THE IMPACT OF FURTHER PBS REFORMS

REPORT TO MEDICINES AUSTRALIA

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EXECUTIVE SUMMARY

"This report evaluates the impact of *Further PBS Reforms* set out in the Memorandum of Understanding between Medicines Australia and the Commonwealth Government agreed in May 2010. In reviewing the effect of the 2010 reforms, the report also provides an update on the savings arising from 2007 *PBS Reform*. The report estimates the influence of the 2010 pricing reforms on key contributors and beneficiaries in the future.

KEY FINDINGS

- The report demonstrates that PBS reforms are working and delivering savings. It is estimated that the 2007 PBS Reform package is likely to deliver $14.5 billion in the period to 2017-18. The 2010 Further PBS Reform will deliver an additional $3.4 billion in savings to Government and consumers in the same time period.
- The report demonstrates that there have been multiple price disclosure price cuts of varying magnitude across the F2 formulary since its introduction in 2007. This confirms that there is a high level of market competition between suppliers in the off patent (F2 formulary) market, resulting in price reductions.
- The report further demonstrates the effectiveness of the market based price disclosure mechanism including EAPD in moderating PBS prices and shows that over two-thirds of all reform savings (69%) in the time period to 2017-18 are likely to come from this measure alone.
- It is noteworthy that some policy elements of the 2010 *Further PBS Reforms*, such as the statutory 16% price reduction and Expanded and Accelerated Price Disclosure (EAPD), are permanent and therefore will continue to deliver savings from PBS medicines as they come off patent.
- Manufacturers (originators more so than generics) will contribute the bulk of the savings (85%) from Further PBS Reform, with Government the overwhelming beneficiary of the reforms (94%) in the period to 2017 –18.
- As intended by the introduction of substantial reforms to the PBS, over the past seven years, projected overall PBS expenditure will remain constrained. It is evident that the impact of any new listings on the projected PBS expenditure is not likely to threaten the sustainability of the PBS.
- The report notes a significant decline in the number of new innovative medicines listed on the PBS since 2009-10. Access to innovative new medicines hit an historic low in 2011-12 with the lowest number of new medicines listed in 20 years. Although details underpinning this trend are beyond the scope of the study, this slowdown in listing merits further investigation.
- Based on the analysis in this report, the sustainability of the PBS in the medium term is assured and the savings measures introduced under the 2007 PBS Reforms, and furthered through the 2010 Further PBS Reform, have contributed to that assurance.

FIGURE A: CUMULATIVE SAVINGS FROM PBS REFORMS, $M

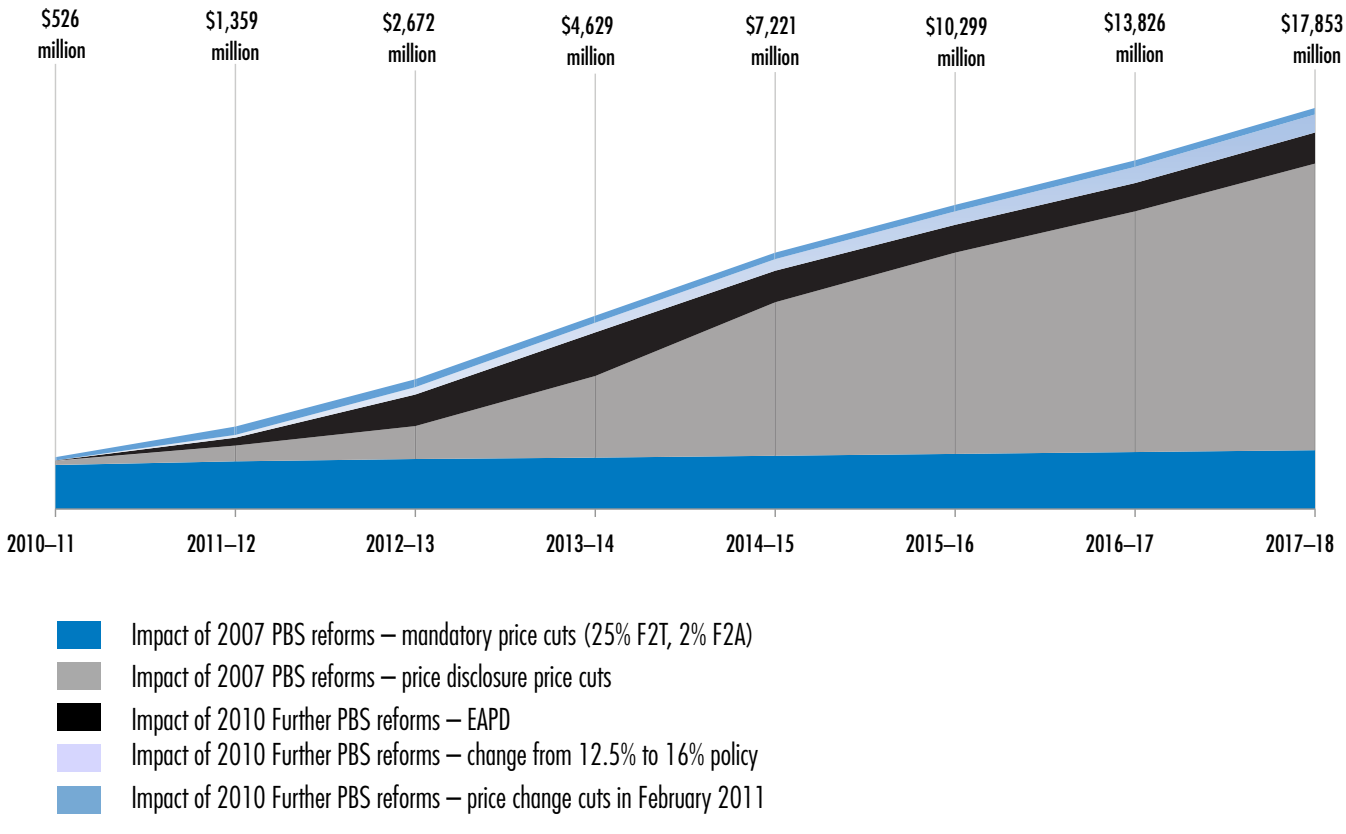


FIGURE B: PBS EXPENDITURE UNDER DIFFERENT POLICY SCENARIOS, 2010-11 TO 2017-18, $M

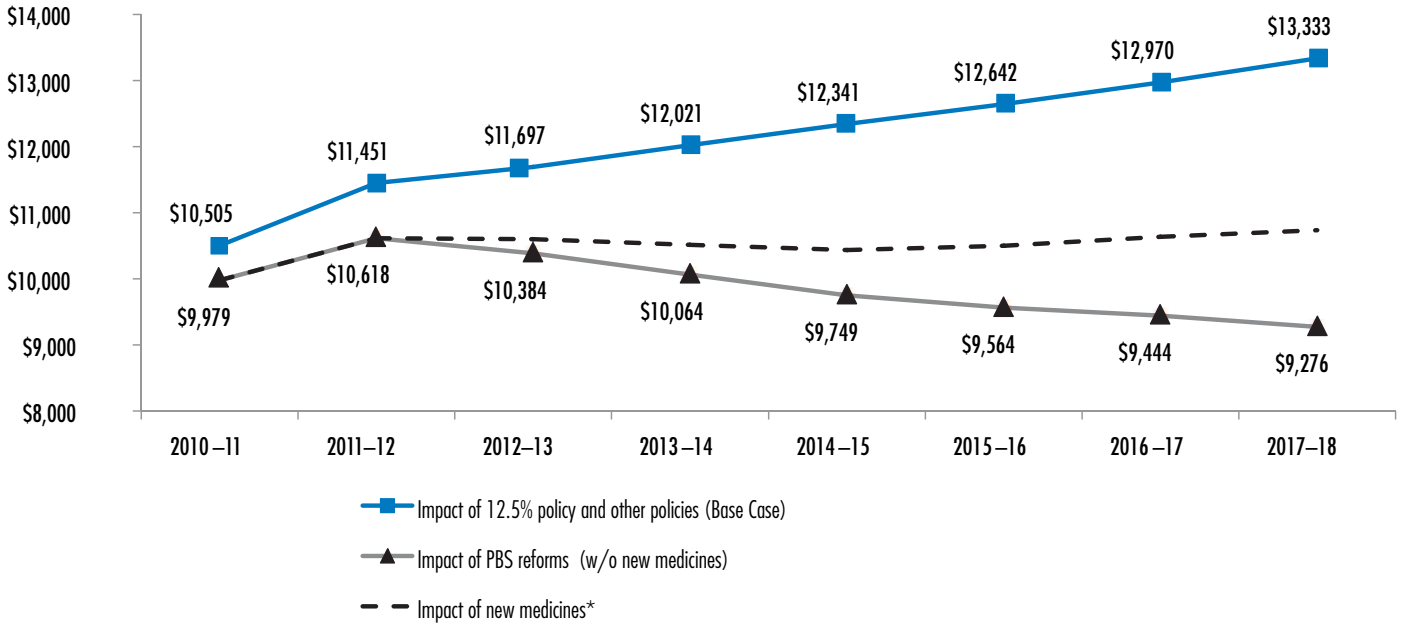
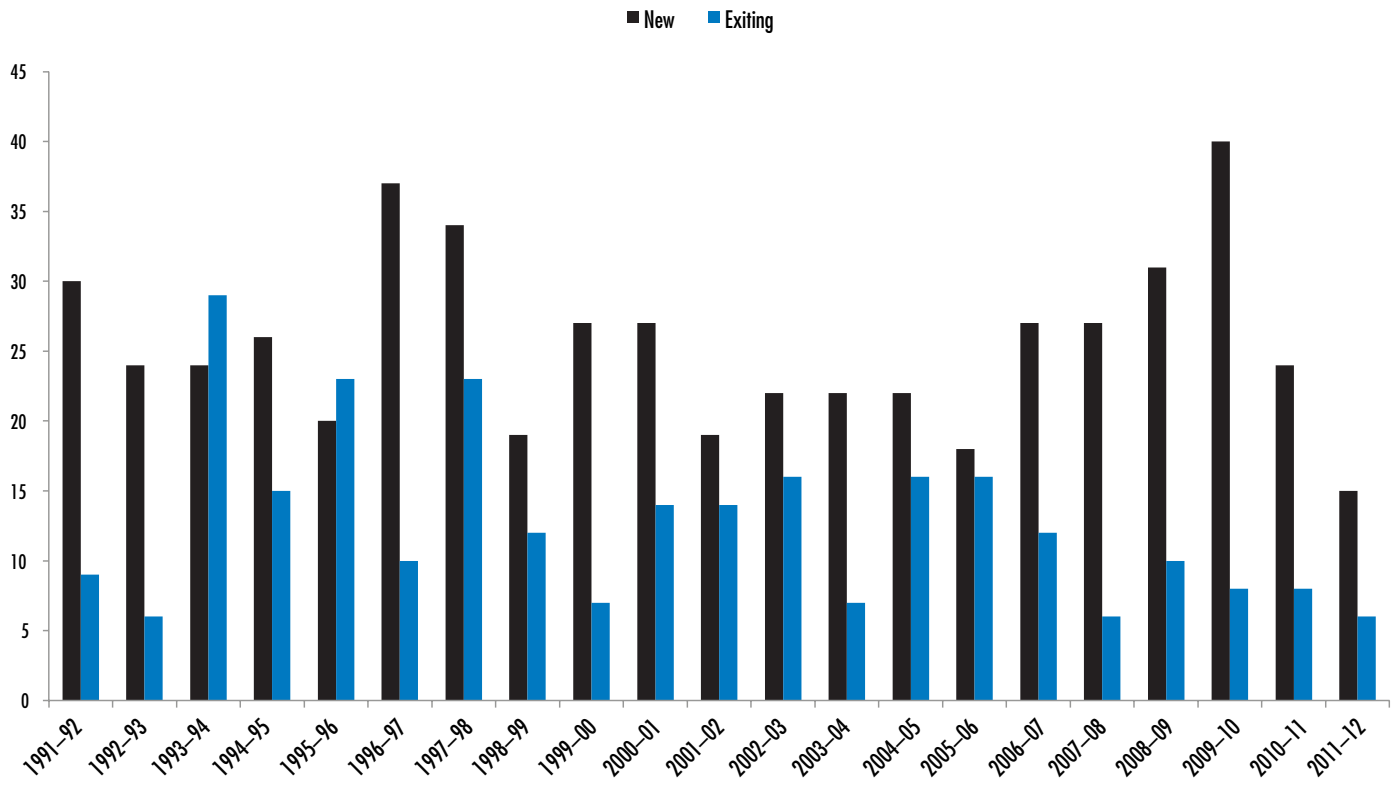


FIGURE C: NEW AND EXITING PBS MEDICINES, NUMBER, 1991-92 TO 2011-12



SUMMARY OF KEY ASSUMPTIONS

			ASSUMPTIONS		
Volume growth (year on year)					3.5%
Entry of first generic					1 month after patent expiration
16% price reduction					1 month after patent expiration
Minimum market size for generic entry					$5 million
Number of price disclosure rounds					4 rounds
Price Disclosure		ROUND 1	ROUND 2	ROUND 3	ROUND 4
Size of cut in relation to Round 1		100%	100%	67%	50%
Probability of price cut		67%	30%	13%	5%
	SIZE OF PRICE CUT	EFFECTIVE PRICE CUT APPLIED			
$500m and over	60%	40%	18%	5%	2%
$100-$500m	45%	30%	14%	4%	1%
$50m-$100m	40%	27%	12%	4%	1%
$30m-$50m	38%	25%	11%	3%	1%
Up to $30m	28%	18%	8%	2%	1%
Timing of price disclosure price cuts from entry of first generic and entry into EAPD		Round 1	Round 2	Round 3	Round 4
	Time (in months)	24	36	48	60

The modelling excludes expenditure on the Repatriation Pharmaceutical Benefits Scheme (RPBS) administered by the Department of Veterans Affairs. Biological and small molecule medicines are treated in the same way in the modeling.

INTRODUCTION

This report sets out the results of a project undertaken by the Centre for Strategic Economic Studies (CSES) at Victoria University for Medicines Australia estimating the impact of the package of changes to the Pharmaceutical Benefits Scheme (PBS) known as Further PBS Reforms, which came into effect on 1 December 2010. The elements of this package of reforms are contained in a Memorandum of Understanding between Medicines Australia and the Commonwealth Government.

