# Chapter 2

# Key issues

2.1 Community pharmacy plays a critical role in the delivery of primary healthcare to the Australian community. Throughout the inquiry, submitters and witnesses acknowledged that the sector requires a certain level of regulation. However, the committee heard that some red tape is hampering pharmacies' ability to deliver efficient and high quality care, contrary to the objectives of the National Medicines Policy.

2.2 This chapter discusses some of the issues raised with respect to:

- Pharmacy Rules;
- National Medicines Policy objectives; and
- state/territory regulation.

## Pharmacy Rules

2.3 The Pharmacy Guild of Australia (PGA) submitted that the community pharmacy model is strongly supported by consumers, as well as business owners who have invested $15 billion in the sector. Executive Director, David Quilty, contended also that the Pharmaceutical Benefits Scheme (PBS) is the 'most fiscally sustainable part of the health system'.[1]

2.4 Other submitters raised concerns about the community pharmacy arrangements, which they argued prioritise commercial interests. The Grattan Institute submitted that 'existing red tape is designed principally to protect the interests of pharmacy owners, not consumers'.[2] Another submitter—Rhodes Management—said that the arrangements restrict medicines access and supply, and complete structural reform is required to reduce red tape inefficiencies, commencing with consumer and government centric charters.[3]

2.5 The Pharmacy Rules was the area of most concern. Rhodes Management supported removing these rules, arguing they limit the number of community pharmacies and where they can operate.[4] The Grattan Institute presented similar arguments and stated that the Pharmacy Rules:

- tend to protect incumbent pharmacies and restrict market entry; and

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1 David Quilty, Executive Director, Pharmacy Guild of Australia, *Committee Hansard*, 27 November 2017, p. 2.

2 Grattan Institute, *Submission 6*, p. 3.

3 Rhodes Management, *Submission 8*, pp. 2, 4–5 and 7–11.

4 Rhodes Management, *Submission 8*, pp. 2 and 5. Executive Director, Michael Rhodes, argued that, internationally, deregulation in these two areas has not caused the 'sky to fall down': *Committee Hansard*, 27 November 2017, p. 19.

- stifle competition between pharmacies, raising retail drug prices—a cost borne by patients and taxpayers—and limiting choice for many consumers.[5]

2.6 Dr Shane Jackson, National President of the Pharmaceutical Society of Australia (PSA), indicated that the effect of the Pharmacy Rules is definitely an issue for some PSA members: 'individual members have cited location rules as a barrier to entry…in establishing a pharmacy'.[6]

2.7 The Grattan Institute advocated replacing the Pharmacy Rules with 'simpler regulations which focus on ensuring patients have appropriate access to good-quality medicines'.[7]

2.8 In its submission, the Australian Medical Association (AMA) argued patient outcomes would improve with specific changes that allowed pharmacies and medical centres to share premises:

> The AMA supports high quality primary health care services that are convenient to patients, enhance patient access and improve collaboration between health care professionals. Co-location of medical and pharmacy services would clearly facilitate this.[8]

2.9 However, Mr Quilty told the committee that, based on current evidence, the 'location rules work well in achieving their purpose' in a cost effective manner:

> In pharmacy, there's little need for the provision of further government subsidies to provide access in, if you like, subeconomic areas. There's a small amount of rural pharmacy maintenance allowance that is provided for very small towns. But unlike other health professions—for example, GPs and medical practitioners—there hasn't been a need for large amounts of government subsidies because the location rules have ensured that new pharmacies locate themselves in those underserved areas.[9]

2.10 The committee notes that the Review of Pharmacy Remuneration and Regulation (King Review) received few, if any, submissions approving all aspects of the Pharmacy Rules.[10] Further, its interim report pointed out that two recent reviews have recommended the removal of these rules:

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5 Grattan Institute, *Submission 6*, pp. 3 and 5.

6 Dr Shane Jackson, National President, Pharmaceutical Society of Australia, *Committee Hansard*, 27 November 2017, p. 7.

7 Grattan Institute, *Submission 6*, p. 5.

8 Australian Medical Association, *Submission 2*, p. 1. Co-location of these services is currently not permitted under the Pharmacy Rules.

