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Cutting a better drug deal

Stephen Duckett

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Overview

Australians pay too much for prescription drugs. Patients and taxpayers continue to pay much higher prices for medicines listed on the Pharmaceutical Benefits Scheme (PBS) than they should. This report identifies savings of over $500 million a year if the government pursues a better drug deal. With a mounting budget repair task, and the need to find money to fund new and better drugs, the government should grab this low-hanging fruit.

The government should reform two components of the PBS pricing policy. The first is 'price disclosure', a policy introduced in 2007 in a bid to cut costs of 'generic drugs' that are no longer covered by a patent. It has not gone far enough or fast enough. The second is the 'therapeutic group premium' policy, which was introduced in 1998 in a bid to stop the government wasting money on over-priced drugs that are chemically different but have the same outcomes for patients as cheaper drugs. The policy is now full of loopholes and no longer works.

The Grattan Institute has previously published three reports that tackled these issues and identified savings: *Australia's bad drug deal* (March 2013), *Poor pricing progress* (December 2013) and *Premium policy?* (June 2015). This report updates the savings estimates. There is some good news, but mainly bad news.

The good news is that price disclosure has been working, albeit slowly. Our March 2013 report identified more than $1 billion in savings that could be made each year, based on retail prices, with a better policy. In terms of wholesale prices – the approach used in this report – that is more than $600 million in savings each year. Price disclosure has forced prices down over the past few years, and we now estimate there are about $93 million in savings still to be made from reform. However, Australian drug prices remain unacceptably high, at 3.7 times higher than the best international prices.

Price disclosure should be supplemented by a new and more effective policy of benchmarking Australian prices to the best prices paid by comparable countries. Australia could have saved over $1.2 billion over the past four years had international benchmarking been in operation.

The bad news is that Australia's therapeutic group premium policy is weak and getter weaker. Our June 2015 report identified $320 million in savings that could be made each year if this policy were applied consistently across seven groups of commonly used drugs in Australia. In this report we update the analysis, to find that strengthening the policy as well as extending Australia's relatively small list of therapeutic groups from seven to 18 would together save more than $445 million a year.

These pricing reforms should be complemented by introducing more competition to retail pharmacies, which would both save patients more and provide better access to quality health care.

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1 Pricing of generic drugs

1.1 Prices of generic drugs are falling too slowly

The policy of 'price disclosure' was introduced in Australia in 2007 in a bid to cut the prices of generic drugs – drugs that are no longer under patent. Under the policy, drug companies are required to reveal how much they actually charge pharmacies for generic medicines over a 12-month period. The government then uses this information to calculate the average price pharmacies pay after discounts, and reduces the amount it pays to pharmacies for each drug accordingly.

Drug prices are cut in two rounds each year, in April and October. In October 2016, the prices of 97 drugs were cut, on average by 27 per cent. The prices of 64 drugs are listed to fall in April 2017, on average by 24 per cent.

Price disclosure has worked, but too slowly. The price of generic drugs in Australia has fallen substantially, but it has taken many years. If a more effective policy had been in place, the savings to the government (and therefore taxpayers and patients) would have been much greater.

A better policy is 'international benchmarking'. We called for such a policy for Australia in our March 2013 report, *Australia's bad drug deal* and again in our follow-up *Poor pricing progress* report released later that year.[1] We repeat that call now.

Benchmarking looks at the prices paid for the same drugs by other comparable jurisdictions. It is widely used for drug pricing, even though there are some limitations of the approach because there may be undisclosed price discounts in some countries.[2] Nevertheless, Canada, New Zealand, Japan and most member states of the European Union use benchmarking to various degrees when setting prices for their drugs.

Australia should do the same. The government should establish an independent pricing authority which would set a price for each drug, based on an international benchmark. If this were done, Australia would pay less for generic drugs listed on the PBS.

1.2 Australia will achieve comparable prices – eventually

Generic drugs in Australia are becoming much cheaper, even under the inferior 'price disclosure' policy. Australian prices are still higher than the best international prices for most drugs, but Figure 1.1 on page 9 suggests we are on track to reach parity – eventually.

In our December 2013 report, *Poor pricing progress: price disclosure isn't the answer to high drug prices*, we analysed the prices of seven drugs: olanzapine, anastrozole, letrozole, quetiapine, atorvastatin, venlafaxine, and mycophenolic acid. Since then, Australian prices for these seven drugs have fallen, from 16 times the best price in the benchmark regions of the UK, New Zealand, and Ontario, to five times the best international price.[3]

For instance, the price of atorvastatin – the most prescribed drug on the PBS – has fallen from more than nine times the benchmark best price in 2013, to about 1.5 times.[4]

1.3 Australia's prices can fall a lot further

For this report, we compared Australian prices to those in the UK, New Zealand, and two Canadian provinces – Ontario and Alberta. We

1. Duckett et al. (2013a); and Duckett et al. (2013b).
2. Wagner et al. (2004).
3. Duckett et al. (2013b).
4. Mabbott et al. (2016).

looked at 19 drugs (listed in Figure 1.3 on page 10) which were subject to price disclosure cuts in October 2016 (four of them will be cut further in the April 2017 round).[5]

After the April 2017 round of price reductions, Australia's prices will still be, on average, 3.7 times higher than the benchmark best price. Nonetheless, this is a big improvement on the 16-times-higher finding in our 2013 report.

Price disclosure has particularly improved drug prices in Australia compared to Canada. In 2013, we found that Australia was paying on average more than twice the Canadian price for the seven drugs considered. Now, Canada is paying on average almost twice what Australia does. Indeed, for 17 of the 19 drugs considered, Australia now has cheaper prices than either Ontario or Alberta.

