR)
- residential medical management reviews
- Medschecks / Diabetes Medschecks.

##### *Aboriginal and Torres Strait Islander Programs*

- Quality Use of Medicines Maximised for Aboriginal and Torres Strait Islander Peoples (QUMAX)
- section 100 Pharmacy Support Allowance Program
- Aboriginal and Torres Strait Islander Workforce Program.

##### *Rural support programs*

- Rural Pharmacy Workforce Program
- Rural Pharmacy Maintenance Allowance.

##### *eHealth*

- Electronic Prescription Fee (which is claimed in full by the IT providers).

Submissions to the Review noted that many services and programs delivered by community pharmacy are underfunded or not funded at all. Pharmacy owners and employees often described how valuable they believed these services to be for the local community and expressed concerns about the pharmacy's ability to continue to provide these services without appropriate funding.

In many cases, pharmacies had previously been able to absorb the cost of providing such community services, as they were subsidised by manufacturer discounts on medicine prices. This is now proving difficult as a result of the government's price disclosure policies, which have reduced pharmacy profits.

The following section sets out some examples of services provided by community pharmacies without any direct government funding (although some pharmacies may charge patients for the service). This is not intended to be a complete list.

Pharmacy owners also described many programs and services that they provided that were currently underfunded. These included medicine review programs, dose administration aids, and support for aged care facilities. These programs are discussed in more detail elsewhere in the Report.

## PHARMACY SERVICES THAT DO NOT RECEIVE DIRECT FUNDING

### *Home delivery*

Many pharmacy owners described the home delivery services they provided for their elderly, disabled or limited mobility patients. Often this service goes above and beyond merely dropping off medicines, as the pharmacist delivering the medication regularly engages with patients who are isolated and provides additional support as well as referral to other health services where necessary.

These pharmacists explained that their home delivery service supported patients to stay in their home rather than moving to aged care facilities. As one community pharmacy owner explained:

“My pharmacy provides up to 100 deliveries per week to the very elderly, disabled and those with poor mobility. Our delivery staff member is one of our most experienced and frequently comes back to us with issues regarding patients that require intervention. We frequently organise doctors appointments, liaise with other carers and family members when we determine that help is needed. Many of these patients are suffering social isolation and the pharmacy interaction is often one of the few contacts the patient receives. It is impossible to come up with hard data on the benefit of such a service but I know from experience that it has kept people out of hospital and out of nursing care.”<sup>212</sup>

### *Minor ailments, wound care and triage*

The Panel has heard many accounts of the valuable first aid, wound care and minor ailment treatment that community pharmacies provide on a daily basis. We have

met with pharmacy owners in country towns who described how their community relied on them for this type of care when local GPs were closed or had long waiting times.

One community pharmacist employee explained:

“Pharmacists are the best triage depot in the entire health system. Accessibility, better than GP practices and hospitals, mean a huge portion of the population use the pharmacy as first port of call for medical issues. These range from splinters to anaphylactic reactions, sunburn to shingles. Pharmacists treat many of these ailments successfully and keep people out of hospital emergency departments and doctors surgeries. Pharmacists also ensure many of these people do seek further medical treatment where they may otherwise not have done avoiding more serious consequences. There is no professional recompense for this service even though it saves the health system, dare I say, millions of dollars.”<sup>213</sup>

### *Unwanted medicines return service*

Under the national Return of Unwanted Medicines (RUM) project, pharmacists receive unwanted medicines from consumers (which they must check do not contain any sharps or Schedule 8 medicines) and then place the unwanted medicines in the RUM-approved containers. Pharmacies arrange delivery and pick-up of the containers from their wholesaler. Pharmacies do not receive funding for this service.

The project serves the important purpose of reducing risks associated with storage of old and unwanted medicines in the home and the unsafe disposal of medicines. The RUM project website explains:

“Evidence over many years confirms that medicines ‘stored’ in the home can be the

<sup>212</sup> Douglas Roberts, Submission No. 101.

<sup>213</sup> Mark Shaw, Submission No. 162.

source of poisonings of children, and the source of confusion with aged patients.”

Accident and Emergency departments of major hospitals report alarming rates of poisonings of children due to household poisons (one in four admissions).

Aged patients are often confused by the variety of medicines previously prescribed and then superseded by subsequent medicines.

Medicines, and chemicals in general, can contaminate the environment when discarded via landfill sites and sewerage facilities.”<sup>214</sup>

The submission from Tony Riley for National Return and Disposal of Unwanted Medicines Limited states:

“The National Return and Disposal of Unwanted Medicines Project (NatRUM) is a fine example of the voluntary work and also an important example of one of the many professional services undertaken every day by virtually all community pharmacies in Australia. For no remuneration, each community pharmacy collects and disposes of any unwanted medicines from their patients ensuring that these medicines are safely stored until such time that they are appropriately incinerated in an environmentally secure facility ...”<sup>215</sup>

*Liaising with hospital staff upon admission and discharge, and more generally with other health professionals*

The Panel has heard numerous accounts of the valuable support community pharmacists provide upon patients’ admission to and discharge from hospital. Pharmacy owners described the often daily requests from hospitals for pharmacies to send through patients’ medication records upon admission, and the significant amount of time that their pharmacists had to dedicate to this task.

A community pharmacy owner explained this role – in particular, relating to their aged care patients:

“Hospital admissions for patients in aged care facilities are expected, and it is important in ensuring a smooth transition between both settings. Pharmacists play a vital role in liaising with nursing staff, hospital staff and doctors to facilitate the delivery of medication in a timely manner. This involves ensuring there are no duplications of medications, as well as no interactions with the patient’s current medication profile. Pharmacists often are the only healthcare professionals with the patients’ most current medication profile therefore are constantly called upon to provide this to other healthcare professionals. Pharmacists are not currently reimbursed when they intervene, as Clinical Interventions cannot be claimed for when residents reside in a Residential Aged Care Facility.”<sup>216</sup>

Sue Edwards, an academic pharmacist, explains why this type of support provided by community pharmacy is so important:

“It is known that communication problems between settings of care are a significant factor in causing medication errors and adverse drug events. Literature reviews have reported unintentional variances of 30–70% between the medicines patients were taking prior to admission and what they were prescribed on admission. As many as 12%–18% of these errors were considered potentially harmful. Australian data shows that patients with one or more medicine omitted from their discharge summary are 2.3 times more likely to be admitted to hospital as those with no omissions. Medication reconciliation is a formal process that has been demonstrated to improve the continuity of medicines management, reducing medication errors

<sup>214</sup> See the [Return Unwanted Medicines \(The RUM Project\)](#) website.

<sup>215</sup> Tony Riley, Submission No. 158.

<sup>216</sup> Salim Nathwani, Submission No. 148.

by 70% and adverse drug events by over 15%.”<sup>217</sup>

Similarly, when patients are discharged from hospital, community pharmacists often play a role in reconciling medications, repacking and delivering dose administration aids, and liaising with GPs about medication changes. Several pharmacy owner submissions explained that discharges often occurred late on a Friday afternoon, as hospitals sought to release patients before the weekend, which meant pharmacy staff had to stay back past regular closing hours to assist with medications.

A pharmacy owner explains:

“community pharmacists need to be involved in the transition of patients from hospital back to their home. The detailed knowledge and trusting relationships community pharmacists have with their patients determine that they are ideally positioned to contribute more in transitional care and care coordination.

Personally, I have been involved in many instances of trying to sort out a patient’s medication after discharge, where there were discrepancies between the discharge notes, prescription and supplied medication. These interventions can take hours at a time, trying to locate the prescribing doctor, the doctor who managed the discharge, the clinical pharmacist in the hospital and the patient or the patient’s family. At present, there is no mechanism for reimbursement for time involved in such a process. All we can claim is a dispensing fee, if in fact we need to dispense anything, and possibly a clinical intervention fee if it fits the criteria. Hardly fair payment for hours of work that results in life saving interventions.”<sup>218</sup>

<sup>217</sup> Sue Edwards, Submission No. 176 (reference to [Australian Commission on Safety and Quality in Health Care, Medication management](#) (2013)).

<sup>218</sup> Steve Lewis, Submission No. 184.

## AN EXPANDED ROLE FOR PHARMACISTS IN THE HEALTHCARE SYSTEM

In the Review of Pharmacy Remuneration and Regulation Discussion Paper, it was noted by stakeholders that the skills, knowledge and expertise of pharmacists is currently underutilised within the health system. Subsequent consultations have reinforced this view, and the Panel believes that there is significant opportunity to better utilise the skills of pharmacists to support improved access to health services and improved health outcomes for the community.

An example of an extended scope of practice for pharmacists is found in Canada, where pharmacists are remunerated for a range of services beyond dispensing medicines.

The Deloitte Literature Review explains:

### “Pharmacists scope of practice: Canada

Other than dispensing services, pharmacies can provide a variety of other services; however, these vary in each jurisdiction.

The scope of services provided by pharmacies is provided below (note that not all jurisdictions provide the full range of services):

- emergency prescription refills
- renew/extend prescriptions
- change medicine dosage/formulation
- make therapeutic substitution
- prescribe for minor ailments
- initiate prescription medicine therapy
- order and interpret lab tests
- administer a medicine by injection.

Services that are publicly funded vary by jurisdiction. Some immunisation services are covered, and the span of government-funded immunisation is reviewed annually and adjusted. Advanced medicine review services receive public funding in only three jurisdictions. Some jurisdictions will pay for these services on



a per service basis. For example, for renewing or extending prescriptions or changing doses, the highest public remuneration for this service is \$20 per assessment in Alberta, and the lowest is \$6 in Saskatchewan. Another example is assessments of minor ailments; for this service Saskatchewan pays \$18 per assessment while Quebec pays \$16 per assessment.<sup>219</sup>

An example of a medicine review service provided by some jurisdictions is the MedsChecks service offered in Ontario, which is similar to the MedsCheck service offered in Australia. This is a government funded service which is offered to patients who are taking three or more prescription medicines. This service aims to ensure adherence to medicine and to provide information to the patient. It involves a discussion with the patient and pharmacist. Initially, a pharmacist was paid \$50 for a 30 minute medicine review; however, in 2010 this was increased to \$60. This service is also provided in the patient's home and pharmacists are paid \$150 for this service (Dolovich, 2016; Grindrod, 2013)."<sup>220</sup>

In some countries, pharmacies are remunerated for supporting patients to manage chronic conditions such as diabetes and asthma.

For example, in the United Kingdom, there are a large number of pharmacy services that are locally commissioned and funded. These are listed on the Pharmaceutical Services Negotiating Committee website.<sup>221</sup> The current list includes a broad range of clinical and broader support services provided by

pharmacists for diabetes, asthma and other chronic diseases.

Pharmacies across Australia are already delivering a range of programs and services as described above, which anecdotally are providing significant benefits to local communities. The Panel notes that all Community Pharmacy Programs for which funding is currently provided under the Sixth Community Pharmacy Agreement (6CPA) are subject to a cost-effectiveness assessment by an independent health technology assessment body.

However, it must be recognised that there is a broader need for coherent data and evidence to demonstrate the benefits and value of the services provided by pharmacies. There is also a need for an effective system to identify, support and roll out these programs nationally based on local area needs.

The Pharmaceutical Society of Australia (PSA) submission advocates the need to better utilise pharmacists' skills through the support and remuneration of appropriate evidenced-based services.

"Australians are missing out on evidence-based pharmacist care. Compared to much of the developed world, Australia is lagging behind in implementing innovative care models which make best use of the unique skills and expertise of pharmacists to prevent and manage chronic and complex conditions.

Pharmacists in Australia are one of the largest, most trusted and most accessible groups of health professionals. Similarly, community pharmacies in Australia have provided, and will continue to provide a vital network for primary and preventative community based health care. Whilst pharmacists' unique skills and expertise have been historically underutilised, there is a significant opportunity, within the current health reform environment, to ensure that pharmacists' skills are better utilised to

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<sup>219</sup> Deloitte Access Economics, *Remuneration and regulation of community pharmacy: Literature review* (November 2016) (reference to information from the Canadian Pharmacists Association, 2016).

<sup>220</sup> Deloitte Access Economics, *Remuneration and regulation of community pharmacy: Literature review* (November 2016), page 41.

<sup>221</sup> Pharmaceutical Services Negotiating Committee, *Services database* (8 May 2017).

contribute to improved health outcomes for all Australians.

PSA has continued to advocate for pharmacists' important contribution in the following areas to be recognised and appropriately remunerated;

- Prevention: i.e. Evidence-based screening and risk assessment;
- Public Health: i.e. Immunisation;
- Primary Care: i.e.: Triage, referral and the management of minor ailments;
- Optimising Medicines Use: i.e. Medication management services, medication reviews, medicines information and adherence services;
- Effective Care Transitions: i.e. Medication reconciliation and care coordination;
- Collaborative models of care: i.e. Health Care Homes, Pharmacists in General Practice and Pharmacists in Aboriginal Health Services.

PSA wishes to reiterate to the Panel that despite uninformed commentary to the contrary, all of the above services are well within the current approved scope of practice for pharmacists and covered within the Competency Standards required of all registered pharmacists.”<sup>222</sup>

## DEVELOPING, SUPPORTING AND EXPANDING VALUABLE PHARMACY SERVICES

In the Panel's view, it is clear that pharmacy programs and services should be supported where they are evidence based, are of benefit to patient health outcomes, provide value for money and are effectively integrated with other local health services. The pharmacy profession should be collecting evidence and data that clearly demonstrates the value of these services. Strong advocacy and leadership is required to develop an effective evidence base, secure appropriate funding

and drive the development and expansion of such services.

In relation to current funding provided for service delivery, transparency has been raised as an issue:

“PSA has previously flagged, and shares concerns raised in the ANAO 5CPA report regarding the transparency of information relating to service delivery, including geographic spread, and reach to consumers who stand to benefit the most. This lack of transparency makes it difficult to evaluate whether or not valuable and cost-effective pharmacy services are being delivered to all consumers – despite repeated calls by PSA over successive agreements for more robust evaluation and transparency.”<sup>223</sup>

In 2013 the Royal Pharmaceutical Society in England released a report titled *Now or never: Shaping pharmacy for the future*. The report focused on the significant opportunities available for pharmacists to expand their services in areas such as advice and minor ailments, long-term conditions management and supporting the elderly and vulnerable people at home and in care. They acknowledged various local examples of effective and coordinated approaches to expanded pharmacy services but noted that these had failed to expand to larger-scale, consistent, ongoing program delivery.

The report stressed the need for pharmacists to better advocate for their own future with a stronger focus on care-giving and better integration with primary and other healthcare teams. It further stressed that pharmacists needed to put this into action through developing more direct patient services and working in interdisciplinary teams across GP,

<sup>222</sup> Pharmaceutical Society Australia, Submission No. 481, page 22.

<sup>223</sup> Pharmaceutical Society Australia, Submission No. 481, page 27.

nursing and social care services to apply for funding:

“Pharmacists and employers should not wait for national solutions but should drive change at a local level, proving their case for service provision to clinical commissioning groups, local area teams and local government commissioners by making and winning tenders.

Pharmacists must appreciate the financial constraint and intense scrutiny of quality facing the NHS. They must show how they can meet patient needs better and more efficiently than many existing providers. This will have to be done by developing new services through reallocation of existing funding: there will be no new money.

Pharmacists must collaborate with each other across community, social, secondary and tertiary care and with other healthcare professions, to develop models of care which enable commissioners to deliver integrated patient pathways, and ensure patients have consistent access to support with medicines use as they move between care settings.”<sup>224</sup>

The report also stressed the government’s responsibility to support this type of pharmacy-driven service delivery:

“There will likely be a need for bold decisions on the part of NHS England and the Department of Health ... about how national contracting for community pharmacy will go forward, and how the balance of dispensing and supply, compared with medicines optimisation services will be struck within a newly commissioned modern pharmacy service that can meet the health needs of the population ...”<sup>225</sup>

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<sup>224</sup> J. Smith, C. Picton & M. Dayan, *Now or never: Shaping pharmacy for the future*, Royal Pharmaceutical Society (2013).

<sup>225</sup> J. Smith, C. Picton & M. Dayan, *Now or never: Shaping pharmacy for the future*, Royal Pharmaceutical Society (2013).

The Panel believes that the same arguments apply in the Australian context.

Submissions to the Review described a multitude of gaps in the current healthcare system, providing statistics and multiple examples to demonstrate their point. They also provided a vast array of proposed solutions which would be led by pharmacies or involve pharmacists in some way. While the Panel is not in a position to conduct a thorough evaluation of the information provided and recommend specific solutions and programs to be funded, it supports the development of appropriate funding and evaluation models to support innovation in pharmacy-related services.

The government should investigate how best to support pharmacy programs that meet local needs, are able to demonstrate improved health outcomes for consumers, and provide value for money. Primary Health Networks (PHNs) may play a role in this.

The Eastern Melbourne Primary Health Network noted in its submission:

“The lack of a funding model to support pharmacist positions within innovative programs that seek to improve medicine safety, achieve better therapeutic outcomes, and reduce potentially avoidable medicines-related hospital admissions is an obstacle to progress, and shifts implementation to professions less specialized in the QUM [quality use of medicines] domain. The experience of EMPHN is that access to a willing, accessible and qualified workforce to provide advanced services beyond the community pharmacy is hampered by the lack of a remuneration model. PHNs generally are interested in collaborative and interdisciplinary care that would see non-dispensing pharmacists working within General Practices, Residential Aged Care Facilities, and community nursing services. Currently, sustainable remuneration is lacking. Future change

should consider a broader range of professional pharmacy services funded outside of Community Pharmacy Agreements.”<sup>226</sup>

The Panel notes that the 6CPA does provide an increase in government funding for pharmacy programs. In addition to supporting the continuation of existing pharmacy programs from the Fifth Community Pharmacy Agreement (5CPA), funding is set aside for the trial and future support of new and expanded pharmacy programs. The implementation of trials and new pharmacy programs is still in the very early stages, and it is too early to determine whether this funding will be successful in addressing the issues identified above. The Panel again reiterates the need for an effective system to identify valuable, evidenced-based pharmacy programs and support their expansion to areas that need them.

## HOME MEDICINES REVIEWS

The HMR program has been in operation in Australia for over 15 years. Under this program, accredited pharmacists undertake a comprehensive clinical review of a patient’s medicines, in the patient’s home, upon referral from a GP.

Under the 5CPA the government introduced a cap on the number of HMRs that a service provider could deliver each month, with the maximum set at 20. The cap was introduced to address a projected overspend of allocated funding for the program.

The program was a significant focus of feedback received by the Panel during consultations. There was much anecdotal evidence provided of the benefits of the

program and the problems caused by the introduction of the cap.

Many stakeholders also referred to statistics about medicine-related hospital admissions. It has been put to the Panel that 230 000 admissions to Australian hospitals each year were related to medicine misadventure, with an estimated cost of \$1.2 billion per year.<sup>227</sup> Similar medicine review programs exist in many countries around the world, with numerous studies demonstrating the potential benefits they can provide in reducing medicine-related errors. Examples of studies conducted in New Zealand and Sweden are included below:

**“New Zealand** – An evaluation of MUR [Medicines Use Review] services provided by pharmacists in New Zealand was undertaken to identify the types of drug-related problems and interventions provided during MURs. In total, 353 consultation records from 5 MUR providers were included in the analysis. A total of 886 medicine-related problems were identified, which resulted in 844 interventions. Most commonly, problems with health literacy and non-adherence to medicines were reported. The most common interventions provided were patient counselling and recommendations regarding medicine adjustments.”<sup>228</sup>

**Sweden** – A prospective randomised controlled trial in Stockholm was conducted to investigate whether a pharmacist-led medication review reduces the number of medicines and the number of medicine-related problems. A significant decrease in medicine-related problems was observed in the intervention group as well as a significant difference in change in self-rated health between the groups. The study concluded that the addition of a skilled pharmacist

<sup>226</sup> Eastern Melbourne Primary Health Network, Submission No. 209, page 2.

<sup>227</sup> Professional Pharmacists Australia, Submission No. 134; and Debbie Rigby, Submission No. 358.

<sup>228</sup> Hatah et al. 2014 (referenced in Deloitte Access Economics, *Review of pharmacy remuneration and regulation: Literature review* (November 2016)).

to the primary care team may contribute to reductions in numbers of medicine and maintenance of self-rated health in elderly patients with polypharmacy.”<sup>229</sup>

The Australian Government should investigate options to optimise the current HMR program, with the aim of reducing medicine-related problems and avoidable hospital admissions.

In particular, an increase in the current cap on services provided each month should be considered, combined with more targeted eligibility criteria to ensure the program reaches patients with the greatest need. Further, the government should investigate the potential benefits of opening the referral pathways to allow hospital staff to refer patients upon discharge. Other professionals, such as Aboriginal Health Workers, may also be able to initiate the process for a medicine review.

In their submission to the Review, the Guild argued that a more targeted approach that ensured HMRs were available to those patients most at risk was the best way to ensure the sustainability of the program:

“All Federally-funded pharmacist professional services should be evaluated for their clinical and cost-effectiveness with established medicines management services such as Home Medicines Reviews (HMRs) targeted at those patients with greatest clinical need and the least capacity to pay.

There is evidence to support highly targeted medication reviews being more cost-effective. An Australian Government funded cost-benefit analysis of the HMR program indicated that patients with multiple chronic conditions who are taking multiple medicines (greater than 12 medicines) provide the best value for

money in terms of savings to the health care system.

However, the report found that while there were savings from avoided GP visits, specialist visits, reduced medical investigations, reduced drug costs and a reduction in hospital admissions – the potential savings vary considerably and in many HMRs the estimated annual economic value of these savings was insufficient to offset the total cost of the HMR. Further, the report recommended that measures to improve the targeting of HMRs to those patients most likely to result in economic benefits should be implemented to ensure the future sustainability of the program.

The Guild agrees with the findings of the report and believes that HMRs should continue to be available for those at-risk patients who stand to derive the greatest clinical benefit from the service.