9 David Quilty, Executive Director, Pharmacy Guild of Australia, *Committee Hansard*, 27 November 2017, p. 6. Mr Quilty also discussed the policy and objectives of the Pharmacy Rules, including in an historical context: p. 8.

10 King, S., Watson, J. and Scott, W., *Review of Pharmacy Remuneration and Regulation*, Interim Report, Prepared for the Department of Health, June 2017, p. 6.

- the National Commission of Audit's 2014 report *Towards Responsible Government*, which found that deregulating ownership and location rules could encourage competition within the sector, leading to more efficient delivery and the development of alternative retail models;[11] and
- the 2015 *Competition Policy Review* (Harper Review), which reported that ownership and location rules are anti-competitive and contrary to the objectives of the National Medicines Policy, limiting consumers' ability to choose where to obtain pharmacy services and suppliers' ability to meet consumers' demands.[12]

2.11 The committee notes that, since the King Review delivered its interim report, the Productivity Commission has also published its *Shifting the Dial* report, which recommended changes to the community pharmacy model.[13]

***Department response***

2.12 The Department of Health (Department) endorsed the Pharmacy Rules, arguing that consumers benefit from a well-distributed network of community pharmacies that matches population demographics:

> The Location Rules ensure that the community pharmacy sector remains viable and able to meet consumers' needs throughout Australia, including (and especially) in rural and remote areas, while also allowing competition between pharmacies. These factors are important to achieving the objectives of the Community Pharmacy Agreement [CPA], National Medicines Policy and the PBS more broadly.[14]

2.13 The Department added that the Pharmacy Rules have always been an integral component of the CPAs and 'any regulatory intervention in the community pharmacy network [must be] consistent with the goals of reasonable access and efficient and equitable access to PBS medicines'.[15]

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11 National Commission of Audit, *Towards Responsible Government*, 2014, Recommendation 19, http://www.ncoa.gov.au/report/index.html (accessed 15 February 2018).

12 Harper, I., Anderson, P., McCluskey, S. and O'Bryan, M., *Competition Policy Review*, March 2015, Recommendation 14, http://competitionpolicyreview.gov.au/final-report/ (accessed 15 February 2018).

13 Productivity Commission, *Shifting the Dial, 5 Year Productivity Review*, Inquiry Report No. 84, 3 August 2017, https://www.pc.gov.au/inquiries/completed/productivity-review/report/productivity-review.pdf (accessed 15 February 2018).

14 Department of Health, *Submission 7*, p. 9. Also see: Michael Meaney, *Submission 9*, p. 1; David Quilty, Executive Director, Pharmacy Guild of Australia, *Committee Hansard*, 27 November 2017, p. 2, which supported these objectives.

15 Department of Health, *Submission 7*, p. 6.

### *Previous reviews*

2.14 Since 2000 there have been seven reviews that have considered the Pharmacy Rules.[16] According to the Grattan Institute, pharmacy regulation is an area of 'policy purgatory' in which the Australian Government chooses not to implement change:

> The Productivity Commission's recommendations should be considered in the context of the policy limbo to which multiple previous reports on pharmacy regulation have been consigned.
>
> Independent reviews of pharmacy regulation have been ignored by successive governments. This policy purgatory now houses a plethora of independent reviews, Grattan Institute research and national audits. Report after report disappears, with the only explanation being that the pharmacy industry has far too great an influence on its own regulation.[17]

2.15 The Grattan Institute remained optimistic but warned that a 15-year cycle of review is creating public cynicism and disengagement. It argued that 'pharmacy regulation is overdue for reform, not further review with implementation stymied by vested interests'.[18] Rhodes Management added that the status quo is perpetuating inefficiency and red tape that affects consumers:

> Unless the government talks about true innovation nothing will change and a 10-year time horizon will further facilitate more palpable waste, red tape and inefficiency and ultimately that is not right for patients.[19]

### *Committee view*

2.16 The Pharmacy Rules are intended to support consumer access to medicines as articulated in the National Medicines Policy. However, the argument that this is aided by placing limits on the location of pharmacies is difficult to sustain. Clearly, it is of considerable benefit to existing pharmacies and makes the establishment of new pharmacies quite difficult.

