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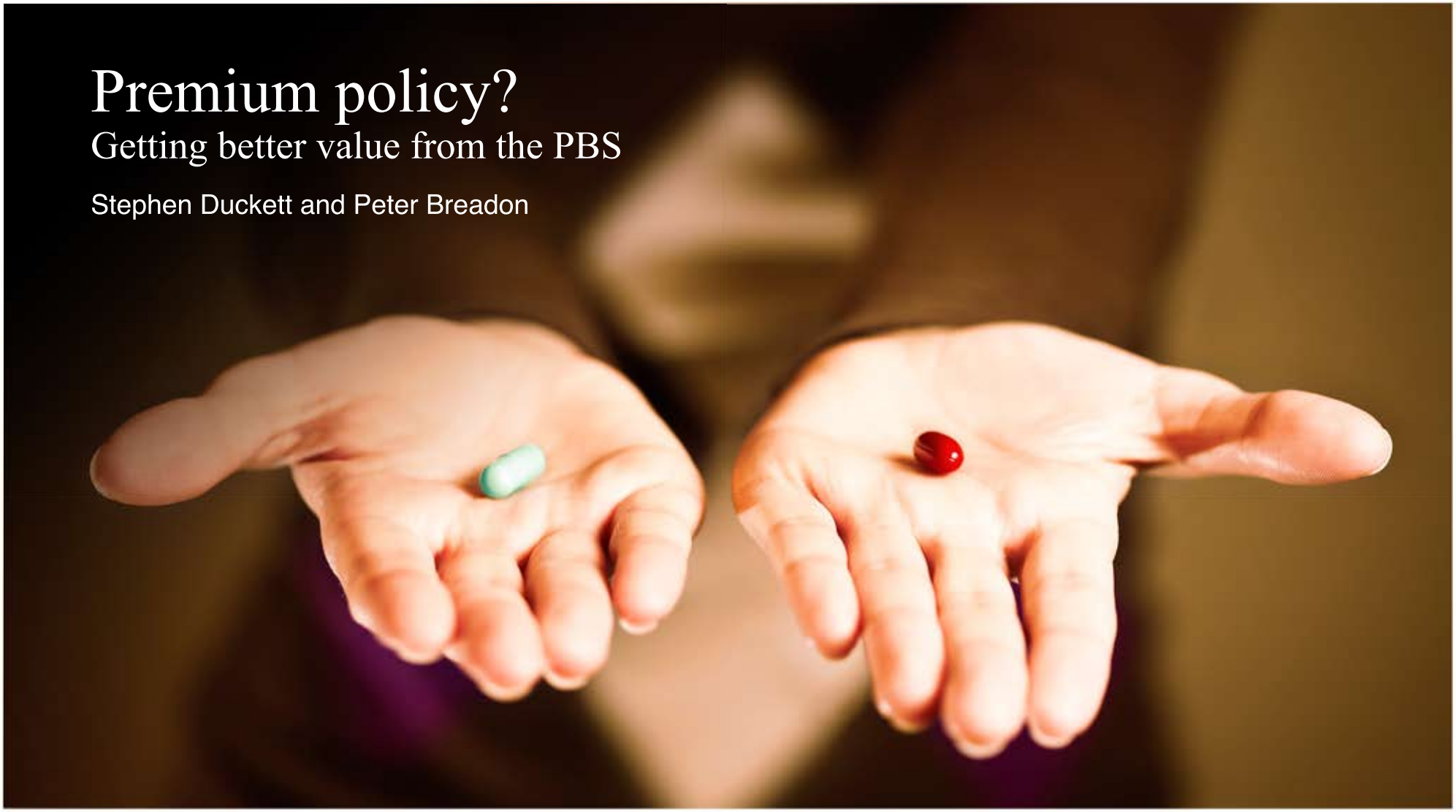
Premium policy?

Getting better value from the PBS

Stephen Duckett and Peter Breadon



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Overview

Australia is paying far too much for drugs on the Pharmaceutical Benefits Scheme. There are two ways to get a better deal. Earlier Grattan reports showed that government should negotiate better prices for drugs, as other countries do. This report examines a second solution: only paying for the best-value drug when cheaper drugs work just as well as more costly ones.

The government's current policy to avoid spending money on low-value drugs is broken, and the waste amounts to $320 million a year. The idea behind the policy is good, but its implementation is all wrong.

Some PBS drugs are interchangeable. Although these drugs are equally effective and safe for most people, their prices vary. For the expensive options, drug companies are charging more than their drug is worth. The extra costs do not reflect extra benefits for patients, and they are mostly paid by the government.

A policy called the therapeutic group premium aims to stop the government wasting money on over-priced drugs. If a patient gets an expensive drug when a cheaper one is just as good, the patient pays part of the extra cost through a premium. Patients can avoid the premium by switching to the better value drug. If a patient faces a health risk from taking the cheaper option, their doctors can get the premium waived.

This policy has been in place since 1998, but it has been so watered down that it no longer works. An arbitrary rule allows more and more drugs to escape the policy. The loophole makes premiums smaller and less frequently applied. Premiums shrink further due to the data and statistical adjustments that are used to calculate them. Both the data and the adjustments are chosen by the pharmaceutical industry.

As a result, there are now premiums on only two drugs. Even these are far too low. Patients don't seem to know about these fees and, predictably, they do not switch to cheaper drugs.

The government should implement the policy as it was intended. Australia should compare broader groups of drugs, as it used to do and as other countries still do. Premiums should be calculated using comprehensive data, not surveys selected by drug companies. Patients should be told if they will pay a premium so they can switch drugs to avoid it. Getting the policy right would cut government spending without risking health. In the longer term, patients will save too.

This policy is not the only problem with PBS pricing. The PBS routinely pays many times what other countries and state governments pay for the same drug. Even policies that do work to cut prices, such as price disclosure, should be much stronger. To get better value, Australia should establish an independent drug purchasing agency, like New Zealand's PHARMAC, to negotiate drug prices and administer the therapeutic group premium policy.

The government faces tough decisions about its budget, and meeting future health care needs. Getting a better deal for drugs is not one of these tough decisions. It should be easy. It is time for the government to make that choice.