Currently HMRs are not well targeted. Under MBS item 900, while there are ‘at risk factors’ to guide GPs to target patients for an HMR service, there are currently no patient eligibility criteria for referral other than ‘people living in the community’. The ‘at risk factors’ are not mandatory and only perform an advisory function, and the patient eligibility (i.e. people living in the community) applies to an overwhelming majority of the population.”<sup>230</sup>

The Guild also argued in their submission that HMRs should be linked back to community pharmacies (reversing the direct referral system that was introduced in 2011). The Panel disagrees with this position, as it has not seen any evidence to suggest that independent or corporate consultant pharmacists provide a lower-quality service. The Pharmacy Guild of Australia (the Guild) argued that the introduction of the direct referral system, together with a lack of targeting, inevitably led to a large increase in the volume of HMR services being undertaken

<sup>229</sup> Lenander et al. 2014 (referenced in Deloitte Access Economics, *Review of pharmacy remuneration and regulation: Literature review* (November 2016)).

<sup>230</sup> Pharmacy Guild of Australia, Submission No. 486, page 104.



and, in particular, large volumes of HMRs being conducted by a relatively small number of accredited pharmacists.

The Panel has not seen any evidence to suggest that any one model, independent or corporate consultant pharmacists or community consultant pharmacists, provides any variation in quality service.

The Panel considers that these issues are best addressed through the introduction of:

- better targeted eligibility criteria
- a requirement for the HMR to be loaded into the MyHealth Record
- consideration of a different payment when the medication review is not conducted at the patient's home.

The consultant pharmacy model supports the view of medicine review as an advanced area of pharmacy practice. Further, the continuation of the direct referral system provides better choice for consumers and GPs, who can refer to those consultant pharmacists who they believe provide a high-quality service. It also supports the Panel's vision for more flexible delivery of pharmacy programs, as explained elsewhere in the Report.

In referring to the various medicine review programs, one consultant pharmacist submitted that:

"Pharmacists (should) be required to have additional training and credentialing to deliver these services, as an advanced level of knowledge and skills are required to deliver in a cost-effective manner. There is existing credentialing for Advanced Practice Pharmacists that could underpin recognition of those with appropriate skills and expertise.

To suggest that all pharmacists can deliver all medication management programs is naive at best, and potentially harmful and not cost-effective."<sup>231</sup>

The Panel agrees and supports the current additional training requirements and standards for pharmacists who carry out HMRs.

The HMR program was planned around the visit to the home to allow the pharmacist to best understand the patient's total medication profile, including complementary medicines. The Panel notes that the current program does allow for reviews to be undertaken at a location other than a patient's home if required for cultural reasons or for the pharmacist's safety. Prior approval must be sought before undertaking the review.<sup>232</sup>

However, the Panel has received feedback from multiple sources that suggests that the general community and even service providers are not always aware of this exception or perhaps that the exception is being implemented too narrowly. Accordingly, the government should ensure that the exception is appropriately promoted to relevant stakeholders – for example, Aboriginal Health Services.

The Panel notes that access to a universal medicine and healthcare record for patients (as detailed elsewhere in this Report) will support the quality delivery of the HMR program and thereby reduce avoidable medicine-related problems and hospital admissions.

The Panel has had many submissions made to it about the value of HMRs and Residential

<sup>231</sup> Debbie Rigby, Submission No. 358, page 3.

<sup>232</sup> Details are available at Sixth Community Pharmacy Agreement, [Home Medicines Review](#).



Medication Management Reviews (RMMRs), including appropriate consultations with Aboriginal and Torres Strait Islander people about their medicine.

The Panel considers that, to motivate people to best use their medication appropriately and to make sure they do not take unnecessary or harmful medications, consultation with the patient provides incremental benefits almost every time it occurs. These consultations processes therefore provide additional value and they may well assist with considerable savings within the health system.

## DOSE ADMINISTRATION AIDS

A DAA is defined as an adherence device designed to assist medication management for a patient by having their medications divided into individual doses and arranged according to the dose schedule throughout the day. A DAA can be either a unit-dose pack (one single type of medication per compartment) or a multi-dose pack (different types of medication per compartment).<sup>233</sup>

DAAs are generally used with the aim of improving a patient's compliance with their medication regime and reducing the risk of medication errors. Unfortunately, there appears to be a lack of quality studies examining the impact of DAAs on medication adherence and clinical outcomes.<sup>234</sup> However, studies that do exist generally do indicate benefits in compliance related to using DAAs for some health conditions.<sup>235</sup>

A more recent evaluation of DAAs has confirmed that:

“The identified overseas evidence is generally of poor to fair quality and has limited applicability to the Australian DAA initiative. That said, the available literature is inconclusive as to whether DAAs are effective in improving medication adherence, clinical outcomes, patient satisfaction; or whether DAAs are cost effective.”<sup>236</sup>

The Australian Government has recognised the value of DAAs through the Pharmacy Practice Incentives Program (PPIP). This program provides incentive payments for eligible accredited pharmacies for the number of DAA services (or clinical interventions) supplied for the relevant period. Pharmacies are required to make a claim for the payment, which is administered by the Guild.

It has been put to the Panel that the funding received under the PPIP is not sufficient to cover the costs of supplying DAAs. The Guild submitted:

“Trading terms on generic medicines have, until now, been able to cross-subsidise the costs associated with a range of core services that pharmacies have been providing to patients either free or below cost – which has contributed to the perception of affordable health care services by consumers.

One example of these services are DAAs. Community pharmacies pack about 11 million DAAs a year. While the volume of services being delivered is indicative of there being limited barriers to access for consumers, the cost of DAAs has been reported as being a barrier by consumers despite their perceived high value. While

<sup>233</sup> Australian Department of Health and Ageing, *Evaluation of the DAA/PMP Programs* (June 2010), page 6.

<sup>234</sup> R. Elliot, ‘*Appropriate use of dose administration aids*’, *Australian Prescriber* (April 2014).

<sup>235</sup> Department of Health and Ageing, *Evaluation of the DAA/PMP Programs* (June 2010), page 33.

<sup>236</sup> Department of Health, *Evaluation of 6CPA PPI Program: Dose administration aids* (November 2016), page 7. The evaluation also noted (at page 4) that there are “currently no studies that have assessed the effect of the Australian DAA initiative on adherence to medication”.

incentive payments under the CPA have gone some way to help offset the cost of providing this service, pharmacies are not paid a fee for service by the Federal Government and the incentive payment does not fully cover the cost.”<sup>237</sup>

The Guild’s comments are reflected in the statements of many pharmacy owners in their submissions to the Review, which indicated that the provision of DAAs was a vital service for the community. Pharmacy owners indicated that, in their experience, DAAs reduced medication errors and improved adherence. Pharmacy owners also indicated that the provision of DAAs was an underfunded service and that cost was a barrier for some consumers to access this service (pharmacies generally charge a weekly fee to supplement the cost of the DAA service).

One community pharmacy owner emphasised the importance of Webster pack (a form of DAA) services:

“For some people I provide the service for free if they can’t afford to pay, and yet they need a Webster pack to self-manage their medication at home. This situation cannot continue as the remuneration levels to my pharmacy continue to drop. The service has been cross-subsidised previously by the profit levels in the dispensary, but this is no longer able to happen.

With the growth of the numbers of aged people in every community around Australia, this problem is affecting every community pharmacy. The benefits of the service are to the CLIENTS, who have greatly increased compliance to their medication regime, and thus enjoy better health and longevity, and to the GOVERNMENT, because of less hospital visits because of medication misadventure.”<sup>238</sup>

<sup>237</sup> Pharmacy Guild of Australia, Submission No. 486.

<sup>238</sup> Judy Plunkett, community pharmacy owner, Submission No. 336.

A specific issue that has been raised through the Review’s consultation process is that DAAs supplied to residential aged care facilities do not attract the PPIP payment. The only remuneration pharmacists receive for providing this service is from fees charged to patients, which is generally insufficient to cover costs.

A pharmacy owner commented:

“The nursing home wanted us to provide the packs for no charge at all however I refused and they now begrudgingly pay me \$2.50 per resident per week regardless of how many packs they need. We get \$5.00 per pack from our community patients and the final cost of these with labour and materials is closer to \$8-10. Why do we do it? Until recently I have justified this loss/subsidising because it is a community service but this is unsustainable and a complete review of pharmacist’s remuneration by Aged Care Facilities need to be done.”<sup>239</sup>

Meditrax, an organisation of accredited pharmacists specialising in medication management services for aged care facilities, stated:

“Currently many aged care facilities utilise their own staffing resources to re-check the accuracy of DAA’s supplied, to minimise the significant error rate that can occur, often because of inadequate pack-chart discrepancy auditing. Discrepancies can readily occur if a change to a medication chart is not well communicated to the supply pharmacy. It is suggested to be considered an essential component in the allowance for supply pharmacists’ packing and provision of DAA’s.

Recommendations:

I. A separate payment system for the packing and provision of DAA’s to aged care facilities by supply pharmacists.

<sup>239</sup> Joanne Sorensen, community pharmacy owner, Submission No. 55.

II. Consideration and inclusion of essential chart-pack discrepancy auditing of 100% of charts to be included in the payment amount, or separately funded.”<sup>240</sup>

Carlene Smith, community pharmacist, specified certain services which she believed required government funding, including DAAs for aged care:

“This happens across the country, usually the pharmacy wears the cost [refers to the Strategic Direction for DAAs].

Although this is a 5CPA document it is very comprehensive regarding the benefit and use of DAA.

DAA for aged care has never been funded through Community Pharmacy Agreements. It is such a valuable service that saves medication use (by the facility only having 7 days supply on hand rather than one month) and errors in administration (staff mistakes in choosing the wrong medication are almost eliminated). Pharmacies have worn the cost by utilising the ‘profit’ of dispensing.”<sup>241</sup>

The Panel considers that the costs associated with the supply of important services such as DAAs are currently insufficiently reimbursed to pharmacies. This can also present a barrier to access for some consumers.

The Panel has seen a range of different DAA models during its consultations. These include high standard models involving machine packing and robust checking, with manual packing as a backup.

However, the Panel has also seen DAA facilities in community pharmacies that raise concerns about safety controls for the medicines being dispensed and the potential for high error rates that could result in medicine misadventure for the patient.

The high incidence of errors in manual packing of DAAs has also been reported in various studies. For example, research published in the *Australian Pharmacist* found that:

“The rate of errors (10.8% of DAAs) was higher than these observed previously ...”<sup>242</sup>

This shows a clear need to strengthen existing standards and associated mechanisms to enforce compliance so that risks to patients using DAAs are appropriately mitigated.

It is not the Panel’s intent to define the minimum standard for an acceptable dispensing using a DAA. However, the Panel believes that such a standard needs to be established and enforced. The Panel considers that some of the completely manual packing processes for DAAs that it has witnessed do not meet an appropriate minimum standard.

#### OPTION 8-1: DOSE ADMINISTRATION AIDS – STANDARDS

The government should establish clear, enforceable minimum standards for the supply of medicines by community pharmacies, including for dose administration aids (DAAs). There should also be appropriate compensation provided to community pharmacies for the dispensing of medicines using DAAs (in recognition that this tends to be a higher-cost activity than dispensing in manufacturer’s packaging).

<sup>240</sup> Meditrax, Submission No. 136.

<sup>241</sup> Carlene Smith, community pharmacist, Submission No. 32.

<sup>242</sup> S. Hussainy et al., ‘How accurate are manually prepared dose administration aids in residential aged care facilities?’, *Australian Pharmacist* (April 2012).

## THE PROVISION OF MEDICINES AND MEDICINE ADVICE IN AGED CARE FACILITIES

The Panel recognises that the provision of medicines and medicine-related services to patients of residential aged care facilities (RACFs) is complex.

While the Panel has decided not to provide any specific recommendations relating to this area, it notes that several parts of this Report do overlap with aged care service provision, and it is mentioned where relevant. The Panel also notes the following important areas for discussion.

In 2012, the Department of Health released the Guiding Principles for Medication Management in Residential Aged Care Facilities (building on guidelines released by the former Australian Pharmaceutical Advisory Council in 2002).

The Department of Health guidelines recognise a number of changing factors within the residential aged care sector that are affecting the provision of medicines, including the following:

- People are older and more frail when they enter residential aged care.
- Residents' care needs are more complex, as the prevalence of chronic conditions increases markedly with age, resulting in more complex care needs.
- The use of multiple medicines by residents is common in RACFs, given their complex care needs. Sommers et al. (2010) identified polypharmacy (defined as the concurrent use of five or more medicines) in 91.2 per cent of the RACF residents in their study, with an average of 9.75 medicines per person.

- The use of 'high-risk' medicines is common in RACFs given the incidence of conditions requiring use of these medicines. High-risk medicines such as anticoagulants, insulin, chemotherapy agents, narcotics and sedatives require careful monitoring. Error rates are not necessarily higher than with any other medicines, but, when problems occur, the consequences can be severe.
- Movement of residents across care settings challenges continuity of medication management.
- Staffing profiles are changing. There are decreasing numbers of registered and enrolled nurses in the sector and a corresponding increase in the number of unlicensed assistants in nursing/personal care workers (however titled). Medication-related tasks are increasingly delegated to these unlicensed workers.
- Obtaining timely access to general practitioners continues to be a problem for both individual resident care needs and facility-wide roles in medication management and quality improvement. RACFs in rural and remote areas face additional barriers in access to both general practitioners and pharmacists.<sup>243</sup>

The Panel, through its consultation process, has heard many accounts of community pharmacies being heavily relied upon by RACFs to address the increasing medication-related needs of patients. Many community pharmacies are providing important services below cost or for no direct remuneration. One

<sup>243</sup> Department of Health, *Guiding principles for medication management in residential aged care facilities* (October 2012).

example is the provision of emergency medicines (often as a 24-hour service). Andrew Robinson, community pharmacy owner, gave the following example in his submission to the Review:

“Last night at 4am I was called out to a nursing home to get some (relatively inexpensive) medication to make someone’s (sic) end of life comfortable. This is part of our commitment to the aged care facility we service. However, as an owner of the business, I can’t afford to send out on call pharmacist when we don’t make any income from this delivery, but at double time, minimum 3 hour engagement would simply not make sense.

Why is there no system to pay for this service given that, if a pharmacist didn’t attend, these patients would end up in hospital. End of life may not but antibiotics for pneumonia is another common call out reason. The cost of an ambulance transfer, 2 paramedics to transport, a triage nurse to receive in at hospital, then an attending doctor to review and admit the patient, then the cost of the hospitalisation, versus paying a pharmacist a few hundred dollars to do the service. Economics 101. Unfortunately the expectation from years of cross subsidy has created a lost value in the critical service pharmacists play in these situations.”<sup>244</sup>

The Panel agrees that the service described above is valuable and should be recognised appropriately.

The government should ensure appropriate arrangements and remuneration are made available to allow RACFs to have 24-hour emergency medicine and advice available. This may be through an arrangement with a local community pharmacist, but it could also be supported by distance-based technology.

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<sup>244</sup> Andrew Robinson, community pharmacy owner, Submission No. 66.

We note that this discussion overlaps with the recommendation for the government to investigate the viability of a ‘medicine hotline’ as described above.

As discussed above, the Panel recognises the importance of DAAs in RACFs, especially for supporting medication safety. It notes that, under current funding arrangements set out within the 6CPA, DAAs for RACFs are not directly funded.

Again the Panel has heard many accounts of community pharmacies providing DAAs to RACFs free of charge or below cost price.

It is the Panel’s understanding that the provision of these services by a community pharmacy allows the RACF to alter its workforce (e.g. have fewer registered nurses).

The Panel has discussed remuneration for DAAs above and would like to reiterate that funding for the provision of DAAs to patients in RACFs requires further consideration by the government. In particular, it notes that the value of these services has been recognised by the Department of Veterans’ Affairs, which provides remuneration per pack.<sup>245</sup>

## SUPPORTING INTEGRATION OF SERVICES AND MORE FLEXIBLE PHARMACY SERVICES

The Panel encourages programs to be run in a variety of settings, including community pharmacy and other areas of private practice – for example, pharmacists located in general practices, running private consulting businesses or operating in other interdisciplinary settings within the primary care system. A more flexible approach to the delivery of pharmacy services will support

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<sup>245</sup> Department of Veterans’ Affairs, [Dose Administration Aid Service: Pharmacists information booklet](#).

integration of healthcare services while also encouraging innovation in business models.

One trial in the United Kingdom has demonstrated significant benefits associated with clinical pharmacists working in general practice teams:

“A three year pilot which is deploying clinical pharmacists into GP practices may also be a key development for collaborative, cross sector pharmacy practice (Ridge, 2015). Within this pilot, clinical pharmacists are working as part of the general practice teams to resolve day-to-day medicine issues and consult with and treat patients directly. This includes providing extra help to manage long-term conditions, advice for those on multiple medicines and better access to health checks (NHS England, 2016b). A trial in 37 community pharmacies in Bradford City freed an estimated 900 hours of GP time across 27 practices by promoting self-care and pharmacist consultation before contacting the GP surgery.”<sup>246</sup>

The Panel is aware of similar arrangements operating in Australia but notes that they appear to be rare.

In their submission to the Review, Professional Pharmacists Australia stated:

“We have a vision for the future, that includes pharmacists who:

- work in healthcare teams to provide integrated care for patients in GP practices, community health centres, clinics, rehabilitation centres and hospitals
- provide follow-up support to patients leaving hospital to help them manage their medicines, keep an eye out for possible adverse effects and prevent them from relapsing and being readmitted to hospitals.

- are funded to consult with patients in their pharmacy, or during home visits to review, monitor and educate them about their medicines
- are part of a team working at the local level to help make decisions about the healthcare services needed by their communities
- work in or closely with aged care facilities to support residents to take medicines safely and effectively, and to monitor and recommend changes to their medicines.”<sup>247</sup>

As described above, advocacy and leadership is needed within the pharmacy profession to demonstrate the need for such services, secure appropriate funding, as well as develop effective data collection and evaluation mechanisms to be able to demonstrate value and outcomes. There is also a need to consider appropriate remuneration mechanisms for the program.

A schematic approach to pharmacy programs is put forward by the Panel in **Figure 15**.<sup>248</sup>

#### **OPTION 8-2: COMMUNITY PHARMACY PROGRAM – KEY PRINCIPLES**

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

- a. be based on evidence of effectiveness
- b. may or may not involve government paying for some or all of the cost of the service to some or all patients
- c. 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

<sup>246</sup> Deloitte Access Economics, *Remuneration and regulation of community pharmacy: Literature review* (November 2016), page 88.

<sup>247</sup> Professional Pharmacists Australia, Submission No. 314, page 3.

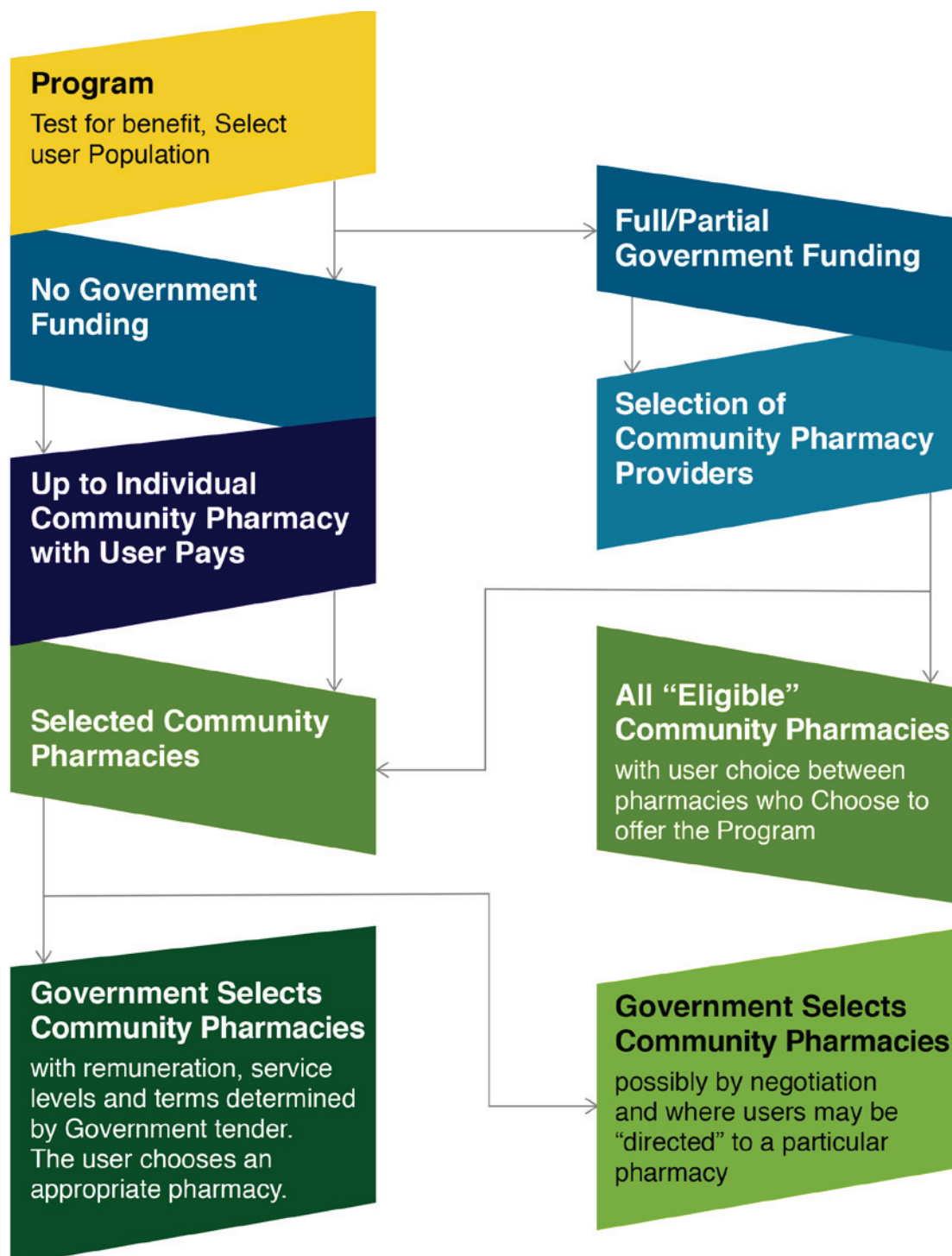
<sup>248</sup> Source: Illustration from the Panel.



government payment) through pharmacies/pharmacists that are selected by the government (for example, through a tender process or as a result of negotiation between the government and the relevant pharmacies or pharmacists)

- d. for some programs, government remuneration for the program will be channelled through the users of the program (or their representatives) so that the 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.

