

**Review of Pharmacy Remuneration and Regulation
Submission #208; 23-Sep-2016; Grattan Institute**



23 September 2016

Submission to Review of Pharmacy Remuneration and Regulation

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Overview

Pharmacies have an important role in providing the highest quality primary health care to the Australian community. Improving efficiency and access to care in pharmacies is crucial to improving the sustainability of the health system.

This submission focuses on four areas that we believe are overdue for reform: the pharmacy ownership rules, the location rules, the health services that pharmacists provide, and the broader regulation of entities receiving funding under the Pharmaceutical Benefits Scheme (PBS). We recommend reforms in these areas to better the consumer experience, at lower cost to consumers and taxpayers.

First, **we recommend that the pharmacy location rules be lifted in urban areas.** International experience shows that this is likely to improve access by permitting an increase in the number of pharmacies per person. Rural areas are unlikely to benefit from this deregulation and should be exempt from it.

Second, **we recommend cautious removal of the pharmacy ownership rules.** Like the location rules, these appear much more effective in protecting the commercial interests of pharmacy owners than in serving the public interest. And by tightly restricting the number of pharmacies that can be owned by a single person, they lock owners into small-scale and inefficient business models. Dispensing costs could be much lower if this were not the case.

International experience shows, however, that the savings from liberalisation are unlikely to be shared with consumers and government if removing the ownership rules leads to extreme concentration of ownership, as has occurred in some countries.

The risk of oligopoly is not a reason to preserve the ownership rules – we have the Australian Competition and Consumer Commission for that. However, care must be taken to ensure that the benefits of deregulation are shared by all parties.

Third, **we recommend allowing pharmacists to provide a much broader range of health services,** including vaccinations, prescription repeats and chronic disease management. The change would improve consumer access and convenience while reducing costs and some of the burden on general practice. It would also partially offset the fall in average pharmacy income that is likely to follow deregulation – a fair compromise.

Fourth, **we recommend a root-and-branch effort to fix the formulation and implementation of all PBS policies,** including pharmacy regulation. The usual reform channels are clearly not working. For more than a decade, independent reviews have called for reform of the sector and been largely ignored. A Prime Minister, no less, has intervened to preserve the restrictions.

Independent research and audits all show that the pharmaceutical industry has far too great an influence on its own regulation. The enduring existence of the location and ownership rules suggests that the community pharmacy sector does too.

Thus while we welcome this Review, we hope that it proves to be the last of its kind. A 15-year cycle of inquiry, recommendations and further review can only be breeding public cynicism and disengagement. No more reviews – pharmacy regulation is overdue for reform.

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1 Pharmacy location rules should be abolished in urban areas

A maze of complex rules, few of which would pass a pub test of common sense, govern the establishment, relocation and expansion of pharmacies in Australia. Collectively, the rules confer an advantage on the owners of existing pharmacies that incumbent business owners in few other industries enjoy, while restricting opportunities for new pharmacists and stifling consumer choice and access.

For more than a decade, independent experts have made the case exhaustively for abolishing the location rules. Both economic theory and available empirical evidence support a lifting of the location rules in urban areas. In rural areas, however, regulatory safeguards should be retained to ensure an adequate level of access.

1.1 The location rules are anticompetitive and do not serve the public interest

Pharmacists should be able to a new pharmacy wherever there is consumer demand for one. But in Australia, where a pharmacist can establish a new pharmacy is controlled by bureaucratic red tape that does little to help patients. At present, a number of location rules must be followed when establishing, expanding or relocating a pharmacy if the owner wishes to supply medicines that are publicly subsidised under the Pharmaceutical Benefit Scheme (PBS).

These rules effectively shield pharmacy owners from competition while shutting out new entrants. At the same time, they ensure that consumers have to travel further and to less convenient

places to buy medicines than they would otherwise need to. For example, pharmacies are not allowed to be located within, or directly accessible from, a supermarket. Yet the rules do not preclude pharmacies from selling groceries alongside medicines. This means consumers can still do their grocery and medicine shopping at the same time – they just have to do it at a pharmacy (where it's usually for a higher price).