Summary of recommendations

How to fix the policy

The government should …

Compare more drugs by

- Reinstating drugs that have had price disclosure cuts
- Adding new therapeutic groups of drugs
- Assigning all new drugs to a therapeutic group

Tell doctors and patients about their options by

- Launching an information campaign
- Asking medical clinic software providers to prompt prescribers

The Health Department should …

Make price comparisons fair and accurate by

- Using comprehensive data instead of surveys
- Abandoning conservative statistical tests

How to fix the system

The government should …

Make value a priority by

- Establishing an independent PBS purchasing agency
- Publishing regular independent reports on value in the PBS

The Health Department should …

Set clear boundaries for vested interests by

- Adopting guidelines for working with lobby groups

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1 Getting value from drug spending is the right policy …

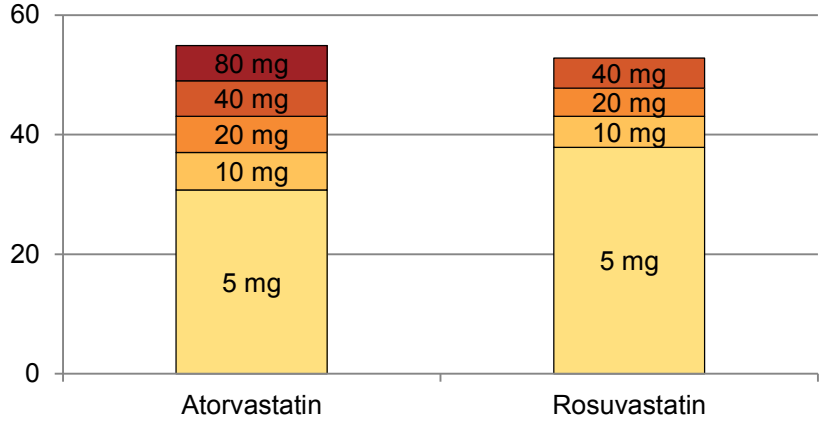
The Pharmaceutical Benefits Scheme (PBS) subsidises hundreds of medicines. Many of them treat the same disease. For example, there are dozens of different drugs that treat high blood pressure.

Some of these drugs can be clustered into therapeutically equivalent groups. These groups of drugs have similar safety and health outcomes and are interchangeable for most people.[1]

Unless there is a good reason, such as an allergy or other reaction to a drug, the cheapest therapeutic equivalent drug should be used. Otherwise, money is wasted on a more expensive drug that is no better than a cheaper one.

Figure 1 shows an example of two interchangeable drugs. Atorvastatin and rosuvastatin both reduce cholesterol. For most people they are equivalent in terms of safety, effectiveness and side-effects. A 20 milligram pill of atorvastatin is interchangeable with a 10 milligram pill of rosuvastatin, but a box of atorvastatin pills costs $13.63 while a box of rosuvastatin pills costs $26.68, almost twice the price.[2]

Figure 1: Two interchangeable drugs for lowering cholesterol
% reduction in LDL cholesterol



Source: Australian Medicines Handbook (2015)

Therapeutic premium policies around the world

British Colombia in Canada and several European countries, including Germany, the Netherlands and Hungary, have policies to promote prescribing of the cheapest drug within therapeutic groups.[3]

[1] Department of Health (2015a). Exceptions to interchangeability are discussed below. Therapeutic equivalent groups include different drugs. Groups with the same active substance (the same molecule) are sometimes also referred to this way, but we refer to them as generic groups.

[2] Both are 30-pill packs. Prices are dispensed price per maximum quantity – retail prices may vary due to discretionary mark-ups and discounts. See the methodological appendix for more information on the analysis in this report.

[3] Dylst, *et al.* (2012). Therapeutic equivalent prescribing programs are also common in Australian hospitals. As one example, a group of hospitals and clinics in Melbourne introduced a therapeutic substitution program in 2006-07 and three years later it was saving around $1 million a year and growing, Larmour, *et al.* (2011).

In these jurisdictions, the government pays a fixed subsidy for any drug in a therapeutic group. Usually this price is the cost of the cheapest drug in the group.[4] If patients get one of the more expensive drugs, they pay the extra cost.

The policy can cut government spending on over-priced drugs by putting pressure on drug companies to cut their price. Otherwise, their drug will have a premium and patients may switch drugs to avoid it (at least one drug without a premium is always available).

It can also prompt doctors and patients to choose better value drugs.[5] Importantly, it does not seem to create the drawbacks of other ways of cutting government spending on medicine, such as across-the-board co-payment increases that can stop people from taking their medicines.[6]

Since 1998, the PBS has had this policy too. It is called the therapeutic group premium.[7] It should not be confused with the brand price premium, which applies to identical drugs (generics) that are made by different manufacturers. The therapeutic group premium applies to drugs that are chemically different, but interchangeable in their impact.

How therapeutic group premiums are supposed to work

The Health Minister determines therapeutic groups drawing on advice from the Pharmaceutical Benefits Advisory Committee, an expert body that also advises on whether drugs should be included on the PBS.[8]

Patient payments for PBS drugs are capped at either $37.70, $6.10 or zero for different types of patient.[9] When a drug costs more than this, the government pays the extra cost.

But for drugs in a therapeutic group, the government limits how much it will pay.[10] It only covers the cost of the cheapest drug. Then drug companies make a choice. They can cut their drug's price to what the government is willing to pay or pass on the extra costs to patients through an additional fee: the therapeutic group

[4] Belgium, Croatia, Latvia, New Zealand, Poland, Slovakia, and British Columbia use the lowest price. Denmark uses the average of the two lowest prices. Since 2006 Germany has set prices at the top of the lowest third of the distribution. The Netherlands uses the product with the price below the average. Ioannides-Demos, *et al.* (2002); Kaló, *et al.* (2008); Paris and Docteur ibid.; Voncina and Strizrep (2011); Szmurlo, *et al.* (2014).

[5] A Cochrane review found that internal reference pricing (benchmarking within either generic or therapeutic groups) may decrease government/insurer costs and prompt shifting to drugs without premiums (but evidence quality was low), Acosta, *et al.* (2014). A systematic review, Lee, *et al.* (2012), found falls in patient and payer costs (not consumption) without significant increases in doctor visits or hospitalisations (except one finding of a short term jump in doctor visits which dissipated and may be due to prescription switching). Excluding a minority of studies on generic substitution does not affect these findings.

[6] Lee, *et al.* (2012)

[7] Ioannides-Demos, *et al.* (2002)

[8] Commonwealth of Australia (2015)

[9] General patients pay a maximum of $37.70 at the pharmacist. Concession patients pay a maximum of $6.10. After patients reach the PBS Safety Net threshold (a certain level of expenditure in a year), these maximum fees fall (to $6.10 for non-concession patients and zero for concession patients). Some surcharges above these limits apply, such as the therapeutic group premium that is the topic of this report.

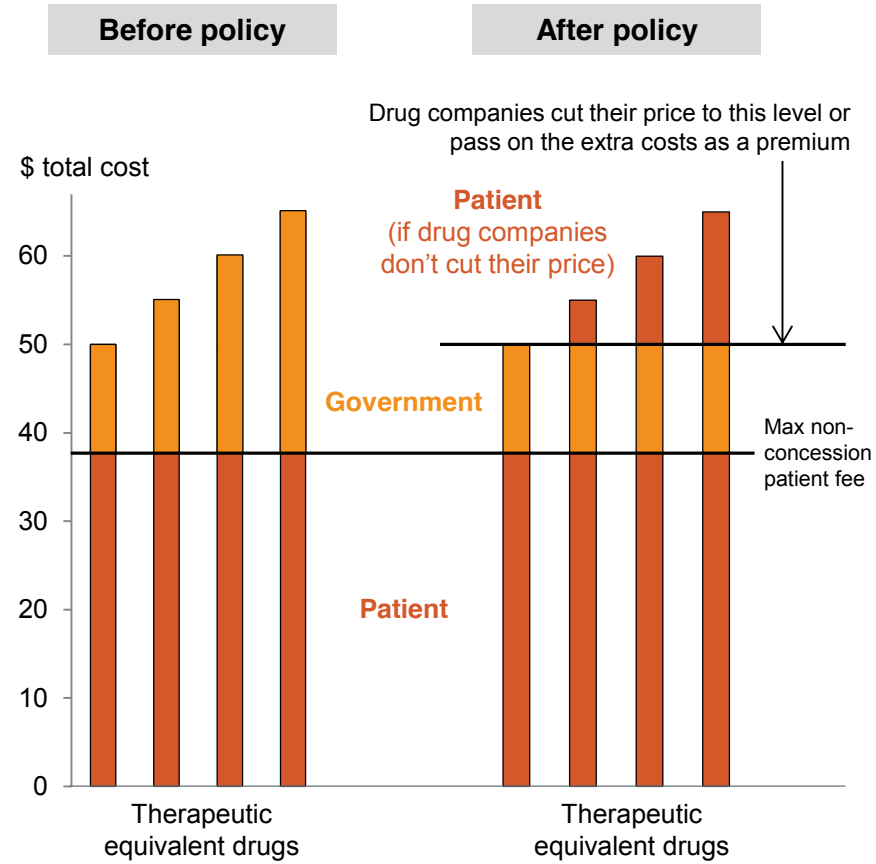
[10] Premiums only apply to drugs that the government helps to pay for (not drugs under the maximum co-payment threshold).