A recent report by the Department of Health and Ageing to the Commonwealth Parliament described the elements of the MOU as follows:

- *Several one-off price reductions as of 1 February 2011:*
  - *A price reduction of two or five per cent for all drugs on Formulary 2 (F2) at 11 October 2010.*
  - *An increase to the price reduction that occurs when a PBS drug transitions from Formulary 1 (F1) to F2 (on the listing of the first new brand) from 12.5 per cent, to 16 per cent.*
  - *Streamlining the PBS listing process, particularly for supply under section 100 arrangements.*
  - *The introduction of data collection for drugs with prices below the general patient copayment (previously only collected for prescriptions attracting Government subsidy) to address gaps in the current PBS prescription data.*
  - *Expanded and Accelerated Price Disclosure (EAPD), which extended price disclosure arrangements to apply to all non-exempt drugs on F2. This means that the Government will be better able to share in the benefits of existing competition between pharmaceutical companies.*

Through a Memorandum of Understanding (MoU) with the Commonwealth Government in May 2010, Medicines Australia (MA) guaranteed that the average price reduction (weighted by volume) for those drugs included in the first main cycle of EAPD (reduction day 1 April 2012) will be a minimum of 23 per cent. The price disclosure cycles were also reduced from 24 months to 18 months (including a 12 month data collection period) and the reporting requirements of manufacturers disclosing data were reduced from four times a year to twice annually. (DOHA 2012a)

As described in the next section not all the components of the *Further PBS Reform* package are modelled in this study.

Further PBS Reform builds on an earlier set of changes known as *PBS Reforms* introduced in August 2007, and the introduction of mandatory price cuts on entry of a new brand in August 2005 (the 12.5% policy). In 2009, CSES undertook a similar exercise for Medicines Australia which modelled the impact of PBS Reforms and was released as a report titled 'The Impacts of *PBS Reforms* on PBS Expenditure and Savings'. The modelling used in this report builds upon the approach used in the 2009 study.

The modelling methodology is described in the next section and highlights some of the differences from the 2009 study, which have been introduced to ensure more accurate and up to date results while utilising the greater amount of information now available to inform assumptions about the operation of key aspects of the policy changes.

The results quoted in this report focus on the savings to Government and patients resulting from the successive waves of reforms – the *PBS Reform* and the components of *Further PBS Reform*. The impacts on other stakeholders – manufacturers (originator and generics), wholesalers and pharmacists – are also included typically as the revenue foregone.

Because this report benefits from more recent data leading to more realistic assumptions about the timing and extent of policy-related price cuts and from further development in the approach to modelling, it is not directly comparable to the 2009 report.

Throughout this report the expenditure and savings estimates are given for the period 2010-11 to 2017-18. The results are based on the expenditure data provided to CSES by the Department of Human Services and includes government expenditure on the Highly Specialised Drugs (HSD) Program and patient contributions. The data excludes expenditure on the Repatriation Pharmaceutical Benefits Scheme (RPBS) administered by the Department of Veterans Affairs (DVA) and therefore does not include or report on any savings to the RPBS from the operation of the *Further PBS Reforms*. Biological and small molecule medicines are treated in the same way in the modelling.

MODELLING APPROACH

The aim of this report is to quantify the effects of each of the separate elements of the two reforms – 2007 PBS Reform and 2010 Further *PBS Reform*. To do this, the modelling methodology is made up of a number of steps.

SCENARIO DEVELOPMENT

The first step develops a number of scenarios designed to isolate the effect of each policy element so its individual contribution can be assessed.

Each scenario is a set of prices reflecting different assumptions about their level and timing. Typically policy operates at the level of the price paid by the pharmacist to the wholesaler or sometimes to the manufacturer, and these prices are used as the basis of the modelling in this study.

The 5 elements of policy change which form the basis of the scenarios are shown in Table 1 and are as follows:

- 25% price cuts in August 2008 for medicines on formulary F2T and 2% price cuts in August 2008, 2009 and 2010 for medicines on formulary F2A – *PBS Reform*
- The introduction of price disclosure price cuts – PBS Reform
- The change from 12.5% cuts to 16% cuts in April 2011 – *Further PBS Reform*
- 2% and 5% price cuts in February 2011 – *Further PBS Reform*
- The introduction of Expanded and Accelerated Price Disclosure (EAPD) – *Further PBS Reform.*

In addition two other scenarios are modelled. The first is a scenario that has no price cuts at all since July 2005. The second is based on all the other price cuts that have occurred in the PBS since July 2005. It is important to note that there are price changes within the PBS that arise for reasons other than those caused by the policies listed above. These include changes arising from 12.5% policy, Community Pharmacy Agreements, on-going price reviews including WAMTC reviews, and ad hoc price increases or decreases.

TABLE 1: SCENARIOS USED IN MODELLING POLICY CHANGES

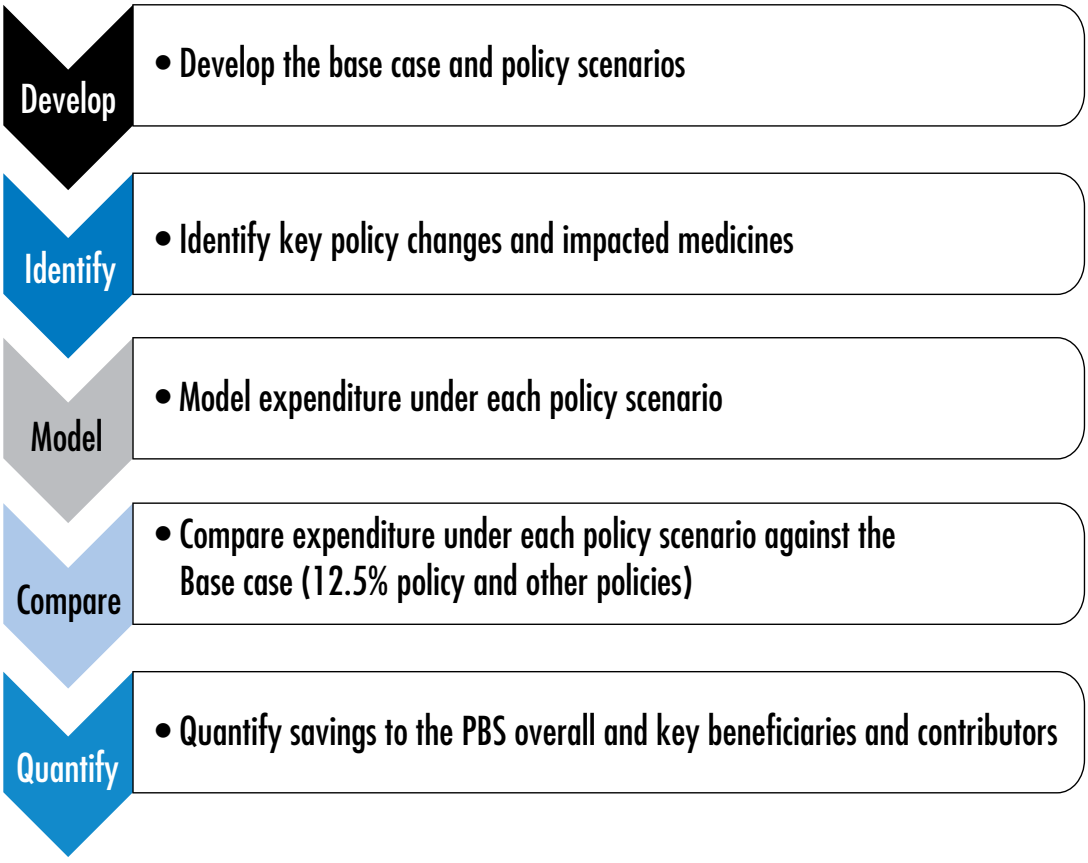
SCENARIO	INCLUSIONS	EXCLUSIONS
1. 12.5% mandatory price cuts and other policies (Base Case)	Price changes arising from Community Pharmacy agreements, on-going price reviews including WAMTC reviews, and ad hoc price increases or decreases plus price changes due to 12.5% mandatory policy only	Excludes 25% price cuts in August 2008 and 2% cuts in August 2008, 2009, 2010; price disclosure price cuts; change from 12.5% to 16% for mandatory price cuts; 2% and 5% cuts in February 2011; changes arising from EAPD from April 2012
2. 25% price cuts in August 2008 and 2% cuts in August 2008, 2009, 2010	Scenario 1 plus price changes due 25% price cuts in August 2008 and 2% cuts in August 2008, 2009, 2010	Excludes price disclosure price cuts; change from 12.5% to 16% for mandatory price cuts; 2% and 5% cuts in February 2011; changes arising from EAPD from April 2012
3. Price disclosure price cuts	Scenario 2 plus price disclosure price cuts	Excludes change from 12.5% to 16% for mandatory price cuts; 2% and 5% cuts in February 2011; changes arising from EAPD from April 2012
4. 16% instead of 12.5% from April 2011 for mandatory price cuts	Scenario 3 plus price disclosure price cuts 16% instead of 12.5% from April 2011 for mandatory price cuts	Excludes 2% F2A and 5% F2T cuts in February 2011; changes arising from EAPD from April 2012
5. Price cuts in February 2011 (2% in F2A and 5% in F2T)	Scenario 4 plus price cuts in February 2011 - 2% in F2A and 5% in F2T	Excludes changes arising from EAPD from April 2012
6. Introduction of EA	Scenario 5 plus changes arising from EAPD	

The effect of each policy element is obtained by comparing expenditure under two different scenarios. For instance the impact of the introduction of price disclosure policy is the difference between expenditure estimated under Scenario 3 which includes these price cuts and Scenario 2 which does not include them.

IDENTIFYING POLICY PRICE CUTS AND MEDICINES AFFECTED

The second step in the modelling exercise involved finding each instance of price change since 2005 due to the different policy elements and identifying the medicines affected by these changes. This was done by examining the changes in the monthly price to the pharmacist as reported in the PBS Schedule in conjunction with lists published by the Department of Health and Ageing of those medicines that have experienced mandatory price cuts and price disclosure price cuts.

FIGURE 1: KEY STEPS IN MODELLING THE IMPACT OF PBS POLICY CHANGES



MODELLING EXPENDITURE FOR EACH SCENARIO

As the next step, PBS expenditure was modelled under each policy scenario shown in Table 1. For the purposes of modelling, actual prices and other listing details of PBS medicines were used up to February 2013. For the period to 2011-12, actual expenditure and usage data was used in the modelling .

The model projects prices, expenditure and usage for the period 2012-13 to 2017-18, for the cohort of medicines for which expenditure data is available for 2011-12. Projection of PBS expenditure and savings are therefore only for this cohort of medicines and does not take account of how old medicines exiting and new medicines entering will affect this cohort in future. The impact of new medicines entering the PBS in the future on overall PBS expenditure is discussed separately in the report.

Starting with actual prices, the prices for each scenario were obtained by progressively reversing the changes brought about by each policy element. To calculate the impact on stakeholders, the dispensed price was calculated under each scenario, as well as the price to the pharmacist for the maximum quantity. Modelling was done at the level of the combination of PBS item codes and manufacturer codes (brand codes). This is for two reasons – firstly, it provides information on outcomes for originator and generic brands, and secondly, it takes into account the different pricing among brands if manufacturers include a price premium. Throughout this report, originator brands are the brands that were the original ones for a particular medicine. Generic brands are all subsequent or follow on brands for that medicine.

The modelling was undertaken using monthly PBS prices from July 2005 to February 2013 and annual PBS expenditure data from 2005-06 to 2011-12. The monthly data is obtained from the electronic version of the PBS Schedule made available by the Department of Health and Ageing (DOHA 2013a). The impact of changes to prices is modelled on a monthly basis to capture exactly when a price change occurs. The monthly prices calculated in this way are converted to an annual basis by taking the average of the monthly prices.

Prices to February 2013 were calculated under the different scenarios using known information from the PBS schedule available from the Department of Health and Ageing. Projections of prices under different scenarios thereafter, however, depend on assumptions made about patent expiries, timing of new brand entry, timing of price disclosure price cuts and other factors which are all subject to different levels of uncertainty.

The estimates of expenditure and savings are arrived at by combining the information about price with the usage data (script volume), which is the same under each scenario. Usage data to 2011-12 is known and projected at a constant growth rate of 3.5% thereafter. Overall savings from each policy scenario were then calculated by comparing successive scenarios. Finally, savings were allocated between beneficiaries namely the Government and consumers and the contributors namely the manufacturers – originators and generics, wholesalers and pharmacists.

The data used in modelling was sourced from the Department of Human Services and Department of Health and Ageing and includes Government expenditure on the Highly Specialised Drugs (HSD) Program through public and private hospitals, as well as patient contributions.

KEY ASSUMPTIONS

The key assumptions used in modelling the impact of policy changes and the extent to which these assumptions differ from the 2009 report are set out below.

MANDATORY PRICE CUTS

For single supplier medicines, the timing of mandatory price cuts (i.e. the 12.5% or 16% policy) was largely determined by patent expiry dates. Assumptions were also made about the entry of a new brand for those other medicines for which this had not yet occurred. However, patent expiry dates are subject to some uncertainty as the dates can vary depending on a number of factors including patent term extension or early patent challenge by a generic company.

In the CSES 2009 report, assumptions were made about medicines that were likely to experience 12.5% price cuts over the period from July 2009 to June 2018. However, actual information on these price cuts from July 2009 to April 2013 is now available. The actual outcomes are different to the assumptions made in the 2009 report. For instance, some medicines did not have the anticipated cuts, or the cut was on a different date. Other medicines took an unexpected price cut. Some examples of these assumptions differing from actual outcomes are as follows. The date expected for new brand entry for atorvastatin (PBS expenditure of $733.2 million in 2011-12 and rosuvastatin ($400.2 million) in the 2009 report was October 2012 whereas the actual date was April 2012. Similarly, the date expected for clopidogrel ($178.5 million) was March 2013 rather than the actual date of April 2010. The A2RAs such as irbesartan ($77.2 million) were expected to experience mandatory price cuts in March 2012 based on the patent expiry date of eprosartan, but this happened in April 2013.

In summary, the assumptions about which medicines would have mandatory price cuts differ between the two studies. For the current study, the CSES model was updated with actual 12.5% or 16% mandatory price cuts for the period from July 2009 to April 2013, which formed the basis for future mandatory price cuts after April 2013. Nevertheless there were some similar assumptions in both studies. For instance, both studies assume that new brand entry would only occur for medicines where annual PBS expenditure was over $5 million, and both studies rely on patent expiry dates from the IMS Health Patent Focus database to estimate when a new (generic) brand is likely to enter triggering the move from the F1 formulary to the F2 formulary.