2.17 The assertion that rural and regional areas would suffer a shortage of pharmacies if metropolitan pharmacies could be freely established is also difficult to sustain. If indeed there are rural and regional areas in which a community pharmacy is needed but not present, there are various ways in which this can be achieved without regulating the location of all other pharmacies.

2.18 The committee understands that, despite multiple reviews favouring change, the Australian Government has chosen to disregard calls for more competitive and consumer-oriented arrangements. Information presented to the committee reinforces these calls for reconsideration of the Pharmacy Rules to ensure they remain fit for purpose.

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16 Department of Health, Answer to Question on Notice, received 7 December 2017.

17 Grattan Institute, *Submission 6*, p. 7.

18 Grattan Institute, *Submission 6*, pp. 7–8.

19 Rhodes Management, *Submission 8*, p. 3.

**Recommendation 1**

**2.19 The committee recommends that the Australian Government reconsider its commitment to the Pharmacy Rules and investigate options to enhance competition in the delivery of pharmaceuticals listed on the Pharmaceutical Benefits Scheme, with priority given to consumers rather than pharmacy owners.**

## National Medicines Policy objectives

2.20 Submitters and witnesses told the committee that, in some respects, pharmacy regulation is not supporting the objectives of the National Medicines Policy. In particular, the viability of the community pharmacy sector is being affected, and medicines are not being supplied in the safest and most efficient manner possible.

### *Viability of community pharmacies*

2.21 The PGA explained that community pharmacies are small businesses that provide a range of professional health services to the community.[20] As such, they are affected by pharmacy specific, as well as general business, red tape issues. For example, in the sphere of pharmacy regulation:

- pharmaceuticals listed exclusively on the PBS under section 100 of the *National Health Act 1953* (Cth) (Act) are not covered by the Community Service Obligation,[21] meaning that pharmacists can pay more for these specialised medicines than the price on which their remuneration is based;
- a community pharmacist cannot charge a person more than the applicable patient co-payment, meaning that they cannot pass on any additional costs (surcharges) imposed by wholesalers; and
- there are inadequate arrangements to streamline processes that manage shortages of medicines and mitigate the impact on patients, causing increased workload for pharmacists and affecting patient satisfaction.[22]

2.22 The PGA argued that community pharmacies have limited ability to absorb costs such as retail lease occupancy costs and payroll taxes.[23] It argued that Goods and Services Tax (GST) arrangements are particularly burdensome and can create significant cash flow issues. Although GST is not chargeable on PBS medicines, it is paid throughout the supply chain and presents cash flow difficulties for pharmacists

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20 Pharmacy Guild of Australia, *Submission 4*, p. 1.

21 For further information on the Community Services Obligation, see: Department of Health, 'Community Service Obligation for Pharmaceutical Wholesalers', http://www.health.gov.au/internet/main/publishing.nsf/Content/community-service-obligation-funding-pool (accessed 15 February 2018).

22 Pharmacy Guild of Australia, *Submission 4*, pp. 5–7. Also see: David Quilty, Executive Director, Pharmacy Guild of Australia, *Committee Hansard*, 27 November 2017, p. 11.

23 Pharmacy Guild of Australia, *Submission 4*, p. 2. Also see: Grattan Institute, *Submission 6*, p. 6, which argued that allowing community pharmacies to provide a broader range of health services could contribute to remuneration, as well as engender a more collaborative approach to healthcare.

who may need to pay significant sums to suppliers on the rendering of an invoice.[24] The PGA's submission explained:

> The ability for a pharmacy to claim and receive reimbursement for the GST component before the supplier's [GST] invoice is due to be paid directly affects the pharmacy's cash flow with other subsequent flow on effects (e.g. overdrafts). Additionally, the need for pharmacies to manage the bespoke GST arrangements that apply to medicines result in a significant increase in paperwork for no apparent benefit to their patients.[25]

2.23 Some witnesses and submitters commented on the burden of having to operationalise various government policies or procedures—for example, Paid Parental Leave scheme arrangements[26] and the Uniform Recall Procedure for Therapeutic Goods.[27] Referring to the latter, Mr Quilty said that there is significant work for pharmacies involved in medicines recalls:

> ….particularly if patients have received medicines that may put their health at risk and the pharmacy needs to follow up with those patients. And it may not actually be that the pharmacy itself has dispensed that medicine; it may have been dispensed by another pharmacy. So, given the fact that medicines come with health ramifications, and, if a medicine has been tampered with, there can be serious repercussions, the work that pharmacy has to do is significant.[28]

2.24 Submitters and witnesses remarked also upon the burden incurred by community pharmacies in administering PBS Safety Net arrangements.[29] The Pharmaceutical Society of Australia (PSA) submitted that these arrangements

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24 David Quilty, Executive Director, Pharmacy Guild of Australia, *Committee Hansard*, 27 November 2017, p. 9.

25 Pharmacy Guild of Australia, *Submission 4*, p. 2.

26 Pharmacy Guild of Australia, *Submission 4*, p. 1.

For further information on the Paid Parental Leave scheme, see: Department of Human Services, 'Paid Parental Leave scheme for employers', https://www.humanservices.gov.au/organisations/business/services/centrelink/paid-parental-leave-scheme-employers (accessed 15 February 2018).

27 For further information on medicines recalls, see: Department of Health, Therapeutic Goods Administration, 'Recalls', https://www.tga.gov.au/recalls and 'Uniform recall procedure for therapeutic goods (URPTG)', https://www.tga.gov.au/publication/uniform-recall-procedure-therapeutic-goods-urptg-v20 (both accessed 15 February 2018).

28 David Quilty, Executive Director, Pharmacy Guild of Australia, *Committee Hansard*, 27 November 2017, p. 9. Also see: William Kelly, Chair, Pharmacy Board of Australia, *Committee Hansard*, 27 November 2017, p. 10, who argued that in relation to PBS listed medicines recalls, community pharmacies have a higher degree of responsibility than other retail venues due to their professional obligations.

29 For further information on the PBS Safety Net, see: Department of Human Services, 'Pharmaceutical Benefits Scheme (PBS) Safety Net', https://www.humanservices.gov.au/individuals/services/medicare/pharmaceutical-benefits-scheme-pbs-safety-net (accessed 15 February 2018).

routinely distract pharmacists from their duties and affect the timely provision of healthcare.[30]

### *Committee view*

2.25 The committee recognises that the efficient operation of community pharmacies is essential to the delivery of healthcare services. The committee heard that pharmacists are diverted from their core duties due to intervening red tape issues, many of which are within the purview of the Australian Government. The committee considers that it would be beneficial to relieve this pressure, commencing with a focus on GST issues.

**Recommendation 2**

**2.26 The committee recommends that the Australian Government investigate options to align the payment of Goods and Services Tax with business practices, to enable small businesses to better manage cash flow issues.**

2.27 The committee notes that the cost of supplying some medicines is not covered by the PBS, the RPBS or any other arrangement. The committee accepts that policy reasons might account for certain pharmaceutical items. However, the committee does not accept that community pharmacies should be exposed to costs attributable to wholesalers which are passing on costs arising from government imposed obligations.

**Recommendation 3**

**2.28 The committee recommends that the Australian Government:**

- **investigate the extent to which community pharmacies are exposed to unnecessary costs as a result of government policies in relation to the supply of pharmaceutical benefits; and**
- **implement measures to ensure that community pharmacies are not inadvertently exposed to costs arising from wholesalers' compliance with regulatory requirements.**

### *Safe and efficient medicines supply*

2.29 Submitters argued that the safe and efficient supply of medicines is diminished by current technologies. The committee also received information that suggests the Community Services Obligation (CSO), which requires wholesalers to supply PBS medicines at an agreed price and within certain timeframes, is impeding the equitable distribution of PBS and RPBS items.