1.2 Empirical evidence supports abolishing the location rules in urban areas

International evidence suggests that consumers would benefit from a lifting of the location rules.

OECD research has found that relaxing constraints on competition in professional services (including pharmacists) does not generally reduce service quality.¹ Instead, it improves access. When similar deregulation occurred in Europe, access to pharmacies improved for consumers living in urban areas:² new pharmacies opened and average opening hours increased.³ After Iceland, Sweden and Norway liberalised pharmacy regulation, opening hours increased from 42 to 53 hours per week, on

¹ Productivity Commission (2005), p 263

² All five of the countries that had, in some way, deregulated the establishment and relocation of pharmacies, saw an increase in the ratio of pharmacies to people in urban areas. Vogler, et al. (2014)

³ Vogler (2014), p 8

average.⁴ In Norway and Sweden the number of community pharmacies increased by 32 and 36 per cent, respectively.⁵

However, accessibility in rural areas of these countries did not improve. In fact, it may have worsened, were it not for the fact that safeguards were retained to prevent pharmacies from leaving the area without or with fewer pharmacies.

1.3 Deregulation may not affect prices

There is little evidence on the impact that deregulation had on subsidised medicine prices in these countries. This is to be expected – all of these countries have public healthcare systems where drug prices are set by government.

However, over-the-counter (OTC) medicine prices were free to move, and should have done so. When new pharmacies were able to open, competition should have intensified (at least in urban areas), putting downward pressure on prices.

However, researchers have been unable to confirm the impact of liberalisation on the prices of over-the-counter (OTC) medicines. Price studies on OTC medicines are rare, and show that prices fell after liberalisation in some countries, but not in others. It is not possible to conclude from this evidence that liberalisation in community pharmacy stimulates price decreases.⁶

⁴ Ibid

⁵ Ibid. Results were not reported for Iceland.

⁶ Vogler (2014), p 6

1.4 The available evidence is imperfect

The evidence we have cited in this chapter and the next comes from a review of the impact of pharmacy deregulation in nine different European countries.⁷ It has a number of limitations. There were gaps in the data collected,⁸ and translation issues complicated the research.⁹ Further, the review was commissioned by an industry body (although it was conducted by a government research institute, and drew on independently conducted studies).¹⁰ Nevertheless, the review provides the most comprehensive contemporary source of evidence we have on the effects of pharmacy deregulation.

⁷ Including five deregulated countries (England, Ireland, the Netherlands, Norway, Sweden) and four rather regulated countries (Austria, Denmark, Finland, Spain). Vogler, *et al.* (2014). Previous studies looking at the impact of pharmacy deregulation are older and only look at a few countries. Lluch and Kanavos (2010); Anell (2005)

⁸ Especially in the countries that had a deregulated pharmacy sector.

⁹ Sometimes the original study was only available in a foreign language. In these cases, access to the executive summary and an oral summary was provided by a research partner.

¹⁰ The Austrian Health Institute was established by federal statute, with the Austrian Federal Government its only shareholder. Its research activities are not bound by its shareholder. Gesundheit Österreich GmbH (2015)

2 The ownership rules should be cautiously lifted

The ownership rules, much like the location rules, appear much more effective in protecting the commercial interests of pharmacy owners than in serving the public interest. They also lock pharmacists into inefficient business models, elevating the cost of dispensing paid by consumers.

There is little justification for preserving the ownership rules, but care must be taken to ensure that all parties enjoy the benefits of deregulation. International experience shows that the savings from removing ownership restrictions are unlikely to be shared with consumers and government if oligopoly is allowed to result.