It is important to note that there are some medicines on formulary F2 that are also subject to mandatory price cuts (of 12.5% now 16%) if a new brand lists on the PBS if this has not already occurred since August 2005. For these medicines, it was necessary to estimate when new brand entry might occur. To do this, listings on the Australian Register of Therapeutic Goods (ARTG) over the past two years were examined to identify when these medicines on F2 might have a new brand entry and a mandatory price cut. This procedure was not used in the 2009 study. The remainder of medicines on F2 which were considered potential candidates for mandatory price cuts were allocated to new entry dates across the forecast period, in descending order of PBS expenditure. The medicines in this latter group with the largest PBS sales are buprenorphine ($46.4 million), goserelin ($50.8 million) and mesalazine ($46.1 million).

In the current study, the assumptions about which medicines would incur mandatory price cuts and when this would happen are the same across all the scenarios modelled. For the Introduction of EAPD scenario, the cut is 16% rather than 12.5% from April 2011.

PRICE DISCLOSURE

Price cuts arising from price disclosure (PD) are a feature of both *PBS Reform* and *Further PBS Reform*. In the PBS Reform package, price disclosure only applied to medicines on F2, including those entering F2 from F1. Initially this was restricted to those medicines on formulary F2A starting 1 August 2007 with the provision of extending price disclosure for other medicines on F2 formulary from January 2011. Therefore, only those medicines on the F2 having new brand entry were required to enter the PD cycle of reporting prices and being subject to price disclosure if price discounts averaged across brands was above a threshold of 10%. This was compulsory for the new brand itself and voluntary for other brands of the medicine.

The Expanded and Accelerated Price Disclosure (EAPD) arrangements in the *Further PBS Reform* package meant that all medicines in F2 at October 2010 were then obliged to enter the PD cycle and be subject to price disclosure starting on December 2010. This was now compulsory for all brands of the medicine. In a presentation by the Department of Health and Ageing in November 2010 titled 'Expanded and Accelerated Price Disclosure: What's New? What's Different' (DOHA 2010a), it was estimated that at the time there were 45 medicines subject to PD under the old arrangements and there would be approximately 220 under EAPD at that time.

In essence, the difference brought about by EAPD is that all medicines on F2 are now subject to price disclosure. Previously it was only those with a new brand entry. For instance, simvastatin ($160.4 million) and pantoprazole ($103.9 million) had price cuts in April 2012 under EAPD, but would not have had a cut at that time under the price disclosure arrangements within the 2007 *PBS Reform*.

At the time of modelling for the 2009 report, only a handful of medicines had experienced price cuts from PD and there had been only sufficient time for one round of cuts. There was therefore little evidence, for forecasting purposes, on which to base assumptions about which medicines would be subject to price disclosure and the size of the cut (if there was one), and whether there would be one or multiple rounds of price cuts for each medicine. It was therefore assumed that medicines that take the mandatory price cut on entry of new brand (12.5% policy) would also take a PD price cut in the future determined by the reporting timelines then in place. The size and the probability of PD price cuts was determined by the PBS expenditure on the medicine (market size) and it was assumed that there would only be one round of price cut per medicine.

In modelling the impact of *Further PBS Reforms* in 2013, there is more evidence available to estimate the probability and size of price disclosure price cuts with greater confidence. The following section provides an insight into the experience with price disclosure to date which formed the basis for key assumptions relating to price disclosure including EAPD, namely the probability of price cuts, number of rounds and the size of price cuts in each round.

EXPERIENCE TO DATE WITH PRICE DISCLOSURE

Up to December 2012, some 96 medicines had experienced price disclosure price cuts, with 4 of these (fluconazole, ondansetron, sodium chloride and tramadol) having different price cuts for different forms of administration (injection and oral – injection and infusion for sodium chloride), bringing the overall number of medicines/forms price cuts to 100. Of these medicines/forms, 14 had experienced two rounds of price cuts, 6 had three rounds and 2 had four rounds.

Recently, the Department published a list of 62 medicines in the Second Main Cycle that will have a cut in April 2013 (DOHA 2012b). Of these, 29 will be first round cuts, 30 will be second round cuts following a first round cut in April 2012, 2 will be second round cuts and 2 will be third round cuts following first round cuts in April 2011. Of the 69 medicines with a first round cut in April 2012, 30 (43.5%) will have a second round cut in April 2013.

For Transitional Cycles 1, 2 and 3 the numbers of medicines in each cycle is known, as they were listed in Fact Sheet 2 Transitional Cycles (DOHA 2010b). Of the 11 medicines in Transitional Cycle 1 for instance, 4 had not had any cut by December 2012, 3 medicines had only one round of cuts, 3 had two rounds and 1 had three rounds. Combining the experience of Transitional Cycles 1, 2 and 3, shows that of the 46 medicines involved, 32.6% had no price cut, 37.0% had one cut only, while 17.4% had two cuts, 8.7% had three cuts and 4.3% had four cuts.

In October 2010, there were 239 medicines in formulary F2 with some having multiple forms of administration bringing the number to about 300. Deducting the 46 that were already in price disclosure brings the total newly entering price disclosure to 254 because of EAPD. Of that total, 66 (26.0%) had a price cut in April 2012.

Under the arrangements for *PBS Reform*, there were 31 first round price cuts for 29 medicines, whereas there were 69 cuts for the first round under EAPD in April 2012. This does not preclude there being further first round cuts in later periods, or there being second, third or fourth round cuts in the future.

Based on experience to date, on average the first round cut is 29.2%, with 23.3%, 25.9% and 47.7% as the average cuts in second, third and fourth rounds. Taking all price cuts together, the average reduction is 29.7%. The cumulative price reduction for those medicines experiencing two or more rounds of price cuts is given in Table 2.

While it is possible to discuss patterns based on average price cuts, in reality there are wide ranges for price cuts. For instance, first round cuts have varied between 9.0% and 82.8%.

TABLE 2: CUMULATIVE AVERAGE PRICE DISCLOSURE PRICE CUTS TO APRIL 2013

	NUMBER	CUT, %
One round only	83	29.2%
Two rounds	38	44.1%
Three rounds	6	67.3%
Four rounds	2	72.5%

In summary, the experience to date suggests that about two thirds (67.4%, i.e. 100%-32.6%) of medicines in the price disclosure cycle will have at least one round of price cuts, with about 37% having one round only, about 17% will have two rounds of cut only, about 9% will have three rounds of cuts only and about 4% will have four rounds of cuts only. Put another way, this means that the chance of a medicine having a first round cut is 67.4%, a second round is 30.4% (17.4%+8.4%+4.3%), a third round cut is 13.0% (8.4%+4.3%) and a fourth round cut is 4.3%.

PRICE DISCLOSURE ASSUMPTIONS IN THE MODELLING

Based on this, it is assumed that there will be at least 4 rounds of price cuts and that any medicine in the price disclosure cycle will have a 67% chance of having a first round price disclosure price cut. This probability falls for subsequent rounds as shown in Table 3.

TABLE 3: PROBABILITY OF PRICE DISCLOSURE PRICE CUTS

	FIRST	SECOND	THIRD	FOURTH
Probability	67%	30%	13%	5%

Another area of uncertainty is the size of the price cuts in each round. Experience to date suggests that the average first round cut lies within PBS cost ranges. For those medicines that cost the PBS over $30 million, the size of the cut increases as the cost to PBS increases. Below $30 million, however, the size of the cut has little relationship to PBS cost with cuts varying across a range of 24% to 32%. Similarly there appears to be no relationship, for now, between the size of cuts in second, third and fourth rounds and the cost of the medicine to the PBS. This could simply be due to the limited number of medicines that have taken a third or fourth round of price cuts to date.

Based on this, it was assumed that the cost to PBS determines the size of the price cut in the first round. For those medicines with PBS costs of $500 million or above, the model assumed a 60% price cut in the first round. Similarly, for those medicines that cost the PBS between $100 million and $500 million in 2011-12, the cut was set at 45%, between $50 million and $100 million it was 40%, between $30 million and $50 million it was 37.5% and otherwise 27.5%

In addition the size of the cut was assumed to be the same in the first and second rounds but for the third round it is 67% of the first round and in the fourth round it is 50% of the first round cut.

These assumptions are summarised in Table 4.

TABLE 4: ASSUMPTIONS ABOUT SIZE AND PROBABILITIES OF PRICE DISCLOSURE PRICE CUTS

	SIZE OF CUT (%)	FIRST	SECOND	THIRD	FOURTH
Size of cut in relation to First Round		1.000	1.000	0.670	0.500
Probability of cut (%)		67.0	30.0	13.0	5.0
$500m and over	60.0	40.2	18.0	5.2	1.5
$100-$500m	45.0	30.2	13.5	3.9	1.1
$50m-$100m	40.0	26.8	12.0	3.5	1.0
$30m-$50m	37.5	25.1	11.3	3.3	0.9
Up to $30m	27.5	18.4	8.3	2.4	0.7

While it can be assumed that medicines will have a 67% chance of a first round price cut, this does not identify which medicines would actually be subject to this cut. To get around this it is assumed that all medicines in the price disclosure cycle will have a probability adjusted price cut which will be a percentage of the base assumption. Thus for medicines in the range $500 million and over, the model assumes that they all have a probability adjusted cut of 40.2% (i.e. 60.0%*67.0%) instead of the base assumption of 60.0%. In the second round all these medicines would have a probability adjusted price cut of 18.0% (60.0%*100%*30.0%) and so on. The resulting sizes of price cuts are shown in the body of Table 4.

Further price cuts from price disclosure in the future follow on from the assumptions about mandatory price cuts after April 2013. The first round price cut is assumed to occur 24 months after new brand entry, the second round 12 months later and the third round 12 months after the second and so forth.

MODELLING RESULTS

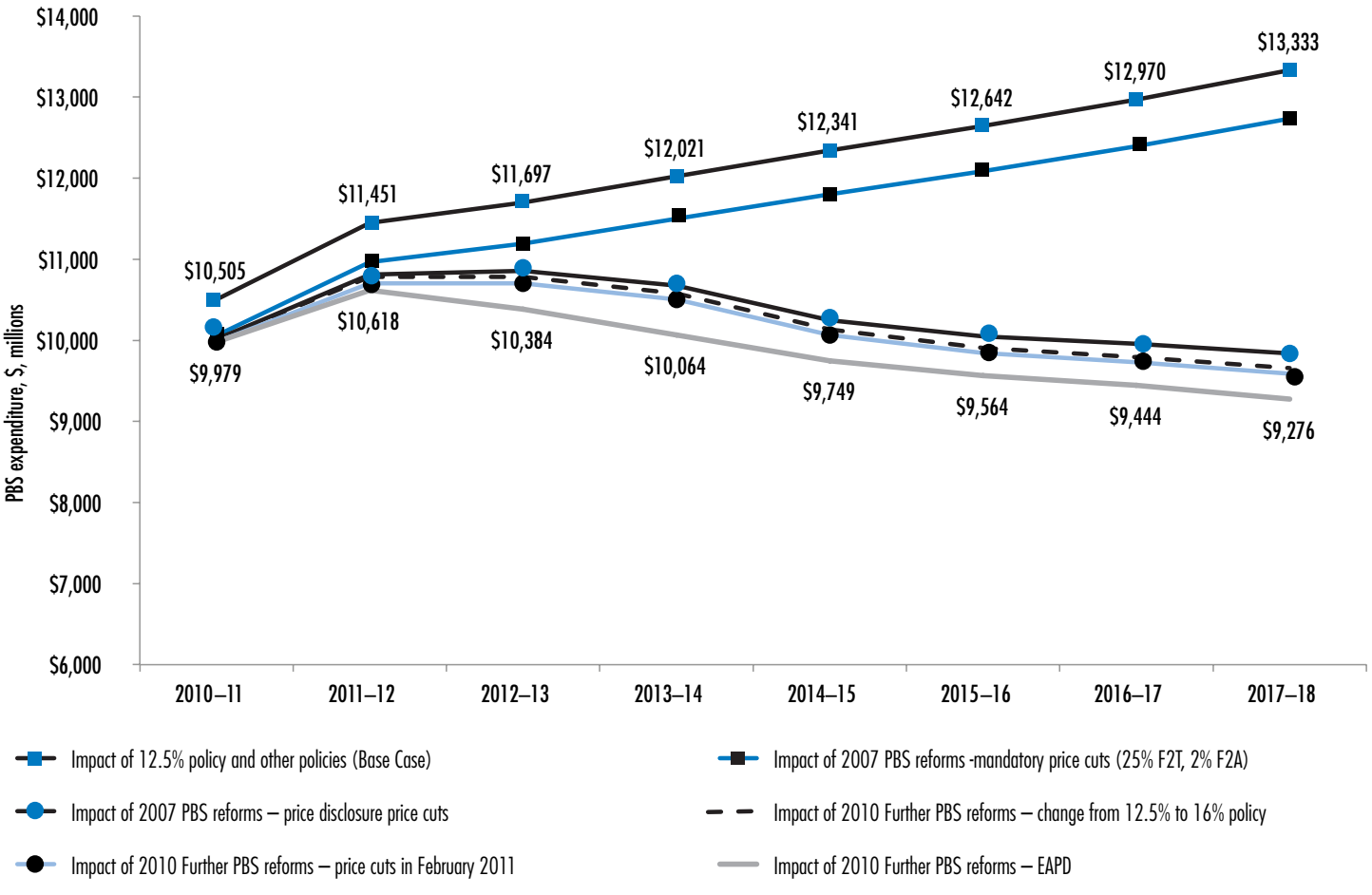
IMPACT OF PBS POLICY CHANGES ON GOVERNMENT AND PATIENT EXPENDITURE

To assess the impact of *Further PBS Reforms* the impact of each policy element since 2005 was modelled as a separate scenario as described earlier. The estimated PBS expenditure for each scenario and the resulting estimates of savings obtained from each element of policy change are summarised in Tables A1 and A2 in the Appendix.

Figure 2 illustrates the level of expenditure under the different policy scenarios. The difference between the scenarios shows the impact of each element of policy change most of which are quite large.