### *Community Services Obligation*

2.30 Rhodes Management argued that the CSO should be abolished:

> The CSO is a $200M waste of money that funds inefficiency in the wholesaler supply chain under the auspices of guaranteeing supply mainly to remote or regional pharmacies…The problem is suppliers cherry pick

30 Pharmaceutical Society of Australia, *Submission 3*, p. 3.

> larger orders over smaller orders so they can recoup the delivery costs incurred.[31]

2.31 Instead, Rhodes Management proposed that a consignment stock arrangement and/or regional hub arrangement be implemented for rural and regional Australia.[32] Executive Director, Michael Rhodes, explained:

> The reason for that is that, particularly for high-cost medicines and highly specialised medicines, supply and demand can be infrequent. You could have a regional hub arrangement where certain pharmacies will stock some of the medicines on a consignment basis in order to not impede supply to consumers.[33]

2.32 Mr Rhodes conceded that the industry has not embraced the notion of consignment stock but argued that this arrangement would also solve cash flow issues, including those associated with the payment of GST:

> Consignment stock's just like any other inventory transaction. The only difference is that you'll supply the stock and not be invoiced for it until you sell it…It's actually frankly unreasonable for any pharmacy—in fact, any pharmacy chain, for that matter—to be bearing that cost, and particularly paying the GST on that, before they've sold the medicine...So this is about ensuring that the manufacturer and the wholesaler bear the responsibility for their efficient supply to the market, using a consignment arrangement. Once it's sold, it then it gets invoiced for, so you're not burdening that business with cash flow issues.[34]

2.33 Michael Meaney, a practising pharmacist, added another dimension to the argument, submitting that large manufacturers are moving away from wholesale distribution to a direct-to-pharmacy model.[35]

***Department response***

2.34 The Department responded to concerns about distribution, telling the committee that the Act does not prohibit any particular distribution model. Further, there is no evidence that the supply chain is failing community pharmacies or

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31 Rhodes Management, *Submission 8*, p. 6. Also see: Michael Rhodes, Executive Director, Rhodes Management, *Committee Hansard*, 27 November 2017, p. 15, who argued that this would represent massive savings for the Australian Government and taxpayers.

32 Rhodes Management, *Submission 8*, p. 11.

33 Michael Rhodes, Executive Director, Rhodes Management, *Committee Hansard*, 27 November 2018, p. 13.

34 Michael Rhodes, Executive Director, Rhodes Management, *Committee Hansard*, 27 November 2018, p. 18. His evidence added that the Australian Government could facilitate consignment stock arrangements.

35 Michael Meaney, *Submission 9*, pp. 1–2.

consumers, including in regional and remote areas.[36] Departmental officer Penny Shakespeare said:

> If we had patients who were seeking scripts and they were going unfilled, we would hear about that fairly quickly through direct contact from people who were trying to fill the scripts. We also have regular contact with the parties in the supply chain, including pharmacies, who tell us when there are problems with the supply chain. We also speak, obviously, with the wholesalers because we have deeds with them.[37]

2.35 Ms Shakespeare confirmed that Australian Government policy is to support the CSO approach, rather than a consignment stock arrangement.[38]

***Committee view***

2.36 The committee is not convinced that consignment stock is an appropriate response to the claim that smaller rural and regional pharmacies are subject to an inadequate service. Consignment stock would transfer the cost of inventory up the supply chain without necessarily addressing the problem. It would make more sense to quantify the dimensions of any problem and consider a more tailored response.

***Current technologies***

2.37 The PSA submitted that reliance on outdated technologies unnecessarily burdens community pharmacies, detracts from the consumer experience, and potentially lowers the quality of healthcare. Its submission claimed the implementation of electronic prescribing and electronic prescriptions reform would likely contribute to 'a more efficient healthcare system as well as enhanced medication safety and quality use of medicines for patients and families'.[39]

2.38 The committee heard that a centralised electronic system is urgently required for PBS Safety Net arrangements. The PSA described existing manual processes as 'one of the most archaic features' of the arrangements, which result in administrative burdens for pharmacists, for example:

- as patients can have medicines dispensed at any pharmacy, keeping track of up-to-date PBS Safety Net records can be challenging for pharmacists (who need to trace historical information); and

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36 Penny Shakespeare, First Assistant Secretary, Technology Assessment and Access Division, Department of Health, *Committee Hansard*, 27 November 2017, pp. 21 and 23.

37 Penny Shakespeare, First Assistant Secretary, Technology Assessment and Access Division, Department of Health, *Committee Hansard*, 27 November 2017, p. 23.

38 Penny Shakespeare, First Assistant Secretary, Technology Assessment and Access Division, Department of Health, *Committee Hansard*, 27 November 2017, p. 24.