2.1 The ownership rules inflate costs

Australia has extensive restrictions on pharmacy ownership. In all states and territories, only pharmacists can own pharmacies.¹¹ In addition, the number of pharmacies that a pharmacist can own or have a financial interest in is restricted in all states (but not territories).¹²

These restrictions ensure that most pharmacies operate with high capital costs and low economies of scale.¹³ This leads to higher

¹¹ This includes corporate entities controlled by pharmacists. However, in all jurisdictions except the Australian Capital Territory, there are varying provisions to this rule, for example permitting friendly societies, relatives of pharmacists, and Aboriginal Health Services to own or co-own a pharmacy. Hattingh (2011)

¹² There are no restrictions on the number of pharmacies a pharmacist can own or have a financial interest in both the Northern Territory and the Australian Capital Territory.

¹³ Productivity Commission (2005), p 263

dispensing costs, which the PBS covers through dispensing fees paid to the pharmacy.¹⁴

If Australia were to abolish the pharmacy ownership rules, large groups of pharmacy retailers could merge under a single owner, with economies of scale driving down their average procurement, logistic and marketing costs. Supermarkets could use their already large and well-established supply networks, retail outlets and customer bases to supply medicines at particularly low costs. Removing the ownership rules would thus likely lead to a fall in the cost of dispensing medicines.

2.2 The savings may not be passed on

While significant cost savings could be achieved through the liberalisation of pharmacy ownership rules, it isn't at all clear that these would be *automatically* passed on to consumers or taxpayers.

2.2.1 Government would not automatically save

Except for the 'dollar discount' (which pharmacies don't have to offer consumers) the prices of subsidised medicines are fully regulated by government.¹⁵ As such, consumers and taxpayers would only save if government lowered PBS dispensing fees to reflect lower dispensing costs. The historically weak

¹⁴ Ibid

¹⁵ This is a competition reform allowing pharmacists to discount the cost of a prescription subsidised by the PBS by up to one dollar.

administration of the PBS suggests this may not eventuate, as Chapter Four discusses.

However, having large industry participants in subsidy negotiations with government (as opposed to government and the Guild alone) may strengthen government's hand in negotiations, or enable the establishment of a two-tier subsidy structure wherein large suppliers must charge a lower dispensing fee.

2.2.2 Consumers would not automatically save

As Chapter One shows, it is unclear whether the unregulated prices of over-the-counter medicines would fall. Price studies show that the removal of pharmacy location and ownership restrictions in other countries has not necessarily led to this result.

The lack of price reductions may be due to the concentration in market power that liberalisation permits. For example, three large wholesale companies own 81 per cent of pharmacy chains in Norway.¹⁶ In the absence of effective regulatory action, markets may become concentrated, leading to oligopolies¹⁷ and hurting consumers. Oligopolies can reduce competition by using their market dominance to deter new entrants, and align their product ranges to their supplies rather than to the needs of the consumer.¹⁸

¹⁶ This means that the supply chain and the pharmacy are owned by the same entity. Vogler, *et al.* (2014)

¹⁷ A state of limited competition, where the market is shared by a small number of producers and sellers.

¹⁸ Vogler, *et al.* (2006)

2.3 Government needs to ensure that the benefits of increased competition are shared

We do not raise these risks of deregulation in order to discourage it. Preserving an extremely inefficient dispersion of ownership in order to prevent oligopoly makes little sense. Fighting oligopolies is a job better left to the Australian Competition and Consumer Commission.

Instead, regulation can ensure that an adequate level of competition, access and service quality is maintained – irrespective of who owns pharmacies and where they are located. For example, competition can be preserved through more reasonable limits can be placed on the number of pharmacies held by an individual market player.¹⁹ Adequate access can be upheld through financial incentives for operating pharmacies in remote areas.²⁰ Service quality can be guaranteed through requirements for pharmacies to keep a minimum amount and range of medicines on stock and to fill prescriptions within a given period of time.²¹

Ultimately, care must be taken to ensure that all parties share the benefits of deregulation. Regulators must ensure that greater concentration of ownership does not lead to abuse of market power, and government must ensure that cost savings achieved by larger retailers are reflected in the dispensing fees they are paid.