In the absence of *PBS Reforms*, PBS expenditure in 2011-12 would have been over $11.4 billion. However, PBS expenditure was at least $800 million lower than that. As at February 2013, there were over 800 medicines listed on the PBS. The modelling shows that the overall expenditure on this cohort of medicines is likely to have peaked in 2011-12. Excluding the cost of new listings in the future, the overall expenditure on this cohort will start to decline in the time period to 2017-18. These waves of price cuts have successfully driven down the prices paid by the Government and patients for medicines on the PBS. There is no doubt that successive reforms have created 'headroom' for further investment in important new medicines in the future.

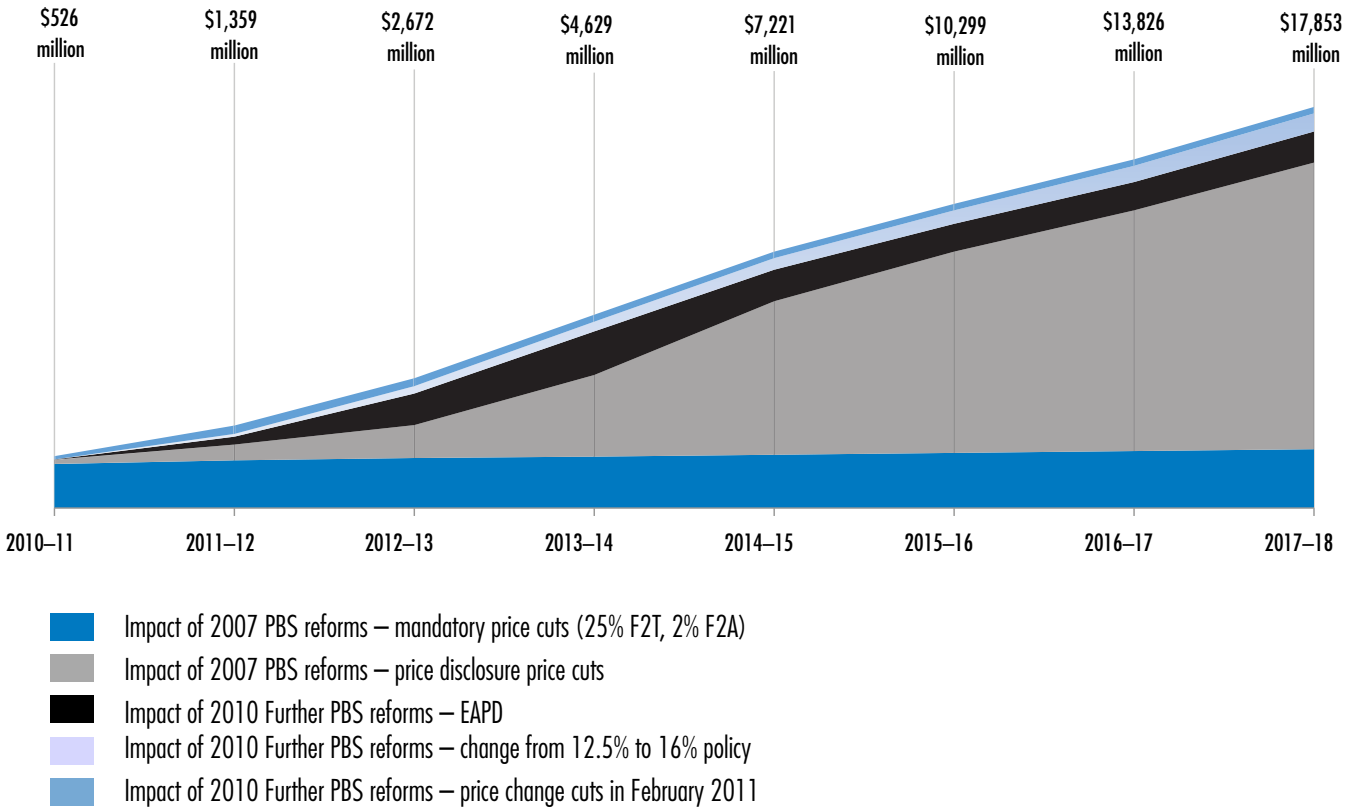
FIGURE 2: PBS EXPENDITURE UNDER DIFFERENT POLICY SCENARIOS, 2010-11 TO 2017-18, $M



Savings from each subsequent pricing reform and ongoing policies will continue to grow overtime (see Figure 3), and their impact will continue to moderate PBS prices and contribute to savings for the Government and patients. Overall, the modelling estimates that these savings will rise from nearly $526 million in 2010-11 to nearly $18 billion in 2017-18.

In terms of the effectiveness of each PBS policy in generating savings, the modelling confirms the effectiveness of 2007 *PBS Reforms*, and in particular that price disclosure has successfully moderated PBS prices and expenditure. The modelling further demonstrates that the changes introduced in *Further PBS Reform* are providing an additional layer of savings over and above the 2007 *PBS Reforms*.

*FIGURE 3: CUMULATIVE SAVINGS FROM DIFFERENT POLICY CHANGES, $M



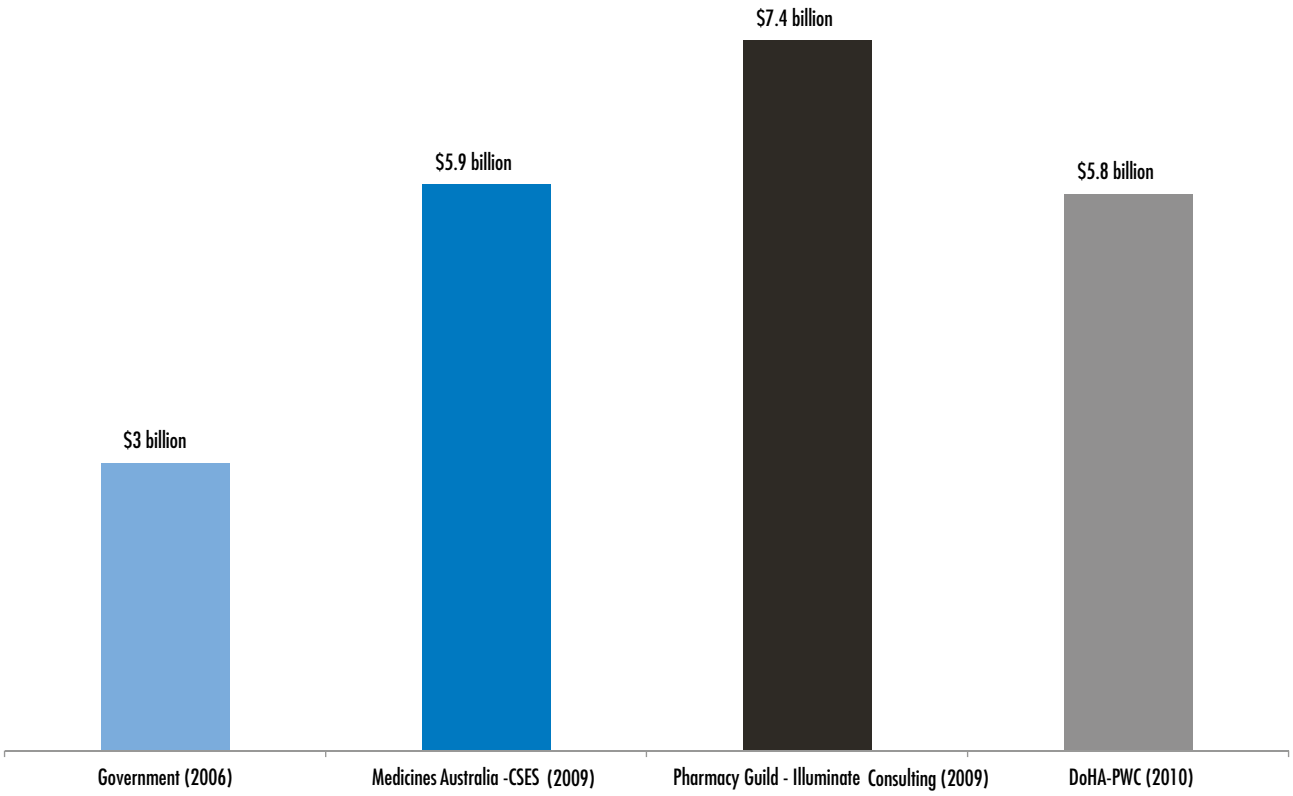
*Excludes savings to the Repatriation Pharmaceutical Benefits Scheme administered by the Department of Veterans Affairs. Includes potential savings from patent expired biological medicines.

UPDATE ON THE 2007 PBS REFORMS

In 2009, CSES modelled the impact of the 2007 PBS Reforms. As discussed earlier, the modelling exercise was conducted using assumptions based on limited experience with the price disclosure mechanism. In particular, there was much uncertainty around the probability and size of price cut. By contrast, in 2013 there is more information available to more closely define these assumptions to estimate future savings to the PBS.

Based on the 2009 modelling results, the Government was estimated to save close to $6 billion in the time period to 2017-18 (CSES 2009). The 2009 estimate was almost twice the original Government estimate of $3 billion over 10 years (DOHA 2013b). Subsequent to the 2009 report, a number of savings estimates were published including the Governments own estimates revised upwards based on modelling by PriceWaterhouseCoopers (PWC) (DOHA 2013c). Every subsequent estimate confirmed that the Government may have significantly under estimated the savings from the 2007 PBS Reform as it took a very conservative view of the savings likely to accrue from price disclosure price cuts.

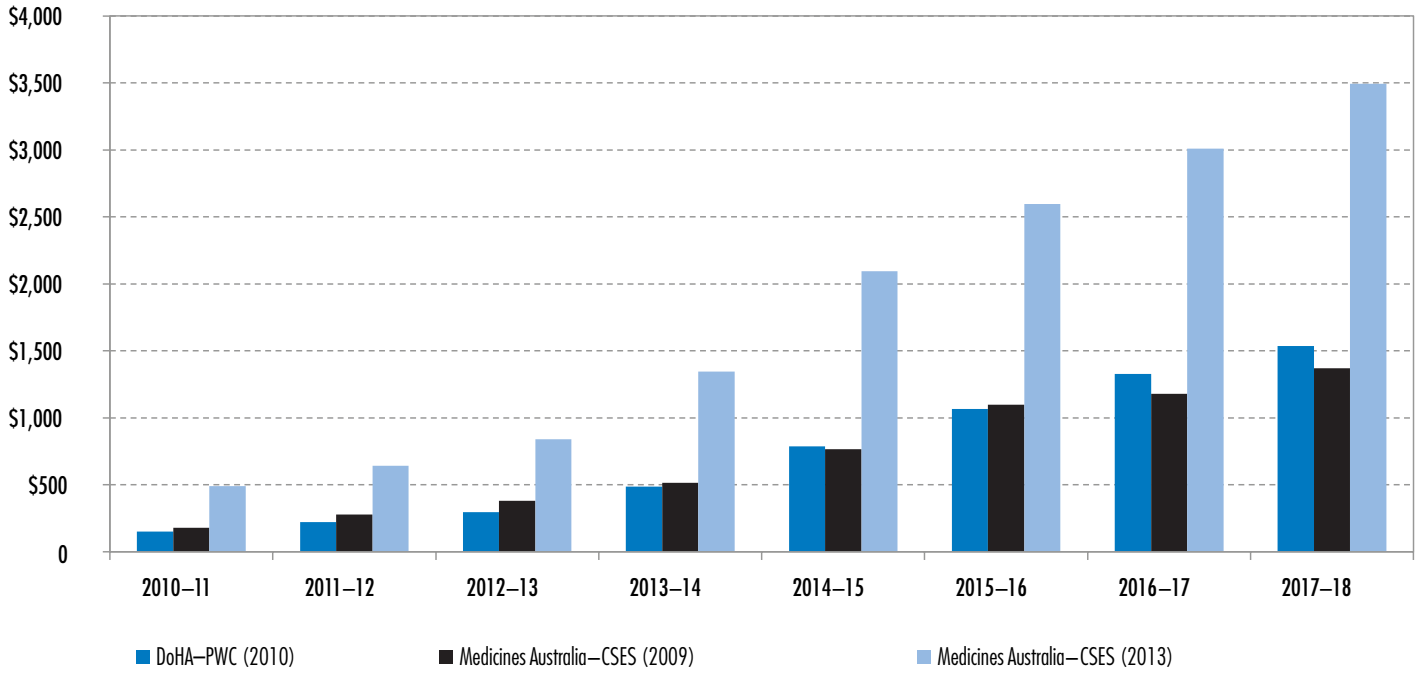
FIGURE 4: ESTIMATES OF THE SAVINGS FROM 2007 PBS REFORM, $B



Experience to date with price disclosure confirms that for a range of medicines in the F2 formulary there is a high level of market competition among brands. This is driving multiple rounds of price cuts leading to greater savings than previously anticipated by the Government. Based on this experience, the modelling in this study suggests that the overall savings from the 2007 PBS Reforms in the time period to 2017-18 are now likely to be around $14.5 billion as opposed to the previously reported $5.9 billion. This is almost five times the original Government's estimates ($3 billion) and over two times the Government's revised estimates as reported in the PWC report ($5.8 billion-high estimates).

It is important to note that 70% of the total savings ($14.5 billion) estimated in this study in the time period to 2017-18 is likely to come from the price disclosure mechanism alone. This underscores its effectiveness in driving down the prices of multiple brands in the F2 formulary (see 3 in the Appendix).