However, Australia's drug prices remain more than twice that of the UK, and 3.6 times higher than New Zealand's, as seen in Figure 1.2 on page 9. The latest Australian price for anastrozole (Arimidex), a breast cancer drug, is $19.20 for a box of 30 1mg tablets. In the UK, it is just $2.45. Australia had the lowest price for only three of the 19 drugs we considered.

1.4 International benchmarking beats price disclosure

The high cost of drugs is a problem not only for Australian taxpayers; it also affects the health of some patients. In the past 12 months, an estimated 8 per cent of Australians delayed getting, or did not get, their prescribed medication due to the cost.[6]

5. This comparison uses ex manufacturer prices, before any wholesale mark-ups and pharmacist dispensing fees.
6. ABS (2016).

Price disclosure is helping. The prices of 18 of the 19 drugs looked at are now below $38.30 – the maximum price paid by patients who do not have a concession card and are below the Safety Net threshold.

However, for 16 of those drugs, international benchmarking would reduce prices more than price disclosure, as shown in Figure 1.3 on page 10. Non-concessional patients would save an additional $6.43 per pack, on average, under international benchmarking.

1.5 Australian pharmacist mark-ups are internationally competitive

The final price that patients pay for their drugs is determined after pharmacist fees and mark-ups are added to the wholesale price.

As outlined in Box 1 on the following page, Australia's pharmacist fees and mark-ups are competitive with those in the benchmark regions. As a result, most of the savings to patients from drug pricing reform will come from the wholesale price of the drug itself.

1.6 Benchmarking would have led to more savings, faster

Price disclosure is gradually bringing our generic drug prices into line with international rates. But the government could have saved a lot more money earlier if it had introduced international benchmarking. In the year 2013, had international benchmarking applied, the government would have saved more than $635 million (in 2016 dollars) on the wholesale prices of 25 of the most prescribed drugs in the PBS. In the year 2016, the savings would have been $93 million under international benchmarking. Pursuing the slower 'price disclosure' process instead of transparent international benchmarking conducted by an independent pricing body cumulatively cost the government more than $1.2 billion between 2013 and 2016 (Figure 1.4 on page 10).

Box 1: Pharmacist mark-ups in Australia and overseas

In **Australia**:[a] A handling and dispensing fee of $3.54 for medicines less than $180. For medicines between $180 and $2,089.71, a fee of $3.54 plus a mark-up of 3.5% on the amount above $180. Medicines over $2,089.71 attract a fee of $70.92 per item. A 'ready-prepared' fee of $7.02 per prescription also applies.

In the **UK**:[b] A fee of £8.40 per item, and an unregulated pharmacy mark-up (negotiated between the wholesaler and pharmacist).

In **New Zealand**:[c] A prescription charge of NZ$5 per subsidised item for people aged 13 and older, with the government covering handling and dispensing fees. An additional pharmacy mark-up of 4% for medicines with a subsidy value of less than NZ$150, or 5% for those with a subsidy value of more than NZ$150.

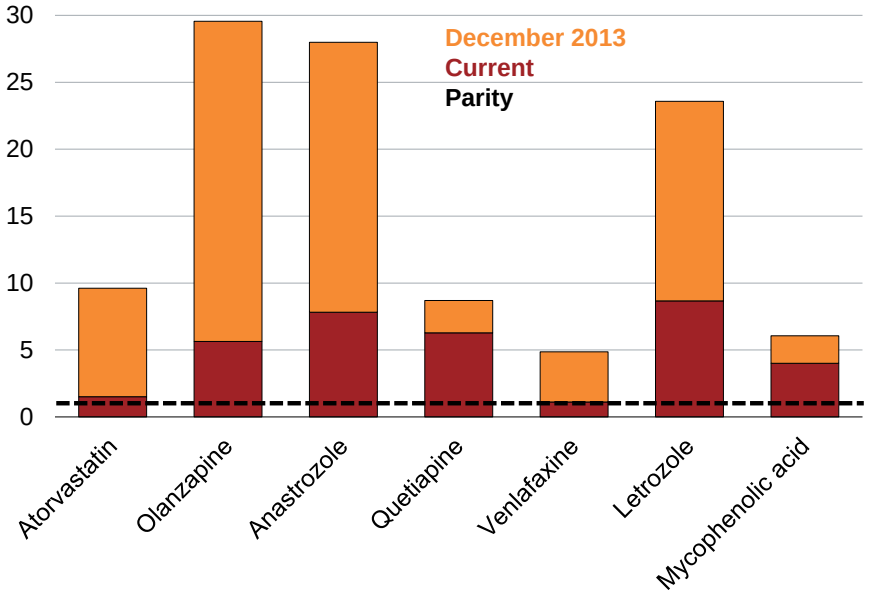
In **Ontario**:[d] A dispensing fee of C$7 per item, and a mark-up of 8% on the drug price.

In **Alberta**:[e] A dispensing fee of C$12.30 per item, plus two allowable mark-ups, of either 3% or 7%.

a. Department of Health (Cth) (2016a).
b. National Health Service (UK) (2016).
c. Foster et al. (2011); and New Zealand Government (2016).
d. Ministry of Health and Long-Term Care (Ontario) (2015).
e. The 7% mark-up cannot exceed a total of C$100. Government of Alberta (2016).