¹⁹ Vogler (2014), p 9

²⁰ Ibid

²¹ Ibid

3 Pharmacists should be allowed to provide more health services

Pharmacists are highly trained, have deep expertise in medicines, are among the most trusted of all professionals,²² and are found in communities throughout Australia. Yet their role is far more limited in Australia than in many other countries.

Australians miss out as a result. People have to wait longer and travel further to see a GP for a service that their local pharmacist could just as easily provide. Sometimes they become sicker in the interim, increasing costs on the individual and the health system.

There is good evidence that pharmacists can safely administer vaccinations, provide repeat prescriptions to people with simple, stable conditions, and work with GPs to help patients manage chronic conditions. Allowing them to do so would improve the Australian health system by improving consumer access to care while reducing pressure on the primary care system.

3.1 Pharmacists should be allowed to administer a broader range of vaccines

Every year in Australia, nearly 1.3 million GP visits involve a vaccination to prevent a disease, with no diagnosis or other treatment involved. In many other countries, including Canada, England, Wales, Ireland and the USA,²³ these vaccinations would take place in a pharmacy, freeing up GPs to provide complex care more quickly to those who require it.

²² After nurses and on par with doctors. Roy Morgan (2016)

²³ Houle, *et al.* (2013)

In Australia, only doctors, nurses and Aboriginal health workers can administer vaccinations – even though the international experience clearly shows that pharmacist-provided vaccinations are safe.²⁴ Change has begun in recent years with pharmacists in most states now administering some vaccines, principally for influenza.²⁵

Research in Canada²⁶ and the United States²⁷ shows that when pharmacists were allowed to provide a broader range of vaccinations, patients reported improved accessibility, convenience and satisfaction. Successful trials in New Zealand showed that pharmacist vaccinators were far easier to see than a doctor.²⁸

Allowing pharmacists to vaccinate would improve their income while saving the health system money. Vaccinating in a pharmacy tends to be cheaper and more convenient than in a GP clinic.²⁹ It may also reduce hospital costs, since improved access to

²⁴ Guidelines similar to those used by nurses and pharmacist immunisers overseas can be adopted in Australia to protect patient safety and privacy.

²⁵ In some states, pharmacists can also administer measles and pertussis vaccines. Pharmacy Guild of Australia (2016)

²⁶ Papastergiou, *et al.* (2014)

²⁷ McConeghy and Wing (2016)

²⁸ McMichael (2012)

²⁹ Prosser, *et al.* (2008) showed that in the US, pharmacists could deliver vaccines for around 40% of the GP cost. Labour costs, as well as vaccine costs were lower in pharmacies, and people visiting pharmacies had a shorter wait than those seeing doctors.

immunisations can reduce vaccine-preventable hospital admissions.

3.2 Pharmacist should be able to issue simple prescription repeats

Doctors generally write prescriptions for up to six months' supply of medicines. After this time patients must return to get a new script, even if their needs have not changed. For people with long-term health needs that medication has under control, these visits may not require the advanced skills of a GP.³⁰ Pharmacists could do it instead.

Pharmacists should be able to continue medications for more long-term conditions, when the patient and GP agree, and when the patient's condition is stable. It would be straightforward.³¹ After a GP has made a diagnosis and created a treatment plan, they would be able to share the patient's record with the pharmacist, if the patient agrees. When a patient asks the pharmacist for a repeat script, the latter could look up the patient's record, confirm the medication, and issue the script.

Depending on the condition, the doctor could allow the pharmacist to issue continuing scripts for up to 18 months. Of course, if the

³⁰ At least 3.4% of all visits to the GP are 'less complex' visits that involve getting repeat prescriptions for problems previously treated by a doctor. The number could be higher. Depending on how missing data is treated, the proportion of visits that involve continuing medications (repeats) could be closer to 6.2%.