premium.[11] Figure 2 shows the way the system is intended to work.

In cases where a patient should not change drugs for health reasons, doctors can order exclusions from the therapeutic group premium. The exclusions can be due to drug reactions, drug interactions or if changing drugs is likely to confuse the patient.[12]

This report looks at how the policy is run and whether it is working. It explains its impact and flaws, and ways to fix both this specific policy and drug pricing more broadly. It shows that poor implementation has undermined the policy's intention. It does not investigate other ways to promote dispensing of more cost effective, therapeutic equivalent drugs.[13]

Figure 2: The idea behind the policy: government pays for what works



Note: Hypothetical example for non-concession patients above the PBS Safety Net threshold.
Source: Grattan Institute

[11] A mix of price cuts and premiums is also allowed. The premium does not count towards the Safety Net, beyond which patients pay less.
[12] Department of Health (2014a)
[13] Examples are: policies which place financial incentives on doctors, instead of patients (such as Germany's physician drug budgets; drug substitution by pharmacists (which is not allowed under Australia's therapeutic group premium policy); or New Zealand's approach of only subsiding one or two drugs that are therapeutically equivalent. This report does not evaluate these options.

2 But its implementation is flawed …

The idea behind the therapeutic group premium is good, but there are three flaws in how it is implemented. First, the policy ignores many interchangeable drugs. Second, the premiums patients must pay are too low, exposing the government to the cost of over-priced drugs. Third, patients are not fully informed about the policy, leaving them no chance to respond by choosing a cheaper option.

2.1 Few groups and narrow groups

The fewer drugs that the policy applies to, the less impact it will have. Australia's scheme is very narrow, with only four groups:

- angiotensin II antagonists (most often used to reduce blood pressure)
- H2-receptor antagonists (to reduce gastric acid)
- proton pump inhibitors (to reduce gastric acid)
- venlafaxine and venlafaxine derivatives (antidepressants).

Germany, by contrast, has more than 30 groups (see Box 1) and in the Netherlands all drugs are included in a therapeutic group.[14]

Box 1: Germany's therapeutic groups (selected)

- ACE inhibitors
- Alpha-blockers
- Aminoquinolines
- Angiotensin II antagonists
- Anticoagulants, oral
- Antidiabetics (derived from Sulphonylurea)
- Antipsychotics
- Azole antifungals
- Benzodiazepines
- Beta-blockers
- Calcitonins
- Cardiac glycosides
- Dimethicone and simethicone
- Diuretics
- Fibrates
- Fluoroquinolones
- Glucocorticoids, oral
- H2-antagonists
- Heparins, low molecular
- Insulins
- Macrolides (newer)
- Prostaglandin synthase
- Selective serotonin reuptake inhibitors
- Serotonin 5HT3 antagonists
- Statins
- Testosterone-5-alpha reductase
- Triazoles

Source: Statutory Health Insurance Funds Association (Germany) (2012)

In Australia, not only are there few groups, they are shrinking in number and size. Legislation excludes any drug that has had a

[14] Germany also has generic and multi-drug product groups. All groups cover over 60% of prescribing, Kanavos and Reinhardt (2003). In the Netherlands only therapeutically unique drugs that are the first pharmacological treatment for previously intractable conditions are exempt, Ioannides-Demos, *et al.* (2002).

price cut due to a separate policy called price disclosure.[15] Since a growing list of nearly 300 drugs can get price disclosure cuts, this clause has had a big impact on therapeutic groups.

The reason is to avoid comparing the prices of drugs that face competition between multiple brands (such as those that go through price disclosure cuts) with prices of drugs that are still under patent and do not have multiple brands. But this rule makes little sense. The drugs are equivalent, even if the number of brands for each drug is not. The government should seek the best value among interchangeable drugs, whether or not low prices are driven by brand competition.

To take one example, the blood pressure therapeutic group has five drugs. There are two other drugs of the same type listed on the PBS – candesartan and irbesartan – but in 2014 they were removed from the group because of price disclosure. Other countries with a similar group keep them in.[16]

Drugs have been removed from all four therapeutic groups in recent years because of price disclosure.[17] Whole therapeutic groups, such as the groups for statins, have been shut down. Two of these cholesterol-lowering drugs, atorvastatin and rosuvastatin, were the most costly drugs for government in 2013-14, costing the PBS $570 million.[18]

Removing drugs from therapeutic groups weakens the policy. Like any shopper looking for a good deal, the government will get better value if it compares the price of a greater number of interchangeable products. A drug that is dropped might be the cheapest drug, so the government no longer gets the best possible deal. Perversely, it is drugs that have been through price disclosure cuts that are left out of the groups – drugs that are likely to be the cheapest option.

Even if the drug that is removed is not the cheapest in the group, the government still loses. If the drug had stayed in the group, its price would fall to match its cheapest competitor. If the drug is dropped from the group, its price can stay high.

2.2 Few premiums and low premiums

The PBS website describes the therapeutic group premium policy in this way: “The Australian Government, through the PBS, subsidises up to the price of the lowest priced drug in the group.”[19]

[15] *National Health Act* 1953, Commonwealth of Australia (2015). Price disclosure cuts the wholesale price of drugs to reflect the discounts that manufacturers and distributors give to pharmacists, bringing the price closer to the real cost of the drug in the market. As discussed in previous reports, the policy is flawed, containing loopholes that reduce price disclosure reductions (e.g. purchases in the first month of each reporting period are not included, reductions of less than 10% do not count), Duckett*, et al.* (2013).

[16] Such as Germany.

[17] In 2014 candesartan and irbesartan were removed from the angiotensin II antagonists group and rabeprazole was removed from the proton pump inhibitor group. In 2013 cimetidine and ranitidine were removed from the H2-receptor antagonists group and venlafaxine was removed from the venlafaxine and venlafaxine derivatives group. See amendments PB7 and PB77 of 2013, and PB23 and PB80 of 2014 to the *National Health Act* 1953.

[18] Department of Health (2015b). The final statin group was abolished in 2014 when only one drug remained (as required by the Act).