FIGURE 5: ESTIMATES OF THE SAVINGS FROM 2007 PBS REFORM, 2010-11 TO 2017-18, $M

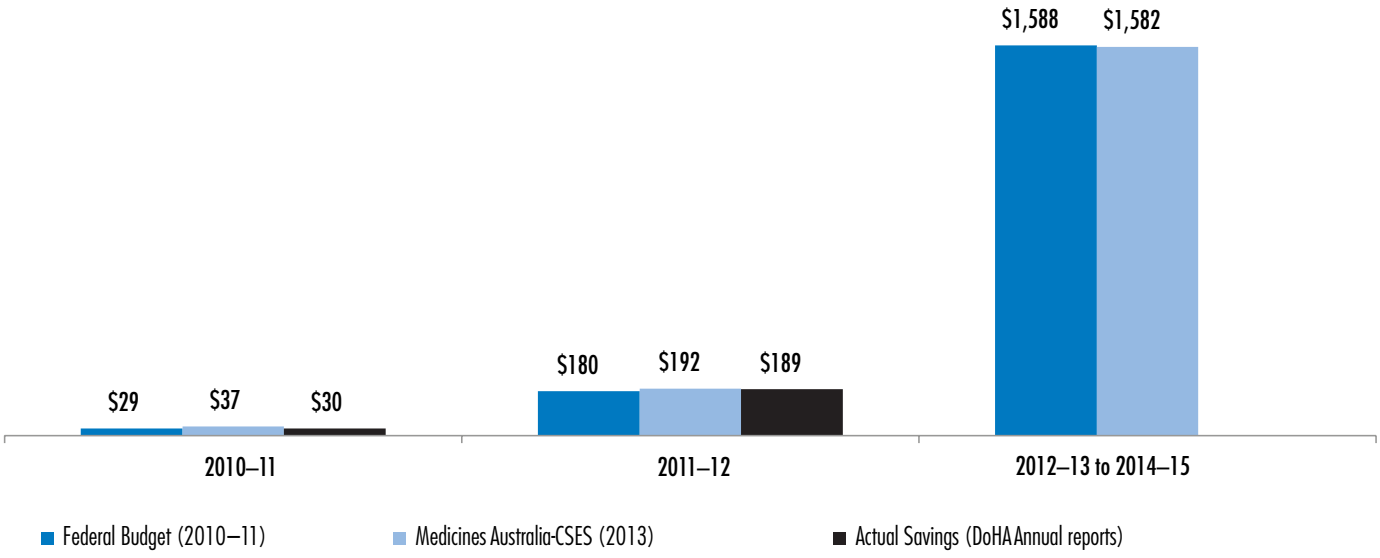


OVERALL IMPACT OF *FURTHER PBS REFORMS*

As shown in Figure 6, the overall savings from the 2010 *Further PBS Reforms* in the MOU time period (2010-2015) is likely to be $1.81 billion which compares well with the Government's own savings estimates of $1.79 billion in the same time period.

Encouragingly, the actual savings from *Further PBS Reforms*, as reported in annual reports of the Department of Health and Ageing (DOHA), are broadly in line with both 2010-11 Federal Budget estimates and the estimates in this study (see Table A4 in the Appendix).

FIGURE 6: ACTUAL AND PROJECTED SAVINGS FROM FURTHER PBS REFORM, 2010-11 TO 2014-15, $M



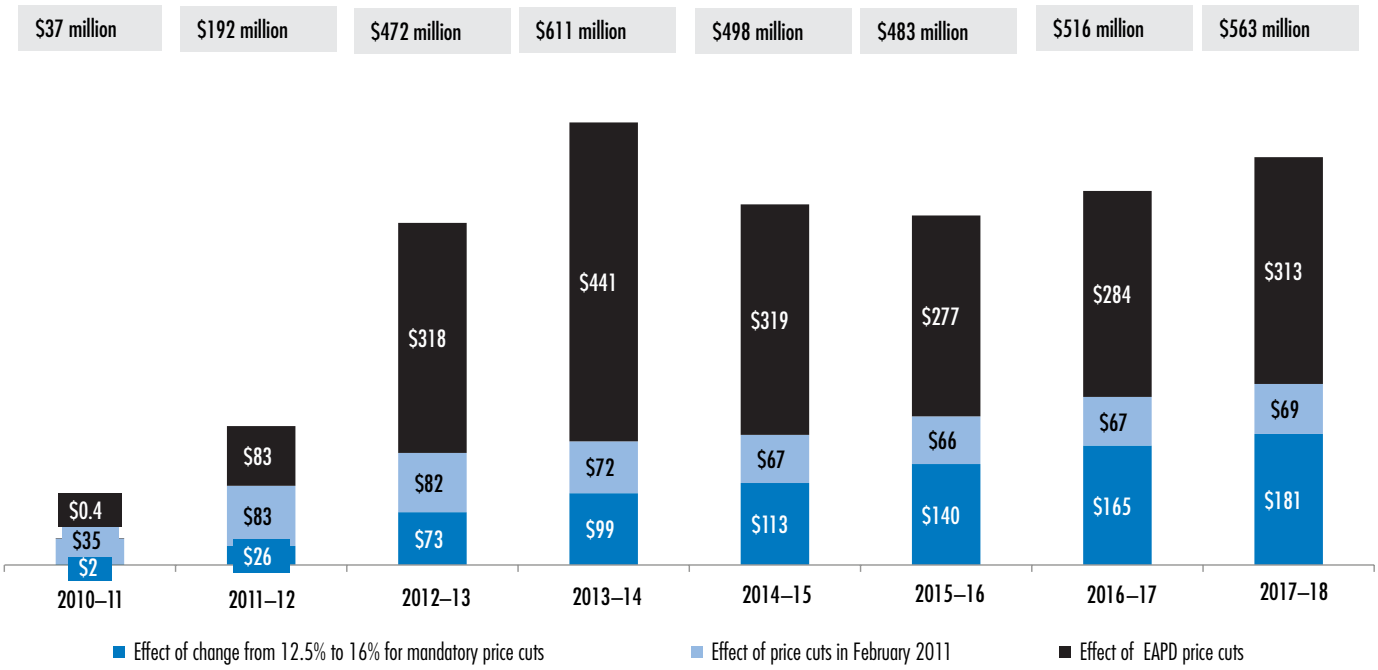
In the time period to 2017-18, the *2010 Further PBS Reforms* are likely to save close to $3.4 billion in savings additional to those from those arising from 2007 *PBS Reform*. As shown in Figure 7, the savings from each measure within the 2010 *Further PBS Reforms* varies over time. This is largely due to the effect of ongoing policies and also how the price disclosure price cuts are allocated across the two reforms.

Overall, in the time period to 2017-18, the savings from 2010 Further PBS Reforms are likely to be over $3 billion including:

- Change from 12.5% policy to 16% policy – $799 million;
- Mandatory 2% and 5% price cuts on 1 Feb 2011 – $539 million; and
- Expanded and Accelerated Price Disclosure (EAPD) – $2,035 million.

It is also very important to note that the 16% policy and the EAPD are both ongoing policies with no end date, which means that these policies will continue to moderate PBS prices in the F2 formulary in the future (see Table A5 in the Appendix).

FIGURE 7: SAVINGS FROM FURTHER PBS REFORM, 2010-11 TO 2017-18, $M



IMPACT OF FURTHER PBS REFORMS ON PARTICIPANTS

As noted previously, the *Further PBS Reforms* will deliver at least $1.8 billion in the time period of the MOU and close to $3.4 billion in the time period to 2017-18. As shown in Table 5, the two beneficiaries of these savings would be the Government (94%) and the patients (6%), while the key contributors to these savings are overwhelmingly the manufacturers.

TABLE 5: SAVINGS BY PARTICIPANTS FROM FURTHER PBS REFORMS, $M

	2010–11 to 2014–15	% of benefit	2010–11 to 2017–18	% of benefit
Government	1,702.2	94%	3,165.9	94%
Patients	108.1	6%	206.5	6%
Total savings	1,810.3	100%	3,372.4	100%

In particular, the off patent originator brands will contribute over half of all the savings in the time period to 2017-18. Generic brands will contribute nearly a third of all the savings (32%-36%) in the same time period. The remaining savings will come from pharmacists (8%-9%) rather than the wholesalers (6%).

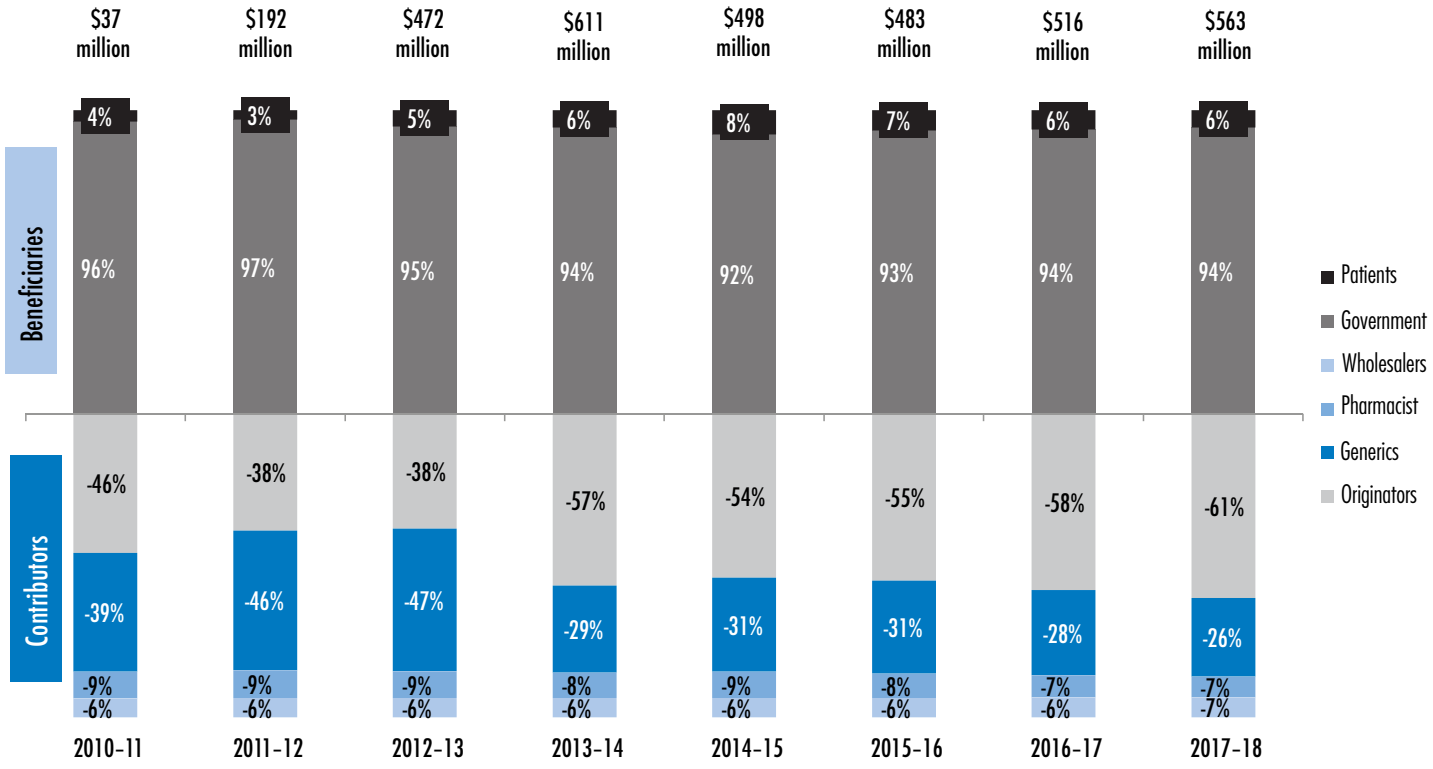
TABLE 6: REVENUE FOREGONE BY PARTICIPANTS FROM FURTHER PBS REFORMS, $M

	2010-11 to 2014-15	% of contribution	2010-11 to 2017-18	% of contribution
Pharmacists	-156.0	9%	-271.1	8%
Wholesalers	-115.8	6%	-217.3	6%
Off patent originator brands	-883.7	49%	-1,790.0	53%
Generic brands	-654.8	36%	-1,094.2	32%
Total contributions	-1,810.3	100%	-3,372.6	100%

Figure 8 provides a year by year account of savings from *Further PBS Reforms* and shows the per cent contribution to overall savings by beneficiaries and contributors. The overwhelming majority of the savings will accrue to the Government (92%-97%). Patients will receive some benefits however these benefits will accrue mostly to general patients rather than their concessional counterparts (see Table A6 in the Appendix).

In terms of the key contributors, as shown in Figure 8, manufacturers will provide the bulk of the savings from the 2010 *Further PBS Reforms*, with originators contributing more than generics. It is important to note that the contribution from the generic brands is likely to be higher in the first few years of the Reforms as EAPD has essentially fast tracked some of the price disclosure savings. However, in the long run, originator brands will contribute a higher proportion of the savings to PBS reforms than their generic counterparts.

FIGURE 8: IMPACT OF FURTHER PBS REFORM ON PARTICIPANTS, 2010-11 TO 2017-18, $M



SENSITIVITY ANALYSIS

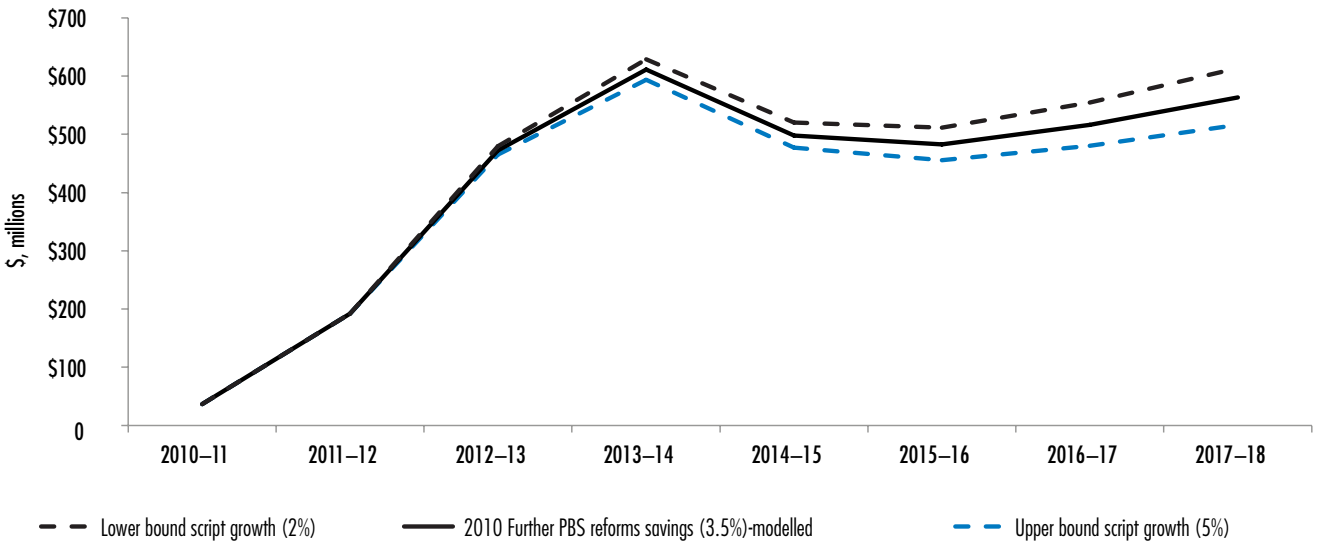
When modelling the impact of *Further PBS Reforms*, a number of assumptions were made to address uncertainty surrounding some of the key variables. To guage the sensitivity of the model to change in some of these parameters, a sensitivity analysis was performed in two areas.