³¹ A number of GPs don't require seeing a patient for a repeat prescription – they might leave a copy at their front desk, with or without a charge. See Duckett and Breadon (2013), p 25.

patient's condition changed, they would return to their doctor to discuss their condition and review their medication.

Surveys of pharmacists in Australia suggest that most are willing to take on these roles with further training.³² Pharmacists in many other countries are already doing it. In recent years Canada, England, the Netherlands, Scotland and the USA have expanded the scope of their pharmacy practices in regard to prescribing.³³ Studies suggest that pharmacist prescribing can improve patient health and access to treatment,³⁴ and is positively regarded by both patients and pharmacists.³⁵

3.3 Pharmacists should be able to assist with chronic disease management

Managing chronic care is a significant and growing part of GP workload. More than half of GP visits involve managing at least one chronic condition.³⁶ Many of these visits involve managing medications or making dosage adjustments, rather than diagnosing conditions.

A large body of research suggests that chronic conditions are best managed in coordinated health care teams that can deal with the complicated demands of treating chronic disease.³⁷ Australia has

³² Hoti, *et al.* (2010). See also The Pharmacy Guild of Australia (2010)

³³ Including emergency prescription refills, renewing/extending prescriptions, changing drug dosage/information, therapeutic substitutions, prescribing for minor ailments, and prescription drug treatment. Mossialos, *et al.* (2015)

³⁴ Tsuyuki, *et al.* (2015); Backus, *et al.* (2015)

³⁵ McCann, *et al.* (2015); Makowsky, *et al.* (2013)

³⁶ Britt, *et al.* (2012)

³⁷ Proia, *et al.* (2014); Hirsch, *et al.* (2014)

made headway in using practice nurses and chronic care coordinators, but there is also an important place for pharmacists in managing chronic disease.³⁸ They could:

- Review a patient's medication, check for any adverse drug interactions and ensure that patients understand the medicines they are taking
- Adjust doses and discontinue or alter the medication
- Help treat acute conditions in chronic care patients, while avoiding adverse interactions with their existing medication
- Give patients compliance packaging (with all the pills they need to take each day packaged together)
- Inform GPs and other health practitioners of any relevant information about the patients' plan
- Issue repeat prescriptions, as discussed above
- ensure medications are being used properly and safely, and are able to identify any potential adverse drug reactions.

In many other countries, pharmacists are starting to do this. England and Scotland are at the forefront of transforming the role of pharmacists in chronic disease management, while Australia,

³⁸ Some Australian pharmacies already offer partial chronic disease care (including smoking cessation and weight management) as part of their routine practice, but could do so more effectively if the care was more expansive and formally integrated into primary care based disease management.

Canada, the Netherlands and USA report more limited progress.³⁹ Research in Canada found that both pharmacists and physicians appear to favour a more collaborative approach to chronic disease management: they agree on the benefits for patients but remain uncertain about the best ways of collaborating in the absence of changes to infrastructure and reimbursement.⁴⁰

Systematic reviews and meta-analyses of international randomised controlled trials found that pharmacist interventions significantly improve blood pressure management, blood glucose and cholesterol levels.⁴¹ They can also help patients with chronic conditions to more reliably take their medication and manage their own illness,⁴² potentially leading to lower hospital costs, with fewer admissions caused by errors in dosage and/or misuse of medication.⁴³

3.4 Expanded roles are a fair compromise

Removing the location and ownership rules, as we recommend, is likely to reduce the average pharmacy owner's income. Current owners will have to compete with a larger number of other pharmacies and large industry entrants such as supermarkets.

Allowing pharmacists to charge for the broader range of health services they are trained to provide will help them weather the transition by bringing in more income. This reform would make life better for both pharmacists and consumers.