[19] Department of Health (2014a)

But the way drug premiums are set is not that simple, or that sensible. It is needlessly complex and opaque – a "kludge" (see definition in Box 2) that obscures the policy's failure to achieve its objective.

There is no defending the way the government calculates therapeutic group premiums. The steps in the process are shown in Box 3. At every step, the current process reduces both the likelihood of premiums being charged and their likely size, as the following sections show.

The statistics are significant

To calculate the price cut or premium a drug should attract, the government needs to compare the prices of drugs within a therapeutic group. To overcome the fact that drugs come in different doses (such as 20mg), each with its own price, the government sets a weighted average price for each drug. The weighted average is calculated from the price of all doses of a drug, but is skewed towards the more commonly used ones. That skew reflects how the drug is used in practice and how much it typically costs to treat a patient with that drug.

To determine how much a drug is being used, the government consults surveys about prescribing. A survey of about 1000 GPs, each recording about 100 patient visits, is often used.[20] The result of this approach is that estimates are based on a small number of observations. In fact, a drug can be selected as the cheapest based on as few as 65 recorded prescriptions.

Box 2: A victory for kludge?

If your eyes glaze over when you read about how therapeutic group premiums are calculated, you are suffering from kludge. The term originally referred to a clumsy but expedient software patch: an inelegant workaround for a short-term problem. The problem with kludges is that they accumulate and linger, making software complex, unstable, unreliable and hard to maintain.

Political scientist Steven Teles has applied the term to public policy. He argues that kludges lead to waste and confusion and create opportunities that vested interests can exploit:

"Policy complexity is valuable for those seeking to extract rents from government because it muddies the waters, making it hard to see just who is benefitting and how, and so obscuring the actual mechanism of political action that it is difficult to mobilize against it".[21]

Kludges – like the redundant statistical manipulations used to set therapeutic group premiums – help obscure the failures in how a policy works. Some commentators in America suggest that lobbyists actively cultivate kludge for this very reason.[22] Given the close involvement of lobbyists in the design and implementation of the therapeutic group premium policy, it may be a case in point.

[20] The BEACH survey of GPs, Britt*, et al.* (2014). Only a minority of these will involve relevant prescribing and the sample size will be further reduced through data cleaning.

[21] Teles (2012)

[22] See Wallach (2015), a review of Drutman (2015).

Drawing conclusions about Australia from such a small sample is risky. There is a good chance the surveyed doctors will not represent prescribing by all doctors in the country. The government employs a test known as statistical significance to see whether a conclusion drawn from a sample is likely to reflect the broader population.[23] It checks whether the gaps between the weighted drug prices it has calculated pass this test. If they do not, they are ignored.

Checking for statistical significance when using data of this kind is sensible, but it creates a problem. The smaller the sample, the further apart weighted prices must be before they are significantly different. Because price differences are calculated using a small amount of data, many are not considered significant. Yet the price gaps still exist and cost the government millions of dollars a year.

To make the process even more conservative, there are two different tests for significance: one for the group as a whole and another that compares each drug to the cheapest drug.[24] The comparisons between individual drugs should suffice. Adding a test for the whole group is redundant and can lead to more price gaps being ignored.

Box 3: How therapeutic premiums are calculated

- Drug companies suggest a data source from a list of allowed options, including several surveys of what GPs prescribe. If more than one source is nominated, the Health Department chooses which source to use and that choice is fixed for three years (unless a drug company contests it).
- Drug companies clean the data, removing entries that are incomplete, improbable or incorrect and submit it to the Health Department for review and analysis.[25]
- The government enters the data into a spreadsheet that adjusts current prices according to prescribing volumes and generates a national estimate. It identifies a benchmark drug: the drug with the lowest upper 95 per cent confidence interval.
- For a price cut or premium to occur, first a statistical test must find a significant difference between drug prices in the group. Then a different statistical test must find a significant difference between a single drug's adjusted price and the benchmark drug's adjusted price.
- The government provides the spreadsheet and its results to drug companies and invites them to propose any changes to their prices.
- If their price is significantly higher than the cheapest drug, companies can choose to reduce the price they charge the government, or charge a premium, or a mix of both.

Source: Department of Health (2009)

[23] For a non-technical explanation of statistical significance and its limitations see Figueiredo Filho*, et al.* (2013).

[24] The first is a global chi-square test, the second is a pair-wise z-test. Both tests must find significant difference. Yet another conservative choice is how the cheapest drug is chosen. It is not the drug with the lowest weighted average. Instead, it is the drug with the lowest upper confidence interval. In other words, instead of using the most likely price, the highest probable price is used.

[25] Both cleaned and original data are provided, with explanations of adjustments.

Fortunately, all of these statistical hurdles are unnecessary. Since 2012, the government has had comprehensive dispensing data.[26] Because it now knows exactly which drugs are being dispensed through the PBS, there is no longer any need to use survey data or conservative statistical manipulations.[27] But the way the policy works has not been updated to take advantage of this opportunity.

As well as being unnecessary and inaccurate, the data manipulations are costly, time-consuming and impose a significant red tape burden on drug companies. The pharmaceutical industry lobby group, Medicines Australia, has complained that the process "generates substantial financial and administrative costs to both the Government and industry".[28] In 2008, they estimated the cost of purchasing survey data at $110,000 to $120,000 a year for each company, on top of the burden of collecting, collating and analysing data, and verifying calculations.[29]

Although the industry has complained about the process, it had a great influence over its development. The process for comparing prices was designed by a series of working groups that included industry lobby groups.[30] The cascade of statistical tests described above was designed by "industry experts" after a joint government-industry working group rejected different statistical methods proposed by an independent review.[31]

The extent and timing of industry involvement in the process may also create opportunities for gaming. Drug companies nominate data sources and buy and clean the data, all of which must then be policed by the Health Department.

In addition, drug companies are only asked to cut prices or impose a premium after they know how big the statistically significant gaps are. If significant price gaps are found, they are in a good position to cut their price as little as possible, keeping price differences but keeping them small enough to avoid statistical significance.[32] In fact, the government publishes a manual that gives explicit instructions about how to maximise prices while minimising the risk of a premium.[33]

[26] Including for drugs which were paid for without a government subsidy ('under co-payment' purchases), where community pharmacy industry data was previously the most reliable source.
[27] These data are far superior to the surveys, but are not perfect. One source of inaccuracy is that the data will not count prescriptions that were never filled.
[28] In a submission to the Productivity Commission on regulatory burdens, Shaw (2008).
[29] Ibid.
[30] Medicines Australia and the Generic Medicines Industry Association.
[31] An independent review by Ernst and Young proposed bootstrapping. A government manual notes that a joint Pharmaceutical Benefits Branch (Health Department) and Medicines Australia (pharmaceutical industry lobby group) working group responded to the report by agreeing the approach described in this chapter, Department of Health (2009).
[32] This is especially true as they have the same prescribing data and price-weighting spreadsheet as the Health Department.
[33] An example in the manual explains how to reduce the z-score, which tests the significance of the difference between adjusted prices, to just below 1.96, the point at which a therapeutic premium would be imposed. It goes on to provide further tips: "Of course, there are still the strategic questions of whether one strength is more important to a [drug company] than the others, and how much of a buffer to leave against possible surprise developments.", Department of Health (2009).