Figure 1.1: Australia still pays multiples of the benchmark price for seven common drugs

Australian ex manufacturer prices as multiples of the lowest price in the UK, New Zealand or Ontario, December 2013 and now

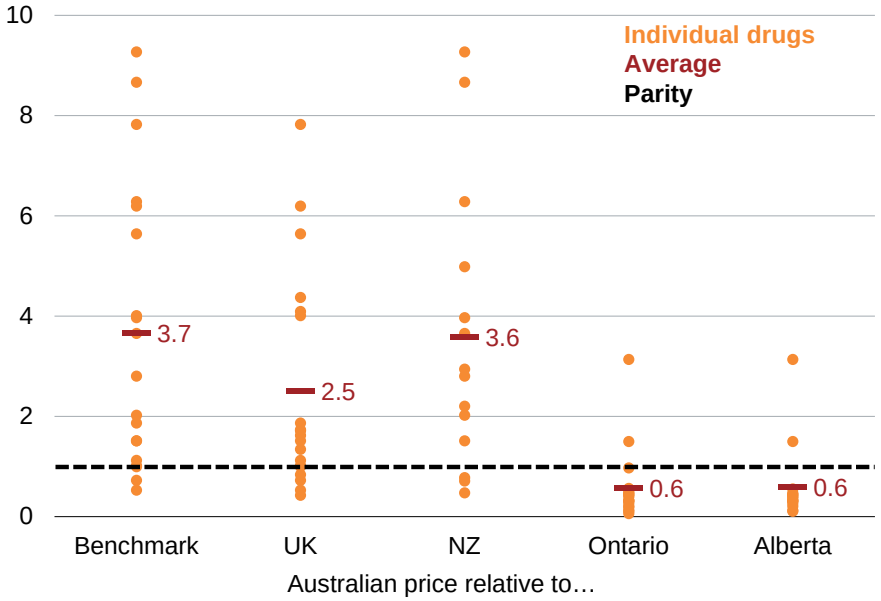


Notes: Based on nominal doses. Drugs ordered by prescribing volume.

Source: Grattan Institute analysis as described in Appendix A.

Figure 1.2: For most drugs looked at, Australia pays higher prices than the UK and New Zealand but lower prices than Canada

Australian ex manufacturer prices as multiples of overseas prices, after April 2017 price disclosure cuts

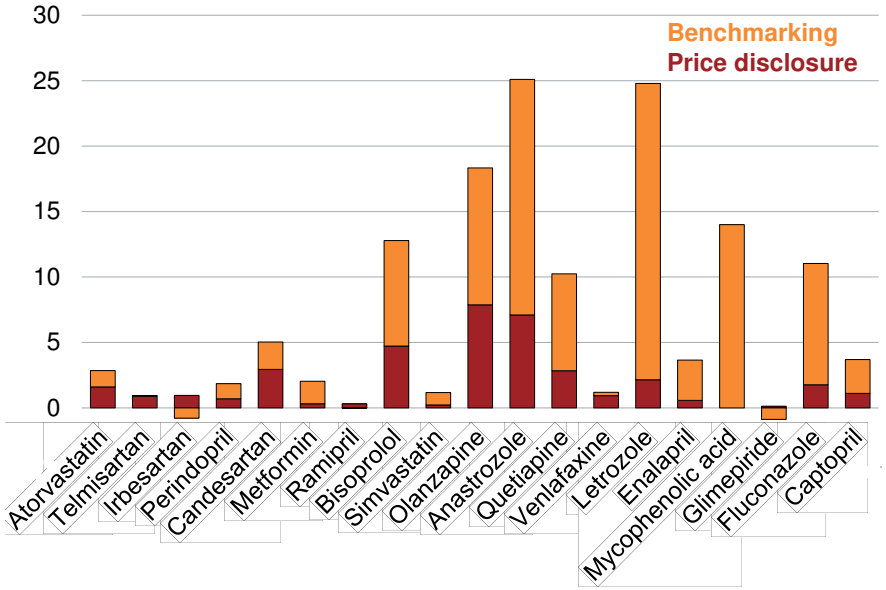


Notes: Benchmark refers to lowest price in the UK, New Zealand, Ontario and Alberta. Based on nominal doses.

Source: Grattan Institute analysis as described in Appendix A.

Figure 1.3: Patients could save even more from benchmarking than price disclosure

Actual savings to patients from price disclosure and unrealised savings from benchmarking between April 2016 and April 2017 price disclosure cuts, $ per box

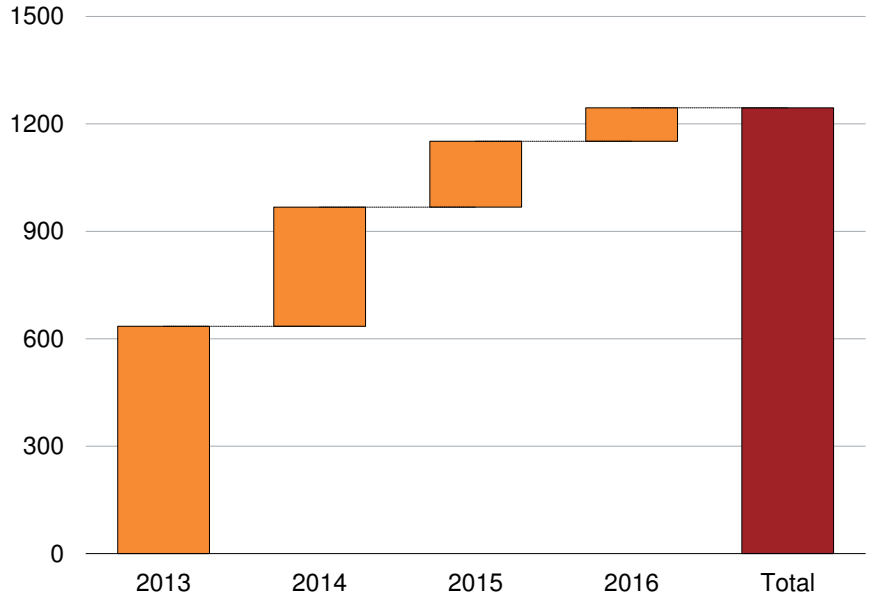


Notes: Savings are for non-concessional patients above the Safety Net. Based on nominal doses. Drugs ordered by prescribing volume.