Figure 15: An approach to the determination of community pharmacy programs



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

### BACKGROUND

Through the Council of Australian Governments (COAG), the Australian Government has made a number of commitments to closing the gap in disadvantage between Indigenous and non-Indigenous Australians across health, education and employment.

In relation to health, the government has committed to close the gap in life expectancy between Indigenous and non-Indigenous Australians within a generation (by 2031) and to halve the gap in mortality rates for Indigenous children under five within a decade (by 2018). Achieving health equality for all Australians is a key priority in this regard.

Central to closing the gap in life expectancy is the government's commitment to Aboriginal and Torres Strait Islander people having timely and affordable access to Pharmaceutical Benefits Scheme (PBS) medicines as well as quality use of medicines (QUM) and medication management support services.

There are a number of programs that have been implemented in urban, regional and rural and remote locations to improve access to, and affordability of, medicines, including:

- the section 100 Remote Area Aboriginal Health Services (RAAHS) Program
- the section 100 Pharmacy Support Allowance Program

- Quality Use of Medicines Maximised for Aboriginal and Torres Strait Islander Peoples (QUMAX)
- Closing The Gap (CTG) PBS Co-Payment Measure.

The Panel notes that, although they are related, these programs operate independently with differing eligibility criteria applied for each. This raises difficulties for both consumers in terms of access and for pharmacists and other health professionals with respect to administration.

In considering how pharmacy options may contribute to improved health outcomes for Aboriginal and Torres Strait Islander people, the Panel has questioned whether currently arrangements are sufficient and how might they be improved.

### 9.1. SECTION 100 REMOTE AREA ABORIGINAL HEALTH SERVICES PROGRAM

*Access to medicines for Indigenous Australians under the section 100 RAAHS Program and the CTG 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 in 1999 under section 100 of the *National Health Act 1953* (Cth), provides special arrangements to address barriers in 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 Aboriginal Health Service (AHS) in a remote area can receive PBS medicines from the AHS at the point of consultation without a prescription and without charge.

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

Certain medicines are not made available under section 100 RAAHS arrangements, including:

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

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

The Panel notes that pharmacists supplying PBS medicines under section 100 RAAHS arrangements are not required to be involved in the dispensing of medicines to individual patients and are essentially remunerated as wholesalers. The Panel also notes that the supply of medicines under section 100 RAAHS arrangements is complemented by the section 100 Pharmacy Support Allowance, which provides for:

- medicine management
- training of Aboriginal Health Workers in the handling of medicines
- supervision of medicines held by remote communities, such as out-of-date stock.

Expenditure on the section 100 RAAHS Program was \$27.8 million in 2015–16, which included the cost of PBS medicines and a section 100 bulk supply handling fee. However, the Panel understands that current bulk supply arrangements may lead to wastage and storage issues in remote health services and that the current bulk supply handling fee does not cover the costs of transport to some remote sites. Funding to enable pharmacists to educate AHSs in relation to the storage and QUM is available through the Sixth Community Pharmacy Agreement (6CPA) section 100 Pharmacy Support Allowance.

The Panel notes that, in addition to bulk supply arrangements, some jurisdictions require pharmacies to provide individually labelled medicines to clients of RAAHS on the basis of a 'rural script'. Whereas the difference between a rural script and a PBS script varies depending on the jurisdiction, a key difference is that the pharmacist has no direct contact with the client at the time of dispensing.

Prior to 1 January 2017, pharmacists dispensing medicines on a rural script had only been able to claim the bulk handling fee (\$2.96 as at 1 July 2016) rather than the full PBS dispensing fee of \$7.02, even though the work undertaken is similar to a normal dispense.

Interim pharmacy remuneration arrangements for medicines supplied on a 'rural script', announced by the Prime Minister in November 2016, commenced on 1 January and will operate until 31 December 2017. Under the interim arrangements, a new fee of \$4.57 per PBS item is provided under a 'rural script' – equivalent to a payment of \$4.06 as a 'top-up' of the bulk handling fee (\$2.96) to the

standard PBS dispensing fee (\$7.02) and a proportion of the standard Premium Free Dispensing Incentive Fee (\$0.51).

All PBS medicines supplied under section 100 RAAHS arrangements continue to be eligible for the relevant handling fee, whether supplied in bulk or for a 'rural script'. These payments are administered by the Pharmacy Guild of Australia (the Guild) and have been implemented through a new section 100 Patient Specific Medicine Supply Fee under the 6CPA section 100 Pharmacy Support Allowance (see below). This provides funding for pharmacies to provide QUM and medication management support to remote area AHSs.

The Panel understands that longer-term arrangements are under consideration to enable PBS items for individual clients of RAAHS to be claimed as standard PBS items. Such arrangements would require formal policy approval by government.

## 9.2. CLOSING THE GAP PBS CO-PAYMENT MEASURE

The CTG PBS Co-Payment Measure was established in 2010 to reduce the cost of PBS medicines for eligible Aboriginal and Torres Strait Islander people living with, or at risk of, chronic disease. Under this measure a patient's PBS co-payment is either reduced from the general to concessional co-payment or from the concessional co-payment to nil.

The CTG PBS Co-Payment Measure requires that eligible prescribers be:

- a member, employee or contractor of a general practice participating in the Indigenous Health Incentive under the Practice Incentives Programme (PIP)
- an AHS in a rural or urban setting

- any medical specialist in any practice location provided the patient is eligible and has been referred by a medical practitioner working in a practice that is participating in the Indigenous Health Incentive PBS Co-Payment Measure under the PIP.

Patients must also be registered by an eligible prescriber prior to receiving any CTG script under this measure.

In general, hospital-generated prescriptions are excluded from the CTG PBS Co-Payment Measure.<sup>249</sup>

Under current arrangements, AHSs in remote communities cannot write CTG prescriptions, presumably in recognition of section 100 RAAHS arrangements. The Panel notes that, when a patient from a remote area chooses to travel away from the area serviced by their local AHS, their usual prescriber is unable to provide a CTG script. Hospital prescriptions too are excluded from the CTG PBS Co-Payment Measure.

These current CTG arrangements put unnecessary limitations on remote clients requiring ongoing medications when travelling into urban and rural areas.

As the Kimberley Aboriginal Medical Service located in Djungan, Western Australia, stated in its submission to the Review:

"As Remote Area Aboriginal Area Health Services our clinics operate under the Section 100 RAAHS arrangements rather than the CTG Co-payment measure. Our patients experience substantial difficulty

<sup>249</sup> With the exception being medical specialists working at a hospital treating an eligible patient who has been referred to them by an eligible GP. In such cases, medical specialists are able to annotate CTG prescriptions on their personal prescription pad and not on a hospital prescription.

accessing their medications outside the Kimberley as they are required to find a GP surgery that is participating in the Indigenous Health Incentive under the Practice Incentives Program and obtain a CTG endorsed PBS prescription. Whilst it is possible to register our patients for the CTG co-payment measure, prescribers in our clinics are precluded from issuing a CTG endorsed PBS prescription as we are accessing the S100 scheme. For patients that are required to travel to Perth for further medical treatment this is another hurdle to overcome in an already unsettling time.

All prescribers, irrespective of their clinical setting or location should be able to issue patients with a CTG endorsed PBS prescription if required. This includes prescribers working in a Hospital or a Remote Aboriginal Area Health Service. Enrolment in the CTG PBS co-payment measure should be patient centred, rather than linked to the patient's usual care provider".<sup>250</sup>

The inability of hospitals to provide annotated CTG prescriptions for outpatients was repeatedly presented as an issue to the Review. The problem is illustrated by the case study below:

"Jenny has previously registered for the CTG PBS Co-payment Programme with her usual GP. On her next visit to the local pharmacy Jenny presents the pharmacist with three PBS prescriptions.

The first prescription is annotated with 'CTG' and is written by Jenny's doctor at the rural Indigenous Health Service she attends.

The second prescription is also annotated with 'CTG' and is written by a visiting endocrinologist at the IHS she attends.

The third prescription does not have the 'CTG' annotation and was written by a hospital doctor when Jenny was discharged from the hospital.

Jenny asks her pharmacist if the third prescription from the hospital can also be

dispensed with the CTG co-payment relief.

The pharmacist informs her however that only the first two prescriptions with the CTG co-payment relief can be as they were written by eligible prescribers.

The third prescription cannot be dispensed with the CTG co-payment relief as it was written at a hospital and hospital prescriptions are excluded from the CTG PBS co-payment measure.

The pharmacist informs Jenny that for this particular prescription she would need to pay the full PBS co-payment (currently \$38.80 per item) rather than the concessional rate (\$6.30 per item) she is used to paying for her CTG scripts.

Instead of filling the script, Jenny decides to defer accessing the third prescribed medication due to cost.

However, by deferring her treatment – a medication for the ongoing management of diabetes – Jenny ends up returning to hospital a few weeks later, much sicker than her previous acute episode presentation."<sup>251 252</sup>

Further, the Pharmaceutical Society of Australia (PSA) noted in its submission:

"Allowing remote s100 AHSs to write CTG prescriptions, and hospitals to provide CTG prescriptions to eligible out-patients would go some way to improving access for Aboriginal and Torres Strait Islander people who travel between urban, rural and remote areas."<sup>253</sup>

As noted by the Guild, current arrangements mean that:

<sup>251</sup> Case study adapted from [Closing the Gap \(CTG\) Indigenous Chronic Disease Package PBS Co-payment Measure: Pharmacy staff resource booklet](#) (2016).

<sup>252</sup> In 2013–14, there were around 47 000 hospitalisations for type 2 diabetes (as the principal and/or additional diagnosis) among Aboriginal and Torres Strait Islander people – a rate of 12 426 per 100 000 population: AIHW, [Hospital care for diabetes](#) (2017).

<sup>253</sup> Pharmaceutical Society of Australia, Submission No. 481.

<sup>250</sup> Kimberley Aboriginal Medical Services, Submission No. 103.



“When patients present with an unannotated CTG prescription at a pharmacy, they ... have to be sent back to the registered general practice or a registered non-remote AHS or the pharmacist has to contact the prescriber to clarify their intention causing a delay in access to medicines, even when the patient is known to the pharmacy to be eligible and registered for the CTG PBS co-payment measure.”<sup>254</sup>

Beyond merely reforming current program arrangements, the PSA has suggested:

“[Governments should] consider developing overarching universal medicines access program for Aboriginal and Torres Strait Islander people.”<sup>255</sup>

The Guild suggests that a patient’s CTG registration be more widely identifiable:

“[T]he eligibility for the Closing the Gap (CTG) PBS Co-payment should be verifiable through the patient’s Medicare Card ...  
... the Federal Government should implement an electronic and online registration process for patients accessing the CTG PBS Co-payment measure in order to improve efficiency and access.”<sup>256</sup>

The Panel considers that either of these options could allow eligible patients to pay the same CTG co-payment for their PBS medicines regardless of location and assist their continuity of care.

#### **OPTION 9-1: ACCESS TO MEDICINES PROGRAMS FOR INDIGENOUS AUSTRALIANS**

The access to medicines programs for Indigenous Australians under the section 100 RAAHS Program and the Closing the Gap PBS

Co-Payment Measure should be reformed so that the benefits to the individual follow that individual, regardless of where the prescription is written or dispensed.

### **9.3. PHARMACY OWNERSHIP AND OPERATIONS BY ABORIGINAL HEALTH SERVICES**

*The current inability of an AHS to operate a community pharmacy poses a significant risk to patient health in some rural and remote areas of Australia.*

#### **DISCUSSION**

While the QUMAX and section 100 Pharmacy Support Allowance programs have improved the availability of QUM services for Aboriginal and Torres Strait Islander people, the Panel considers there is still a need to address the ever-increasing demand for medication-related support services to further close the gap in health outcomes.

The Panel notes that AHSs in the Northern Territory are currently able to own and operate a pharmacy business at ministerial discretion.

The Panel noted that, in Alice Springs, the Central Australian Aboriginal Congress Aboriginal Corporation (the Congress) is applying to operate its own pharmacy business under section 90 of the National Health Act. This requires applying for an exemption from Schedule 7 of the *Health Practitioners Act 2004* (NT) under Northern Territory legislation which states that a person may not own a pharmacy unless they are an authorised pharmacy business owner.

The Congress submits:

“[The Congress] provides primary health care services to Aboriginal people living in

<sup>254</sup> Pharmacy Guild of Australia, Submission No. 486

<sup>255</sup> Pharmaceutical Society of Australia, Submission No. 481, page 15.

<sup>256</sup> Pharmacy Guild of Australia, Submission No. 486.

Alice Springs as well as to six remote communities in Central Australia. The Congress expects benefits of establishing its own pharmacy to include:

better access and more effective pharmacy services provided to Aboriginal people in Central Australia including the systematic provision of counselling on the use of medications increased access to the QUM activities including diabetes control, Medscheck, DAAs etc.”<sup>257</sup>

The Congress also suggests that having a ‘public’ pharmacy not owned by a pharmacy group will improve local competition and the pricing of medicines.

However, while the PSA also recognises the benefits of providing culturally appropriate services through an AHS-owned and operated pharmacy, it stated:

“evidence suggests that currently it is difficult for community pharmacies in some rural and remote locations to remain viable – as such, PSA believes it is unlikely that many AHSs would have capacity to absorb [sic] the risk and liability associated with operating a pharmacy business.”<sup>258</sup>

For this reason, the Panel considers that transition or trial arrangements would be important to the consideration of any change to existing ownership restrictions for the AHS.

#### **OPTION 9-2: ABORIGINAL HEALTH SERVICE PHARMACY OWNERSHIP AND OPERATIONS**

All levels of government should ensure that any existing rules that prevent an Aboriginal Health Service (AHS) from owning and operating a community pharmacy located at the AHS are removed. As a transition step, these changes should first be trialled in the Northern Territory, and governments should work together with any AHS that wishes to establish a community pharmacy.

<sup>257</sup> Central Australian Aboriginal Congress Aboriginal Corporation, Submission No. 487.

<sup>258</sup> Pharmaceutical Society of Australia, Submission No. 481.

## 10. FURTHER ISSUES

### 10.1. SECTION 100 HIGHLY SPECIALISED MEDICINES

*The distinction between highly specialised and other Pharmaceutical Benefits Scheme (PBS) medicines is causing administrative inefficiencies and unnecessary risks to patient health.*

#### DISCUSSION

The Highly Specialised Drugs (HSD) Program is one of a number of programs, administered under section 100 of the *National Health Act 1953* (Cth). It provides access to a range of specialised PBS medicines for the treatment of chronic conditions which, because of their clinical use and other special features, places restrictions on where these medicines can be prescribed and supplied.

Historically, PBS medicines supplied under the HSD Program have been restricted to supply through public or private hospitals having access to appropriate specialist facilities. Over time, this has expanded to see the introduction of community access arrangements for medicines for the treatment of Hepatitis B and HIV/AIDS as well maintenance therapy for schizophrenia. More recently, the availability of new Hepatitis C medicines through section 100 HSD arrangements has significantly driven access to these medicines out in the community.

A community pharmacist's submission noted:

“the outcome from the patient side is really encouraging. Having an access to these essential medications through their local pharmacy and, in our case, reduce the need to travel to get them, have been much appreciated by the patients and would have reflected positively on their

compliance and therefore treatment outcome.”<sup>259</sup>

While expanded access has brought with it the opportunity to support an increased role for community pharmacy in primary care through supported community access, it remains that the complexity of dispensing across hospitals and community pharmacy makes the system unduly difficult for consumers to navigate.

In addition, there is perhaps unwarranted complexity for pharmacists and other health professionals in administering access through current section 100 arrangements. In particular, there has been a significant issue with regard to the financial burden for community pharmacy in providing access under current arrangements.

As the Pharmaceutical Society of Australia (PSA) noted in its submission to the Review:

“From a consumer perspective, the categorisation of their medicine as s100, PBS, or RPBS is irrelevant in terms of them accessing the medicine in a timely manner. These items should be included in the same arrangements as the PBS to ensure that the NMP [National Medicines Policy] objective of access to medicines is fully realised”.<sup>260</sup>

As the use of medicines such as HIV antiretroviral and Hepatitis C medicines becomes more commonplace in the contemporary community setting, there is a need to address issues of complexity as potential barriers to access.

The Society of Hospital Pharmacists of Australia (SHPA) submission suggests a measured approach to any future changes:

<sup>259</sup> Emad Sidhom, community pharmacist, Submission No. 35.

<sup>260</sup> Pharmaceutical Society of Australia, Submission No. 481, page 16.

“Appropriate processes should be established to ensure timely access to medicines including high cost PBS medicines. In the rare case when urgent supply of a medicine can make a clinical difference this should be stipulated in the PBS listing and supported by appropriate business rules. SHPA members have indicated that this has occurred in practice since Hepatitis C medicines have become more widely available.

SHPA believes that there has been significant business process reform since the introduction of Hepatitis C medicines to the PBS, and that therefore this is not a major barrier to the timely access of very high cost medicines. For effective supply it is imperative that improved processes are in place prior to the listing of new medications on the PBS.

SHPA member feedback indicates that the current anomaly with some very high cost medicines may not be an ongoing issue as patents expire. Demand for Hepatitis C medicines is likely to substantially decrease over the next three – five years as the patient group stabilises. This means that concerns around major ongoing increases in demand for high cost medicines may not be a solid basis for significant change.”<sup>261</sup>

#### **OPTION 10-1: SECTION 100 HIGHLY SPECIALISED DRUGS**

The Highly Specialised Drugs (HSD) 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 within section 100 HSD arrangements. This should include, for example, harmonising access and fees regardless of where the medicine is dispensed.

<sup>261</sup> Society of Hospital Pharmacists Australia, Submission No. 497.

## **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 medicines that must meet an appropriate level of quality, whether prepared at a Therapeutic Goods Administration (TGA) licensed or non-TGA-licensed facility.*

### **DISCUSSION**

The preparation and supply of chemotherapy infusions in Australia is recognised as a specialist area of pharmacy practice, with fewer than fifty pharmacies (less than 1 per cent) supplying 70 per cent of all chemotherapy infusions subsidised under the PBS.

In recognition of the specialist nature of preparing chemotherapy medicines, fees are paid to a supplying pharmacist in accord with the Efficient Funding of Chemotherapy (EFC) measure. For section 90 approved pharmacies (community pharmacies), these fees include:

- ready-prepared dispensing fee (\$7.02)
- preparation fee (\$83.22)
- distribution fee (\$25.92)
- diluent fee (\$5.14).

Public hospital pharmacies authorised to supply PBS-subsidised medicines are paid on the same basis but are not eligible for the distribution or diluent fees.

In connection with the 2013 comprehensive Review of Funding Arrangements for Chemotherapy Services, an additional fee of \$60 per chemotherapy infusion was introduced in July 2013 as an interim payment to ensure the ongoing viability of

chemotherapy services. Following that review<sup>262</sup>, payment of this fee was continued until the commencement of the Sixth Community Pharmacy Agreement (6CPA) in July 2015.

From July 2015, a revised payment structure for the additional compounding fee was introduced under the 6CPA as part of the government's PBS Access and Sustainability Package. This two-tiered fee was based on payment of a \$40 compounding fee per eligible EFC claim<sup>263</sup>, with a further \$20 being made available per infusion for chemotherapy infusions prepared in a facility holding a TGA manufacturing licence.

Throughout the Panel's national consultations, the majority of stakeholders considered that there is no therapeutic difference between products produced in a TGA-licensed or appropriate non-licensed facility.

A number of local compounding facilities that were not TGA licensed emphasised that they were required to comply with multiple sets of standards and were producing products that were 'identical' to those compounded in TGA facilities.<sup>264</sup>

The Panel also notes concerns relating to the impact of the two-tiered remuneration structure on the viability of local facilities, which often play an important role in rural and remote communities. The PSA noted in its submission:

"PSA has received feedback from pharmacist members which indicates that

the new two-tiered fee structure for chemotherapy compounding, implemented on 1 July 2015, has disadvantaged pharmacies which are not TGA licenced. Additionally, the feedback indicates that the 'one size fits all' approach of the new structure may disproportionately affect rural and remote consumers who rely on local manufacturers for timely access to compounded chemotherapy.

PSA acknowledges that the new fee structure was implemented to reflect the additional costs associated with TGA licensing, however, it also recognises that the new funding model encourages the centralisation of chemotherapy compounding to TGA licensed facilities, and that some States and Territories, namely Tasmania and the Northern Territory, lack any TGA licensed compounders.

PSA would encourage the Panel to consider the impact of the two-tiered remuneration structure on the viability of local facilities and make recommendations to ensure that all Australians have timely and convenient access to medicines which are safe, efficacious and of high quality."<sup>265</sup>

The Panel agrees that these types of local facilities play a vital role in supplying chemotherapy services in many areas of Australia and should receive equality in remuneration for their services, subject to meeting minimum quality and safety standards.

Arguments made in favour of the additional \$20 for TGA-licensed facilities were generally based on recognition of the additional costs to the compounder of holding and complying with a TGA licence. The Panel is not satisfied of there being sufficient evidence to demonstrate these additional costs or that they should be valued at \$20 per claim.

<sup>262</sup> Department of Health, *Report to the Minister of Health: Review of funding arrangements for chemotherapy services* (October 2013).

<sup>263</sup> The \$40 is included within the Preparation Fee outlined on page 26.

<sup>264</sup> Joondaloo Hospital Pharmacy, Submission No. 308.

<sup>265</sup> Pharmaceutical Society of Australia, Submission No. 481, page 19.