The result: premiums often don't exist or are small

When drug companies don't cut their prices to match the best value option in a therapeutic group, premiums are supposed to stop the government paying too much. Given all the flaws in how they are calculated, it is no surprise that the premiums do not achieve this in practice.

There have never been many drugs with premiums, but having so few groups, conservative statistical hurdles and a rule that excludes so many drugs has caused the number to fall to the current record low of two. The premiums are both in the blood pressure drug group (angiotensin II antagonists) and are $3.50.[34]

There are five drugs in this group. To check whether these two premiums are doing their job, we looked at a set of doses (olmesartan 20mg, for example) that are interchangeable. The premiums should cover the gap between the cost of any of these doses and the cheapest alternative in the group.

Figure 3 shows that the cheapest option costs $12.40 while the most expensive costs more than $30. But the current calculations result in a premium of just $3.50 – not even close to covering the gap between these prices. For patients who have a concession or have reached the Safety Net, the government must pay $7.10 or $17.70 beyond the cost of the cheapest drug.[35] For one drug, the premium covers half the total gap. For the other, it covers just one fifth.

Not just that, other drugs in the therapeutic group have no premiums at all. Their prices are not considered different in a statistical sense, but in reality their prices *are* different: each box of pills costs either $1.90 or $5.80 more than the cheapest alternative. In 2013-14, the PBS subsidised over two million of packs of these pills.

The premiums that exist cover just eight per cent of government expenditure beyond the price of the cheapest drug, or $2 million out of $22 million. The premiums perform even worse if you compare the drugs that *should* be in the group. The original group included irbesartan and candesartan, but they were removed because of price disclosure cuts.

The way premiums are set wastes a big opportunity. If premiums covered the full cost gaps for the seven therapeutic groups Australia had in the past, it would save the government $320 million a year, or fund more than 60,000 hospital visits (see Figure

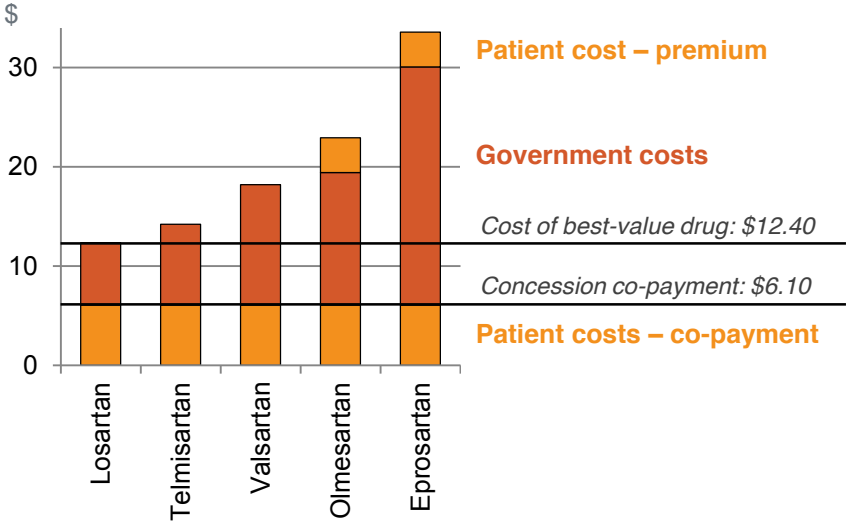
[34] One is rounded up from $3.49. All dollar figures in this section are rounded to the nearest 10c for clarity, but this does not affect per cent figures.

[35] Our aim here is to see how the policy plays out for doses that are widely regarded as substitutable, Pharmacist's Letter/Prescriber's Letter (2013); Department of Health (2014b). We only look at specific doses, so the premium should not necessarily cover exactly the gaps we find, but to achieve their aim they should at least come close. See Figure 3 notes for more information.

4).[36] Many other therapeutic groups could be added, potentially saving much more.

Figure 3: The therapeutic group premium covers a fraction of the real cost gap

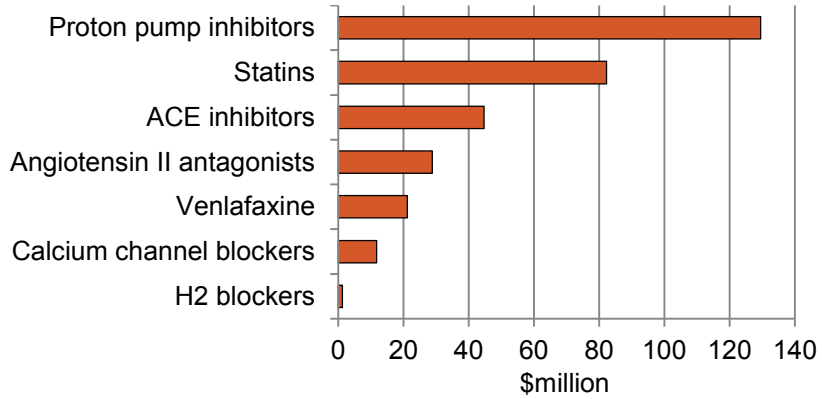
Costs paid by patients and government (concession patients and general patients after Safety Net) per month



Notes: Prices are dispensed price per maximum quantity plus therapeutic group premium. Doses are 50mg, 40mg, 80mg, 20mg, 600mg (left-to-right), which are WHO defined daily doses and also considered equivalent in guidance such as McAuley (2015). Prices are adjusted for pack size. See methodological appendix for more information.
Source: Grattan Institute based on Department of Health (2015c).

[36] These calculations assume reintroduction of drugs that have had price disclosure cuts and an increase in the rate of clinical exclusions by fivefold to 5%. See the methodological appendix for more information.

Figure 4: With premiums that covered the full cost gaps, the government would save $320 million a year for seven groups alone



Source: Grattan Institute using PBS data

2.3 The policy leaves patients and doctors in the dark

Patients don't choose their drugs, their doctor does. In Germany, the doctor is required to tell patients if they order a drug that has a therapeutic group premium.[37] Australia has no such requirement.

Patients and doctors appear to be largely unaware of the premiums. Doctors only order an exemption for drugs with premiums one per cent of the time. It seems very unlikely that doctors would wilfully expose their patients to a premium 99 per cent of the time, and that patients would always accept it without requesting a different drug. A much more likely explanation is that most doctors and their patients are not aware of the policy.

[37] Danzon and Ketcham (2004)

Even if patients find out about the premium at the pharmacy, they will need a new prescription to avoid the surcharge. That might require calling their doctor, visiting a clinic or even waiting for a new appointment, any of which is likely to be more difficult and costly than simply paying the premium.

Even though patients might not be informed about the surcharge, in 2013-14 they paid $1.8 million in premiums on the two drugs that have them.[38] Many might not have known they were paying the premiums. They have a right to know.

As this chapter shows, the premiums don't cover much of the cost gap they are supposed to cover. The next chapter shows that the premiums have very little effect on which drugs are used or how much they cost.

[38] Calculated using current premiums and 2013-14 prescribing volumes.