Source: Grattan Institute analysis as described in Appendix A.

Figure 1.4: Using price disclosure rather than benchmarking cost the Commonwealth Government $1.2 billion over four years

Unrealised savings from benchmarking, $2016 million



Notes: Based on all comparable dose varieties of each drug, inflation adjusted. These savings are based on wholesale prices, in contrast to the $1 billion in savings identified in our 2013 report, Australia's bad drug deal, which were derived from retail price differences between Australia and New Zealand. Wholesale prices were used here because this analysis compares prices across several countries, some with opaque mark-up policies.

Source: Grattan Institute analysis as described in Appendix A.

2 The problem with therapeutic group premiums

2.1 What is a therapeutically equivalent drug?

Among the hundreds of medicines listed on the PBS are clusters of drugs that treat the same disease and achieve similar results; that is, they are drugs in therapeutically equivalent groups.

However, even when the result is similar, the price paid by the government may vary significantly. Before a drug is listed on the PBS, it has to be shown that it is 'better' than another drug.[7] But the extent to which it is 'better' may be small and yet the price difference could be large. Sometimes the difference between drugs may be how they are administered – a tablet compared to an injection, for example – and sometimes how long the effect lasts – one tablet every few hours or one tablet a day.

Some patients will value these differences more than others. But because the therapeutic outcome is similar, many countries have determined that if manufacturers want to charge more for marginally 'better' drugs, then the patient rather than the government should pay the extra cost.

Under this policy, governments subsidise only the cheapest drug within a therapeutically equivalent group. For example, propranolol and pindolol can both be used to treat high blood pressure and angina. For most people, these drugs are equally safe and effective. A 40mg tablet of propranolol is therapeutically equivalent to a 5mg tablet of pindolol.[8] Yet a pack of 100 40mg propranolol tablets costs the PBS $13.58, compared to $31.44 for a box of 100 5mg pindolol tablets.

7. Drugs can also be listed if they are at least equivalent to another drug but offered at a lower price.
8. Cafer (2016).

A therapeutically equivalent drug policy was introduced in Australia in 1998, but the way it now operates is deeply flawed.

2.2 Australia saves less than other countries on therapeutically equivalent drugs

For non-concessional Australian patients, the price of drugs listed on the PBS is capped at $38.30.[9] When drugs cost more than this, the government covers the extra cost.

With therapeutic group premiums, the government only pays for the cheapest drug within a therapeutically equivalent group. For the other drugs in the same group, the manufacturer can either decide to cut their prices to the level that the government funds, or pass on the additional cost to patients as a mark-up. This mark-up is the 'therapeutic group premium'.[10]

While the theory is good, the way the therapeutic group premium operates in Australia is bad. There are too few drug groups, and the current policy tolerates higher prices for drugs which are largely equivalent to cheaper versions.

The policy currently only applies to seven groups:

- ACE inhibitors.

9. General patients pay a maximum of $38.30 at the pharmacist. Concession patients pay a maximum of $6.20. After patients reach the PBS Safety Net threshold (a certain level of expenditure in a year), these maximum fees fall to $6.20 for non-concession patients and zero for concession patients. Some surcharges above these limits apply, such as the therapeutic group premium discussed here.
10. Doctors are able to exempt from the premium patients who may experience an adverse reaction to a therapeutically-equivalent drug. For more information, see Duckett et al. (2015).

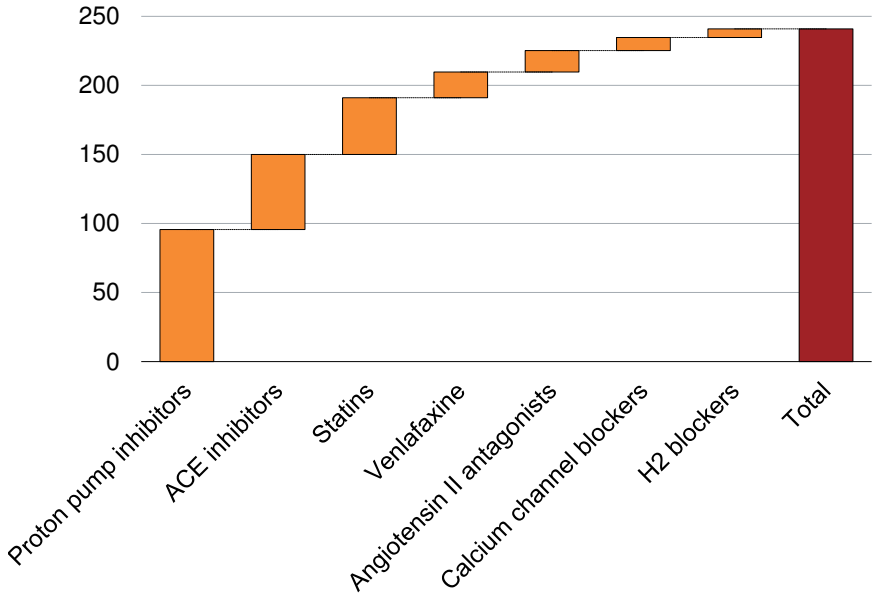
- Angiotensin II receptor antagonists.
- Calcium channel blockers.
- H2 blockers.
- Proton pump inhibitors.
- Statins.
- Venlafaxine and venlafaxine derivatives.