39 Pharmaceutical Society of Australia, *Submission 3*, p. 6. The submission noted that electronic prescription systems have been successfully implemented overseas (for example, Norway, Sweden, Canada and Finland). Also see: Australian Medical Association, *Submission 2*, p. 1, which supported high quality primary healthcare services.

- if a patient spends over the threshold amount before receiving their PBS Safety Net Card, pharmacists need to provide details of medicines supplied and sign a statement in order for the patient to receive a refund.[40]

2.39 Dr Shane Jackson, National President of the PSA, emphasised that manual processes inconvenience and confuse consumers who believe that pharmacies are better connected. Further:

> …pharmacists are aware that sometimes patients miss out on what they're entitled to. For example, if a person or family has obtained PBS medicines from more than one pharmacy but not consolidated their safety net records, they may not realise that they have reached the threshold amount to qualify for a lower co-payment. This is an example of red tape interfering with the implementation of a well-intended government policy of equitable access to necessary medicines for all Australians, and people with chronic conditions are missing out.[41]

2.40 The PSA noted that PBS Online captures electronic information on medicines dispensation and the Medicare Safety Net already has a centralised electronic system.[42] Dr Jackson said:

> Given good connectivity between pharmacies and government, and a well-established practice of information exchange, we feel the implementation of a centrally-administered electronic system for PBS Safety Net arrangements should not be too difficult to achieve. We believe that this is a high priority.[43]

2.41 At an overarching level, Rhodes Management argued that what is required is two new digital portals: one to track the prescribing and dispensing of medicines (the Consultation to Collection (C2C) portal); and one to trade, track and supply PBS medicines in the market (the Pharmacy Supply Chain Portal).[44] Mr Rhodes described, for example, how the C2C portal would benefit pharmacists and consumers:

> Pharmacists should be able to look at your medicine consumption history. …What's important to pharmacists is: they need to know what your medicine consumption has been so that they can assess risk and interactions. Interactions can be: if you're on Lipitor, there may be a drug that you're also taking, or have historically taken, which may render that drug either ineffective or, in the case of some drugs, toxic. Right now, as a

40 Pharmaceutical Society of Australia, *Submission 3*, p. 4.

41 Dr Shane Jackson, National President, Pharmaceutical Society of Australia, *Committee Hansard*, 27 November 2017, p. 3.

42 Pharmaceutical Society of Australia, *Submission 3*, p. 4.

43 Dr Shane Jackson, National President, Pharmaceutical Society of Australia, *Committee Hansard*, 27 November 2017, p. 3.

44 Rhodes Management, *Submission 8*, p. 2.

> pharmacist, that cannot be seen. This is about, obviously, what's right for patients.[45]

2.42 Rhodes Management envisaged that the two proposed portals would:

> …glue everything together informationally and then through process so as to avoid the red tape involved [in] chasing information because of inefficient processes…The simple fact is the information that should be available is disaggregated and the processes they imbue are inefficient, timely and costly ultimately to the detriment of patient health…[Create the two portals] and the legacy of red tape, obfuscation and lack of transparency will be eliminated and most important pave a new way forward for efficiency, value, transparency and patient centric outcomes. It is a 21st century digital solution that dwarfs the 20th century dinosaur obfuscating legacy that are the CPA agreements.[46]

***Department response***

2.43 The Department confirmed that electronic prescriptions are current Australian Government policy, and that governments and software developers are working together to expedite implementation:

> A range of clauses in strategic agreements were reached earlier this year with Medicines Australia, the Generic and Biosimilar Medicines Association and the Pharmacy Guild through the updated and restated Sixth Community Pharmacy Agreement. We are currently working to ensure that we do progress e-prescribing and people are able to take their scripts from their doctors to the pharmacy without having to have a hard copy…we need to work with the states and territories to make the necessary changes to state, territory and Commonwealth laws to ensure that hard-copy scripts are no longer required, and to prescriber and dispenser software that allow electronic scripts to be transmitted from the doctor to the pharmacy at the patient's direction.[47]

2.44 In relation to data capture, Ms Shakespeare acknowledged that the Department receives a lot of medicines information that is used for various policy and compliance purposes. However, she warned of the need for caution with respect to patient data. Ms Shakespeare drew parallels to similar concerns about secondary use of My Health Record data, adding:

> It's something that needs to be carefully considered and balanced. There are public purpose reasons for which we use, and would continue to use, the e-prescribing data.[48]

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45 Michael Rhodes, Executive Director, Rhodes Management, *Committee Hansard*, 27 November 2018, p. 17. More conceptual detail was provided: pp. 13–15 and 17-18.