³⁹ Mossialos, *et al.* (2015)

⁴⁰ Kelly, *et al.* (2013)

⁴¹ Santschi, *et al.* (2014); Tan, *et al.* (2014)

⁴² Zhong, *et al.* (2014); Ryan, *et al.* (2013)

⁴³ Malet-Larrea, *et al.* (2016)

4 A root-and-branch effort to fix PBS policies is required

We welcome this Review's consideration of the regulatory arrangements needed to promote high standards of delivery and accountability among pharmacies, wholesalers, manufacturers and other entities receiving funding under the PBS.

Independent research has consistently highlighted serious concerns in this area. High drug prices, poor administration of the Community Pharmacy Agreement and poor implementation of government policy have brought multi-billion dollar benefits to industry at the expense of consumers and taxpayers.

Endless review cycles have not brought the change required. A root-and-branch effort to fix both the formulation and implementation of PBS policies is required.

4.1 Independent calls for reform of pharmacy regulation have been ignored

Community pharmacy regulation has been subject to four independent reviews since 2000.⁴⁴ In each case, key aspects of the regulation were found to stifle competition and lack a public interest rationale.

In 2000 the independent **Wilkinson National Competition Policy Review of Pharmacy** recommended that the location rules be relaxed, noting that

⁴⁴ The Department of Health and Ageing and the Pharmacy Guild conducted a joint review of the location rules in 2005, and a review of their efficiency and effectiveness of the operation was undertaken by Urbis in 2010 (but public release of the report required the agreement of the Guild and Minister).

*These regulations restrict free and effective competition in the community pharmacy industry... it cannot be shown conclusively that the current restrictions are entirely in the public interest.*⁴⁵

The government never responded publicly to the Wilkinson Review recommendations relating to pharmacy.⁴⁶

A Council of Australian Governments working group subsequently criticised the Wilkinson review for failing to extend this critique to the ownership rules, and for failing to acknowledge that evidence from other health sectors and jurisdictions suggested that these rules were not necessary.⁴⁷

The working group withdrew its own proposed changes to the rules, however, after intervention by Prime Minister John Howard.

In 2005 the **Productivity Commission** noted with concern that governments had failed to act on the Wilkinson Review's recommendations to relax anti-competitive restrictions in pharmacy.⁴⁸ It noted that these were more stringent than those in several other countries and in other health sectors,⁴⁹ and that

*there seems little doubt that whatever the benefits, pharmacy restrictions potentially impose large costs on consumers, taxpayers and the wider community.*⁵⁰

⁴⁵ Wilkinson (2000), p 10

⁴⁶ Ibid., p 262

⁴⁷ Productivity Commission (2005), p 262

⁴⁸ Ibid., p xxii

⁴⁹ Ibid., p 264

⁵⁰ Ibid

Nevertheless, the rules persisted.

In 2014 the **National Commission of Audit** found that

the pharmacy sector is highly regulated and has not been subject to the same level of reform experienced by much of the economy. There remains limited retail choice and competition in the pharmacy sector...

Encouraging greater competition within the sector could be undertaken by moving to deregulate pharmacy ownership and location rules [leading] to more efficient delivery and the development of alternative retail models - such as pharmacists available to dispense medicines at supermarkets.⁵¹

A year later, the 2015 **Competition Policy Review** found that the *current restrictions on ownership and location of pharmacies are not needed to ensure the quality of advice and care provided to patients. Such restrictions limit the ability of consumers to choose where to obtain pharmacy products and services, and the ability of providers to meet consumers' preferences.*

The Review recommended that pharmacy be subjected to immediate reform, and that the

pharmacy ownership and location rules should be removed in the long-term interests of consumers. They should be replaced with regulations to ensure access to medicines and quality of advice regarding their use that do not unduly restrict competition.⁵²

⁵¹ Shepherd, *et al* (2014), p 112

⁵² Harper (2015), p 48-49

4.2 Government is failing to defend taxpayer interests

Over and over again, expert calls for reform of the ownership and location rules have fallen on deaf ears. The rules have remained subject to an infinite cycle of review, culminating in this one.