Furthermore, the Panel does not consider it appropriate to apply differential remuneration levels for products prepared in TGA-licensed versus non-TGA-licensed facilities, as this would appear to imply a difference in quality or safety which has not been borne out in practice.

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.

In this respect, the Panel notes that the Pharmacy Board of Australia's submission highlighted:

“the importance of the standard of practice required in all locations where pharmacists compound medicines (including chemotherapy) and the costs associated with meeting the standard.”<sup>266</sup>

#### **OPTION 10-2: CHEMOTHERAPY COMPOUNDING – PAYMENTS**

There should be no difference in the remuneration paid by the 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 that are prepared in a facility that exceeds the minimum standards.

### **10.3. 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.*

#### **DISCUSSION**

The minimum standards applicable to the preparation of chemotherapy medicines in Australia have not been made clear to the Panel.

The Panel recognises that sterile compounding pharmacies are required to comply with Pharmacy Board of Australia and relevant SHPA guidelines for the preparation of sterile medicines. However, the standards similarly applied to such facilities for the compounding of chemotherapy preparations appear to be overly complex and layered, involving reference to local, state and territory legislation regarding pharmacy practice as well as industry codes, guidelines and pharmacopeial standards.

With this in mind, the Panel has been generally concerned about the standards applied at certain facilities it has observed.

The Panel notes that there are examples of uniform minimum standards being applied in overseas countries. For example, the United States applies additional standards for chemotherapy compounding pharmacies. In particular, the *Drug Quality and Security Act 2013*, introduced after a meningitis outbreak in 2012 was traced to a compounding pharmacy, exempts compounded medicines from certain requirements of the *Federal*

<sup>266</sup> The Pharmacy Board of Australia, Submission No. 22.



*Food, Drug, and Cosmetic Act 1938* where the medicine is compounded by or under the direct supervision of a licensed pharmacist in a registered outsourcing facility meeting applicable requirements.

Canada's National Association of Pharmacy Regulatory Authorities (NAPRA) also has released two model standards in relation to pharmacy compounding – the Model Standards for Pharmacy Compounding of Non-hazardous Sterile Preparations and the Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations. These standards set out core requirements regarding personnel, policies and procedures, facilities and equipment, and general maintenance logs. In addition, the standards include specific requirements for products and preparations.<sup>267</sup>

The Panel considers that, similarly, there should be a clear, uniform set of minimum standards which are applied to all approved chemotherapy compounding facilities within Australia.

In addition, the Panel has also noted concern over the complexity and administrative burden associated with the current reimbursement process for chemotherapy compounding through the PBS.

Martin Quinn, a community pharmacy owner, submitted:

"The provision of chemotherapy, via the PBS is an incredibly complex model and currently requires an extraordinary amount of paperwork to be completed by clinicians, pharmacists and other allied health workers. This administration time should be spent providing improved services to those patients who are already

experiencing a very challenging set of circumstances. One very efficient manner where efficiencies could be achieved is via the elimination of the requirement of a PBS prescription and the use of the chemotherapy protocol as the source document for dispensing. Similar mechanisms have been put into place in residential aged care via the National Residential Medication Chart (NRMCC) which acts as the prescription order for residents in long term residential aged care. The issuing of a prescription is simply replicating the information that is contained within the treatment protocol and is an unnecessary burden on the entire sector."<sup>268</sup>

### **OPTION 10-3: CHEMOTHERAPY COMPOUNDING – UNIFORM MINIMUM STANDARDS**

There should be a clear, uniform set of minimum quality standards for all approved chemotherapy compounding facilities based in a hospital, a community pharmacy or elsewhere. These minimum standards should:

- a. not require that a compounding facility be Therapeutic Goods Administration (TGA) licensed to meet the minimum requirements
- b. mean that a TGA-licensed facility clearly satisfies the minimum standards
- c. reflect the variety of settings that are appropriate for the preparation of chemotherapy medicines, including 'urgent' preparation in a hospital setting or a community pharmacy setting.

<sup>267</sup> Deloitte Access Economics, *Remuneration and regulation of community pharmacy: Literature review* (November 2016), page 28.

<sup>268</sup> Martin Quinn, community pharmacy owner, Submission No. 187.

## 10.4. 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.*

### DISCUSSION

During its consultations, the Panel has observed a variety of settings and facilities for the compounding of chemotherapy medicines. While not all of these facilities operate in the same manner or to the same standard, the Panel has observed examples of practice from which there would be benefit in providing greater access and efficiencies.

One relevant example which operates in New South Wales is in 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).

The SHPA, in its submission to the Review, commented that:

“The difference in medicines compounded by TGA licensed compounders is in the quality of the product, and the certification of its development process. Due to the standards of the manufacturing facility, their products have longer shelf lives and expiry dates. For example, an infusion compounded by TGA licensed compounders may not ‘expire’ for several months, whereas a similar infusion compounded by a non-TGA licensed compounder, may have an expiry of 48 hours or not more than 7 days. As such, TGA licensed compounding facilities are able to compound batch preparations of medicines and distribute to pharmacies and health services who do not have compounding facilities. Due to the cost of

certification most hospital pharmacies are not TGA licensed, and therefore only compound medicines for individual patients.”<sup>269</sup>

The Panel considers that, in as much as public hospitals and other facilities may already be able to engage in limited trade of some medicines that are prepared onsite, such models could provide best-practice references for improving access to chemotherapy medicines.

### OPTION 10-4: CHEMOTHERAPY COMPOUNDING – PRACTICE MODELS

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

## 10.5. TIGHTENING THE LISTING OF GENERIC MEDICINE

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

### DISCUSSION

While the listing of particular medicines on the PBS is outside the scope of inquiry for this Review, the number of different types of a particular medicine that are listed (i.e. the original brand and the generic substitutes) has consequences for the efficiency and effectiveness of the pharmacy supply chain.

<sup>269</sup> Society of Hospital Pharmacists, Submission No. 497, page 65.

This raises issues that are clearly within the terms of reference of this Review.

Having a significant number of types of a particular medicine listed on the PBS means that both wholesalers and community pharmacies must be in a position to supply a particular 'brand' of the medicine (whether original brand or generic brand) if requested.

This potentially raises inventory and related stock-ordering and stock-holding costs throughout the pharmacy supply chain. These costs can be avoided, with potential savings to the PBS, if the government limits the number of listed generic substitutes through a tender process.

Examples of positive outcomes achieved through tightening requirements around generic medicines are found in the Netherlands and Denmark.<sup>270</sup>

In the Netherlands, statutory health insurance is purchased from private health insurers and is mandatory for all Dutch residents. It is funded through a nationally defined, income-related contribution as well as other funding mechanisms. The government has introduced a range of measures to curb expenditure growth on pharmaceuticals, including relating to generic medicines:

"Since 1 July 2005 a number of health care insurers have been making use of the so-called 'preferential pricing policy'. This allows health care insurers to designate specific medicines within a group of medicines with the same active ingredient and mode of administration that are eligible for reimbursement. The preferred medicine is usually the lowest priced generic within the same therapeutic class. Patients who choose a non-preferred

medicine are only reimbursed up to the price of the preferred medicine. In parallel with this reform, health care insurers started to issue tenders for contracts to supply several high-volume drugs. 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).<sup>271</sup>

Denmark has universal, public insurance coverage but similarly limits the reimbursement paid for medicines based on the cheapest brand available:

"Since 2005, the basis for reimbursement was changed to the lowest price paid in the EU. These policies have included generic substitution, prescribing guidelines, and assessment by the regions of deviations in prescribing behaviour. Pharmaceutical companies report a monthly price list to the Danish Health Authority, and pharmacies are obliged to choose the cheapest alternative with the same active ingredient, unless a specific medicine is prescribed. Patients can choose the more expensive medicine, but they have to pay the difference."<sup>272</sup>

#### OPTION 10-5: GENERAL MEDICINE – LISTING ARRANGEMENTS

When an 'original' (or 'branded') medicine comes off patent then the government should hold a tender for the listing of generic versions of the medicine. The 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

<sup>270</sup> Deloitte Access Economics, *Remuneration and regulation of community pharmacy: Literature review* (November 2016), page 25.

<sup>271</sup> Deloitte Access Economics, *Remuneration and regulation of community pharmacy: Literature review* (November 2016), page 10.

<sup>272</sup> Deloitte Access Economics, *Remuneration and regulation of community pharmacy: Literature review* (November 2016), page 68.

meet the distribution and other conditions required by the government at the least cost to the PBS.

## 10.6. MACHINE DISPENSING

*Overseas experience has demonstrated advantages in the use of remote dispensing machines.*

### DISCUSSION

Medicine dispensing machines have been used successfully in hospital and emergency services for a number of years (e.g. by the Royal Flying Doctor Service<sup>273</sup>).

We also note that machine dispensing is currently being successfully used overseas.

The Canadian Government has recently implemented the use of dispensing machines to improve access to medicines for people living in rural and remote regions.

These machines, called PharmaTrust MedCentres, are remote dispensing systems that allow patients to communicate with a pharmacist who might be located elsewhere via videoconferencing. The machines have been installed in rural communities where pharmacies may be scarce.

The machines provide patients with access to pharmacy services in rural and remote communities that do not otherwise have easy access to a pharmacy.

The machines incorporate a television screen and a phone. 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 remote dispensing machines are required to be accredited by the relevant Canadian authority.

The Canadian experience has demonstrated that the use of remote dispensing machines has provided valuable benefits to patients living in rural and remote communities. For example, these patients no longer have to travel vast distances for prescription medicines and can still talk directly with a pharmacist via a video link as part of the dispensing and advisory process.

Robotic dispensing in hospitals is now 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.

For example, a qualitative survey at Sunderland Royal Hospital pharmacy in 2012 suggested that a robotic dispensing machine linked to an electronic prescribing system not only increased efficiency but also offered enhancement of professional aspects of clinical pharmacy.<sup>274</sup>

The United Kingdom National Health Service has also begun trialling remote dispensing machines (similar to those in Canada), which aim to reduce dispensary queues and improve access in remote locations.

<sup>273</sup> The Royal Flying Doctor Medical Chest Program enables early access to medications for both emergencies and definitive care while minimising the need for mail-order pharmacy or patient travel. See Royal Flying Doctor Service, [Telehealth & medical chests](#).

<sup>274</sup> R. Beard, *e-Prescribing and robotic dispensing part 1* (14 February 2014).

Results from these trials have shown that these machines are a viable alternative to conventional pharmacies and can reduce costs, noting that the machines will never fully replace conventional pharmacies.<sup>275</sup>

We note that machine dispensing applications can be assisted and facilitated by a system of electronic prescriptions. However, if the government does not institute a system of electronic prescriptions, the government should investigate the feasibility and security of remote machine dispensing under the current 'paper based' prescription system.

#### **OPTION 10-6: MACHINE DISPENSING**

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

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<sup>275</sup> A.T. Kearney, [The future of community pharmacy in England](#) (2012).

## 11. APPENDICES

The following appendices are included to provide supporting information and context to the Interim Report:

- Appendix A: Summary of Findings and Options
- Appendix B: Review Terms of Reference
- Appendix C: Methodology and Approach
- Appendix D: Understanding Location Models – The Economics of Retail Market Location and Pharmacy Access
- Appendix E: Abbreviations and Explanations
- Appendix F: A History of the Community Pharmacy Agreements (1990–2015)
- Appendix G: Parallel Initiatives to Improve Primary Health Care Services
- Appendix H: People and Organisations Consulted as Part of the Review
- Appendix I: Key Topics and Themes from Submissions.



## APPENDIX A: SUMMARY OF FINDINGS AND OPTIONS

The following table includes the findings and options from the Interim Report.

**Table 11: Summary of findings and options**

### Chapter 2: Consumer Access and Experience

Finding	Option
<b>PRICING VARIATIONS</b> The variation in pricing for medicines due to pharmacy pricing discretion creates consumer confusion.	<b>OPTION 2-1: PRICING VARIATIONS</b> The payment made by any particular consumer for a PBS-listed medicine should be the co-payment set by the government for that consumer or the dispensed price for that medicine, whichever is the lower. A community pharmacy should have no discretion to either raise or lower this price.
<b>THE \$1 DISCOUNT</b> The \$1 discount has not led to appropriate outcomes for consumers.	<b>OPTION 2-2: \$1 DISCOUNT</b> The government should abolish the \$1 discount on the PBS patient co-payment.
<b>PBS SAFETY NET</b> The current PBS Safety Net system is not transparent and is difficult for consumers to document and understand. The lack of transparency and understanding also results in the Safety Net not being utilised to the extent possible, which disadvantages the more vulnerable consumers.	<b>OPTION 2-3: PBS SAFETY NET</b> In relation to the PBS Safety Net, the government should: <ol style="list-style-type: none"> <li>require the PBS Safety Net to be managed electronically for consumers. This expectation should be automatic from the consumer's perspective</li> <li>investigate whether the PBS Safety Net scheme can be adjusted to spread consumer costs over a twelve-month period</li> <li>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</li> <li>investigate and implement an appropriate system which allows payments for opiate dependence treatments to count towards the PBS Safety Net.</li> </ol>
<b>LABELLING</b> The label is a vital part of the supply of PBS medicines. It is relied on by patients and health professionals for the proper identification, dosage, categorisations and monitoring of medicines.	<b>OPTION 2-4: LABELLING</b> All PBS medicines provided to patients should be appropriately labelled and dispensed. Where there is a system in place that involves 'remote' dispensing or 'bulk supply' then this system will require appropriate monitoring to ensure the quality of medicine supply.
<b>CONSUMER INFORMATION ON PHARMACY SERVICES</b> Information about pharmacy services is inconsistent and inadequate to support sufficient consumer awareness and choice.	<b>OPTION 2-5: PHARMACY ATLAS</b> There should be an easily accessible and searchable 'atlas' of all community pharmacies in Australia that provides key patient information, including the services and programs offered by that 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).
<b>CONSUMER MEDICINES INFORMATION</b> While Consumer Medicines Information (CMI) leaflets are generally available, there are variances in how these are provided to consumers. Some consumers may be unaware of the availability of a CMI	<b>OPTION 2-6: CONSUMER MEDICINES INFORMATION</b> A Consumer Medicines Information (CMI) leaflet should be offered and made available to consumers with all prescriptions dispensed in accordance with Pharmaceutical Society of Australia (PSA) guidelines. The PSA guidelines and the distribution of CMIs to consumers need to be audited and enforced to ensure compliance. Pharmacists and the pharmacy industry should continue to work on the improvement of CMIs and the use of technology to make

Finding	Option
and there is a risk that these may not be provided, which could impact on quality of care.	medicines information more available to consumers.
<b>THE BENEFITS OF AN ELECTRONIC HEALTH RECORD FOR CONSUMERS</b> The current paper-based system of prescriptions used in Australia is outdated. It inhibits the creation of a universal medication record for Australians, creates excessive administration, is less convenient for consumers and presents significant challenges in meeting the standard required for quality use of medicines.	<b>OPTION 2-7: ELECTRONIC PRESCRIPTIONS</b> The 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 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 patient who is seeking to fill a PBS prescription.
<b>ELECTRONIC RECORD KEEPING</b> Australia lacks an integrated and effective universal health record system. This reduces consumer access to best-practice care and continuity of care between providers.	<b>OPTION 2-8: ELECTRONIC MEDICATIONS RECORD</b> The electronic personal medications record should cover all Australians and ensure appropriate access by, and links between, community pharmacy, hospitals and all doctors. This record should also include a vaccines register.
<b>MANAGING RISKS ASSOCIATED WITH 'CHANNELLING' PRESCRIPTIONS</b> The introduction of a compulsory electronic prescription record could introduce risks of inappropriate behaviour, such as channelling of prescriptions, that will need to be managed appropriately.	<b>OPTION 2-9: ELECTRONIC PRESCRIPTIONS – CONSUMER CHOICE</b> The choice of where a consumer has an electronic prescription dispensed should remain a decision for that consumer. The consumer may request that the electronic prescription 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 may not direct an electronic prescription to a particular community pharmacy for dispensing. This will require appropriate oversight and enforcement by professional bodies.
<b>MANAGING MEDICINE RISKS ASSOCIATED WITH HOSPITAL DISCHARGE AND READMISSION</b> The lack of a robust framework for the management of medicines between hospitals and community pharmacies creates risks for patients on discharge.	<b>OPTION 2-10: MANAGING MEDICINE RISKS FOR PATIENTS UPON DISCHARGE</b> 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. 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.

### Chapter 3: The Role of Community Pharmacy in Medicine Supply

Finding	Option
<b>THE ROLE OF COMMUNITY PHARMACY</b> There are certain minimum services that all community pharmacies should provide in order to meet consumer and government expectations about the level of consistency that is required from a national pharmacy network.	<b>OPTION 3-1: COMMUNITY PHARMACIES – MINIMUM SERVICES</b> The government should establish a process to determine the set of minimum requirements that a community pharmacy must meet in order to receive remuneration for dispensing. The government should initiate procedures to enforce these requirements and to have them updated at regular intervals. These requirements should be promoted by being incorporated within the Community Pharmacy Service Charter.
<b>COMPLEMENTARY MEDICINES</b>	<b>OPTION 3-2: COMPLEMENTARY MEDICINES – SUPPLY FROM</b>

Finding	Option
Consumers value access to complementary medicines in the community pharmacy setting, where they can receive advice on their selection and use that is backed by an appropriate level of evidence.	<b>PHARMACIES</b> Community pharmacists are encouraged to: <ol style="list-style-type: none"> <li>display complementary medicines for sale in a separate area where customers can easily access a pharmacist for appropriate advice on their selection and use</li> <li>provide appropriate information to consumers on the extent of, or limitations to, the Therapeutic Goods Administration (TGA) role in the approval of complementary medicines. This could be achieved through the provision of appropriate signage (in the area in which these products are sold) that clearly references any limitations on the medical efficacy of these products noted by the TGA.</li> </ol>
<b>PHARMACY ONLY AND PHARMACIST ONLY MEDICINES (SCHEDULE 2 AND SCHEDULE 3 MEDICINES)</b> Complementary medicines pose a risk to consumers when they are not clearly separated from Pharmacy Only and Pharmacist Only (Schedule 2 and Schedule 3) medicines.	<b>OPTION 3-3: PLACEMENT OF PHARMACY ONLY AND PHARMACIST ONLY (SCHEDULE 2 AND SCHEDULE 3) MEDICINES WITHIN A PHARMACY</b> Access to Pharmacy Only (Schedule 2) and Pharmacist Only (Schedule 3) medicines should be clearly separated from complementary medicines within a pharmacy. Options to achieve this might include: <ol style="list-style-type: none"> <li>ensuring that all Pharmacy Only (Schedule 2) and Pharmacist Only (Schedule 3) medicines only be accessible from ‘behind the counter’ in a community pharmacy so that a consumer must always seek assistance or advice in obtaining these medicines</li> <li>requiring that complementary medicines are not displayed ‘behind the counter’ in a community pharmacy.</li> </ol>
<b>HOMEOPATHIC PRODUCTS</b> There are unacceptable risks where community pharmacies are allowed to sell homeopathic products.	<b>OPTION 3-4: SALE OF HOMEOPATHIC PRODUCTS</b> 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 4: Community Pharmacy Remuneration by Government

Finding	Option
<b>SOURCES AND TRANSPARENCY OF PHARMACY REMUNERATION</b> The extent and quality of data and information is currently not adequate to inform decisions and determinations about the costs related to an efficient dispensing service.	<b>OPTION 4-1: ACCOUNTING INFORMATION</b> As soon as possible following the completion of this Review, the government, in consultation with the Pharmacy Guild of Australia and other stakeholders, should: <ol style="list-style-type: none"> <li>determine a set of accounting principles that will apply for community pharmacies in order to provide the relevant information needed to determine the best-practice benchmark cost of a dispense (as these terms are defined in this report)</li> <li>require community pharmacy (as a condition of being approved to dispense PBS medicines) to provide the necessary accounting information to inform consideration in the development of each Community Pharmacy Agreement (including as a basis for the determination of a best-practice pharmacy). The relevant accounting information should be provided</li> </ol>

Finding	Option
	<p>for each financial year and no later than 31 December of the following financial year (beginning with 31 December 2018)</p> <p>c. designate a body within the government (although potentially an existing independent statutory authority with the relevant expertise such as the Pharmaceutical Benefits Remuneration Tribunal or, more broadly, the Australian Competition and Consumer Commission) to provide a recommendation to the government on the best-practice benchmark cost of a dispense as required over time by the government. The first such advice is to be provided as soon as practical and certainly before the end of 2019. The timing of later determinations will depend on the process used in the future by the government to set the remuneration for dispensing PBS medicines</p> <p>d. the information and advice submitted to the government should form the basis for the average remuneration for a 'dispense' to community pharmacy in the future and certainly from the expiration of the Sixth Community Pharmacy Agreement. The provision of appropriate accounting information should be an ongoing requirement to support the development of each Community Pharmacy Agreement.</p>
<p><b>BASIS OF EFFICIENT DISPENSING COST/REMUNERATION</b></p> <p>Remuneration should be based on the efficient costs of dispensing within a best-practice pharmacy.</p>	<p><b>OPTION 4-2: REMUNERATION TO BE BASED ON EFFICIENT COSTS OF DISPENSING</b></p> <p>The remuneration for dispensing paid by government and consumer co-payments to community pharmacy should be based on the costs of dispensing for an efficient pharmacy.</p> <p><b>OPTION 4-3: BENCHMARK FOR AN EFFICIENT DISPENSE</b></p> <p>On the basis of the information that has been made available to the Panel, and given the data limitations, the Panel considers that the current benchmark for a best-practice dispense be set within a range of \$9.00 to \$11.50. This should be reflected in the average remuneration paid to a pharmacy for a dispense.</p>
<p><b>THE COSTS OF DISPENSING</b></p> <p>Remuneration for dispensing should be based on the incremental costs of dispensing rather than fully distributed or stand-alone costs.</p>	<p><b>OPTION 4-4: REMUNERATION FOR DISPENSING – FORMULA</b></p> <p>The remuneration for dispensing should be a simple dispense fee based on the efficient, average, long-run incremental cost of a dispense in a community pharmacy.</p>
<p><b>STRUCTURE OF REMUNERATION FOR DISPENSING</b></p> <p>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 and simplicity of government payments.</p>	<p><b>OPTION 4-5: REMUNERATION LIMITS</b></p> <p>If the government does not place an upper limit on the wholesale payment for a community pharmacist then the 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 either a flat fee or two-part tariff, the average payment for a dispense should equal the required fee determined by the government, following the acceptance of Option 4-4.</p>

Finding	Option
<b>REMUNERATION – ALTERNATIVE SERVICE CHANNELS</b> Government is currently paying different amounts through different mechanisms for the same service supplied by different primary health professionals.	<b>OPTION 4-6: REMUNERATION FOR OTHER SERVICES</b> Government should require that if the same service is offered through alternative primary health outlets then the same government payment should be applied to that service, regardless of the specific primary health professional involved.