46 Rhodes Management, *Submission 8*, pp. 13 and 17.

47 Penny Shakespeare, First Assistant Secretary, Technology Assessment and Access Division, Department of Health, *Committee Hansard*, 27 November 2017, p. 23.

48 Penny Shakespeare, First Assistant Secretary, Technology Assessment and Access Division, Department of Health, *Committee Hansard*, 27 November 2017, p. 24.

### *Committee view*

2.45 The committee heard that there is an immediate need for better digital support in the PBS and RPBS. Information presented to the committee suggests that there are two options: adaption/extension of an existing system for PBS Safety Net arrangements; or implementation of a new system that would benefit all users of the PBS and RPBS. It is not entirely clear why the first option has not eventuated, as this would appear to be in consumers' best interests. The committee accepts that there is merit in the both suggestions and recommends accordingly.

**Recommendation 4**

**2.46 The committee recommends that the Australian Government develop a centralised electronic system for the PBS Safety Net, similar to the Medicare Safety Net.**

**Recommendation 5**

**2.47 The committee recommends that the Department of Health consider the proposal for two new digital portals to track the prescribing and dispensing of medicines; and to trade, track and supply pharmaceuticals on the Pharmaceutical Benefits Scheme and the Repatriation Pharmaceutical Benefits Scheme.**

## State/territory regulation

2.48 Some submitters remarked on state/territory regulation of community pharmacy. Some focussed on a common regulation requiring that only pharmacists can own community pharmacies. The AMA, for example, argued that broader ownership rules would promote more beneficial healthcare models:

> Incorporating pharmacy services into general practice, under the ownership of a medical practitioner, would improve patient care by allowing GPs to lead a team of co-located health professionals, including pharmacists and general practice nurses, in providing multidisciplinary health care to patients at the local community level. It would allow each health professional to work to their full potential in a well-supported environment. Importantly, patient medication management would improve through the close cooperative relationship between the doctor and the pharmacist.[49]

2.49 Similarly, the Grattan Institute submitted that the interests of consumers are not prioritised by pharmacy ownership rules. Instead, inefficient business models and commercial interests are promoted 'by effectively mandating the existence of many, smaller pharmacies…[with] high capital costs for each pharmacy'.[50]

2.50 As discussed earlier, Mr Quilty from the PGA did not agree that pharmacy ownership rules require attention, telling the committee that these rules 'work well':

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49 Australian Medical Association, *Submission 2*, p. 2. Also see: Rhodes Management, *Submission 8*, pp. 2 and 12.

50 Grattan Institute, *Submission 6*, pp. 3 and 5. The submission indicated that the competition in the pharmacy is not regulated in line with other sectors.

> What they ensure is that the owners of pharmacies—who have skin in the game—are registered health practitioners who have obligations in terms of meeting the health needs of their patients. They also ensure that there's actually a diverse ownership of pharmacies.[51]

2.51 Some submitters and witnesses commented particularly on the variation in medicines legislation, and argued that a lack of uniformity adversely affects pharmacy practice and patient care. William Kelly, Chair of the Pharmacy Board of Australia (PBA), provided the following example:

> Drugs of dependence may include a different range of drugs in different jurisdictions and consequently different restrictions may apply to some of the drugs in some jurisdictions. In one jurisdiction, a patient presenting a prescription for a drug of dependence at particular pharmacy must return to the same pharmacy to have prescription's repeat authorisations dispensed. Additionally, in some jurisdictions a repeat authorisation cannot be dispensed if the medication was prescribed in another jurisdiction. Such requirements impact on members of the public during travel and those living in communities located near the boarders.
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> Additionally, schedule 8 medicines require specific storage arrangements in pharmacies. These drugs are subject to particular requirements: for example, when expired drugs need to be destroyed. In some jurisdictions, pharmacists are permitted to destroy them in the presence of authorised health practitioners, such as other pharmacists. In other jurisdictions, a health inspector must be present. Consequently, arrangements then have to be made to store these drugs until an inspector attends the pharmacy, which may be infrequent.[52]