3 As a result, the policy does not work well enough …

How can we tell whether the therapeutic group premium is working? The policy can achieve three goals: it can shift costs from government to patients, prompt switching to better value drugs, or force drug companies to cut prices. There is no sign that the policy is achieving the first two objectives, but there seems to have been some progress in cutting drug prices.

3.1 Barely any costs are shifted

The main aim of Australia's policy is to save the government money. A policy that worked would not just shift costs onto patients, it would also help them avoid the costs of over-priced drugs by giving them the option of cheaper ones. But the policy is failing even on the narrow objective of cost shifting. It only applies to two drugs, and saves the government less than $2 million a year.

3.2 There is no noticeable impact on which drugs are used

Prompting doctors and patients to choose better value drugs has not been stated as the primary aim of Australia's policy, but it should be. Getting people to use better-value drugs would save money for patients too, not just the government.

Similar policies have achieved drug switching overseas and it is clear why.[39] If there is no health reason for an exemption, many doctors would be expected to prescribe a drug without a premium to save their patients money and avoid having to order an exemption. Many patients would also be expected to ask for the cheaper option.

But there is little evidence of drug switching in Australia. Four drugs and eight individual drug doses (such as 40mg or 20mg) have had a premium introduced in the last five years. All of them are in the blood pressure therapeutic group.[40]

In some cases, doses lost market share after the premium was introduced. In some cases, they actually gained market share. But overall, their share of dispensing remained extremely stable.

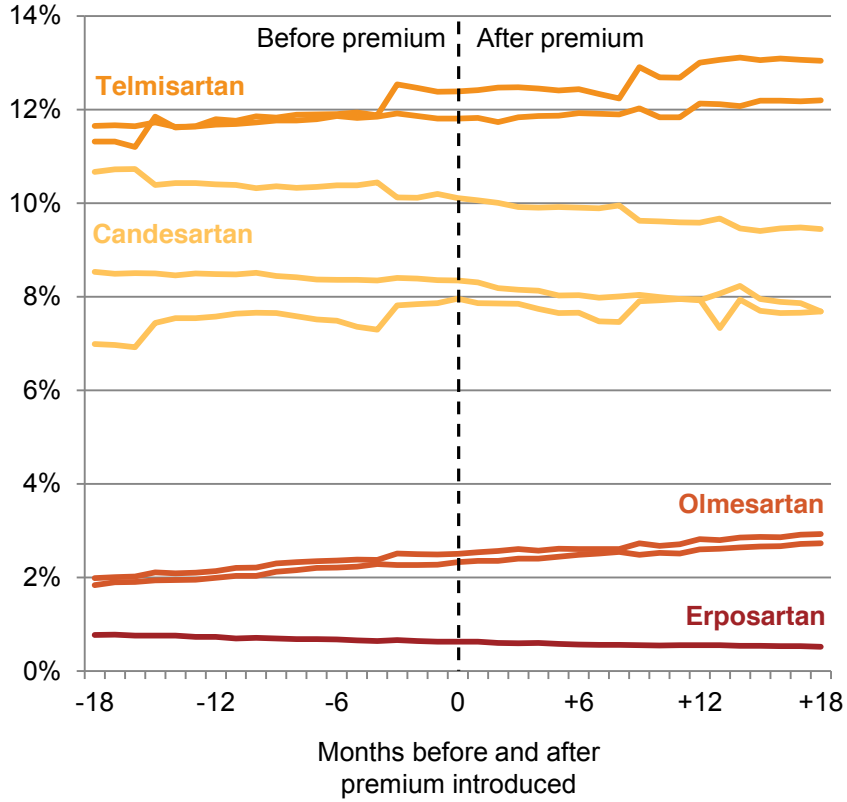
The introduction of premiums had no noticeable impact on previous trends, as Figure 5 shows. This is confirmed by further analysis in the methodological appendix, which found extremely small changes after the introduction of premiums.

The premiums applied were likely too low to shift prescribing much, particularly when patients and doctors may not have been aware of them.

[39] See footnote 5.

[40] We did not investigate earlier applications of premiums, as these did not commence during the period covered by our dataset. Earlier applications of the policy may have been more successful.

Figure 5: Premiums don't have much impact on market share
Share of angiotensin II antagonist dispensing



Note: Doses with premiums introduced in 2011 and 2012. Market share among all doses of all 'sartan' drugs (excluding combination products). See methodological appendix for more information.
Source: Grattan Institute analysis of PBS data.

3.3 Premiums may be pushing prices down

The policy could also force drug companies to compete with the best value alternatives.[41] A company with a price above the lowest-cost choice might cut their price to reduce the premium on their drug, or remove it completely.

By far the broadest and most active of the current therapeutic groups is the one for blood pressure drugs, which we looked at earlier. Prices have declined in this group, which is unsurprising. The price of a drug generally falls over time. When a drug goes off-patent, allowing multiple companies to produce it and compete by offering lower prices, the price often falls substantially.[42] Prices may also fall because of price negotiations with the government or the need to compete against newly-invented drugs.

Because drug prices often go down, falling prices alone do not prove that the therapeutic group premium is working to cut prices. If it is working, we would see bigger price declines for more expensive drugs: the drugs that risk having a premium if their prices stay high.

In the last six years, the price of drugs in the blood pressure therapeutic group fell by four per cent a year, on average. But the price of the cheapest drugs fell more slowly, by less than one per cent.[43]

[41] The interchangeable drugs with the lowest price.
[42] The PBS also applies a cut of 16% when the first generic enters the market.
[43] The cheapest drug refers to the drug with the lowest weighted average monthly treatment cost in any month. Changes refer to annualised average monthly falls. See the methodological appendix for more information.

Although this is not conclusive, it does suggest the policy is having an impact.[44] The Health Department also suggests that the policy has achieved substantial price cuts for drugs in other groups, which drug companies chose to concede rather than impose a premium.[45]

While the policy seems to have made some progress in reducing drug prices, it has not done enough. Big price gaps between substitutable doses remain. These gaps cost the government over $20 million a year for the blood pressure group alone, as the previous chapter shows.[46]

The therapeutic price premiums have done little to nudge prescribing in the right direction or to achieve the less beneficial goal of shifting costs from the government to patients. But it is encouraging that, despite being narrow and weak, the policy may have lowered the price of some drugs. If therapeutic price premiums are improved, they could achieve much more.

[44] Some of the difference may be explained by reversion to the mean. Our analysis uses a different benchmarking approach (therapeutic effect instead of prescribing volumes) so may identify different lowest-cost drugs. See the methodological appendix for more information.
[45] Such as high-potency statins, before this group was abolished, personal communication.
[46] This is the value of remaining price gaps after the premium is applied, using only the current group which excludes irbesartan and candesartan.

4 The problem and the system can be fixed

Fixing the policy

The therapeutic group premium policy has been law for nearly 20 years, under successive governments. But its design and implementation have reduced it to a hollow gesture.

The policy is supposed to send a price signal to get patients to switch to drugs that are better value. But the signal is weak and the person who is supposed to respond to it – the patient – is probably unaware of it.