1. Prescription volume growth in future.
2. Probability and size of price disclosure price cuts.

IMPACT OF CHANGE IN VOLUME GROWTH ASSUMPTIONS

In modelling the impact of *Further PBS Reforms* and other pricing scenarios, CSES assumed a constant script volume growth of 3.5% per annum from 2012-13. To test the sensitivity of savings estimates to change in script volume assumptions, two additional scenarios, namely 2% script growth (lower bound) and 5% script growth (upper bound) were also modelled. The sensitivity analysis indicates that the impact of different growth assumptions changes the savings estimates by around five per cent of the estimated savings from *Further PBS Reforms* in the time period to 2017-18 (See Figure 9 and Table A7 in the Appendix).

FIGURE 9: SAVINGS FROM FURTHER PBS REFORM AND GROWTH ASSUMPTIONS $M



SENSITIVITY TO CHANGE IN PROBABILITY AND SIZE OF PRICE DISCLOSURE PRICE CUTS

The modelling shows that price disclosure is likely to be a key contributor to savings in the time period to 2017-18, so it was important to test how sensitive the results were to the assumptions behind price disclosure. When modelling the impact of Further PBS Reforms including price disclosure into the future, assumptions around the probability and size of price cuts were made based on historical data. Evidence to date shows that:

- there is a higher probability of a price disclosure price cut in the first round than in subsequent rounds;
- medicines could take multiple price disclosure price cuts; and
- there is some correlation between the size of the market (based on sales) and level of discounting and therefore the size of price cut.

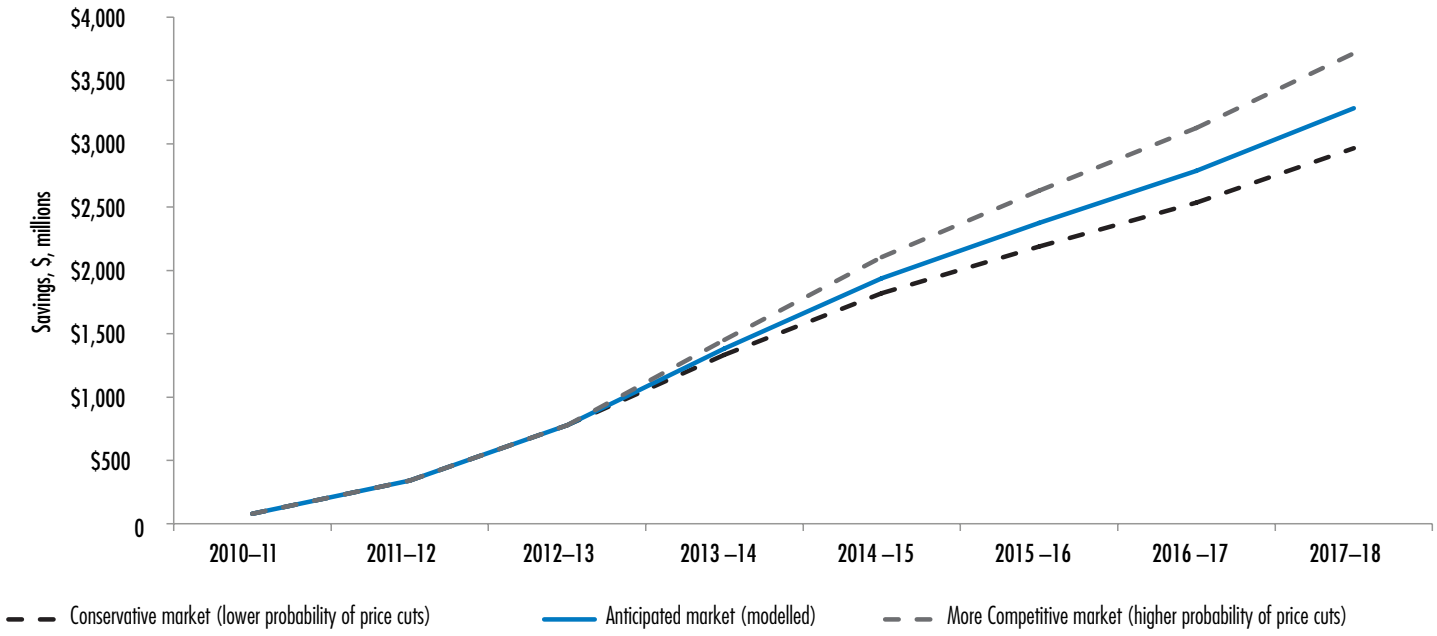
Sensitivity analysis was undertaken with two alternative scenarios – a less competitive (conservative) market where the probability of a price cut would be lower (than modelled) or one where the competition was higher with a higher probability of a price cut than anticipated in the model. The scenarios set out in Table 7 were modelled to gauge the sensitivity of the savings estimates to price disclosure assumptions.

TABLE 7: ALTERNATIVE PRICE DISCLOSURE PROBABILITIES, $M

Probability of cut	First	Second	Third	Fourth
Lower bound (conservative)	60%	23%	6%	0%
Modelled	67%	30%	13%	5%
Upper bound (more competitive)	77%	40%	23%	15%

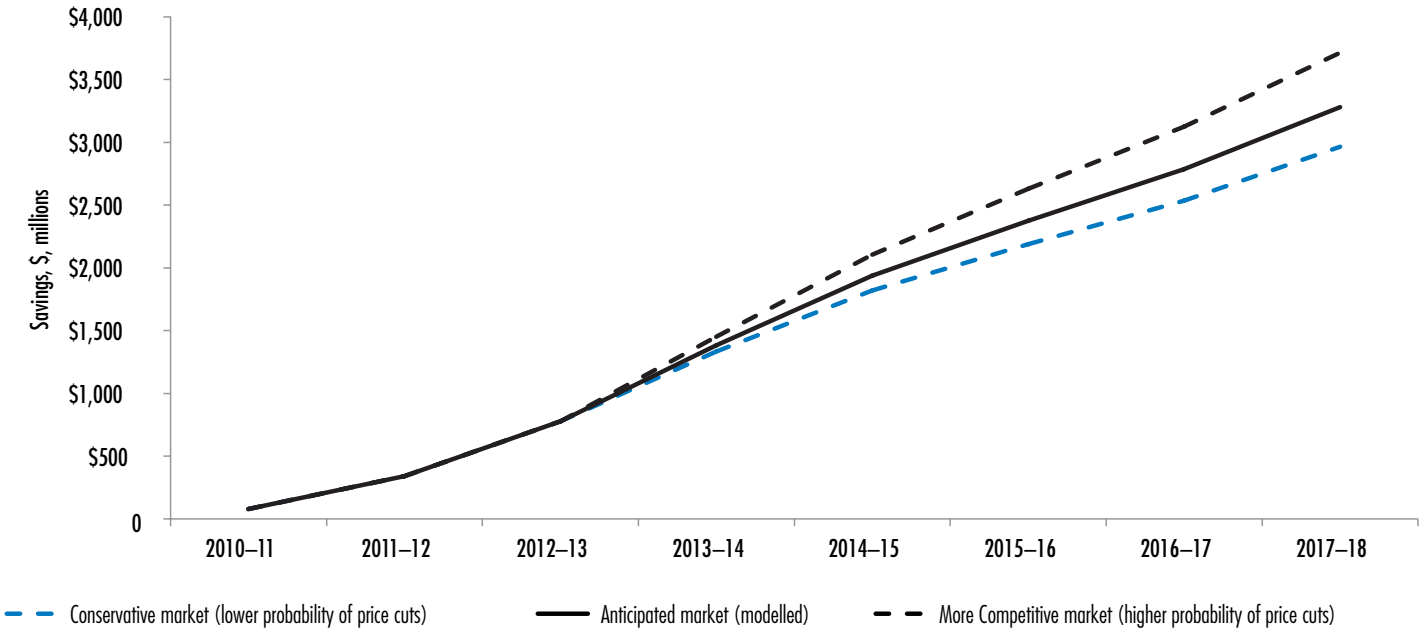
As stated earlier, one difference between the 2007 price disclosure mechanism and the 2010 version under Further PBS Reforms (EAPD) is the timing of the price cuts. Therefore, any change in market conditions will impact both versions of the price disclosure. Figure 10 shows the sensitivity of savings estimates due to price disclosure (including the changes under EAPD) to changes in the assumptions about market conditions. In a conservative market, the estimated savings from price disclosure including EAPD are likely to be $970 million or 8% lower than anticipated. In a more competitive market, the estimated savings from price disclosure including EAPD are likely to be $1.3 billion or 11% higher than anticipated in the modelling (see Table A8 in the Appendix).

FIGURE 10: SAVINGS FROM PRICE DISCLOSURE INCLUDING EAPD, $M



Similarly, Figure 11 shows the sensitivity of savings estimates from both the 2010 Further PBS Reforms package and price disclosure to change in market conditions. In a conservative market, the estimated savings from Further PBS Reforms and price disclosure are likely to be $923 million or 7% lower than anticipated. In a more competitive market, the estimated savings from Further PBS Reforms and price disclosure are likely to be $1.26 billion or 10% higher than anticipated in the modelling (see Table A9 in the Appendix).

FIGURE 11: SAVINGS FROM FURTHER PBS REFORM AND PRICE DISCLOSURE, $M



ACCESS TO NEW MEDICINES

This section looks at the listing of new medicines on the PBS in order to:

- assess whether there has been any change in the availability of new medicines on a timely basis; and
- ascertain what impact listings of new medicines might have on future PBS expenditure.

AVAILABILITY OF NEW MEDICINES

Based on an analysis of the PBS Schedule, the PBS has grown from a formulary consisting of 536 medicines in June 1992 to 781 medicines in June 2012 (see Table A10 in the Appendix). On average, over the past 21 years the PBS has added 25.5 new medicines (including combinations) per year. At the same time an average of 12.7 medicines are removed from the formulary each year.

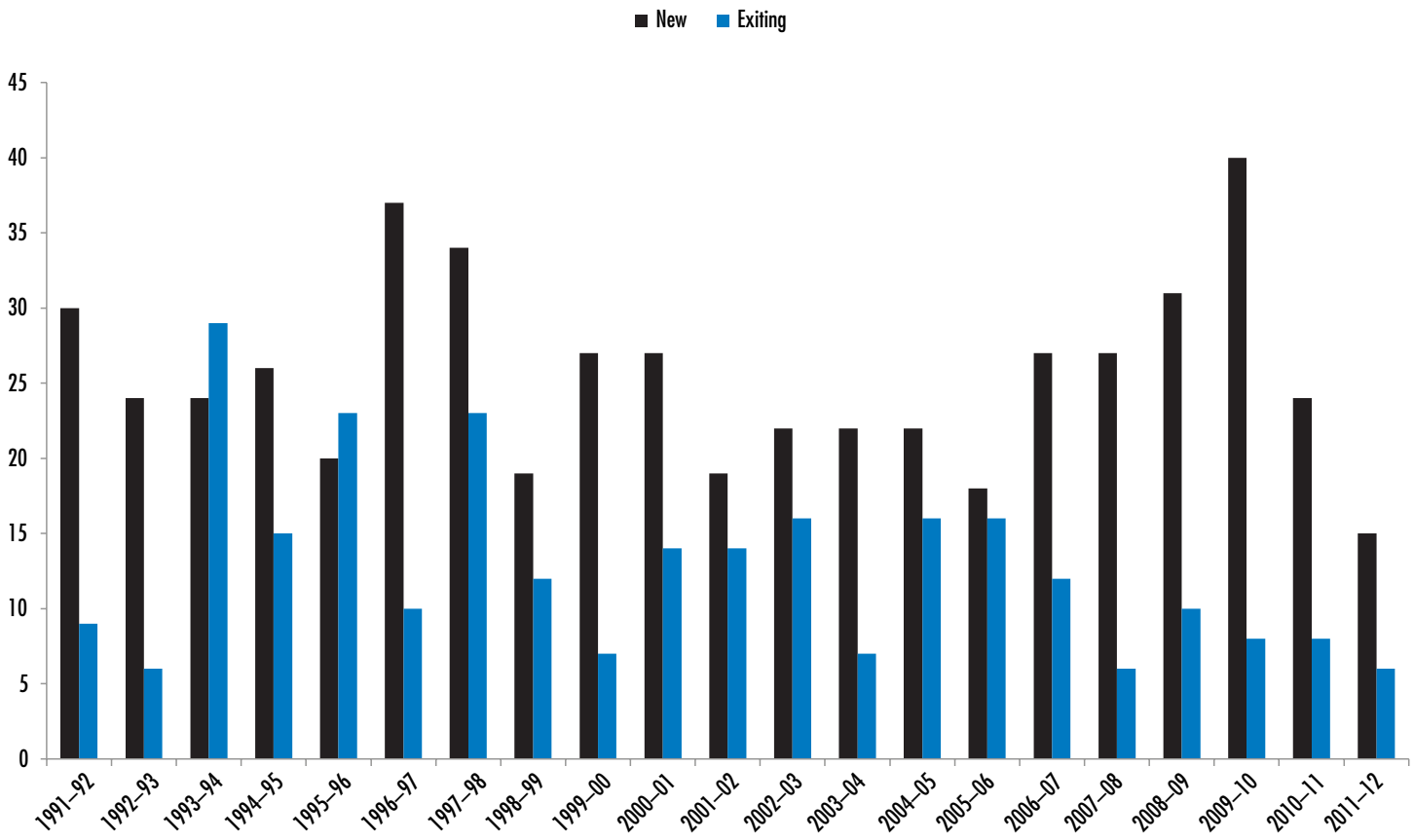
Over the past 5 years, the average number of new medicines has been somewhat higher (27.4) and exiting medicines fewer (7.6). There has been considerable year to year variation, especially in the past few years, from a high of 40 new medicines in 2009-10 to only 15 in 2011-12. The longer term trend however suggests that on average there might be 26 new medicines per year with 13 exiting each year, for a net gain of about 13 medicines.

As shown in Figure 12, the numbers of new medicines listed over the three years from 2007-08 to 2009-10 were significantly higher than the average and well above the levels of the previous 5 years up to 2006-07. Arguably, the operations of the PBAC or the Government more broadly with respect to listing new medicines are not influenced by the effect of the changes contained in the PBS reform package.