The size of therapeutic group premiums is also reduced by Australia's price disclosure policy, because drugs that had been subject to price disclosure are removed from therapeutic groups. As price disclosure has expanded to more drugs, the effectiveness of therapeutic premiums has been reduced still further. There are now only two drugs in Australia which have a therapeutic premium: eprosartan and olmesartan medoxomil.

In our previous report on this topic, *Premium policy? Getting better value from the PBS*, we showed that the government could save about $320 million a year if therapeutic premiums were expanded to completely cover the cost gaps across the seven drug groups we analysed.[11]

Using updated data from August 2015 to July 2016, we calculate that the government could still save more than $240 million a year (see Figure 2.1). This represents more than 2 per cent of the PBS budget for 2016/17.[12]

Figure 2.1: If premiums covered the full cost gaps, the Commonwealth Government could save $240 million a year across seven drug groups
Annual savings from improving current therapeutic group premium policy, $ million



Notes: Groups ordered by savings.

Source: Grattan Institute analysis as described in Appendix A.

11. This assumes that all drugs within a therapeutic group, regardless of whether they have been subject to price disclosure, are reintroduced. An increase in the authority prescription rate to 5% was also assumed. See Appendix A for more detail.
12. The Treasury (Cth) (2016).

2.3 Broadening Australia's therapeutic groups would save over $200 million per year

Many other countries have much broader therapeutic premium policies. Germany, for instance, has more than 30 therapeutic groups, and new drugs are ranked on a scale of 1 to 6 on the extra benefits they give to patients (see Figure 2.2).

If Australia increased the number of therapeutic groups to include many more drugs as Germany has, the savings would be bigger still.

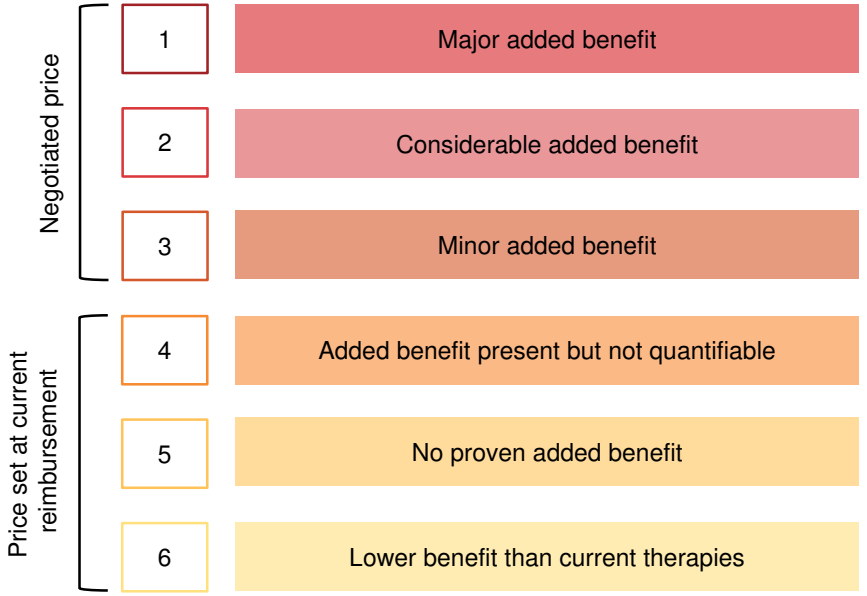
For this report, we added 11 therapeutic groups to the seven analysed in our 2013 report. The new groups were:

- Anti-diabetics (sulphonylurea).
- Anti-psychotics.
- Beta blocking agents.
- Diuretics.
- Fibrates.
- Glucocorticoids (oral).
- Heparins (low molecular weight).
- Insulins.
- Macrolides.
- Selective serotonin reuptake inhibitors.
- Triazoles.

We excluded groups which either had only one listed drug on the PBS or consisted of only authority medicines – that is, medicines that cannot

Figure 2.2: Germany has a graded system for rating equivalence between drugs

German therapeutic drug rating and pricing



Notes: The rating a drug receives can be varied across patient sub-populations.

Source: Lauterbach et al. (2016).

be prescribed without prior approval from the Department of Human Services or the Department of Veteran's Affairs.[13]

As shown in Figure 2.3, the government could save an extra $205 million (beyond the initial savings of $240 million) if it increased the number of therapeutic groups to 18.

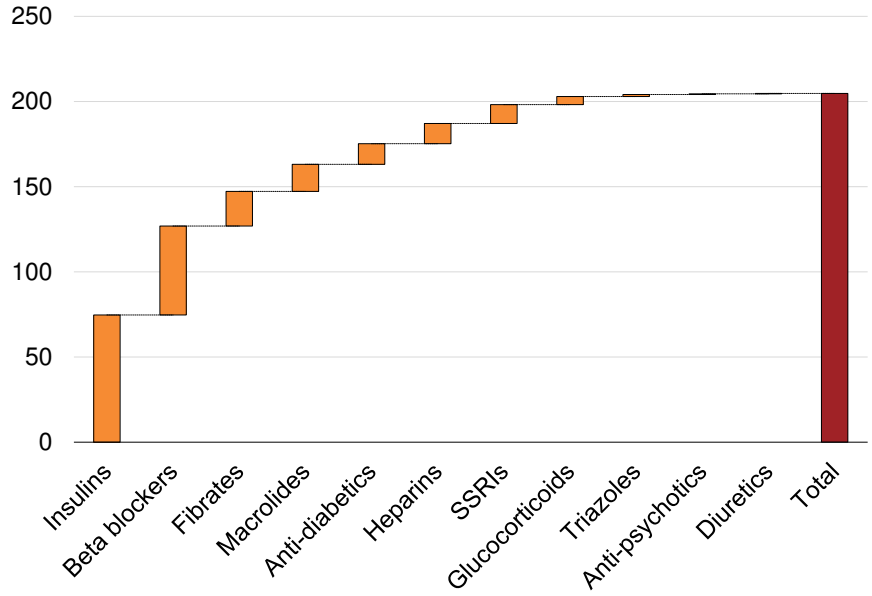
The primary contributors to the increased savings are insulins, beta blockers, fibrates, macrolides, and anti-diabetics. These five groups alone add a further $175 million in savings to the seven therapeutic groupings we considered in our 2013 report.