To make the policy work, the government should:

- change the legislation that excludes drugs that have had price disclosure cuts and restore the drugs and groups that were removed
- include all newly listed drugs in a therapeutic group (unless they have no therapeutic equivalent)
- introduce therapeutic groups that other countries have
- calculate premiums based on dispensing data instead of surveys
- ask the expert Pharmaceutical Benefits Advisory Committee for advice about whether groups should be more ambitious, in particular incorporating drugs that are more dissimilar, and creating groups for products that combine multiple drugs.[47]

This will initially lead to more premiums and higher premiums. The government could consider capping the premiums at first, for example at $10.[48] Whether or not premiums are capped, the government must make sure that doctors and patients understand these costs so they can switch to a cheaper option if it is safe to do so.

When doctors prescribe a drug with a premium they should explain why to their patients. Just as they are now, doctors will be free to get an exemption (called an authority script) if there is a good reason that a patient needs a drug that normally has a premium.

Government should take measures to ensure patients are well-informed. Pharmacists should be required to tell patients if they are being charged a premium and the government should run an information campaign for prescribers, pharmacists and patients.[49]

[47] Australia's groups are within Level 4 groups in the WHO system for classification of drugs (not strictly a system based on therapeutic equivalence). Some countries include drugs from the broader Level 3 groups, or even a mix of different levels. Examples are Latvia, Germany, the Netherlands, Poland and British Columbia, Zuidberg (2010); Province of British Columbia (2015). Germany has a separate category of therapeutic groups that largely focuses on combination doses (multiple drugs provided in one pill).
[48] This and having no premiums under $1 would cut savings to $230 million p.a.
[49] Such a campaign accompanied the original introduction of therapeutic group premiums, with $3.2 million in government funding over two years, plus

The companies that make software for medical practices should also help. These systems should remind doctors when they prescribe a drug with a premium. This will be much easier for doctors than keeping track of premiums.

Once premiums are larger, and patients and doctors are aware of them, patients will be far more likely to switch drugs. As a result, drug companies will reduce their prices, which will ultimately save money for patients, as well as the government.[50]

The policy will reduce profits for drug companies. There may be claims that this reduces research and development. But savings of $320 million a year, spread across numerous multinational drug companies, are very unlikely to have a meaningful impact on pharmaceutical research investment. To the extent that research and development is influenced, there will be a positive impact. Companies will be more likely to avoid crowded therapeutic classes of drugs, focusing instead on innovative treatments with distinctive benefits.[51]

Fixing the system

The therapeutic group premium policy is just one problem with Australia's pharmaceutical pricing policies. Previous Grattan reports found that the PBS routinely pays many times the prices that New Zealand, the UK and Australian public hospitals (which negotiate prices separately from the PBS) pay for the same generic medicines.[52]

The Australian National Audit Office recently conducted an audit of how the Health Department administers the Community Pharmacy Agreement.[53] The Agreement sets out how pharmacists are paid for dispensing medicines and other services. It governs spending of over $15 billion.[54]

Among many negative findings, the audit reports that the Health Department:

- over-estimated the savings the Agreement would generate savings
- reallocated funding covered by the Agreement without authority
- did not achieve explicit government objectives

additional spending by the Pharmacy Guild, Commonwealth of Australia (1997). Schneeweiss (2007) argues that without a substantial information campaign for patients, prescribers and pharmacists, a policy of this kind cannot be successfully implemented.

[50] Patients below the general co-payment threshold can benefit from price reductions, even though they do not face therapeutic price premiums. These patients can also save money from drug switching to non-premium products, which should be stimulated by our proposed information campaign for prescribers, pharmacists and patients.

[51] For a discussion of investments in so called "me-too" drugs, which offer little or no therapeutic benefit compared to existing therapies, see Gagne and Choudhry (2011); Light and Lexchin (2012); Olfson and Marcus (2013).

[52] Duckett, *et al.* (2013)

[53] Commonwealth of Australia (2015)

[54] Ibid.

- did not keep formal records of meetings with the Pharmacy Guild (which represents pharmacy owners, who receive billions in funding from the Agreement)
- is not in a good position to work out whether the Agreement is achieving value for money.[55]

There is a pattern to these problems of high drug prices, poor administration of the Pharmacy Agreement and the therapeutic premium policy. A serious commitment to getting value for money is needed. A policy being announced is just the start of the story. It is worthless unless it is implemented properly.

The pharmaceutical industry is too closely involved in how the Health Department designs and runs the therapeutic group premium. 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.[56]

More generally, the Health Department should keep lobby groups at arm's length. Consultation with industry experts is crucial 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.[57]

A Lobbying Code of Conduct applies to all Commonwealth public servants, but it only covers consultant lobbyists that 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.[58]

To fill the gap, the Health Department should develop clear standards and processes for working with lobby groups. In this case, lobby group involvement seems to have gone well beyond appropriate consultation. The joint Health Department-industry working group is described as "agreeing" and "determining" how the policy is designed and implemented.[59] New guidelines should make it clear that vested interests can be informed, consulted and debated, but that their agreement is not required before proposals go to the Health Minister.

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

[55] 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).
[56] Duckett, *et al.* (2013). 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.
[57] Australian Public Service Commission (2014)
[58] McKeown (2014)
[59] Department of Health (2009).

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.

The benefits are worth it

The government is right to try to get better value for PBS drugs. But it should not get patients to pay more without their being informed. It should also run the policy as it was intended, instead of letting arbitrary rules minimise its impact.

Done right, therapeutic group premiums would save the government hundreds of millions of dollars a year. Difficult choices are needed about taxes, government spending, reducing the deficit and meeting growing demand for health care. By contrast, fixing this policy should be an easy choice. It is a rare cut in health spending that won't put people's health at risk. After nearly 20 years, it is time that this policy did what it was supposed to do.

5 Methodological appendix

5.1 Data

The analysis in this report is based on Pharmaceutical Benefits Scheme (PBS) date of supply data combined with PBS text files that are available at http://www.pbs.gov.au/info/publication/schedule/archive and current prices available at http:/www.pbs.gov.au.

5.2 Costings

To estimate cost savings we used the six therapeutic groups listed in the Weighted Average Monthly Treatment Cost Manual, as well as venlafaxine and derivatives group listed on the PBS website (which contained venlafaxine and desvenlafaxine).[60]

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 2013-14 volumes from the dataset described above. In line with the current policy, we compared prices using weighted average monthly treatment costs.[61]

These costings are indicative. We assumed that the rate of authority prescribing (clinical exemptions) for premium products increased by roughly five times to five per cent. This reflects the fact that the rate may increase with more and larger premiums and our proposed information campaign. 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 cases.

It is hard to know whether the authority prescribing rate would be below or above five per cent. But our analysis remains conservative for other reasons. Dispensing will have increased since our data period of 2013-14 (even for this period, the volumes may increase as data are updated). We also excluded all combination products (which contain more than one drug) and only included pills and tablets (no sachets, injections or other forms).

An alternative costing approach

We also calculated savings another way, with price cuts or premiums for groups of interchangeable doses, rather than for drugs as a whole. This could be considered to avoid the drawback of drug-to-drug comparisons mentioned above (the risk of doses without direct, non-premium substitutes).