## Chapter 5: The Regulation of Pharmacy for Medicine Supply

*Given the Government's recent commitment in the 2017–18 Budget to continue the current pharmacy location rules, the Panel considers that options 5-1, 5-2 and 5-3 are no longer immediately relevant to this Review. They have been presented but will not be considered further by the Panel. However, the Panel will continue to consider options to modify the location rules that have been put forward on the assumption that the current location rules will be retained.*

Finding	Option
<b>REFORMS TO PHARMACY LOCATION RULES</b> Certain aspects of the pharmacy location rules are limiting competition and are unnecessary in some areas.	<b>OPTION 5-1: LOCATION RULES – REMOVAL AND REPLACEMENT</b> The government should remove the location rules for community pharmacies. It should replace the location rules with one of the alternatives presented below. <b>OPTION 5-2: URBAN LOCATION RULES</b> <b>5-2. ALTERNATIVE 1:</b> The government should undertake an analysis (as per Option 4-2) to determine and implement efficient remuneration for the dispensing of PBS medicines. Following the implementation of efficient remuneration and a suitable transition period (no later than 31 December 2020), the government should remove any restrictions to limit the ability of any qualified pharmacist or pharmacists to establish a pharmacy to dispense PBS medicines at any location in urban areas. <b>5-2. ALTERNATIVE 2:</b> The government should replace the location rules in urban areas in two stages: <ol style="list-style-type: none"> <li>For the first five years, the government should:               <ol style="list-style-type: none"> <li>establish an independent statutory authority (the Pharmacy Location Board (PLB)) of five members, at least two of whom are persons who have been, but are no longer, engaged either directly or indirectly in community pharmacy. No PLB member may be a current pharmacy owner. Any pharmacist wishing to establish a new pharmacy in an urban location would be required to apply to the PLB for a provider number. The PLB would assess all such applications and engage in relevant consultation as it sees fit. The PLB would issue a provider number if (and only if) in the opinion of the PLB, this would materially improve consumer access to PBS medicines</li> <li>undertake an analysis (as per Option 4-2 above) to determine and implement efficient remuneration for the dispensing of PBS medicines.</li> </ol> </li> <li>Prior to the end of the five-year period, the government should assess whether the PLB is required in urban areas or whether consumer access to PBS medicines would be appropriately served by removing any remaining restrictions that limit the ability of any qualified pharmacist or pharmacists to establish a pharmacy to dispense PBS medicines at any location in urban areas.</li> </ol>

Finding	Option
	<p><b>5-2. ALTERNATIVE 3:</b> New pharmacy location rules should be introduced based on existing rules. This includes:</p> <ol style="list-style-type: none"> <li>retention of the prohibition within the location rules relating to the co-location of approved pharmacies in supermarkets</li> <li>the establishment by the Department of Health and the Guild of a joint working group with the aim of identifying and addressing any anomalies that have arisen over time, to ensure the location rules remain responsive to the evolving needs of the community.</li> </ol> <p><b>OPTION 5-3: NON-URBAN LOCATION RULES</b></p> <p><b>5-3. ALTERNATIVE 1:</b> The government should replace the pharmacy location rules in non-urban areas by establishing an independent statutory authority (the Pharmacy Location Board (PLB)) of five members, at least two of whom are persons who have been, but are no longer, engaged either directly or indirectly in community pharmacy. No PLB member may be a current pharmacy owner. Any pharmacist wishing to establish a new pharmacy in a non-urban location would be required to apply to the PLB for a provider number. The PLB would assess all such applications and engage in relevant consultation as it sees fit. The PLB would issue a provider number if (and only if), in the opinion of the PLB, this would materially improve consumer access to PBS medicines.</p> <p>The PLB would also work with the local Primary Health Network (PHN) in any relevant region to determine areas where there is a lack of appropriate pharmacy services and work with the PHN to initiate a tender to seek options by pharmacists to provide the identified services. The government would appropriately fund PHNs and the PLB to carry out these tenders and, where relevant, to provide any subsidy determined through the tender process.</p> <p><b>5-3. ALTERNATIVE 2:</b> New pharmacy location rules should be introduced based on existing rules. This includes:</p> <ol style="list-style-type: none"> <li>retention of the prohibition within the location rules relating to the co-location of approved pharmacies in supermarkets</li> <li>the establishment by the Department of Health and the Guild of a joint working group with the aim of identifying and addressing any anomalies that have arisen over time, to ensure the location rules remain responsive to the evolving needs of the community.</li> </ol>
<p><b>REFORMS IF THE LOCATION RULES ARE RETAINED IN SOME PARTS OF AUSTRALIA</b></p> <p>The policy in respect of pharmacy location rules is unclear. This results in different interpretations of their purpose and intent and reduces the ability to monitor performance and the achievement of outcomes.</p>	<p><b>OPTION 5-4: LOCATION RULES – POLICY OBJECTIVE</b></p> <p>If the government retains the pharmacy location rules (or some version of these rules) following the end of the Sixth Community Pharmacy Agreement then the policy objective of these rules should be clearly stated and the rules modified to ensure that the desired outcomes are achieved over the medium term.</p> <p>The objective of the pharmacy location rules should be to assist the Australian consumer to ensure equitable and affordable access to medicines for all Australians, consistent with the National Medicines Policy, with evidence to demonstrate the achievement of this objective.</p>
<p><b>OVERLAPPING OWNERSHIP AND LOCATION OF PHARMACIES</b></p> <p>The pharmacy location rules have not established robust competition between independent pharmacies</p>	<p><b>OPTION 5-5: LOCATION RULES – OWNERSHIP AND LOCATION</b></p> <p>In areas where pharmacy location rules are maintained, any group of two or more pharmacies, each of which are located within 1.5 kilometres of another pharmacy in the group, that have an overlapping ownership should be considered to be a single pharmacy for the</p>



Finding	Option
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>application of the location rules.</p> <p>The nominal 'location' of this single pharmacy would be the location of the pharmacy within the group that had the smallest turnover (in terms of the number of Pharmaceutical Benefits Scheme scripts dispensed) in 2016.</p> <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>It is also considered that this option should be implemented five years after this Review to allow an appropriate time frame for transition. The oversight of this option should be undertaken by the Australian Competition and Consumer Commission.</p>
<b>PHARMACY ACCESS AND OPENING HOURS</b> In urban Australia, there are pharmacies currently operating with extended hours (from around 7 am to 11 pm); however, consumers often lack information about these pharmacies and they are not evenly spread through urban areas.	<p><b>OPTION 5-6: INFORMATION ON PHARMACY OPENING HOURS</b>            The Pharmacy Atlas (Option 2-5) should include information on pharmacy opening hours.</p> <p><b>OPTION 5-7: 24-HOUR PHARMACY INFORMATION AND RELATED SERVICES</b>            The government should investigate the feasibility of a 24-hour telephone and or internet 'pharmacy hotline' to provide medicine information to consumers Australia-wide.</p>
<b>THE RURAL PHARMACY MAINTENANCE ALLOWANCE</b> There are a number of anomalies in the administration of RPMA payments that serve to reduce the effectiveness of the program.	<p><b>OPTION 5-8: RURAL PHARMACY MAINTENANCE ALLOWANCE</b>            In situations where there is more than one pharmacy within a 10-kilometre area that is receiving the Rural Pharmacy Maintenance Allowance (RPMA), the government should:</p> <ol style="list-style-type: none"> <li>only make payments to a single pharmacy in the area</li> <li>ensure that the pharmacy that receives the RPMA is based on the programs offered by that pharmacy, including services, opening hours and location (centrality and ease of access)</li> <li>ensure that the selection process is transparent.</li> </ol>
<b>VARIATIONS AMONG STATE AND TERRITORY REGULATORY ARRANGEMENTS RELATING TO COMMUNITY PHARMACY</b> The community pharmacy sector is subject to a complex array of regulations made by state and territory governments as well as the Australian Government.	<p><b>OPTION 5-9: HARMONISING PHARMACY LEGISLATION</b>            As early as practicable, the Australian Government, through the Australian Health Minister's Advisory Council, should seek to harmonise all state, territory and federal 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. As an interim measure, state and territory registering bodies need to 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>
<b>TRANSPARENCY IN GOVERNMENT PROGRAMS</b> Community pharmacy expenditure and funding is insufficiently transparent to demonstrate value and performance in meeting the objectives of the National Medicines Policy.	<p><b>OPTION 5-10: TRANSPARENCY</b>            It is important that, for each program that involves public funding, there is sufficient transparency as to the amount of funding provided by the government and the amount of funding provided by the recipient of the service.</p>
<b>EVALUATING, MONITORING AND REPORTING ON REGULATION</b> There is a lack of coordination and consistency in the current	<p><b>OPTION 5-11: EVALUATION MECHANISMS</b>            The government should require the establishment of appropriate evaluation mechanisms to measure compliance and performance.</p>

Finding	Option
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.	

## Chapter 6: The Distribution of Medicines to Community Pharmacy

Finding	Option
<p><b>ENSURING TIMELY MEDICINE ACCESS</b></p> <p>Current supply chain arrangements (terms of trade and supply conditions) involve unnecessary regulation, as well as Community Service Obligation (CSO) payments that appear unconnected with relevant distribution costs, and may be leading to wholesale margins that are higher than necessary for an effective and efficient supply chain.</p>	<p><b>OPTION 6-1: COMMUNITY SERVICE OBLIGATION REMOVAL, RETENTION OR REPLACEMENT</b></p> <p><b>6-1. ALTERNATIVE 1:</b> The government should remove the Community Service Obligation (CSO), and suppliers of PBS-listed medicines should be placed under an obligation to ensure delivery to any community pharmacy in Australia within a specified period of time (generally 24 hours), with standard terms of trade offered to the pharmacy (such as four weeks for payment) using one or more of a specified panel of wholesalers as follows:</p> <ol style="list-style-type: none"> <li>an initial Panel of around five wholesalers would be approved. It is expected that these will include the existing CSO Distributors</li> <li>the relevant terms of trade and other supply conditions may vary between medicines. For example, for high-cost medicines or medicines that have cold-chain supply requirements, the supply conditions may differ from those for low-cost medicines to ensure that there is not an unreasonable risk or cost placed on either community pharmacy or consumers</li> <li>a cap should be placed on the amount that a community pharmacy contributes to the cost of a medicine. This cap should be in the range of \$700 to \$1000.</li> </ol> <p><b>6-1. ALTERNATIVE 2:</b> The government should retain the current CSO arrangements but ensure that all service standards, such as the 24-hour rule, are uniformly implemented.</p> <p><b>6-1. ALTERNATIVE 3:</b> The government should conduct a separate review of the CSO to ensure current arrangements demonstrate value for money. A review would also present an opportunity to potentially streamline existing or remove unnecessary regulation. Such a review would require the full cooperation of the CSO Distributors, which would provide financial data and other relevant information to government.</p>
<p><b>PROCEDURES AND REMUNERATION FOR THE SUPPLY OF HIGH-COST MEDICINES</b></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.</p>	<p><b>OPTION 6-2: SUPPLY OF HIGH-COST MEDICINES</b></p> <p>In line with Option 6-1, patients should be able to receive high-cost medicines from the community pharmacy of their choice.</p> <p>A cap should be placed on the amount that a community pharmacy contributes to the cost of a medicine. This cap should be in the range of \$700 to \$1000 so that all PBS-approved community pharmacies can supply all PBS medicines required by the public.</p>

## Chapter 7: Future Community Pharmacy Agreements

Finding	Option
<b>THE COMMUNITY PHARMACY AGREEMENT PROCESS</b> The Sixth Community Pharmacy Agreement (6CPA) process was not adequate, as reflected in the submissions to this review. The Australian National Audit Office (ANAO) was also critical of some of the processes in the Fifth Community Pharmacy Agreement (5CPA), which have been partially addressed in 6CPA.	<b>OPTION 7-1: SCOPE OF COMMUNITY PHARMACY AGREEMENTS – DISPENSING</b> 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. <b>OPTION 7-2: SCOPE OF COMMUNITY PHARMACY AGREEMENTS – WHOLESALING</b> The government should ensure that the regulation and remuneration of wholesaling of PBS-listed medicines should not form part of future Community Pharmacy Agreements. <b>OPTION 7-3: SCOPE OF COMMUNITY PHARMACY AGREEMENTS – PROGRAMS AND SERVICES</b> The regulation and remuneration of professional programs offered by community pharmacies should not form part of future Community Pharmacy Agreements. <b>OPTION 7-4: COMMUNITY PHARMACY AGREEMENT PARTICIPANTS</b> The parties invited to participate in future Community Pharmacy Agreements must include the Pharmacy Guild of Australia (as a representative of the majority of approved pharmacists), the Consumers Health Forum of Australia (as the peak representative consumer body in Australia on health-related matters) and the Pharmaceutical Society of Australia (as the peak representative body for pharmacists in Australia).

## Chapter 8: Health Programs Offered by Community Pharmacy

Finding	Option
<b>LEVERAGING PHARMACY AND PHARMACIST CAPABILITY</b> Significant opportunities exist for the better use of community pharmacy and pharmacist programs and services in improving the health of Australians.	<b>OPTION 8-1: DOSE ADMINISTRATION AIDS – STANDARDS</b> The government should establish clear, enforceable minimum standards for the supply of medicines by community pharmacies, including for dose administration aids (DAAs). There should also be appropriate compensation provided to community pharmacies for the dispensing of medicines using DAAs (in recognition that this tends to be a higher-cost activity than dispensing in manufacturer's packaging). <b>OPTION 8-2: COMMUNITY PHARMACY PROGRAM – KEY PRINCIPLES</b> The range of programs offered by community pharmacy should be underpinned by the following principles: <ol style="list-style-type: none"> <li>be based on evidence of effectiveness</li> <li>may or may not involve government paying for some or all of the cost of the service to some or all patients</li> <li>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 government payment) through pharmacies/pharmacists that are selected by the government (for example, through a tender process or as a result of negotiation between the government and the relevant pharmacies or pharmacists)</li> </ol>

Finding	Option
	<p>d. for some programs, government remuneration for the program will be channelled through the users of the program (or their representatives) so that the users will decide which community pharmacies (or pharmacists) to use to deliver the program</p> <p>e. adequate funding for the above needs to be found outside PBS expenditure.</p>

## Chapter 9: Access to PBS Medicines and Community Pharmacy Services for Aboriginal and Torres Strait Islander People

Finding	Option
<p><b>SECTION 100 REMOTE AREA ABORIGINAL HEALTH SERVICES PROGRAM</b></p> <p>Access to medicines for Indigenous Australians under the section 100 RAAHS Program and the CTG PBS Co-Payment Measure has created a number of challenges in ensuring a consistent level of care to the intended patient group.</p>	<p><b>OPTION 9-1: ACCESS TO MEDICINES PROGRAMS FOR INDIGENOUS AUSTRALIANS</b></p> <p>The access to medicines programs for Indigenous Australians under the section 100 RAAHS Program and the Closing the Gap PBS Co-Payment Measure should be reformed so that the benefits to the individual follow that individual, regardless of where the prescription is written or dispensed.</p>
<p><b>PHARMACY OWNERSHIP AND OPERATIONS BY ABORIGINAL HEALTH SERVICES</b></p> <p>The current inability of an AHS to operate a community pharmacy poses a significant risk to patient health in some rural and remote areas of Australia.</p>	<p><b>OPTION 9-2: ABORIGINAL HEALTH SERVICE PHARMACY OWNERSHIP AND OPERATIONS</b></p> <p>All levels of government should ensure that any existing rules that prevent an Aboriginal Health Service (AHS) from owning and operating a community pharmacy located at the AHS are removed. As a transition step, these changes should first be trialled in the Northern Territory, and governments should work together with any AHS that wishes to establish a community pharmacy.</p>

## Chapter 10: Further Issues

Finding	Option
<p><b>SECTION 100 HIGHLY SPECIALISED MEDICINES</b></p> <p>The distinction between highly specialised and other PBS medicines is causing administrative inefficiencies and unnecessary risks to patient health.</p>	<p><b>OPTION 10-1: SECTION 100 HIGHLY SPECIALISED DRUGS</b></p> <p>The Highly Specialised Drugs (HSD) 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 within section 100 HSD arrangements. This should include, for example, harmonising access and fees regardless of where the medicine is dispensed.</p>
<p><b>CHEMOTHERAPY COMPOUNDING – PAYMENTS</b></p> <p>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 TGA licensed or non-TGA-licensed facility.</p>	<p><b>OPTION 10-2: CHEMOTHERAPY COMPOUNDING – PAYMENTS</b></p> <p>There should be no difference in the remuneration paid by the 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 that are prepared in a facility that exceeds the minimum standards.</p>

### **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.

### **OPTION 10-3: CHEMOTHERAPY COMPOUNDING – UNIFORM MINIMUM STANDARDS**

There should be a clear, uniform set of minimum quality standards for all approved chemotherapy compounding facilities based in a hospital, a community pharmacy or elsewhere. These minimum standards should:

- a. not require that a compounding facility be Therapeutic Goods Administration (TGA) licensed to meet the minimum requirements
- b. mean that a TGA-licensed facility clearly satisfies the minimum standards
- c. reflect the variety of settings that are appropriate for the preparation of chemotherapy medicines, including ‘urgent’ preparation in a hospital setting or a community pharmacy setting.

### **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.

### **OPTION 10-4: CHEMOTHERAPY COMPOUNDING – PRACTICE MODELS**

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

### **TIGHTENING THE LISTING OF GENERIC MEDICINE**

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

### **OPTION 10-5: GENERAL MEDICINE – LISTING ARRANGEMENTS**

When an ‘original’ (or ‘branded’) medicine comes off patent then the government should hold a tender for the listing of generic versions of the medicine. The 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 required by the government at the least cost to the PBS.

### **MACHINE DISPENSING**

Overseas experience has demonstrated advantages in the use of remote dispensing machines.

### **OPTION 10-6: MACHINE DISPENSING**

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

## APPENDIX B: REVIEW TERMS OF REFERENCE

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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;



- 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: METHODOLOGY AND APPROACH

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As expected from a consumer-focused approach, the Review has sought to obtain a robust and diverse evidence base to inform the options presented in this Interim Report. This has included consideration of information and data from a breadth of sources to appropriately recognise the challenges and opportunities faced across the community pharmacy sector.

Following the release of the Discussion Paper, the Panel commenced a national consultation process, which was held from 1 August 2016 to 7 September 2016.

The consultations offered a valuable opportunity for the Panel to speak directly with interested parties and gain a firsthand view of community pharmacy in Australia and the factors contributing to patient health outcomes and the quality use of medicines.

The Panel has engaged directly with over 1200 people who attended the 16 public forums held in all capital cities as well as in major regional centres, select remote areas and online through a live national webcast.

During the consultation process, the Panel was also fortunate to hold over 90 site visits and consultations with pharmacists, consumer organisations, Aboriginal Health Services, members of the medicine supply chain and state and territory governments.

The Review received an overwhelming response to the Discussion Paper, with over 500 submissions made by interested parties from the pharmacy, wholesaling, hospital and consumer sectors. This included a strong response from individual pharmacy owners and employee pharmacists, which represented approximately 57 per cent of submissions to the Review.

A summary of the themes of submissions received are presented in Appendix I.

The level of response highlighted the sector's strong engagement with the issues raised in the Discussion Paper and a willingness to have their say on the future of community pharmacy.

Overall, the submissions contained a wealth of information to inform the Panel's deliberations that ranged from responses to specific questions posed in the Discussion Paper, personal financial information, commercial and third-party data, commissioned research, personal case studies and experiences, consumer views and references to overseas arrangements.

All submissions in response to the Discussion Paper were considered by the Panel in preparing this Interim Report.

To complement the information obtained through the submissions and the national consultation process, the Review commissioned independent research and analysis from the following external consultants and subject matter experts.

## QUALITATIVE AND QUANTITATIVE CONSUMER RESEARCH (HALL AND PARTNERS | OPEN MIND)

Qualitative research was conducted with consumers of pharmacy services with the objective of understanding their perspectives and experiences in more detail. This comprised 20 face-to-face group discussions, 26 in-depth interviews and two online forums conducted with consumers and patients from across Australia. In addition, quantitative research was conducted through an online self-completion survey which sought to identify which services and programs that consumers value from community pharmacy. The survey comprised questions tailored to suit consumers as well as professionals working in pharmacies. This resulted in valuable feedback and insights from over 1800 members of the Australian public and the pharmacy industry.

## TARGETED CONSULTATIONS WITH CONSUMER ORGANISATIONS (CONSUMERS HEALTH FORUM OF AUSTRALIA)

Our targeted consultations with consumer organisations involved the collection and collation of the views of consumer organisations with the aim of identifying consumer attitudes, expectations and priorities in relation to the provision of medicines and pharmacy services in Australia.

It involved in-depth telephone interviews with identified stakeholders to gather consumer representative views as well as telephone focus groups with a subset of consumer stakeholders to test the themes arising from interviews.

## PHARMACY COST MODELS AND ANALYSIS (MEDICI CAPITAL)

The Review was assisted by an independent pharmacy valuation firm in developing pharmacy cost models, including the analysis of the financial remuneration, costs and cost drivers for community pharmacy associated with dispensing. This was in addition to the analysis of front-of-store sales (over the counter and retail items) and key PBS data variables.