Our analysis is conservative. There are further savings to be made by looking back to the reason drugs were listed on the PBS. If the very basis for listing a drug was that it was therapeutically equivalent to another drug but cheaper, and that second drug comes off patent, then the first drug should logically become cheaper too. But that does not happen. One study has estimated potential savings of over $500 million from forcing price reductions in these circumstances.[14]

2.4 More comprehensive therapeutic premiums would discourage 'ever-greening'

Pharmaceutical manufacturers are increasingly taking out low-quality (secondary) patents to extend the longevity of a drug's original patent. This is called ever-greening (see Box 2 on the next page). It delays the entry into the market of generic competitors, and consequently costs the PBS millions of dollars.[15] Broader and more comprehensive therapeutic premiums would address this problem by grouping therapeutically equivalent drugs and subsidising only at the price of the cheapest.

Figure 2.3: By extending the number of therapeutic groups to 18, the Commonwealth Government could save an extra $205 million a year
Annual savings from improving current therapeutic group premium policy, $ million



Notes: Groups ordered by savings.

Source: Grattan Institute analysis as described in Appendix A.

13. Department of Health (Cth) (2012).
14. See Karnon et al. (2017). There may be some double counting between the estimates in that paper and our estimates, but there will also be additional potential savings that we have not captured.
15. Moir (2016).

This reduces the ability of pharmaceutical companies to sustain high prices well beyond the original patent duration by ever-greening.

While patents are an important incentive for companies to invest in research and development, the government should not otherwise be safeguarding the profit margins of pharmaceutical companies. A stronger therapeutic group premium policy would reduce the ability for pharmaceutical companies to charge inappropriately high prices for marginal innovations to drugs.[16]

2.5 Improvements in drug quality are not matching the increase in prices

As patents expire for blockbuster drugs which treat large numbers of patients, newer drugs are not sustaining the original level of innovation.

A recent study found that for 68 per cent of pharmaceutical innovations, the quality-adjusted price was significantly higher than that of an existing, comparable technology. The median new 'innovation' improved quality by 1 per cent but increased price by 8 per cent.[17] This trend is likely to be similar within therapeutic groups.

16. Ghinea et al. (2016).
17. Hult et al. (2016). The average price increase of a new pharmaceutical innovation was 139 per cent, associated with an average quality improvement of 26 per cent. Some of the increase in quality-adjusted price of new drugs may also come from pharmaceutical companies recouping higher fixed costs in drug research and development. Recently, research and development investment costs have substantially increased primarily in response to increasing market size (with more patients to treat). A 10 per cent increase in potential market size was found to be associated with a 14 per cent increase in research and development investment. Increases in demand by patients which are unmatched by increases in the supply and quality of drug ideas lowers research and development productivity; see Pauly et al. (2016). Declining research and development productivity appears, nevertheless, to be a general problem; see Bloom et al. (2016).

Box 2: Ever-greening with venlafaxine and omeprazole

Pharmaceutical companies often apply for secondary patents for their drugs relating to new chemical compositions, processes or treatment methods. This is known as ever-greening and is designed to sustain the higher prices companies can charge for patented drugs. It can delay by years the introduction to the market of generic drug competitors.

Venlafaxine (and desvenlafaxine), used to treat depression, and omeprazole (and esomeprazole), used to treat heartburn and acid-related disorders, have been the subject of ever-greening in Australia.

Venlafaxine and desvenlafaxine are therapeutically identical; venlafaxine is metabolised into desvenlafaxine in the human body. However, when desvenlafaxine (Pristiq) was introduced and patented after the expiration of the original venlafaxine patent, there was a prescribing shift in favour of desvenlafaxine. This is estimated to have cost taxpayers $47.2 million in 2014-15.[a]

Similarly, omeprazole and esomeprazole (Nexium) are therapeutically equivalent in preventing gastric acid production. After the original omeprazole patent lapsed and esomeprazole was introduced and patented, there was a prescribing shift towards esomeprazole which is estimated to have cost taxpayers $132.9 million in 2014.[b]

a. Moir (2016).
b. Ibid.

Much of the price increase for new drugs is associated with greater convenience in administration.[18] For example, patients may prefer to have a tablet rather than several injections, and this convenience is the 'innovation' of the new drug.

Pharmaceutical companies can charge for this additional convenience. But most other countries with publicly subsidised pharmaceutical schemes do not subsidise the extra costs for these marginal benefits.

Categorising the added benefit of any new drug, as Germany does, is therefore an important step in a robust therapeutic premium policy. If a new drug simply adds to an existing therapeutic group, the government should only be covering the cost of the most efficient way of achieving the therapeutic outcome.

Such a policy approach would also encourage pharmaceutical companies to be more innovative in seeking to create new drugs and therapeutic groups that deliver significantly better treatment for patients.