However, the increase in listings begins around the time of the introduction of PBS Reform measures in 2007. This suggests that the savings made available by the impact of the mandatory 12.5% price cuts and the introduction of PBS reform created more "headroom" for the listing of new medicines which are likely to enter as members of the F1 formulary and be immune to some extent from the operations of PBS Reform.

The decline over the last two years is notable. Analysing this is beyond the scope of this report, however it merits further investigation.

FIGURE 12: NEW AND EXITING PBS MEDICINES, NUMBER, 1991-92 TO 2011-12



IMPACT OF NEW MEDICINES ON FUTURE PBS EXPENDITURE

The impact of new medicines that might be listed on the PBS over the next 5 years is not included in the calculations of projected PBS expenditure or savings. In general, it might be expected that a new medicine entering the PBS will be protected by patent and that this protection will extend for a number of years. On average, a new medicine will have about 8 years on the market before patent expiry. Most new entrants after June 2012 will therefore be exempt from the effects of PBS reform at least over the period to 2017-18 and for some years beyond, and hence are not expected to contribute to the savings calculated in this report.

However, it is anticipated that new medicines will add to the overall PBS expenditure in future, so to predict the course of this expenditure over the next five years it was necessary to take account of their impact in terms of additional expenditure on the PBS. To estimate the impact of new medicines on overall PBS expenditure, the level of expenditure for the typical PBS medicine was calculated and applied to additional new medicines entering the PBS. As shown in Figure 12, in 2011-12 Government PBS expenditure was $9,108 million on 825 medicines, for an average cost of $11.04 million per medicine. The annual growth in the cost per medicine over the past 5 years has averaged 4.1%.

Assuming that the PBS formulary increases by 20 medicines per year and the average cost of each grows by 4% per year, it is estimated that the net effect of the new medicines would be an additional $1,459 million per year in PBS expenditure (see Figure 13) by 2017-18. Alternative approaches based on the sales profile of a typical new PBS medicine and econometric analysis of the relationship give broadly similar results.

Overall based on this estimate, starting in 2012-13, $4.9 billion in new medicine expenditure could be added to the PBS expenditure in the time period to 2017-18 against a total saving to Government of $16.5 billion from 2007 PBS Reform and 2010 Further PBS Reforms in the same time period (see Table A11 in the Appendix).

FIGURE 13: PBS EXPENDITURE ON NEW MEDICINES AND PBS REFORMS SAVINGS, $M

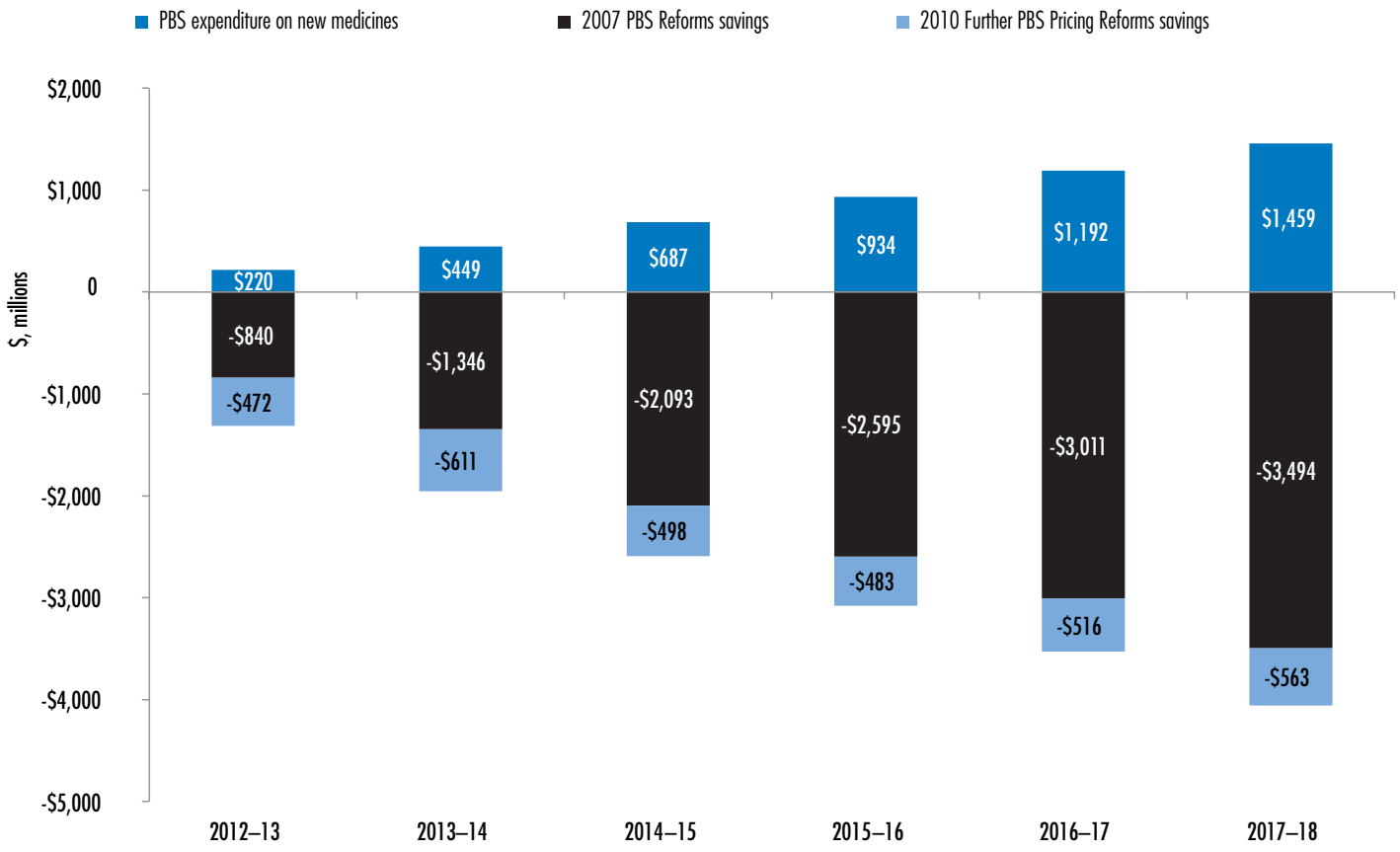


Figure 14 shows the impact of new listings on projected PBS expenditure in the time period to 2017-18. The analysis shows that even after including the impact of new medicines, overall PBS expenditure remains relatively flat in the period to 2017-18 (see Table A12 in the Appendix) and the growth in PBS expenditure is negligible (see Figure 15).

FIGURE 14: NEW MEDICINES AND PBS EXPENDITURE, DIFFERENT POLICY SCENARIOS, $M

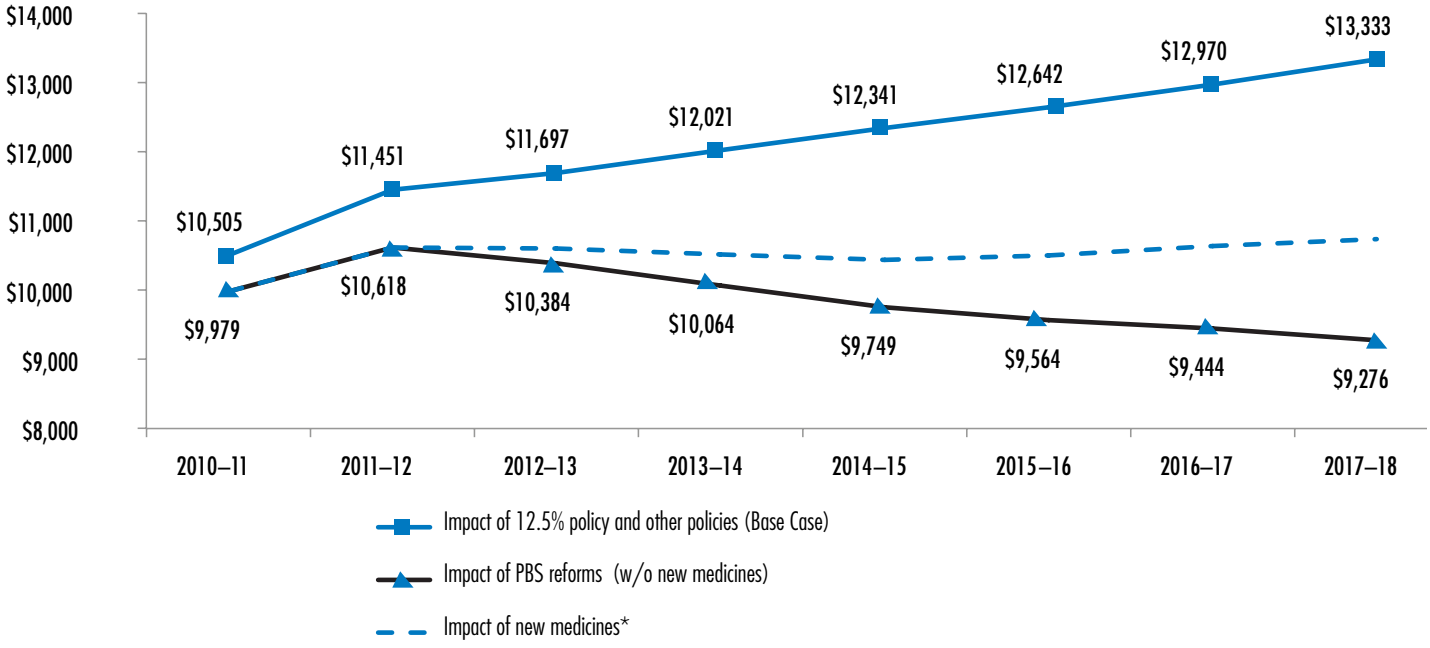
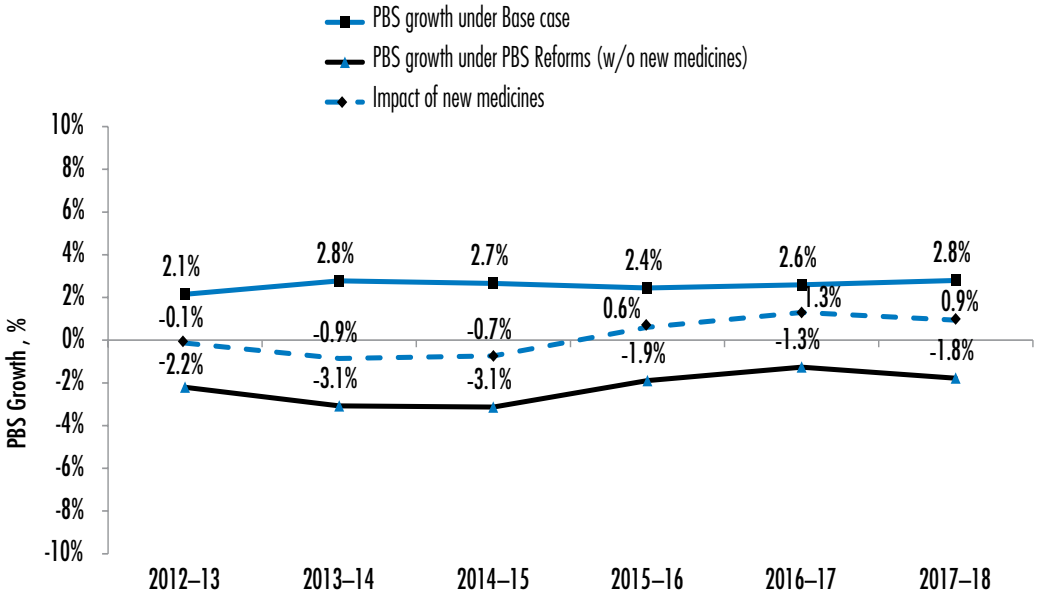


FIGURE 15 : IMPACT OF NEW MEDICINES ON PBS EXPENDITURE GROWTH, $M



SUSTAINABILITY OF THE PBS

Unlike its equivalents in New Zealand and elsewhere, the PBS has never operated to an annual budget specified by the Government, either in absolute terms or as a percentage of GDP or overall budget expenditure. Nevertheless, various reports such as the two Intergenerational Reports from the department of The Treasury (2002, 2007) or the Productivity Commission's reports on ageing and medical technology (2005a, 2005b) have projected PBS expenditure and other medical expenditure as rising from about 6% of GDP to 10% in 2045 and have concluded that the predicted growth is unsustainable. While other studies have questioned whether health will become that important, they have acknowledged that health spending will rise as a percentage of GDP.

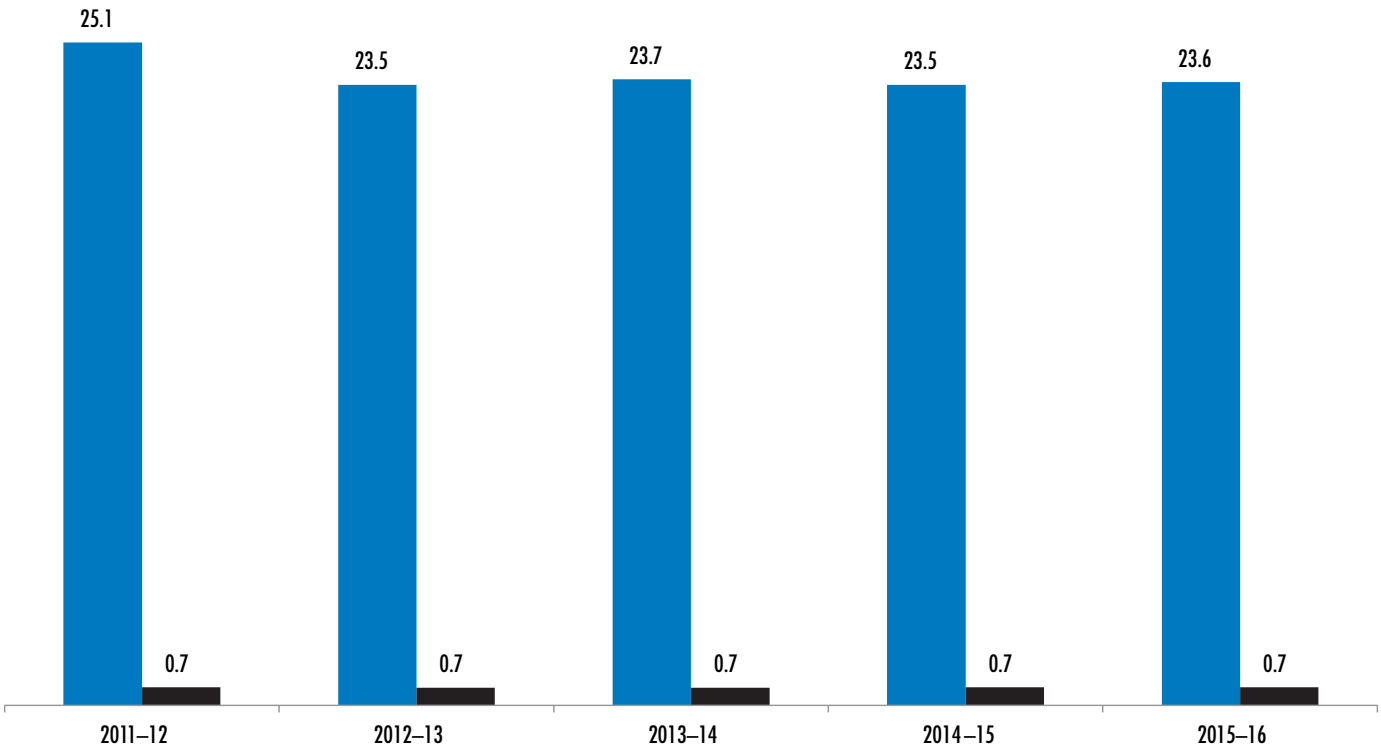
In the United States, two recent studies (Hall and Jones 2007; Fogel 2008) have concluded that health will account for around 30% of GDP by 2050. The first of these studies points out that leaving aside influences such as the ageing of the population and other demographic changes and the greater use of medical technologies, spending will increase because, as incomes rise, people will spend proportionally more on health than other consumer goods. This is because more health spending raises both the quality of life and the quantity of life by extending life span, and this is not a characteristic of any other products that people might buy.