## INTERNATIONAL LITERATURE REVIEW (DELOITTE ACCESS ECONOMICS)

The international literature review entailed a comprehensive study and analysis of literature relating to the models in place for the remuneration and regulation of community pharmacies in twelve overseas jurisdictions, including a comparative analysis of selected overseas models with Australia's current arrangements under the Sixth Community Pharmacy Agreement (6CPA).

## PHARMACY FINANCIAL SURVEY (HALL AND PARTNERS | OPEN MIND)

The pharmacy financial survey involved the conduct of a quantitative survey to obtain financial data regarding the level and structure of remuneration for community pharmacy for dispensing of medicines under the PBS and the delivery of professional services. The survey assisted in the collection of data to build representative financial models of pharmacy in different locations across Australia, reflective of different business models and any other operating conditions.

## PROVISION OF FINANCIAL ANALYSIS AND MODELLING TO SUPPORT THE REVIEW (RSM AUSTRALIA)

The financial analysis and modelling work included the modelling of the level and structure of remuneration for community pharmacy for the dispensing of medicines under the PBS and the wholesaling, logistics and distribution of medicines from manufacturer to community pharmacy as well as detailed financial mapping of the financial costs flowing through the pharmacy supply chain.

The options presented in this Interim Report are based on the best information available to the Panel.

The information and data gathered through consultations, submissions and expert consultancies has contributed equally and without bias to this evidence base. To be as transparent as possible and to encourage public trust in the Review process, all non-confidential submissions and consultant reports have been published on the Review website with the agreement of authors.

To ensure our options for consideration align, wherever possible, with the Australian Government's broader healthcare agenda, the Panel also considered:

- a. the findings and recommendations from other relevant Reviews, namely the:
  - i. National Commission of Audit Report, *Towards responsible government*
  - ii. Competition Policy Review (Harper Review)
  - iii. Australian National Audit Office *Report No. 25 (2014–15) Administration of the Fifth Community Pharmacy Agreement*
  - iv. Australian National Audit Office *Report No. 9 (2016–2017) Community Pharmacy Agreement: Follow-on audit*
  - v. Productivity Commission Research Paper, *Efficiency in health*
- b. more recent government initiatives, designed to introduce major reform to Australia's primary healthcare system in relation to access, support, coordination and the provision of quality care.

## APPENDIX D: UNDERSTANDING LOCATION MODELS – THE ECONOMICS OF RETAIL OUTLET LOCATION AND PHARMACY ACCESS

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The following more detailed analysis on the use of economic models is provided in support of the review conclusions concerning pharmacy location rules presented in Chapter 5 (The Regulation of Pharmacy for Medicine Supply).

### SUMMARY

The location rules for community pharmacy in Australia limit the potential for new pharmacies to open or for existing pharmacies to relocate. There are questions about the effects of these rules with competing claims made that they either increase and decrease consumer access.

The economic theory around the entry and location of competing retail outlets is well developed and uncontroversial. It provides important results that can assist in understanding the location rules and the interaction between these rules and other parts of the regulation and remuneration of community pharmacy in Australia. In brief, the operation of a ‘free market’ for retail outlets can lead to:

- a. for a fixed number of retail outlets, those outlets locating either ‘too close’ or ‘too distant’ from an economic perspective. However, there are often strong incentives for outlets to locate in a way that minimises average customer access costs. This is particularly the case when new outlets can threaten to enter the market
- b. for a variable number of retail outlets (i.e. entry by any outlet that believes it is profitable to do so), there may be too few outlets but, if there are fixed costs of entry and ‘economic rents’ (i.e. if incumbent outlets make operating profits that exceed their fixed costs), there will often be economically excessive entry. In other words, the gain in customer access created by an increased number of outlets is more than offset by the costs of establishing and operating the extra outlets.

Also:

- c. the examination of the location and number of retail outlets and any ‘price control’ cannot be analysed separately.

These three conclusions from economic theory are critical to the Review of Pharmacy Remuneration and Regulation. For community pharmacy in Australia, government funds provide a substantial part of most pharmacy’s revenue and profit. As such:

- a. If, from the perspective of consumer access, there is a tendency for excessive entry of pharmacies in a region then this reflects that government payments to pharmacies in that region (e.g. the dispensing fee and any other fees paid by the government, including the Rural Pharmacy Maintenance Allowance) are too high and economic welfare will be improved by reducing these payments. If, in contrast, there are too few pharmacies in a region for appropriate consumer access, government payments to pharmacies in that region are too low and economic welfare will be improved with improved consumer access by raising these payments.
- b. If the government sets the level of pharmacy remuneration so that the number of pharmacies in a region is at the appropriate level for consumer access overall then it is likely that these pharmacies will distribute themselves over the region over time approximately in

ratio with the distribution of customer demand. This is particularly the case where the government does not prevent entry by a new pharmacy that can compete against and potentially ‘displace’ an existing pharmacy.

Together, these implications mean that, while the distribution of pharmacies in a region may not be ‘perfect’, if there is an issue of too many or too few pharmacies overall then this should be dealt with by a change in government remuneration for pharmacies. It is possible that some sort of ‘location rules’ or government process to locate pharmacies in a region could improve ‘access’ for some consumers (while lowering access for others). However, existing location rules that are based on arbitrary distances and proxies for consumer ‘traffic flow’ are unlikely to improve consumer access. Indeed, these rules may reduce consumer access both by limiting the number of pharmacies in recognised high-traffic-flow areas and preventing pharmacies from locating in areas that may have a higher traffic flow than that measured by the proxies used in the rules. Further, by removing the threat of entry, the location rules themselves can provide incentives for pharmacies to cluster.

The remainder of this note is divided into two parts. The first part presents the economic theory relating to the location and entry of retail outlets. The second part then considers how the economics presented in the first part of this note applies to the Australian situation.

## THE ECONOMICS OF RETAIL OUTLET LOCATION

There is a large number of ‘location models’ used in economics to predict where retail outlets will locate relative to the distribution of consumers.

For example, in Appendix C of its submission to the *Competition Policy Review draft report*, the Pharmacy Guild of Australia presents a simple fixed-price, two-outlet, linear Hotelling model. This model has a uniform distribution of consumers so that access is maximised if the two outlets space themselves evenly along the line. It has linear distance costs (i.e. the loss to each consumer increases proportionately to distance as access decreases) and identical fixed prices for each outlet. There is no threat of entry in the model. The existing outlets do not have to be concerned about a third outlet commencing operations.

In this framework, competition can lead to ‘minimum differentiation’ (i.e. excessive clustering of outlets), as shown in the Guild’s submission.

However, it is well known that this result is extremely sensitive to the specific modelling assumptions, including the number of outlets and the access cost for consumers. As Church and Ware (2000, p. 402) state, “the principle of minimum differentiation is not robust”.

For example, using the same Hotelling framework, if there are four outlets, fixed prices and no threat of entry by a fifth outlet, the outlets will be bunched in two different locations. In this situation, from the perspective of consumer access, there is excessive bunching of outlets. However, *given there are only chosen two locations*, these locations minimise average consumer access costs.

Similarly, if the Hotelling framework is modified to allow for entry (i.e. any outlet that considers that it can profitably enter the market can do so) then, with sequential entry by outlets, the outlets will be evenly spread so that, given the number of outlets that enter, average consumer access costs are minimised.



Alternatively, we could modify the Hotelling framework so that there are only two outlets with no possibility of entry but allow each outlet to independently set its own prices. Further, suppose that the cost of access for a customer increases at an increasing rate (formally, a quadratic cost function) as an outlet moves further from that customer. In this situation, the standard Hotelling model leads to an excessive ‘spread’ of the two outlets.<sup>276</sup>

Critically, the Hotelling results also depend on the nature of customer preferences in the model. In a ‘circular city’ model (customers are distributed around a circle rather than along a line) the distribution of outlets tends to be ‘optimal’. Given the number of retail outlets, these outlets spread themselves in a way that ‘mirrors’ the customer population base. This ‘spread’ minimises the average access cost for customers, with or without either the threat of entry or regulated prices.

In summary, while the Hotelling analysis presented by the Guild is correct, *given only two outlets, regulated prices and no entry*, the extreme clustering noted in the analysis breakdowns and can be reversed once the relevant modelling assumptions are varied. Importantly, the Hotelling framework presented by the Guild shows that there are significant pressures on outlets to locate in a way that reduces average consumer access costs once there are more than two outlets, and particularly if there are no restrictions on the potential for entry by competing outlets. As Church and Ware (2000, p. 395) note, in such a situation, “[g]iven the same number of brands, the sequential entry and socially optimal locations are the same”. While there may be ‘too many’ or ‘too few’ outlets, the policy issue is the number of outlets, not their location.

Intuitively, the decision about location for a retail outlet involves two offsetting factors. First, each business wishes to move to the location with the greatest flow of customers. This raises the business’s profit by raising the demand for the products it sells. Secondly, each business wishes to locate away from its competitive rivals. Locating close to rivals increases competition in terms of ‘sharing’ customer flow, reduced prices (if prices are not regulated) and other factors that attract customers.

The market outcome for outlets depends on the interplay of these two factors. As Tirole (1988, p. 286) notes, “although firms like to differentiate for strategic purposes, they also want to locate where the demand is”. The actual balance between these factors will depend on the exact market circumstances.

For example, price regulation reduces the competitive loss of profits when firms cluster. Thus, we would expect to see more clustering when there is tight price regulation than when outlets compete over prices.

When there are more outlets sharing the flow of customers at a particular location, the incentives are stronger for each outlet to move away from the cluster to a location where there may be lower overall customer flow, but the outlet is not sharing that flow with as many competitors. This means that the ‘minimum differentiation’ result breaks down as soon as there are more than two outlets.

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<sup>276</sup> If there are only two outlets, each of which can set its own price, with no threat of entry and linear customer access costs then there is no ‘simple’ solution to the Hotelling model. However, the ‘minimal differentiation’ result is no longer stable.

When it is possible for a new outlet to enter and locate in an area that is underserved from the consumers' perspective, there is a strong incentive for existing firms to locate their outlets to minimise underserved areas. Entry intensifies competition and reduces the profit of incumbent outlets. Thus when entry is possible, incumbent outlets have an incentive to minimise any 'gaps' in the market as this deters new entry and protects their individual profits. For this reason, the potential for entry may not lead to an optimal number of outlets, but it does create strong incentives for the outlets that do emerge to locate in a way that minimises average customer access costs.<sup>277</sup>

There may also be a third factor that promotes clustering: if consumers face significant search costs and so will reduce their costs by shopping in a location where there are numerous outlets. It should be noted that in this situation clustering *benefits* consumers by reducing their costs of 'shopping around'. It has not been suggested that this third factor is significant for community pharmacy in Australia and so is not analysed in any detail here.

## THE ECONOMICS OF ENTRY

The economic analysis of outlet location discussed above shows that, for a given number of outlets, location *may* be an issue in terms of customer access. However, there are significant economic factors that suggest that location will *not be a key problem*, particularly if there is the potential for new outlets to enter the market. Rather, the key issue for both customer access and broader economic welfare will be the number of outlets that emerges in any region.

It is relatively simple to show that there can be excessive entry at a retail level. For example, the 'circular city' model will generally lead to excessive entry from an economic perspective.<sup>278</sup> More generally, Mankiw and Whinston show that, for homogeneous products, if new outlets are able to commence operations without regulatory restriction but there are excessive 'economic rents' available for market participants, then as a 'general rule' there will be excessive entry.<sup>279</sup>

'Economic rents' can arise if either moderate levels of retail competition (what economists call 'imperfect' competition) or when there is price regulation and the regulated prices are above the average operating costs for each retail outlet. In other words, there are economic rents when the operating profit of an outlet exceeds the fixed costs of establishing the outlet.<sup>280</sup> In such a situation, new entry of outlets will be encouraged as each potential competitor observes that it is able to make profit by opening a new outlet and gaining some of the economic rent. This process will continue until the economic rent disappears – when the operating profits of the marginal outlet just cover the fixed costs of establishing the outlet.

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<sup>277</sup> For details on the economics of retail outlet location, see J. Church & R. Ware, *Industrial organization: A strategic approach*, McGraw Hill, Boston, MA (2000), section 11.4; and J. Tirole, *The theory of industrial organization*, MIT Press, Cambridge, MA (1988), section 7.1.

<sup>278</sup> See J. Tirole, *The theory of industrial organization*, MIT Press, Cambridge, MA (1988), section 7.1.2.

<sup>279</sup> G. Mankiw & M.D. Whinston, 'Free entry and social inefficiency', *RAND Journal of Economics*, vol. 17 (1986), pages 48–58.

<sup>280</sup> It should be noted that operating profit and fixed costs are used here as economic terms. Accounting costs and profits must be modified to satisfy the economic definition. For example, a putative wage for an owner who also works in an outlet is not an accounting cost but an economic cost.

Such entry is excessive because there are too many ‘small’ outlets, each expending resources to set up in the market. Economic welfare would be improved with fewer outlets, each with more sales.

It is possible to have too little entry, particularly if there is a relatively ‘thin’ market and the benefits to consumers from retail entry that are not captured by an outlet, are relatively high. For example, in a simple Hotelling model, if there are too few customers and the regulated price for an outlet is too low, then even a single outlet may fail to open, even though this failure of supply could lead to a substantial loss to consumers. Put simply, any operating profit that even a single outlet could generate will not cover the relevant fixed costs of establishing the outlet, even though the operating profit and the consumer benefits *together* do cover the fixed costs.

Both excessive and insufficient entry depends on the level of ‘economic rents’ or the gap (if any) between operating profits and fixed establishment costs. If this gap can be manipulated by the government then the issue of excessive or insufficient entry can be overcome.

For example, if there is excessive entry so that, without restrictions, too many outlets will open in a region, this can be ameliorated by the government reducing the operating profits of each outlet. The government could tax each outlet or, if the government controls operating profit – for example, through price controls – then the government could directly lower that profit. Conversely, if there is insufficient entry, the government can encourage entry by a subsidy or direct payment to an outlet.

Regulatory options are discussed in more detail below.

## APPROACHES TO REGULATING OUTLET NUMBERS AND LOCATIONS

The discussion of entry and location presented above implies that, as a matter of economics, a free market is unlikely to lead to a number of outlets that efficiently supplies consumers. In some situations, there will be excessive entry with too many ‘small’ outlets. However, it is also possible that there will be too few outlets in a region, particularly where the consumer population is low but the benefits to consumers from increased access are high. Further, outlets may not locate in an optimal way to trade off the costs of provision (economies of scale) and customer access. However, location problems are likely to be reduced if new outlets can threaten to commence operations and location problems are likely to be less significant than problems with the number of outlets, particularly where there are significant ‘economic rents’ available to outlets.

In such a situation, government regulation may be able to improve the market outcome. Church and Ware identify three forms of regulation.<sup>281</sup> In summary (and the context of this Review) these are:

1. *First best*: The government can perfectly regulate the number of outlets, the prices and other characteristics that matter to consumers and determine outlet profit, and the specific locations to maximise economic welfare.
2. *Behavioural second-best*: The government regulates the remuneration level of outlets (and hence their operating profit) but then leaves it to free-entry to determine the exact number and location of outlets.

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<sup>281</sup> J. Church & R. Ware, *Industrial organization: A strategic approach*, McGraw Hill, Boston, MA (2000), page 374.

3. *Structural second-best*: The government regulates the number and location of outlets but leaves it to competition to determine the remuneration (and hence profit) of each outlet.

The government will often face significant (and potentially overwhelming) information issues when considering first-best regulation. The government would need to make judgments for each relevant region about the number of outlets that should be located in the region, the prices that can be charged by these outlets over their entire product range, and the exact location of each outlet in the region. In this sense, directly applying first-best regulation is unlikely to ever be practical.

At the same time, the government could approximate first-best regulation through a tender process. The government can seek tenders from potential outlets about their location, the amount (if any) of government subsidy they would require to operate, the services they will provide consumers and the prices they will charge consumers. This might be done on a region-by-region basis. The tender process would be greatly simplified if the government stated the number of outlets that it will allow in advance so that outlets can tender knowing the number of other outlets that they will compete with if they are successful in the tender.

A competitive tender would allow potential outlets to reveal information to the government. The government would not need to determine all remuneration for the outlets. Rather, the outlets will reveal an indication of their expected profits through their bids. Similarly, the government can use the bids to help determine the services that are most likely to fit with the regional demographics.

That said, a tender process can be time consuming and costly, particularly when dealing with (potentially) hundreds of different locations and thousands of potential outlets.

Behavioural second-best regulation uses the economics of location choice to simplify the regulatory process. As discussed above, if there are no restrictions on entry then the location choice of outlets will often be aligned with customer traffic flow. This mix of outlet locations will trade off consumer access and economies of scale and can maximise economic welfare. If this distribution is satisfactory, the regulatory issue is reduced to a determination of the appropriate level of government subsidy (or taxation) to control the overall number of outlets. If there are too many outlets, the government can reduce any payments to each outlet. This will lead to some outlets exiting, reducing the number of outlets to a preferred level. Conversely, if there are too few outlets then the government can increase the level of payment to each outlet. This will lead to new outlets entering, raising the number of outlets to a preferred level. Further, this process is likely to align with customer access. Outlets that close are likely to be those with the weakest flow of customers, while new outlets will find it most profitable to open in underserved areas.

Regulation through remuneration can differ by region. If there are too few outlets in one region, the government can raise the remuneration to outlets that establish in that region. At the same time, it can reduce remuneration in other regions where there is an excessive number of outlets.

*Structural second-best regulation* is most relevant where outlets, for some reason, choose poor locations from the perspective of customer access and the government cannot otherwise correct this location problem. As noted above, location problems are most likely to arise where there are limitations on entry. However, even then, there are economic incentives for outlets to locate in line with customer traffic-flow.

If the government believes it can improve on the market-determined locations for outlets, it can set 'site-specific licenses' for the chosen locations. This will also determine the number of outlets that the government allows. However, such regulation does not determine the profit of each outlet. If the government is concerned about pricing to consumers, it will want to achieve two objectives through the locational licences. First, it will want outlets in locations that provide desirable consumer access. Secondly, it will want sufficient competition between outlets to ensure that consumers do not face excessive prices.

In general, it will be difficult to address both the location and pricing objectives by simple structural regulation. An attempt to control both the location and profits of each outlet, however, moves the government towards first-best regulation, as discussed above.

In summary, if the issue of outlet distribution can be met by allowing outlets to choose their own locations with the threat of entry, as is implied by the economic analysis presented above, then behavioural second-best regulation provides the simplest and most implementable form of government outlet regulation.

However, if the issue of outlet location is the key concern then the government may seek to use structural second-best regulation. Such regulation risks leaving consumers exposed to excessive pricing. In such a situation the government may be drawn to first-best regulation.

If the government seeks to implement first-best regulation, it should recognise the practical difficulties it faces. A tender-process is likely to reduce these difficulties. However, a large tender process over many locations and thousands of outlets is likely to be costly and may provide limited benefits compared with behavioural second-best regulation.

## APPLICATION TO COMMUNITY PHARMACY IN AUSTRALIA

Our aim here is not to provide a comprehensive overview of the location rules but to bring together some observations drawn from the submissions and economics literature in an attempt to answer the question whether there is any evidence of an 'entry' problem in Australia.

It can be argued that the 'overall' number of community pharmacies in Australia is appropriate. In terms of pharmacies per head of population, Australia appears to be in line with many other OECD countries. This could mean that, at present, there is not an overall 'entry problem' as discussed in the first part of this note. In other words, there is not either excessive or insufficient entry of community pharmacy on a national basis.

This does not mean, however that there are not local issues of entry. These issues may be reflected by either:

- Too many pharmacies in some regions and too few pharmacies in other regions; and/or
- Pharmacies seeking to enter and establish in some areas but being prevented by the entry restrictions, which reflects that government is over compensating incumbent pharmacies in these areas and leaving them with economic rents paid either directly by users or indirectly by taxpayers.

The Pharmacy Guild of Australia claims that, overall, there is reasonable access to community pharmacies in Australia. It states that, “[i]n the capital cities, the average resident is located less than one kilometre from the nearest pharmacy, while 97% of consumers are no further than two and a half kilometres from a pharmacy. Outside of capital cities, country residents are just 6.4 kilometres on average from the nearest pharmacy, with 65% having a pharmacy within two and a half kilometres”.<sup>282</sup> However, the National Rural Health Alliance argues that “[t]here is evidence of probable lower levels of access to pharmaceuticals for people living outside major cities, but the publicly available recent data are insufficient to clearly quantify the extent”.<sup>283</sup> As such, it is possible that there are issues of too few pharmacies being present in some regional and remote areas.

Even if there are an appropriate number of pharmacies in urban locations, this does not mean that they are appropriately distributed across urban areas or that government remuneration is appropriate for the support these pharmacies.

The issue of dispersion of urban pharmacies is considered below.

For remuneration, it follows from the economic analysis in the first part of this note that, if the overall number of pharmacies is appropriate but there are economic rents accruing to these incumbent pharmacies, there will be attempted entry by new pharmacies. This attempted entry may be unsuccessful due to the location rules (structural second-best regulation). However, the attempted entry would signify excessive government remuneration to the existing pharmacies (behavioural second-best regulation). An immediate consequence is that, if there is evidence of economic rents accruing to existing pharmacies in an area, such as attempted entry by new pharmacies in that area, then, with or without the location rules, an appropriate government response to avoid the inappropriate use of public funds is to reduce any government remuneration to the relevant pharmacies.

There is evidence available to the Review about attempted entry in a range of locations. For example, the submission from Chemist Warehouse presents a list of 52 areas where it would like to establish a pharmacy (the exact locations are confidential).<sup>284</sup> The Ingham Family Medical Centre notes its failed attempt to enter the provision of pharmacy services in Ingham.<sup>285</sup>

There is other evidence of economic rents accruing to some pharmacies. Such rents will be part of the ‘goodwill’ of a community pharmacy when it is sold or when a new owner buys into the business. It can be difficult to separate out the part of ‘goodwill’ that is associated with economic rent and the part relating to standard non-monetised business assets. However, under an earlier version of the location rules, Terry White Chemists noted that “the focus on relocation promoted the practice of pharmacists trading in approvals and in the period leading up to October 2011, it was common practice for approvals to be bought and sold for up to \$500,000 and sometimes more”.<sup>286</sup>

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<sup>282</sup> Submission No. 486, page 46.