18. Aitken et al. (2016).

3 Reforming retail pharmacy

The Review of Pharmacy Remuneration and Regulation is evaluating the rules governing the location and ownership of pharmacies, and the services that can be provided by pharmacists, to ensure patients have 'reliable and affordable access to medicines'.[19] This review should save patients more by adding extra competition to the pharmacy industry.

3.1 Location and ownership rules

Existing location rules restrict the establishment, relocation and expansion of pharmacies across Australia. Several independent reviews of the pharmacy sector over the past decade have found these rules to be anti-competitive, especially in urban areas.[20]

Far from serving the public interest, these rules tend to protect incumbent pharmacies and restrict market entry.[21] Stifling competition between pharmacies results in higher retail drug prices – a cost borne by patients and taxpayers. It also limits the choice of drugs for many consumers.

These rules should be replaced with simpler regulations which focus on ensuring patients have appropriate access to good-quality medicines. Similar reforms in Europe have improved pharmacy access for urban consumers, with more pharmacies opening, and average opening hours increasing.[22]

Australia's rigid ownership rules also lock in inefficient business models. By effectively mandating the existence of many, smaller pharmacies, the rules enforce high capital costs for each pharmacy, protecting commercial rather than public interest.

The rules should be carefully relaxed, under the supervision of the Australian Competition and Consumer Commission. It is important to prevent abuse of market power by a more concentrated sector, which could arise from major pharmacy mergers. Nevertheless, the introduction of more competition would bring the pharmacy sector more in line with how other sectors are regulated.

Allowing pharmacies to merge would create economies of scale. Larger scale would facilitate lower procurement, logistics and marketing costs. Some of these cost savings may then be passed onto consumers.

3.2 An expanded role for pharmacists

Passing on lower costs to patients could reduce the incomes of community pharmacists. To mitigate this, the role of pharmacists should be expanded so they become part of a coordinated team providing health care to their local community. In particular, local pharmacies, as part of a team with general practitioners, should be empowered to:

- **Administer vaccinations.** Currently, this role takes up GPs' time, which could better be used managing more complex medical cases.
- **Give drug information to patients, review their medication and adjust doses when required.**
- **Prescribe repeat medications** for patients with simple and stable medical conditions.

19. Department of Health (Cth) (2016b).
20. Duckett et al. (2016).
21. Wilkinson (2000, p. 10).
22. OECD (2014, p. 8).

- **Work with GPs** to manage treatment for patients with chronic diseases.[23]

Pharmacists are highly skilled health care professionals. With appropriate further training, they could safely perform these additional roles.[24] And giving pharmacists the authority to administer vaccinations and provide repeat prescriptions has been found to improve patient satisfaction and access to treatment.[25]

Managing the care of patients with chronic diseases is an increasingly important part of the health care system. At present, this responsibility rests primarily with GPs. But coordinated health care teams, which include physicians, nurses and pharmacists, have been found to be most effective in managing patients' chronic conditions.[26]

In fact, pharmacists and physicians believe a more collaborative approach produces better results for patients.[27] These coordinated health care teams could be funded by a combination of public money and private stakeholders.

23. For more discussion of these recommendations, see Duckett (2013).
24. For example, pharmacists can now provide influenza vaccinations in most Australian states. Overseas, nurses and pharmacist immunisers are required to adhere to guidelines which protect patient safety and privacy. Similar guidelines could be adopted in Australia.
25. Backus et al. (2015); McConeghy et al. (2016); Papastergiou et al. (2014); and Tsuyuki et al. (2015).
26. Hirsch et al. (2014); and Proia et al. (2014).
27. Kelly et al. (2013).

4 Institutional reforms

Australian patients deserve a competitive drug pricing policy, as exists in the UK and Germany. Australia could pay much less for its drugs by using international comparisons to inform Australian drug prices and by tightening existing policies.

These savings have been left on the table because Australia does not have the right institutions and responsibilities in place. These are particularly important when the revenue of vested interests and their powerful lobby groups depends directly on government decisions.

The Pharmaceutical Benefits Advisory Committee should use international prices as a guide for setting prices for drugs listed on the PBS. This should be done in concert with the existing price disclosure policy.

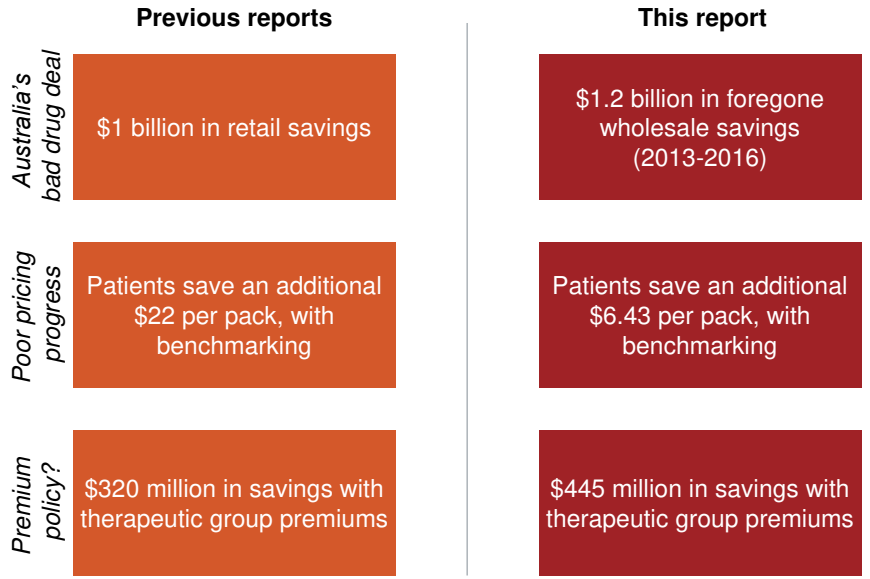
The pharmaceutical industry is too closely involved in Australia's therapeutic group premium policy. After nearly two decades of operation in Australia, the policy is full of loopholes. It should be strengthened, so it is more like the pharmaceutical pricing policies used in comparable countries such as Germany. This could deliver cost savings of $445 million a year (see Figure 4.1).