This pharmacy sector's immunity to reform is not the only problem with the regulation of the PBS:

- Our 2015 report, *Premium Policy*, showed that implementation of a key policy (the therapeutic group premium) has been so watered down that more than \$320 million a year is wasted on drugs that provide no additional therapeutic benefit.⁵³
- Our 2013 reports, *Australia's Bad Drug Deal* and *Poor Pricing Progress*, showed that the PBS was paying many times the prices that New Zealand, the United Kingdom and Australian public hospitals were paying for the same generic medicines, costing Australian taxpayers more than \$1 billion a year.⁵⁴

Other independent research has found similarly troubling problems. In a 2015 audit of how the Commonwealth Health Department administers the Community Pharmacy Agreement,⁵⁵ the Australian National Audit Office reported, among many negative findings, that the Health Department:

- over-estimated the savings the Agreement would generate

⁵³ Duckett and Breadon (2015)

⁵⁴ Duckett and Breadon (2013a); Duckett, *et al.* (2013c)

⁵⁵ Commonwealth of Australia (2015)

- reallocated funding covered by the Agreement without authority
- failed to achieve explicit government objectives
- did not keep formal records of meetings with the Pharmacy Guild (which represents pharmacy owners, who receive billions in funding from the Agreement)
- was not in a good position to work out whether the Agreement was achieving value for money.⁵⁶

There is a pattern to these problems of high drug prices and poor administration of the therapeutic group premium policy and the Pharmacy Agreement. Industry players clearly have too great a say in their own regulation.⁵⁷

4.3 A stronger approach is required

One part of the solution is to set up an independent body to set drug prices, including therapeutic premiums. New Zealand's PHARMAC plays this role effectively.⁵⁸

⁵⁶ A broader 2014 capability review of the Health Department also found serious problems. It evaluated the Department in ten domains with possible ratings of: strong; well-placed; development area; and serious concern. Only one domain was rated as well-placed, with seven development areas and two areas of serious concerns, Australian Public Service Commission (2014).

⁵⁷ Duckett and Breadon (2015)

⁵⁸ Duckett and Breadon (2013a). New Zealand does not have a therapeutic group premium, although it does use therapeutic group pricing in a different way: by subsidising only the cheapest one or two therapeutic equivalents.

More generally, the Health Department should keep lobby groups at arm's length. Consulting industry experts is vital to getting policy right, but the risks of regulatory capture are real: senior Health Department employees have noted the risk of more junior staff being captured by influential stakeholders.⁵⁹

A Lobbying Code of Conduct applies to all Commonwealth public servants, but it only covers consultant lobbyists who work for third parties. It does not cover lobby groups for professional groups or members, such as Medicines Australia, the Generic Medicines Industry Association or the Pharmacy Guild.⁶⁰

To fill the gap, the Health Department should develop clear standards and processes for working with lobby groups. It is clear, in the case of the therapeutic group premium policy at least, that lobby group involvement went well beyond appropriate consultation. The joint Health Department-industry working group was described *by the Department itself* as “agreeing” and “determining” how the policy is designed and implemented.⁶¹

New guidelines should make it clear that vested interests can be informed, consulted and debated, but that they do not determine policy and their agreement is not required before proposals go to the Health Minister.

However prices, premiums and policies are set, there is too little scrutiny of whether the PBS is getting good value. The Health Department or the Pharmaceutical Benefits Advisory Committee

⁵⁹ Australian Public Service Commission (2014)

⁶⁰ McKeown (2014)

⁶¹ Department of Health (2009)

should produce an annual PBS Performance Report that compares Australian prices to those in other countries and reports on whether policies such as the therapeutic price premium are doing their job.

Decades ago, the PBS was one of the best and most innovative drug purchasing programs in the world, but it has fallen far behind. More of the same policies won't put it back on track. A root-and-branch effort to fix both the formulation and implementation of PBS policies is required.

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