<sup>283</sup> Submission No. 484, page 3.

<sup>284</sup> Submission No. 218.

<sup>285</sup> Submission No. 313.

<sup>286</sup> Submission No. 458, page 14.



There is also evidence of economic rents accruing to pharmacies in shopping centres, albeit that the shopping centre owners may, in turn, be able to seize these taxpayer-funded rents. For example, Sunil Narula notes that, “[w]hen a Pharmacist in such a new suburb establishes a new Pharmacy; the process is, in general, put to tender by a developer and the Pharmacist that ‘bids the highest’ gains the right to open in this new suburb. Once established there is little or no chance of any other Pharmacist having the ability to open under the *current* Pharmacy location rules. The end result is that the ‘highest bidder’ must now get a return on the investment he or she makes and by inference this results in higher prices to the patients that have no option in this suburb but to shop in this Pharmacy”.<sup>287</sup>

It should be noted that the presence of economic rents does not necessarily imply that existing pharmacy owners are gaining the benefits of these rents. As the shopping centre example shows, these rents may be able to be seized by landlords.

The potential for rents to have been transferred raises issues about transition if the government reduces remuneration to existing pharmacies in order to eliminate these rents. The cost of this policy change may fall on parties who do not benefit from the rents. As submission No. 1, from a pharmacy owner, notes, the owner took out a loan of \$2 million to buy into the pharmacy. To the degree that the price the owner paid for a share of the pharmacy includes economic rents then the seller gained the expected future value of these rents through the sale price. Eliminating the rents will clearly harm the new owner. However, such harm must be balanced against the ongoing harm to taxpayers if there is excessive government remuneration to community pharmacies. These taxpayer funds could be reallocated to socially valuable alternative uses.

### IS THERE ANY EVIDENCE THAT THE LOCATION RULES (UNDESIRABLY) CHANGE THE DISTRIBUTION OF PHARMACIES?

The economic theory discussed in the first part of this note indicates that, in the absence of the location rules, including the restrictions on pharmacists establishing new pharmacies, for a given number of community pharmacies the distribution of community pharmacies will be approximately consistent with the distribution of population. This may vary. For example, if there are particular communities with high demand for medicines, we would expect to see more pharmacies serving these communities. If there are areas of concentrated foot traffic that differs from the residential population density (e.g. CBD areas where individuals who live in other areas find it convenient to buy medicines) then we would expect to see what appears to be a ‘cluster’ of pharmacies in these areas.

Further, note that the distribution of these pharmacies may not be ‘optimal’ from a social perspective. In particular, areas of ‘thin’ population may have no pharmacy even though, as a society, we would like to see people in these areas able to access medicines.

The submissions to the Review provide both formal and informal evidence relating to the distribution of pharmacies.

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<sup>287</sup> Submission No. 472, page 3 (emphasis in original).

Formal evidence is provided in the Deloitte Access Economics report. It provides an analysis of the distribution of pharmacies per head of population over Australia and shows that there is significant variation, even in urban areas. For example, the submission notes that, at the PHN level, “South Perth has the highest number of people per pharmacy at 32% above the national average ... whereas Central and Eastern Sydney has the least number of people per pharmacy at 23% below the national average”.<sup>288</sup> Deloitte also notes that the location rules, by limiting entry, restrict the ability of new pharmacies to open in areas of population growth. Deloitte provides the example of the Blacktown and Seven Hills area of Sydney. The submission also notes areas of clustering – for example, “Westpoint Blacktown Shopping Centre, where there are at least nine pharmacies within an area of 340m<sup>2</sup>”.<sup>289</sup>

A range of submissions highlight the potential for underserved areas to arise under the location rules and the potential for ‘gaming’ of these rules. For example, Submission No. 505 from an owner-pharmacist notes that the current location rules can lead to clustering and underserved areas. The submission discusses how two community pharmacies were relocated from Invermay to the centre of Launceston, “[b]oth within 200m of another pharmacy and leaving Invermay without a pharmacy”.<sup>290</sup> The potential for ‘gaming’ is presented by Ingham Family Medical Centre submission, which argues that, when they sought to open a new pharmacy, “a false and misleading statement [was given] to ACPA”.<sup>291</sup>

If the existing location rules were providing appropriate access to consumers, compared to the alternative of pharmacies choosing their locations, then it would be expected that the rules would be supported by consumers. After all, the objective is consumer benefit. However, the Consumers Health Forum of Australia (CHF) recommends the opposite. It states that “[t]he Federal Government should remove existing location rules and allow new pharmacies to be established by competition for the benefit of consumers”.<sup>292</sup>

## PHARMACY DISTRIBUTION AND THE REMOVAL OF THE LOCATION RULES IN URBAN AREAS

In urban areas where there is evidence of economic rents, would removal of the location rules, with appropriate behavioural regulation to remove the economic rents and protect against excessive entry, lead to a desirable distribution of community pharmacies?

The economic theory outlined in the first part of this note indicates that this is likely. However, it would be useful if there were direct analysis based on the distribution of outlets that would be chosen by pharmacies in the absence of the location rules.

In Australia, we are in the fortunate situation that this analysis was carried out for community pharmacies in Metropolitan Melbourne using data collected in 1979–80, covering 50 Statistical

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<sup>288</sup> Submission No. 218A, page 21.

<sup>289</sup> Submission No. 218A, page 25.

<sup>290</sup> Paragraph 10.

<sup>291</sup> Submission No. 313, page 13.

<sup>292</sup> Submission No. 483, page 10.

Retail Areas, prior to the introduction of the location rules.<sup>293</sup> Waterson uses the actual distribution of pharmacies to calibrate a location model for pharmacy distribution. He then considers the optimal distribution of pharmacies to trade off consumer access costs and economies of scale in pharmacy. Thus, his analysis provides a guide to whether the distribution of pharmacies across metropolitan Melbourne with behavioural second-best regulation is significantly different from the distribution that allows an efficient level of throughput for community pharmacies while minimising consumer access costs.

Waterson presents his results in table 1 of the paper:

- While Waterson notes that he “cannot obtain a complete answer to the question of whether there are too many pharmacies ... the model suggests that the market-determined number of pharmacies would be socially excessive in the absence of any regulation”.
- When comparing the actual distribution of pharmacies with the optimal distribution, assuming “that price setting under the PBS was carried out in such a way as to create the right total number of pharmacies in this area as a whole”, Waterson notes that the optimal and actual distributions are “extremely close”.<sup>294</sup>

These empirical results for metropolitan Melbourne are consistent with the economic theory as summarised in part 1 of this note.

While the Waterson paper is only one piece of evidence, it is independent empirical peer-reviewed research that focuses on the distribution of community pharmacies in the absence of location rules but with appropriate remuneration levels. It is also based on Australian data. In this sense, it provides input that is directly relevant for one of the key issues of concern for this Review.

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<sup>293</sup> This analysis is published in M. Waterson, ‘Retail pharmacy in Melbourne: Actual and optimal densities’, *The Journal of Industrial Economics*, vol. 41 (1993), pages 403–419.

<sup>294</sup> M. Waterson, ‘Retail pharmacy in Melbourne: Actual and optimal densities’, *The Journal of Industrial Economics*, vol. 41 (1993), page 417.

## APPENDIX E: 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).
AHI	Administration, Handling and Infrastructure fee.
AHS	Aboriginal Health Service.
APP	Approved price to pharmacist.
Approved Ex-manufacturer Price	Has the meaning given in Part VII of the Act.
Approved Pharmacist	Has the meaning given in Part VII of the Act.
Approved Supplier	Has the meaning given in Part VII of the Act.
Assisted value added (AVA)	Equal to the value of outputs less the value of inputs in the presence of government subsidy.
Australian College of Pharmacy (ACP)	One of three major providers of CPD programs for pharmacists in Australia (the others being the PSA and the SHPA). The ACP was established in 1978.
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	The series of agreements between the Commonwealth and the Guild

TERM	DEFINITION
Agreements (CPAs)	(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 24 hours, and that meet compliance requirements and service standards.
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.
Continuing professional development (CPD)	Refers to the way that health practitioners maintain, improve and broaden their knowledge, expertise and competence and develop the personal and professional qualities required throughout their professional lives.
CSS	Customer Service Statement.
Dangerous drug	Has the meaning given in the Determination.
Determination	The determination in force from time to time under subsection 98B(1)(a) of the Act.
Distributional equity	<p>The extent to which the current arrangements, and any proposed changes to those arrangements, achieve the government’s objective of ensuring that:</p> <ul style="list-style-type: none"> <li>▪ Australians have equitable access to affordable medicines and related services, regardless of their location and wealth</li> <li>▪ pharmacies receive equitable remuneration to compensate them</li> </ul>

TERM	DEFINITION
	for the efficient costs of supplying medicines and related services on behalf of the government.
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).
Economic efficiency	<p>The extent to which current arrangements and any proposed changes to those arrangements encourage the:</p> <p>efficient use of medicines and related services, as well as other goods and services (i.e. consumption efficiency)</p> <p>efficient supply of medicines and related services as well as other related goods and services and the efficient use of resources by those activities (i.e. production efficiency).</p>
Economic rents	'Monopoly' or 'super normal' profits and rates of return that exceed normal rates of return.
Effective rate of assistance	The change in value added before and after government assistance (e.g. subsidy), expressed as a proportion of value added before government assistance.
Efficient Funding of Chemotherapy (EFC)	Refers to PBS medications that are distributed under alternative arrangements provided for under section 100 of the Act.
Ex-manufacturer price	As applicable, the approved ex-manufacturer price; or proportional ex-manufacturer price for a pack quantity (other than the pricing quantity) of a listed brand.
Fiscal sustainability	The extent to which the current remuneration arrangements and any proposed changes to those arrangements are sustainable in the medium to longer term.
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.



TERM	DEFINITION
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).
Horizontal integration	Refers to the merging of entities that pursue the same line of business (e.g. mergers among retailers or among wholesalers).
Listed brand	Has the meaning given in Part VII of the Act.
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.
Medicines review services	Aimed at maximising an individual patient's benefit from their medication regime and prevent medication-related problems through a team approach, involving the patient's GP and preferred community pharmacy. It may also involve other members of the healthcare team, such as nurses in community practice or carers. An example is a Home Medication Review (HMR).
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.
Nominal rate of assistance	The percentage by which government policies have raised or lowered gross revenue or costs above what they would be without the government's intervention.
Panel	The three independent reviewers appointed to conduct the Review of Pharmacy Remuneration and Regulation.
Pharmaceutical Benefit	Has the meaning given in Part VII of the Act.

TERM	DEFINITION
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 determined by the Minister under section 99L of the Act.
Pharmacy Practice Incentive Program (PPIP)	Supports pharmacies which provide medicines to consumers in 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.
PFDI	Premium Free Dispensing Incentive.
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.
PLHIV	People living with HIV.
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	Introduced by the Guild and PSA in 1997 as a quality assurance program

TERM	DEFINITION
Pharmacy Program (QCPP)	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
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 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.
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	Australia's regulatory authority for therapeutic goods and devices. The TGA conducts a range of assessments and monitoring activities to ensure

TERM	DEFINITION
(TGA)	that products are of an acceptable standard.
Unassisted value added (UVA)	UVA is equal to the value of outputs less the value of inputs in the absence of government subsidy.
Value added	Returns to factors of production (land, labour, capital and enterprise) – that is, the difference between total sales revenue and the total cost of materials and services purchased from other firms.
Vertical integration	The merging of entities that have complementary business interests (e.g. the acquisition of a pharmacy or a pharmacy chain by a wholesaler or vice versa).

## APPENDIX F: A HISTORY OF THE COMMUNITY PHARMACY AGREEMENTS (1990–2015)

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### OVERVIEW

Since 1990, Australian governments have entered into a series of Community Pharmacy Agreements (CPAs). The five-year bilateral agreements are made between the Minister for Health (acting on behalf of the Commonwealth) and the Pharmacy Guild of Australia (the Guild).

The CPAs formally recognise the key role played by community pharmacy in primary health care through the delivery of Pharmaceutical Benefits Scheme (PBS) and Repatriation Pharmaceutical Benefits Scheme (RPBS) medicines and related services. They also recognise that the two parties have a common interest in:

- promoting the sustainability, efficiency and cost-effectiveness of the PBS within the broader context of health reform
- ensuring that community resources are appropriately directed across the health system
- supporting the sustainability and viability of an effective community pharmacy sector.

CPAs essentially encompass three key funding elements, namely:

- community pharmacy remuneration for the dispensing for PBS and RPBS medicines
- additional funding for professional pharmacy services and programs
- the Community Services Obligation (CSO) funding pool for approved wholesalers – which ensures that all Australians have timely access to the PBS medicines they require regardless of the cost of the medicine or where they live.
- In recent agreements, there has also been a commitment by the Australian Government to maintaining the Pharmacy Location Rules.

### SITUATION PRIOR TO 1990

Immediately prior to 1990, remuneration for pharmacists was set by the Pharmaceutical Benefits Remuneration Tribunal and consisted of a dispensing fee and a 25 per cent mark-up on PBS-listed items.<sup>295</sup>

These arrangements provided no specific incentives for improving the efficiency in the structure and performance of community pharmacy in terms of either the total number of pharmacies or the distribution of pharmacies. Indeed, pharmacy location and the national ‘network’ of community pharmacies supplying PBS benefits were at the time characterised by marked inconsistency. In 1987, a Senate committee found that 25 per cent of pharmacies had a competitor within 100 metres and 62 per cent had a competitor within 1 kilometre. Other areas, particularly in regional Australia, struggled to attract or retain even one.

Over and above such evidence, it was also apparent that there was an oversupply of pharmacies nationally.

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<sup>295</sup> National Health Amendment Bill (No. 1) 2000, Explanatory Memorandum.

In 1985 there were just under 5500 pharmacies, with a pharmacy to population ratio of 1:2900. Organisation for Economic Cooperation and Development (OECD) data at the time suggested that the pharmacy to population ratios for most of its member countries ranged from 1:3000 to 1:5000.

Many local pharmacy markets were well below this OECD range in the late 1980s, while some underserved localities, such as rural and remote communities, were well above it.

In 1989–90, almost 105 million prescriptions were dispensed. Between 1985–86 and 1989–90, related government PBS outlays, including pharmacist remuneration, grew from \$616 million to \$1179 million. Overall, this 91 per cent spending growth represented an average compounded growth rate for related PBS outlays during that period of 17.6 per cent.

In the late 1980s, there was a dispute between the government and the Guild around the issue of whether the price paid for dispensing PBS drugs should be based on the average cost of dispensing across all pharmacies or the cost of dispensing in an ‘efficient pharmacy’. No agreement on calculating the price on an efficient pharmacy basis could be reached. The government and the Guild ended this period of unrest after the 1990 election with the negotiation of the first CPA.

## SITUATION POST-1990 TO 2015

The first CPA, 1991–1995, was established to set out a new remuneration pharmacy framework. It was also intended to address the concerns that the ratios of pharmacies to individuals in Australia was higher than that of other OECD countries; however, the geographic distribution of pharmacies was clustered in metropolitan areas and far more scattered in regional, rural and remote areas, meaning Australians living in those areas were going without. As a result, the first agreement included:

- financial incentives – in the form of closure and amalgamation payments – for pharmacies to close or amalgamate in areas where closure would not affect reasonable access to pharmacy services
- restrictions on where a community pharmacy could relocate its existing PBS approval
- additional financial support to community pharmacies in rural and remote areas through an Essential Pharmacy Allowance (just over 400 pharmacies received the allowance).

From 1991 to 1995, the closure and amalgamation payments program resulted in 630 pharmacy closures and 64 mergers, at a cost to government of \$52 million, while the number of pharmacies operating in Australia in 1995 subsequently fell from 5500 to 4950, or a 1995 pharmacy to population ratio of 1:3650.

Since the first agreement, the location rules have been a feature of all CPAs. The Rules are given their effect by a ministerial determination under section 99L of the *National Health Act 1953* (Cth) and administered by the Australian Community Pharmacy Authority (ACPA).

The second agreement, 1995–2000, sought to consolidate the remuneration structure and efficiency gains of the first. However, it eased some of the regulatory restrictions, such as those on the location of pharmacies, particularly in rural and remote areas, and established fee-for-service payments to accredited pharmacists for conducting limited medication reviews for nursing home residents.



The third agreement, 2000–2005, was a more comprehensive agreement than the previous two, moving well beyond pharmacy remuneration and location rules. As well as a framework for determining payments to pharmacies for supply of PBS medicines, the agreement included new ‘risk-sharing’ provisions to deal with situations where estimated prescription volumes and/or average prescription prices and related income exceed or fall short of agreed estimates.

The agreement, worth over \$6 billion, also included the continued maintenance of the location rules on the basis that their removal would disrupt the community pharmacy sector and the supply of medicines to the community. However, significant modifications to the Rules included a relaxation of both new and relocated pharmacy approvals rules, particularly in rural and remote areas.

The first two agreements were designed to assist in moderating the rate of growth in estimated PBS outlays while still promoting reasonable access to community pharmacy services. The third agreement was intended to retain these priorities but add to them the objective of promoting quality enhancement in the provision of funded pharmacy services.

Key components of the fourth agreement, 2005–2010, included:

- further amendments to the location rules intended to provide greater flexibility to respond to ‘community need’ for pharmacy services and to improve access to services. The amendments included a relaxation of the Rules in three key areas:
  - large medical centres
  - smaller shopping centres with a large supermarket
  - larger single pharmacy rural towns
- the establishment of the Community Service Obligation (CSO) funding pool for approved wholesalers, which at that time provided funding of \$150 million per annum (indexed annually) to ensure that all Australians have ongoing access to the full range of PBS medicines through community pharmacies
- \$20 million for e-Health initiatives involving community pharmacies.

The fifth CPA commenced on 1 July 2010 and expired 30 June 2015. It committed funding of approximately \$15.4 billion over the life of the agreement for around 5000 community pharmacies for dispensing PBS medicines and providing pharmacy programs and services, and for CSO arrangements with pharmaceutical wholesalers. A commitment to maintaining the location rules for approved pharmacies was again provided.

The fifth CPA also provided funding to retain services that enhance patient medication management, including a focus on improving quality use of medicines by Aboriginal and Torres Strait Islander peoples. The commitment to supporting rural pharmacies and the rural pharmacy workforce was maintained, and research was to be commissioned on evidence-based best practice in quality pharmacy services. New programs were introduced as part of a quality framework, with incentives available to accredited pharmacies under the new Pharmacy Practice Incentive and Accreditation Program based on the delivery of high-quality patient services.

However, an Australian National Audit Office (ANAO) audit of the 2010 agreement found it lacked transparency. The ANAO reported in March 2015 that there were “shortcomings in key aspects of

Health’s administration at the development, negotiation and implementation phases” of the agreement.

The ANAO also noted that “Until 1 March 2014, Human Services administered most 5CPA professional programs on behalf of Health (valued at \$583 million), while the Pharmacy Guild administered some of the smaller programs (valued at \$67 million). On 1 March 2014, Health transferred responsibility for the 5CPA professional programs administered by Human Services to the Pharmacy Guild, which now administers all 5CPA professional programs on behalf of Health”.

The fifth CPA was highly criticised not only by the ANAO but also by PBS stakeholders and in the media for its lack of transparency and accountability, potential conflicts of interest regarding the Guild’s dual roles as an administrator and the beneficiary of funds, and its failure to deliver a promised gross saving of \$1 billion over five years against Australian Government forward estimates. The Parliamentary Joint Committee on Public Accounts and Audit held a hearing into the ANAO’s *Report No. 25 (2014–15) Administration of the Fifth Community Pharmacy Agreement* in August 2015, which raised the issue of ‘value for money’ and whether the taxpayer was getting value for government spending of \$14 billion over the life of the fifth CPA.

## CURRENT CPA

The sixth CPA, which commenced on 1 July 2015 and is due to expire on 30 June 2020, was developed following pre-negotiation consultations with a broad range of stakeholder groups across the pharmaceutical industry, pharmacy and pharmacists, consumers, peak groups and other organisations. In addition, the sixth CPA was developed with particular consideration towards the findings and recommendations of the ANAO’s audit of the fifth CPA.

The current sixth CPA subsequently contains tougher accountability measures. Several fifth CPA programs were discontinued, while others are subject to ongoing review by an independent health technology assessment body (i.e. the Medical Services Advisory Committee).

The sixth CPA provides around \$18.9 billion in remuneration for community pharmacy as well as funding to support the pharmaceutical supply chain (with a further \$372 million provided for chemotherapy compounding fees). Note that this excludes pharmacy remuneration for dispensing medicines under section 100 special arrangements and an estimated \$4.8 billion from dispensing pharmaceutical items that are priced below the maximum co-payment.

The funding comprises \$15.5 billion from the Australian Government and \$3.4 billion from patient contributions as per **Table 12** below.

**Table 12: Components of the sixth CPA remuneration and funding**

Component	Contributor	\$million (estimated)
Pharmacy remuneration for dispensing (incl. dispensing fee, AHI fee and dangerous drug fee)	Commonwealth	11,112
	Patient	3,025
Premium Free Dispensing Incentive funding	Commonwealth	655
	Patient	N/A
Community Pharmacy Programs and Pharmacy Trials Program	Commonwealth	1,263
	Patient	As set under CPPs
Remuneration for wholesalers to hold and deliver medicines to approved pharmacists (excluding the CSO)	Commonwealth	1,414
	Patient	385
CSO funding pool	Commonwealth	976
	Patient	N/A
Fee for CSO distributors to distribute National Diabetes Services Scheme products	Commonwealth	28
	Patient	N/A
Diabetes Services Scheme products	Patient	No additional patient charge
<b>Total</b>	Commonwealth	15,476
	Patient	3,410
	<b>Total</b>	<b>18,886</b>
Chemotherapy compounding fees	Commonwealth	372

**Note:** The Commonwealth also estimates that community pharmacy will receive up to a further \$4.8 billion from dispensing pharmaceutical items that are priced below the maximum co-payment.