In its Budget in May 2012, the Commonwealth Government produced estimates for both the growth in GDP and in overall budget expenses for the period 2011-12 to 2015-16. These are reproduced in Table A13. Over the past few years both GDP and Government payments have increased by about 5% per year.

The Budget papers also report on the projected level of expenditure on "Pharmaceutical services and benefits" and for the PBS to 2015-16. The levels of expenditure on the more general program "Pharmaceutical services and benefits" and the PBS can be expressed both as a percentage of GDP and of overall Government spending. As shown in Figure 16, it is that the PBS falls as a percentage of GDP to 2013-14, but rises moderately thereafter. As a percentage of Government spending, the PBS rises somewhat across the period partly because Government spending is not rising as fast. The more general program "Pharmaceutical services and benefits" show similar trends similar to those of the PBS (see Table A13 in the Appendix).

In summary, the Government is not indicating from its projections that there is any serious issue regarding the sustainability of the PBS. The modelling given in this report demonstrates that policy reforms will continue to moderate overall Government expenditure on the PBS. For this reason, the sustainability of PBS in the medium term is assured.

FIGURE 16: GOVERNMENT PAYMENTS AND PBS EXPENDITURE AS PER CENT OF GDP



Source, The Treasury (2012)

REFERENCES

Centre for Strategic Economic Studies (CSES) 2009, 'The Impact of Reforms on PBS Expenditure and Savings', Victoria University, Melbourne.

Department of Health and Ageing (DOHA) 2010a, 'Expanded and Accelerated Price Disclosure: What's New? What's Different', Canberra, November, available at www.pbs.gov.au.

Department of Health and Ageing (DOHA) 2010b, 'Fact sheet 2 Transitional Cycles', Canberra, November.

Department of Health and Ageing (DOHA) 2012a, 'Report to Parliament on the meeting of the Pharmaceutical Industry Discussion Group (PIDG) to identify and examine potential unintended consequences of the 2010-11 Budget Measure Further Pharmaceutical Benefits Scheme (PBS) Pricing Reform', Canberra, February, available at http://www.health.gov.au/internet/main/publishing.nsf/Content/6949EAD468236A50CA2579BF007AF906/$File/20120306-%20PIDG%20-%20Report%20FINAL%20DEP%20SEC%20CLEARED%20_B5__amended.pdf, accessed on 28 Feb 2013.

Department of Health and Ageing (DOHA) 2012b, 'Price Reductions for Second Main Cycle', Canberra.

Department of Health and Ageing 2013a, 'Schedule of Pharmaceutical Benefits', DOHA, Canberra, available at www.pbs.gov.au.

Department of Health and Ageing 2013b, 'Strengthening Your PBS: Preparing for the Future', DOHA, Canberra, available at http://www.health.gov.au/internet/main/publishing.nsf/Content/Strengthening-your-PBS.htm, accessed on 26 March 2013.

Department of Health and Ageing 2013c, 'The Impact of PBS Reform', DOHA, Canberra, available at http://www.health.gov.au/internet/main/publishing.nsf/Content/95DCCB478B78DBD9CA2576C500130B0A/$File/Impact%20of%20PBS%20Reform%20Report.pdf, accessed on 26 March 2013.

Fogel, R. 2008, 'Forecasting the Cost of US Health Care in 2040', NBER Working Paper No. 14361, National Bureau of Economic Research, Cambridge, Mass.

Hall, R. E. and Jones, C.I. 2007, 'The value of life and the rise in health spending', Quarterly Journal of Economics, vol. 122, no. 1, pp. 39-72.

Productivity Commission 2005a, 'Economic Implications of an Ageing Australia', Research Report, Productivity Commission, Canberra, March.

Productivity Commission 2005b, 'Impacts of Advances in Medical Technology on Healthcare Expenditure in Australia', Research Report, Productivity Commission, Melbourne, August.

The Treasury 2002, 'Budget Paper No. 5: Intergenerational Report 2002-03:', Canberra, May, available at http://www.budget.gov.au/2002-03/bp5/html/index.html.

The Treasury 2007, 'Intergenerational Report 2007', Commonwealth of Australia, Canberra, April, available at http://archive.treasury.gov.au/contentitem.asp?ContentID=1239.

The Treasury 2012, 'Budget Paper No. 1: Budget Strategy and Outlook 2012-13', Canberra, available at http://www.budget.gov.au/2012-13/content/bp1/html/index.htm.

APPENDIX

TABLE A1: PBS EXPENDITURE IN THE TIME PERIOD TO 2017-18, UNDER VARIOUS SCENARIOS, $M

	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18
12.5% mandatory price cuts and other policies (Base Case)	10,505	11,451	11,697	12,021	12,341	12,642	12,970	13,333
25% price cuts in August 2008 and 2% cuts in August 2008, 2009, 2010	10,059	10,968	11,193	11,501	11,802	12,085	12,395	12,737
Price disclosure price cuts	10,016	10,810	10,856	10,676	10,247	10,047	9,960	9,839
16% instead of 12.5% from April 2011 for mandatory price cuts	10,014	10,784	10,783	10,576	10,134	9,907	9,795	9,658
Price cuts in February 2011 (2% in F2A and 5% in F2T)	9,979	10,701	10,702	10,505	10,068	9,842	9,728	9,589
Introduction of EAPDs	9,979	10,618	10,384	10,064	9,749	9,564	9,444	9,276

TABLE A2: SAVINGS IN PBS EXPENDITURE FROM PBS POLICY INTERVENTIONS (SINCE 2005), IN THE TIME PERIOD TO 2017-18, $M

	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18
25% price cuts in August 2008 and 2% cuts in August 2008, 2009, 2010	446	484	504	521	539	557	576	595
Price disclosure price cuts	43	158	336	825	1,555	2,038	2,435	2,899
16% instead of 12.5% from April 2011 for mandatory price cuts	2	26	73	99	113	140	165	181
Price cuts in February 2011 (2% in F2A and 5% in F2T)	35	83	82	72	67	66	67	69
Introduction of EAPDs	0	83	318	441	319	277	284	313

TABLE A3: IMPACT OF 2007 PBS REFORM – COMPARING PAST AND CURRENT ESTIMATES, $M

	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18
DoHA-PWC (2010) – High estimates	151	220	296	488	787	1,065	1,327	1,535
CSES (2009)	180	277	380	514	764	1,097	1,180	1,371
CSES (2013)	489	641	840	1,346	2,093	2,595	3,011	3,494

TABLE A4: 2010 FURTHER PBS REFORMS – PROJECTED VS. ACTUALS SAVINGS, $M

	2010-11	2011-12	2012-13 to 2014-15
Federal Budget (2010-11)	29	180	1587
Medicines Australia-CSES (2013)	37	192	1581
Actual Savings (DoHA Annual reports)	30	189	

TABLE A5: 2010 FURTHER PBS REFORMS SAVINGS, BY MEASURES, $, MILLIONS

	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18
Impact of change from 12.5% to 16% for mandatory price cuts	2	26	73	99	113	140	165	181
Impact of price cuts in February 2011	35	83	82	72	67	66	67	69
Impact of EAPD price cuts	0.4	83	318	441	319	277	284	313

TABLE A6: 2010 FURTHER PBS REFORMS SAVINGS, BY PARTICIPANTS, $M

Beneficiaries	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18
Government	35	186	447	576	458	450	483	530
Patients	1	6	25	35	40	33	33	33
Total	37	192	472	611	498	483	516	563
Contributors	**2010-11**	**2011-12**	**2012-13**	**2013-14**	**2014-15**	**2015-16**	**2016-17**	**2017-18**
Pharmacist	-3	-18	-42	-50	-43	-38	-38	-39
Wholesalers	-2	-12	-30	-39	-32	-31	-34	-37
Manufacturers								
Originators	-17	-74	-179	-346	-269	-265	-300	-341
Generics	-14	-88	-222	-176	-155	-148	-145	-147
Total	-37	-192	-472	-612	-498	-483	-516	-563

TABLE A7: SENSITIVITY ANALYSIS (SCRIPT VOLUME GROWTH) – IMPACT ON FURTHER PBS REFORMS SAVINGS ESTIMATES, $M

	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18
Lower bound script growth (2%)	37	192	466	594	477	455	480	516
Anticipated growth (3.5%)	37	192	472	611	498	483	516	563
Upper bound script growth (5%)	37	192	479	629	520	511	555	614

TABLE A8: SENSITIVITY ANALYSIS (UNDER DIFFERENT ASSUMPTIONS ABOUT PRICE DISCLOSURE) – IMPACT ON PRICE DISCLOSURE SAVINGS INCLUDING EAPD, $M

	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18
Conservative market								
(lower probability of price cuts)	44	236	626	1,164	1,643	1,986	2,304	2,714
Anticipated market	44	236	627	1,215	1,771	2,182	2,566	3,046
Competitive market								
(higher probability of price cuts)	44	236	627	1,289	1,946	2,448	2,923	3,498

TABLE A9: SENSITIVITY ANALYSIS (UNDER DIFFERENT ASSUMPTIONS ABOUT PRICE DISCLOSURE) – IMPACT ON FURTHER PBS REFORMS INCLUDING PRICE DISCLOSURE, $M

	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18
Conservative market								
(lower probability of price cuts)	79	342	777	1,332	1,819	2,189	2,534	2,963
Anticipated market	79	342	777	1,380	1,939	2,375	2,784	3,281
More competitive market								
(higher probability of price cuts)	79	342	777	1,450	2,105	2,630	3,125	3,713

TABLE A10: NEW AND EXITING PBS MEDICINES, NUMBER, 1991-92 TO 2011-12

Year	New	Exiting	Number at 30 June
1991-92	30	9	536
1992-93	24	6	554
1993-94	24	29	549
1994-95	26	15	560
1995-96	20	23	557
1996-97	37	10	585
1997-98	34	23	596
1998-99	19	12	603
1999-00	27	7	624
2000-01	27	14	637
2001-02	19	14	642
2002-03	22	16	648
2003-04	22	7	663
2004-05	22	16	669
2005-06	18	16	672
2006-07	27	12	686
2007-08	27	6	705
2008-09	31	10	728
2009-10	40	8	759
2010-11	24	8	775
2011-12	15	6	781
Average since 1991-92	25.5	12.7	
Average since 2007-08	27.4	7.6	

TABLE A11: ANTICIPATED EXPENDITURE ON NEW MEDICINES VS. PBS REFORMS SAVINGS, $M

	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18
PBS expenditure on new medicines	220	449	687	934	1,192	1,459
2007 PBS Reform savings	-840	-1,346	-2,093	-2,595	-3,011	-3,494
2010 Further PBS Reforms savings	-472	-611	-498	-483	-516	-563

TABLE A12: PBS EXPENDITURE IN THE TIME PERIOD TO 2017-18, UNDER VARIOUS SCENARIOS PLUS IMPACT OF NEW MEDICINES, $M

	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18
12.5% mandatory price cuts and other policies (Base Case)	10,505	11,451	11,697	12,021	12,341	12,642	12,970	13,333
25% price cuts in August 2008 and 2% cuts in August 2008, 2009, 2010	10,059	10,968	11,193	11,501	11,802	12,085	12,395	12,737
Price disclosure price cuts	10,016	10,810	10,856	10,676	10,247	10,047	9,960	9,839
16% instead of 12.5% from April 2011 for mandatory price cuts	10,014	10,784	10,783	10,576	10,134	9,907	9,795	9,658
Price cuts in February 2011 (2% in F2A and 5% in F2T)	9,979	10,701	10,702	10,505	10,068	9,842	9,728	9,589
Introduction of EAPDs	9,979	10,618	10,384	10,064	9,749	9,564	9,444	9,276
Impact of new medicines	9,979	10,618	10,604	10,513	10,436	10,499	10,635	10,735

TABLE A13: GOVERNMENT PBS EXPENDITURE AND GDP, 2011-12 TO 2017-18

	2011-12	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18
Nominal GDP, $m	1,479,713	1,549,471	1,635,600	1,723,408	1,811,459	1,902,032	1,997,133
Government payments, $m	371,337	364,209	387,299	404,892	427,251	448,614	471,044
Payments as % GDP	25.1	23.5	23.7	23.5	23.6	23.6	23.6
Pharmaceutical benefits and services, $m	10,539	10,889	11,619	12,393	13,166		
PBS, $m	10,029	10,343	11,031	11,764	12,535		
Pharmaceutical benefits and services as % GDP	0.712	0.703	0.710	0.719	0.727		
PBS as % GDP	0.678	0.668	0.674	0.683	0.692		
Pharmaceutical benefits and services as % payments	2.838	2.990	3.000	3.061	3.082		
PBS as % payments	2.701	2.840	2.848	2.905	2.934		

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