We based the dose substitutions on Pharmaceutical Benefits Advisory Committee relativity sheets if they were comprehensive

[60] Ibid.; http://www.pbs.gov.au/browse/therapeutic-group
[61] Ibid.

and compared exact doses.[62] Where this was not the case, we used the World Health Organisation's defined daily doses (DDDs).[63] The exception is statins, where we used the Australian Medicines Handbook and substituted based on LDL lowering effect.

In addition to the exclusions and assumptions above, this costing did not assume substitution between tablets and capsules of different types (such as enteric-coated and non-enteric-coated). We only made single pill-for-pill substitutions, except in one case, were we substituted one pill with two pills. This method generated a savings estimate of $250 million a year.

5.3 Interrupted time series analysis

We used a linear regression to confirm that premiums had little, if any, impact on the market share of pharmaceutical products within their therapeutic group.

The only premiums analysed are those that began within the period covered by the monthly data, and had at least an 18-month period before the introduction of the premium to allow the before-and-after analysis described below.[64]

These were premiums on candesartan, eprosartan, olmesartan and telmesartan. The premiums were applied in April 2011 (candesartan) and April 2012 (others).

There were changes in the coverage of the data during both periods. From July 2010, close-the-gap under co-payment data were included.[65] From July 2012, under co-payment data were included. These patient categories were excluded.[66]

Both patient categories were excluded from the dataset for the interrupted time series analysis. Patients under the co-payment are not exposed to therapeutic group premiums, so these patients are irrelevant to this analysis.

Separate regressions were run for each of the eight angiotensin II inhibitor doses which had premiums introduced in 2011 or 2012. The period was 2009 to 2014.

The dependent variable was the share of prescribing among 'pure' angiotensin II inhibitors (excluding combination pills that include another drug). Independent variables were: time (in months); dummy variables for the presence of a 2011 or 2012 premium to capture a drop in prescribing after the premium was applied; and interactions of time and the dummy variables to

[62] Department of Health (2014b)
[63] See http://www.whocc.no/atc_ddd_index/. If this approach were adopted, we would recommend using systematic reviews of therapeutic impact to guide substitutions rather than DDDs, as this use of DDDs is not recommended by the WHO (although the Netherlands uses it in their therapeutic group pricing policy), Dukes (2003); Zuidberg (2010); World Health Organisation Collaborating Centre for Drug Statistics Methodology (2015).
[64] 'Premiums' refers to therapeutic group premiums, the topic of this report.

[65] Under co-payment refers to dispensing that is paid for entirely by the patient, without a direct government subsidy.
[66] The close-the-gap category for the doses with a premium applied in 2011. The under co-payment data for doses with a premium applied in 2012.

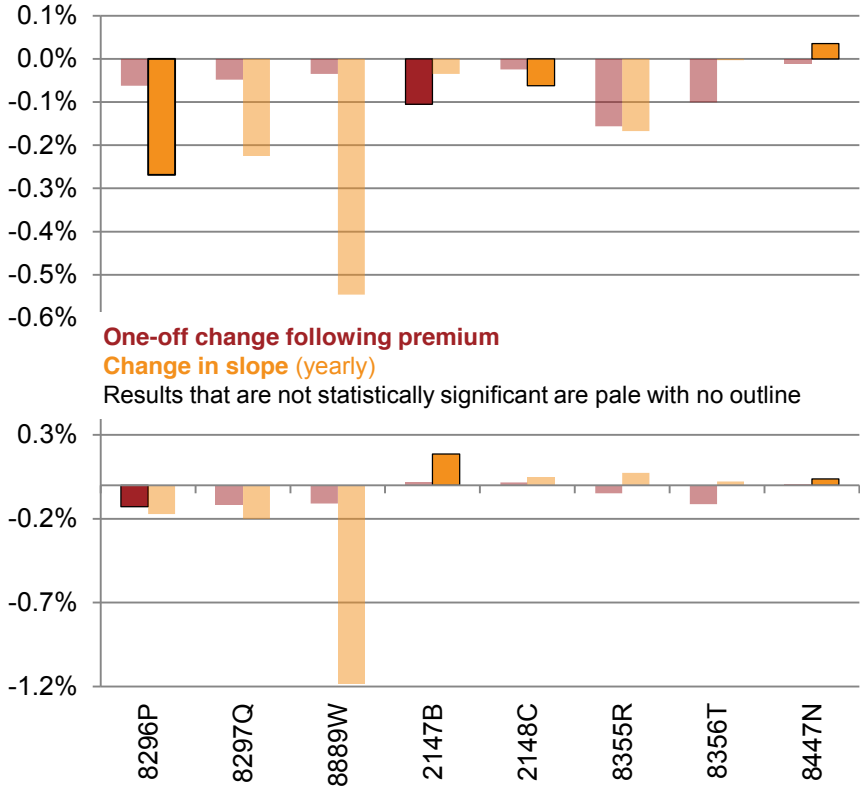
capture any change in the trajectory of market share after the introduction of the premium.[67]

Premium introduction (a one-off effect) only had a statistically significant association with a decline in market share for one of the eight doses. The coefficient was small: a 0.11 per cent fall in market share. Changes in the slope of market share after the introduction of the premium were statistically significant in only three cases. The largest fall was just -0.27 per cent (annually) and one coefficient was very slightly positive.

To put these results in perspective, the statistically significant coefficient that points most strongly towards effectiveness (the 0.27 per cent annual fall in market share) would take over 31 years to bring the market share for that product to zero. This is not a projection – it simply extrapolates linearly (with compounding) – but it does illustrate how meagre the change was. Results of the regression are summarised in Figure 6.

We tested another model with a six month time lag in case the premiums had a delayed effect. This delay may have occurred if people only changed their medication the second time they went to the pharmacist, after having to pay the premium on their previous visit. This model found similar results, with no results that are both statistically significant and large (see Figure 6).

Figure 6: Regression results show that changes are not always statistically significant and are always small
Coefficient (change in pure angiotensin II antagonists market share)



Note: The five-digit PBS drug codes refer to individual doses. Change in slope is the coefficient for monthly trajectory change converted to an annual figure.
Source: Grattan Institute

[67] Note that a dummy variable was included for the 2011 premiums and for the 2012 premiums (which also results in two interaction variables). The results reported are for the premium that applied to each product.

5.4 Price falls for angiotensin II inhibitors

The analysis of price trends for products in the angiotensin II inhibitor therapeutic group covers the period from mid-2009 to mid-2014 (shortly before candesartan and irbesartan were removed from the therapeutic group). It draws on the same data sources described in section 5.1 and excludes under co-payment and closing the gap dispensing.

The price used is the weighted average monthly treatment cost for each drug. We include premiums in calculating this price, as we are investigating the effect on the total price (to government and patients). As with the other analyses, only non-combination products are included. All authority products are excluded to avoid double-counting price changes for the same product.

The analysis compares the average monthly decline for different categories of drug doses (each of which is scaled up to an annual figure):

- all doses in the group
- those that are the cheapest among substitutable doses
- those that are the most expensive among substitutable doses.

This analysis has some limitations. It is possible that greater falls among higher-cost products could be partly explained by reversion to the mean. In addition, our methodology is not the same as the Health Department's. We do not use the same statistical tests to determine the degree of price differences and we have used different data (PBS dispensing data instead of surveys about prescribing). For this reason, out analysis may identify different drugs as the cheapest.

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