Key features of the sixth CPA include:

- the new Administration, Handling and Infrastructure (AHI) fee, which forms part of the government price for a dispensed PBS item and replaces the former pharmacy mark-up. It represents a significant change to the basis upon which community pharmacies are remunerated – both the Guild and the Australian Government recognise that the introduction of the AHI Fee (and de-linking pharmacy remuneration from medicine pricing) is intended to support the sustainability of the community pharmacy sector while removing a barrier to future PBS reform
- a significant increase in investment of up to \$1.26 billion in funding for evidence-based, patient-focused professional programs and services (with a particular emphasis on those which benefit Aboriginal and Torres Strait Islander peoples, and consumers living in rural and remote areas). This represents – as acknowledged by the Guild – a doubling of previous investment in professional services and includes:
  - \$613 million as continued investment for a range of fifth CPA community pharmacy programs
  - \$50 million for a Pharmacy Trial Program (PTP) to trial new and expanded community pharmacy programs which seek to improve clinical outcomes for consumers and/or extend the role of pharmacists in the delivery of primary healthcare services
  - up to \$600 million in additional funding over the term of the agreement to support new and expanded community pharmacy programs
- the requirement that any new or expanded community pharmacy program funding be subject to a cost-effectiveness assessment by an independent health technology assessment body (i.e. the Medical Services Advisory Committee)

- new National Diabetes Services Scheme (NDSS) supply arrangements which include a payment of \$1 for each NDSS product supplied by approved pharmacists; and an additional \$1 per unit fee for CSO Distributors for each NDSS product supplied through CSO arrangements
- new legislation, which came into effect on 1 January 2016, allowing pharmacists to discount the PBS patient co-payment by a maximum of \$1 per PBS supply.

In addition, there are a number of other significant components, including:

- a government commitment to extend the location rules until mid-2020
- new governance arrangements
- new chemotherapy arrangements – a new two-tiered fee structure came into effect from 1 July 2015 whereby \$60 is paid where the compounder holds a manufacturing licence from the Therapeutic Goods Administration (TGA); or \$40 is paid to approved suppliers through the PBS where the compounder does not hold a manufacturing licence from the TGA
- this Review of Pharmacy Remuneration and Regulation.

## APPENDIX G: PARALLEL INITIATIVES TO IMPROVE PRIMARY HEALTHCARE SERVICES

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Healthcare arrangements and practices in Australia operate within a highly dynamic environment. The initiatives represent significant reform opportunities and will be likely to have an impact on the community pharmacy sector.

### RECENT COMMONWEALTH INITIATIVES

There are a number of existing parallel processes currently being undertaken for the planning, delivery and governance of primary healthcare services.

Recent Commonwealth initiatives that can help us understand how primary health care is developing to play a role in the broader health system, and how those areas could usefully serve as an overarching framework with which this Review's recommendations can integrate and link, include the following.

#### *Healthier Medicare Initiative*

In considering recent developments in primary health care arrangements in Australia, a natural starting point is Medicare.

On 22 April 2015, the then Minister of Health Sussan Ley announced a programme of work to deliver a Healthier Medicare and ensure Australians continue receiving the high-quality and appropriate care they need as efficiently as possible. To that end, the Healthier Medicare Initiative includes three priority areas: the Medicare Benefits Schedule (MBS) Review Taskforce; the reform of the Primary Health Care System; and Medicare compliance rules and benchmarks.

### MEDICARE BENEFITS SCHEDULE (MBS) REVIEW TASKFORCE

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The Minister announced that a Medicare Benefits Schedule (MBS) Review Taskforce would be established. The taskforce, led by Professor Bruce Robinson, Dean of the Sydney Medical School, University of Sydney, is considering how the more than 5700 items on the MBS can be aligned with contemporary clinical evidence and practice and improve health outcomes for patients. Taskforce recommendations will be made to the Minister.

### REFORM OF THE PRIMARY HEALTH CARE SYSTEM

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The government also established a Primary Health Care Advisory Group (PHCAG) led by former Australian Medical Association (AMA) President, Dr Steve Hambleton, to investigate options to provide better care for people with complex and chronic illness; innovative care and funding models; better recognition and treatment of mental health conditions; and greater connection between primary health care and hospital care. The advisory group provided its final report to government in December 2015 and the group's role has now concluded.

On 31 March 2016, the government announced its plan to introduce a Health Care Home model – a core recommendation of the advisory group – to improve care for patients with chronic and complex conditions. Under this model, eligible patients will voluntarily enrol with a participating medical

practice known as their Health Care Home. This practice will provide a patient with a ‘home base’ for the ongoing coordination, management and support of their conditions.

The plan will allow local GPs to become medical ‘homes’ where patients with chronic diseases like diabetes could enrol and have all their healthcare needs — from psychology to aged care — coordinated by one doctor. The aim is to keep patients healthier and avoid expensive visits to the hospital.

A two-year trial of the Healthier Medicare package is due to be rolled out from July 2017, involving around 65 000 patients at 200 medical practices in 10 regions nationally, including Nepean– Blue Mountains and western Sydney.

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#### MEDICARE COMPLIANCE RULES AND BENCHMARKS

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The government is also working with clinical leaders, medical organisations and patient representatives to develop clearer Medicare compliance rules and benchmarks. The use of new techniques such as analytics and behavioural economics will provide more information to clinicians to enable them to better manage appropriate practices. As well, more information will be available to patients about fees charged by health professionals so they can make informed choices about their health care.

Each reform area draws on a broad range of expertise and experiences to inform the process, including that of clinicians (GPs and specialists); consumer and patient representatives; academics; Primary Health Networks PHNs; nurses; allied health professionals; health economists; and states and territories.

Another recent government initiative is the Mental Health Reform Package.

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#### MENTAL HEALTH REFORM PACKAGE

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On 26 November 2015, as part of its response to the National Mental Health Commission’s Review of Mental Health Programme and Services, the government announced a Mental Health Reform Package designed to put the individual needs of patients at the centre of Australia’s mental health system.

The commission noted that there is significant spending on mental health, yet too many Australians fall through the cracks or do not receive the full support they need. It is clear that our current ‘one-size-fits-all approach’ is not helping Australians suffering from mental illness as best it can.

The reforms released at the end of November 2016 focus on a number of concrete actions:

- contestable mental health services will be commissioned, not delivered, through the recently established PHNs
- coordinated packages of care will be created for people with severe and complex needs and flexible support for mild and moderate needs
- a new Digital Mental Health Gateway will optimise the use of digital mental health services
- a new approach to suicide prevention, coordinated by PHNs.



The reforms are being rolled out over a three-year period between 2016 and 2019 and will be delivered within the existing funding envelope. The government is also working with states and territories to develop the Fifth National Mental Health Plan to ensure smooth integration of these new reforms.

For the first time, Australians with a severe and complex mental illness will also have access to an integrated care package tailored to their individual needs, as part of broader reforms unveiled by the government on shared collaborative care models like Health Care Homes.

## DIGITAL HEALTH INITIATIVES

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Essentially, the Australian Government's digital health initiatives include MyHealth Record; Telehealth; and the Healthcare Identifiers Service.

Digital health is the electronic management of health information to deliver safer, more efficient, better-quality health care.

The Australian Digital Health Agency was created in July 2016 by the Australian Government to drive the development and delivery of Australia's digital health. To help describe what digital health looks like now and in future, the agency launched a national consultation process on 3 November 2016, with the general public, clinicians, healthcare providers and funders. The findings from the national consultation will be used to develop a national digital health strategy for delivery to government in 2017.

## RELEVANCE OF INITIATIVES

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Although the above is not intended to be an exhaustive listing of recent government initiatives that are relevant to this Review, it should be noted that, in developing our recommendations, the Panel has been cognisant of the broader healthcare reform agenda and how the government is committed to:

- focusing on chronic disease management and mental health programs and services as well as Aboriginal and Torres Strait Islander health, population health, health workforce, eHealth and aged care – key priorities for government
- delivering an efficient and effective primary healthcare system through PHNs, which have been established with the key objectives of increasing the efficiency and effectiveness of services for patients, particularly those at risk of poor health outcomes, and improving coordination care to ensure patients receive the right care in the right place at the right time – that is, where PHNs lead health planning and integration efforts at a regional level in partnership with general practitioners, other primary healthcare providers, secondary care providers and hospitals to facilitate improved outcomes for patients
- enhancing the role digital health can play in improving data collection – for example, reducing adverse reactions to medications and prescribing behaviours.

Other key issues common to broader reform initiatives include:

- improving access to health care in rural and remote areas

- improving health literacy in individuals
- increasing the efficiency and effectiveness of patient outcomes from sustainable investment
- the importance of providing evidence to support future investment in, and reform of, the primary healthcare system.

## APPENDIX H: PEOPLE AND ORGANISATIONS CONSULTED AS PART OF THE REVIEW

### STAKEHOLDER ENGAGEMENT

The Review undertook a comprehensive approach to engaging with multiple stakeholders as part of a National Consultation Strategy. This involved a series of bilateral meetings, public forums, online webcasts, site visits and presentations that have been summarised below.

**Table 13: Stakeholder engagement for a national consultation strategy**

<b>A: Bilateral meetings – December 2015 to March 2016</b>				
<b>In the lead-up to the release of the Discussion Paper, a series of bilateral meetings were held with the following organisations and individuals:</b>				
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>B: Public forums – August 2016 to September 2016</b>				
<b>15 public forums were held at locations in each state and territory as well as an online live national webcast.</b>				
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 <sup>296</sup>				
	Consumer	Pharmacist	Wholesaler	Organisations	Total
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 <sup>297</sup>
<b>Total</b>	<b>50</b>	<b>624</b>	<b>35</b>	<b>152</b>	<b>861</b>

### 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
Nunyarra 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

<sup>296</sup> 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.

<sup>297</sup> While 57 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.

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				

## 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 I: KEY TOPICS AND THEMES FROM SUBMISSIONS

The Review of Pharmacy Remuneration and Regulation released a Discussion Paper in 2016. The Discussion Paper touched on varied and sensitive issues for the pharmacy sector, including ownership and location rules, remuneration arrangements, the current difficulties faced by the industry, and the role of pharmacy as a ‘retailer’ versus health provider.

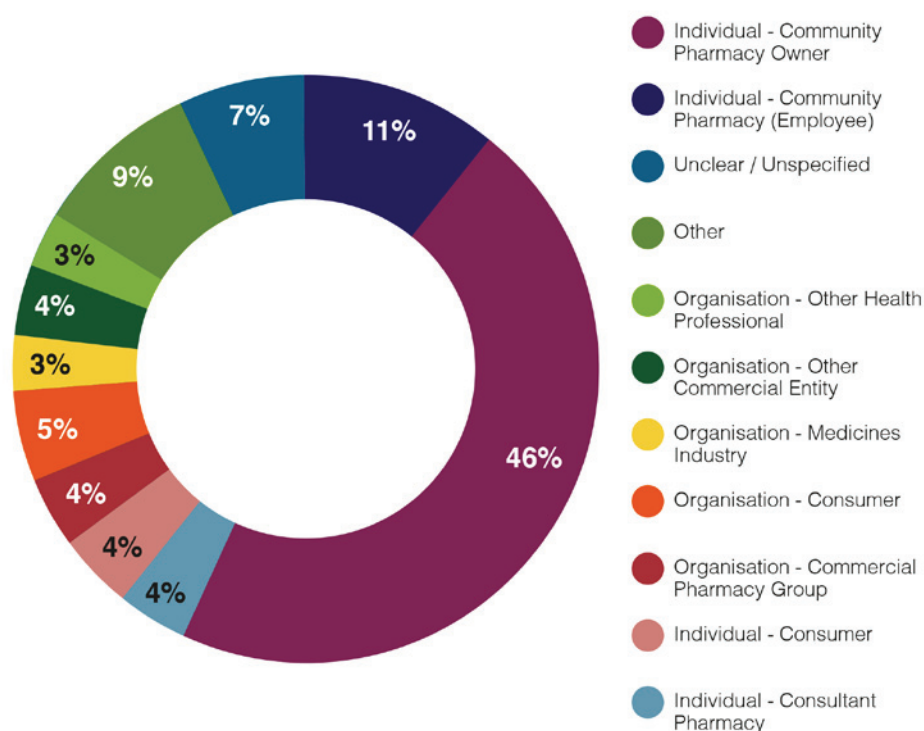
Stakeholders were encouraged to respond to the issues presented in the Discussion Paper through the public submission process. Over 500 submissions were received, with submitters writing in from every state and territory in Australia.

The submissions were broken down by topic into a spreadsheet, to assist in identifying trends and common issues. The following narrative provides a high-level, broad analysis of those trends and issues. Exact statistics as to the breakdown of topics, and positive versus negative responses, have generally not been provided. This is because the large number of submissions received, and the breadth of the topics covered, meant that the breakdown and analysis of themes and trends was not intended to be a precise process

### RESPONDENTS BY CATEGORY

Almost half (46 per cent) of the 503 submissions received came from individual community pharmacy owners. Pharmacists who worked as employees in community pharmacies made up 11 per cent of respondents. Consumer organisations, commercial pharmacy groups, consultant pharmacists and individual consumers each made up 4 to 5 per cent of submissions.

**Figure 16: Respondents by category**



## TOP TOPICS COVERED BY SUBMISSIONS

The top ten topics covered by all submissions were:

1. Location rules
2. Complementary medicines in pharmacies
3. Pharmacy services provided that were not remunerated
4. Dispensing fees
5. State and territory regulations
6. Very high cost medicines
7. Home Medicine Reviews
8. The pharmacy landscape
9. Limitations on what can be sold in pharmacies
10. Quality differences between different pharmacy models.

This list closely overlaps with the most common topics raised by pharmacy owners, though pharmacy owners were more likely to discuss the effects of price disclosure on pharmacy income, and the concept of different remuneration for different pharmacy models. Pharmacy owners were less likely to mention Home Medicines Reviews and the Pharmacy landscape.

Employee pharmacists were more likely to discuss the pharmacy landscape, young pharmacists' concerns about wages and future career paths, and services valued by customers. Consumer organisations were focused on consumer perspectives and were more likely to cover topics such as the affordability of medicines, consumer experiences and the safety net.

## THE PHARMACY LANDSCAPE

More than 10 per cent of submissions made comments about the general pharmacy landscape. Most of these submissions came from community pharmacists and pharmacist employees, though submissions from peak bodies and other organisations also touched on this topic. A number of submissions expressed optimism about the change in pharmacy across Australia, describing the shift in the traditional pharmacist-in-dispensary model to one where the pharmacist is now able to provide multiple health checks and other services. Other submissions were more pessimistic, and worried about the dichotomy between retail and healthcare, describing the proliferation of stores focusing on perfumes, vitamins and emphasising cheap prices.

## REMUNERATION QUESTIONS

In relation to the proposal of different remuneration models for different pharmacy models, the overwhelming majority of respondents were against this option. Submissions that were supportive of different remuneration types cited examples of traditional pharmacies providing services above and beyond those offered at discount style pharmacies. Conversely, some pharmacy owners associated with discount pharmacies stated that, due to the vast numbers of people they reach in the community, they should be given greater remuneration.

Submissions that opposed different remuneration models stated that these measures could cause business model gaming as operators try to maximise payments from government. They also



suggested that significant administrative burdens would be placed on government in order to monitor the different business model types. Some submissions suggested that it would be more important to monitor the ratio of pharmacists to prescriptions in a pharmacy to identify whether customers were receiving adequate levels of service.

Respondents were asked to provide examples of pharmacy services that were provided but not remunerated.<sup>298</sup> The most common examples provided related to:

- liaison with other health providers/services – in particular, hospitals and general practitioners
- dose administration aids
- blood pressure checks
- home delivery services
- support for aged care facilities
- diabetes support services / blood glucose checks
- various screening services.

## PHARMACY MODELS AND PROGRAMS

The Discussion Paper dealt with a range of topics relating to different pharmacy models and pharmacy programs and services. A large number of submissions covered these topics. Submissions were overwhelmingly supportive of pharmacies providing a broad range of services and, in particular, of expanding pharmacists' scope of practice. The majority of these submissions were in favour of Medicare Benefits Schedule (MBS) payments as the appropriate remuneration channel for these services.

Of those submissions that commented on the option of non-dispensing pharmacists (e.g. in general practices), the vast majority were in favour. Very few community pharmacy owners commented on this in their submissions.

Of those submissions that commented on the option of separating remuneration for dispensing from remuneration from advice, a small majority were in favour of the option. These submissions stated that the separation of remuneration for dispensing from remuneration for advice would de-link payments from the purchase of a product and allow pharmacists to give frank and unbiased advice. Community pharmacy owners were equally divided between those in favour and those against this option. Commercial pharmacy groups were largely in favour.

Those who opposed the separation of remuneration for dispensing from remuneration for advice felt that this would create tedious measurement protocols in a pharmacy environment already struggling to meet numerous administrative requirements. In addition, they felt that the separation implied that pharmacists were not providing sufficient advice when providing products to consumers in community pharmacy.

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<sup>298</sup> Some responses referred to pharmacy services which were considered to be insufficiently remunerated.

## REGULATION QUESTIONS

### *Location rules*

Almost half of the submissions that were received commented on pharmacy location rules. A slight majority of those comments were in favour of the current location rules. Community pharmacy owners again were fairly evenly divided on this issue.

Submissions that were supportive of location rules stated that they prevented clustering of pharmacies, leading to improved access for consumers. Some submissions that were supportive of location rules still felt that they could be improved and provided examples of how location rules were being gamed by shopping centre landlords or other pharmacists.

Submissions that opposed location rules stated that they reduced competition and led to inflated pharmacy prices, which in turn led to increased prices for consumers. The inflexibility of the location rules was also considered a source of angst. It was noted that a significant number of pharmacy owners that expressed opinions against the current location rules were associated with Chemist Warehouse.

### *Other regulation questions*

The vast majority of respondents who addressed the issue of pharmacies being co-located with supermarkets were opposed to it. A smaller majority were opposed to the expansion of hospital pharmacies, though a majority of non-community pharmacy owners were in favour.

A number of submissions also commented on ownership laws, with pharmacy owners generally in favour of pharmacy ownership being limited to pharmacists. A few submissions suggested that it would be beneficial to limit the number of pharmacies that a single pharmacist can own. This was in order to reduce corporatisation of the pharmacy market and make entry easier for young pharmacists to acquire their own pharmacies.

A single pharmacy banner group was more critical of the ownership rules than the other pharmacy owners. Consumer organisations and individual consumers raised concerns about monopolies being formed when one pharmacist has interests in multiple pharmacies in the same area (i.e. reducing competition).

## WHOLESALE QUESTIONS

A significant number of submissions commented on the Pfizer supply model. Pfizer supply their medications directly to community pharmacies and do not provide them for supply through the CSO wholesalers. An overwhelming majority of respondents' comments did not support the Pfizer model or, more generally, the option of manufacturers being responsible for delivery.

Of those submissions that commented on the recent changes to the CSO relating to the 72-hour delivery times and the minimum order requirements, the vast majority were critical of the changes.

## CONSUMER-FOCUSED QUESTIONS

### *Access questions*

Many submissions included examples and explanations of the type of pharmacy services that were particularly valued by consumers. The most common example provided was that of Home Medicines Reviews, followed by dose administration aids and Medschecks. Consumer organisations valued Home Medicines Reviews the most, followed by the ability to access electronic prescriptions.

In response to the issue of access for rural and remote communities, the majority of submissions indicated that access was inadequate. The majority of submissions also felt that consumers did not find medications affordable. These submissions were mostly written by consumer organisations on behalf of consumers, pharmacy peak bodies and some pharmacy owners.

### *PBS Safety Net*

Most submissions were supportive of the PBS Safety Net and its purpose in providing protection for consumers who require large numbers of PBS medications. However, submissions did note the difficulty that consumers experience in manually managing their safety net totals. A number of pharmacist submissions stated that they could spend significant amounts of time reconciling safety net totals on behalf of individual consumers.

A few submissions also advised that subsets of the population are missing out on PBS Safety Net benefits. For example, consumers on opioid substitution therapy are unable to have their treatment counted towards the PBS Safety Net.

### *Retail and complementary medicines*

Over one-quarter of the submissions received dealt with the issue of complementary medicines in pharmacy. An overwhelming majority of those submissions were in favour of complementary medicines being available through community pharmacies. Over 90 per cent of pharmacy owners were in favour, and approximately 60 per cent of pharmacy employees were in favour.

Over two-thirds of respondents who addressed the issue were not in favour of any limitations on what could be sold in pharmacies.

### *Services that consumers should expect*

Most respondents who addressed the issue of what consumers should expect felt that ‘advice’ or ‘information’ was something that consumers should expect to receive in pharmacy. The next most common responses were ‘access’ to a pharmacy and ‘counselling’ on medications.

A large number of submissions addressed the issue of quality differences between pharmacy models. The overwhelming majority of submissions disagreed with this premise. Most of the non-supporting submissions came from community pharmacy owners, consisting of over 75 per cent of the submissions that touched on this issue.

It was noted that the majority of submissions that were opposed to the concept of quality differences between different pharmacies models were from owners associated with a single-banner group of pharmacies.

#### *\$1 discount*

Of those submissions that addressed the \$1 discount, over 95 per cent were against the policy. The majority of these submissions came from community pharmacy owners.

## CHEMOTHERAPY

#### *\$20 TGA licensing fee*

The submissions that addressed TGA licensing came from a wide range of submitters, including commercial chemotherapy compounders, pharmacy representative bodies, and hospital and community pharmacy owners.

Submitters were split roughly 50:50 in terms of their support for a higher payment for TGA-licensed facilities. In contrast, a majority of submissions agreed that non-TGA-licensed compounders should be allowed to compound and that funding levels were insufficient.



[health.gov.au/pharmacyreview](http://health.gov.au/pharmacyreview)