The Senate should require the Department of Health to table estimates of potential savings. This would improve transparency and accountability, and maintain public and political focus on keeping the PBS system affordable.

The PBS has served Australians well, but it can be improved. Among the many aspects of the PBS that could be reviewed, the changes to pricing policy proposed in this report should be the priority. Finding savings within existing PBS spending will make it easier to fund new and better drugs, as well as avoiding unpalatable and inequitable savings options.[28] Other aspects of the PBS that can be improved in the future include: price negotiations for new medicines; the nature of the PBS as an open registry; the F1 and F2 formulary allocations; and interlinkages between the PBS and patent policy.

Australia's budget is weak, the population is rising, and the cost of health care is burgeoning. The need for a better drug pricing policy is clear.

Figure 4.1: PBS pricing reform could deliver big savings



28. The 2014-15 Budget, for example, included a proposal to increase PBS co-payments. This has failed to pass the Senate.

A Methodology for estimating available savings

The analysis in this report primarily relies on dispensing volume (Date of Supply) data and drug prices from the PBS website.

A.1 Price disclosure and international benchmarking

Data about Australian price reductions were sourced from the PBS website. International pricing data were retrieved from the websites of the:

- UK Pharmaceutical Services Negotiating Committee;
- New Zealand Pharmaceutical Management Agency;
- Ontario Ministry of Health and Long-Term Care; and
- Alberta Blue Cross.

When multiple prices were available overseas, we chose the more expensive option. A price reduction occurs on all forms of a drug – for example, a 20 per cent reduction on atorvastatin will apply to the prices for a box of 10, 20, 40 and 80mg tablets. We made comparisons on one dose of medicine only, a 'nominal dose' – for example, a pack of 30 40mg atorvastatin tablets. Prices were adjusted for pack size and dose if necessary. The average exchange rate for the year to the end of September 2016 was used: CA$0.98; £0.52; NZ$1.07. Two- and three-year averages are higher (resulting in greater savings) than the values we used.

Comparisons involving multiples of the benchmark price do not include pharmacy mark-ups; they apply only to the ex manufacturer price. When calculating out-of-pocket savings for patients, we added pharmacy mark-ups. Pharmacy mark-ups were calculated using the new Administrative, Handling and Infrastructure fee set out in the 6th Community Pharmacy Agreement.[29] These calculations are approximate because we assumed that only Pharmacy Mark-up and the Ready Prepared Fee of $7.02 were applied. All out-of-pocket cost comparisons are for patients who do not have concessions and are above the Safety Net threshold.

Annual savings were calculated for all nominal dose varieties of each drug which was also listed in at least one other benchmarking region, using dispensing volume data from August to July of each relevant year (*e.g.* August 2015 to July 2016 for 2016 savings). The appropriate yearly exchange rate was used for nominal conversion (*e.g.* for 2015 savings, the exchange rates were averaged between 1 October 2014 and 30 September 2015). These values were then inflated forward to 2016 terms using the Consumer Price Index, for comparison.

The number of total prescriptions remained relatively constant across 2013-2016, at approximately 14-15 million for the original drugs analysed (olanzapine, anastrozole, letrozole, quetiapine, atorvastatin, venlafaxine, and mycophenolic acid). A further 18 drugs were added to this foregone-savings analysis (bisoprolol, candesartan, enalapril, fluconazole, metformin, perindopril, simvastatin, captopril, omeprazole, irbesartan, gliclazide, atenolol, famciclovir, clopidogrel, valaciclovir, rabeprazole, amlodipine, and citalopram), which had relatively stable prescribing at around 35 million in each of the years considered (2013-2016). Additional drugs were added on the basis of total prescribing volume (with these 18 being among the most prescribed), and also being listed in at least one other benchmark region.

29. Department of Human Services (Cth) (2016).

A.2 Therapeutic group premiums

To estimate cost savings, we initially used the six therapeutic groups listed in the Weighted Average Monthly Treatment Cost Manual, as well as the venlafaxine and derivatives group listed on the PBS website. We assumed that the drugs removed due to price disclosure cuts since 2009 were reinstated and that premiums were increased to cover the cost gaps between substitutes. All calculations use the dispensed price per maximum quantity.

Savings were calculated using current prices and co-payment thresholds and 2015-16 volumes from the data described above. In line with the current policy, we compared prices using weighted average monthly treatment costs. These costings are indicative.

We assumed that the rate of authority prescribing (clinical exemptions) for premium products increased by roughly five times to 5 per cent. This reflects the fact that the rate may increase with more and larger premiums. We also increased the rate to reflect that, once premiums apply to all but one drug in a therapeutic group, there may be a small number of doses with a premium that do not have a direct pill-for-pill equivalent without a premium. If this is the case, the government could add a new category of exemption to cover these instances.

In the extension of this analysis, we used the therapeutic groups listed in Germany as a guide and expanded the Australian list by adding a further 11 groups. We did not include the other 12 groups for Australian analysis as those therapeutic groups only consisted of a single drug or had only authority medicines listed. The same costing method was used as outlined above, including a 5 per cent authority prescribing rate.

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