2.52 The PBA supported the harmonisation of legislation to simplify the regulatory environment. It considered that greater consistency could minimise errors and legislative breaches, as well as support the delivery of improved services.[53] The PSA confirmed that uniformity is a priority for pharmacists 'to remove duplication and confusion for patients and families, and enhance quality use of medicines'.[54]

2.53 Mr Kelly observed that harmonisation is a complicated and ongoing issue:

> It's not an easy fix. Our federated system is part of why it happens, but there are simple things I think need to be done. There is a certain degree of harmonisation with uniform poison schedules, but sometimes each of the

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51 David Quilty, Executive Director, Pharmacy Guild of Australia, *Committee Hansard*, 27 November 2017, p. 4. Mr Quilty also expressed the view that there is a need for differentiation in community pharmacies in terms of price and services, particularly for consumers with high needs: pp. 8–9.

52 William Kelly, Chair, Pharmacy Board of Australia, *Committee Hansard*, 27 November 2017, p. 2.

53 Pharmacy Board of Australia, *Submission 5*, p. 2. Also see: William Kelly, Chair, Pharmacy Board of Australia, *Committee Hansard*, 27 November 2017, p. 2, who provided examples of regulatory variation.

54 Pharmaceutical Society of Australia, *Submission 3*, p. 5.

> states has different variations on that. Where it comes into play is in the border towns—Queanbeyan, Canberra, Albury-Wodonga, et cetera—where there are differences, where people might cross the border to get their medicines, see the doctor or the pharmacist. Another good example is a child who might see a specialist at Westmead Hospital in Sydney and who then returns to Canberra with a drug of dependence—something, a particular drug, for ADHD—and that exposes the person and the practitioner to two sets of regulation before the patient gets that particular drug. Harmonisation sounds like a good idea, and we all ought to go for it, but I think there are practical things that can be done at a simple level first—but it ain't new.[55]

2.54 The committee notes that the King Review commented on the 'undue administrative burden for pharmacists' and 'confusion for some consumers' created by regulatory variation.[56]

***Committee view***

2.55 The committee understands that the pharmaceuticals industry is a dynamic environment. In this context, and in view of the Commonwealth's significant expenditure on pharmaceutical benefits, the committee considers it prudent to regularly consider how to best achieve affordable and quality outcomes for the Australian community. To this end, governments should encourage innovation in positive healthcare models provided that quality and accountability is not affected.

2.56 The committee received little information about governments' efforts toward uniform medicines legislation and notes the evidence of Mr Kelly. The committee considers that there are good reasons why governments should be actively working toward legislative consistency in pharmacy regulation, and not be dissuaded by the enormity or complexity of the task ahead.

2.57 The committee questions whether limits on the number of pharmacies that may be owned by an individual pharmacist or company are in the public interest. The committee understands that this is exceptional regulation in that there are no such limits for comparative professions (such as veterinary and dental practices).

**Recommendation 6**

**2.58 The committee recommends that the Australian Government, through the Council of Australian Governments:**

- **investigate and consider options for progressing uniform medicines legislation; and**
- **review restrictions on ownership of pharmacies and whether they serve the interests of the public rather than established owners.**

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55 William Kelly, Chair, Pharmacy Board of Australia, *Committee Hansard*, 27 November 2017, p. 5.

56 King, S., Watson, J. and Scott, W., *Review of Pharmacy Remuneration and Regulation*, Interim Report, Prepared for the Department of Health, June 2017, p. 6.

## Concluding comment

2.59 The Australian Government's 2013 Deregulation Agenda aims to reduce excessive, unnecessary and complex regulation to lift productivity and boost growth. The committee supports this objective but has found that red tape continues to unnecessarily and adversely affect the efficient operation of community pharmacies, to the ultimate detriment of consumers and contrary to the National Medicines Policy.

**Senator David Leyonhjelm**

**Chair**