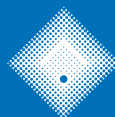


THE IMPACT OF PBS REFORMS ON PBS EXPENDITURE AND SAVINGS

ACTUAL AND PROJECTED FROM 2008-09 TO 2017-18
CENTRE FOR STRATEGIC ECONOMIC STUDIES



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ABBREVIATIONS

CSO	Community Services Obligation
CDPMQ	Commonwealth dispensed price for maximum quantity
CNSN	Concessional non-safety net
CON	Concessional non-safety net and general safety net
CPPMP	Commonwealth price to pharmacist for the manufacturer's pack
CSES	Centre for Strategic Economic Studies
CSN	Concessional safety net
DoHA	Department of Health and Ageing
EMEA	European Medicines Agency
FDA	Food and Drug Administration
GNSN	General non-safety net
GSN	General safety net
MDPMQ	Manufacturer's dispensed price for maximum quantity
MPPMP	Manufacturer's price to pharmacist for the manufacturer's pack
MQ	Maximum quantity
PBAC	Pharmaceutical Benefits Advisory Committee
PBPA	Pharmaceutical Benefits Pricing Authority
PBS	Pharmaceutical Benefits Scheme

KEY FINDINGS OF THE STUDY

This report examines the impact of PBS reform measures on the pharmaceutical industry, pharmacist, wholesalers, Government and patients in the time period to 2017-18. In January 2009, Medicines Australia commissioned CSES to undertake this study to estimate the present and future effect of PBS reforms introduced on 1 July 2007.

INTRODUCTION

Over recent years, the Commonwealth Government through the Department of Health and Ageing has introduced a series of changes to the way the Pharmaceutical Benefits Scheme (PBS) operates. A new policy commenced on 1 August 2005 and imposed a 12.5% mandatory price cut on the entry of the first new brand of a medicine after 1 August 2005. The policy applied only once for each medicine, including for medicines in a reference pricing group where the reduction occurred as a flow-on from another medicine. A more complex package of changes, PBS reforms, focusing on further price cuts was discussed with the industry in May 2006 and finalised as policy in early 2007. Key changes in PBS reforms included:

- Creation of two formularies on the PBS: F1 which consists of single brand medicines, typically protected by patent; and F2 which comprises multiple brand medicines;
- Creation of two sub-formularies in F2 namely F2A and F2T: F2T were those where some brands at least were offering significant discounts and were subject to a 25% price cut on 1 August 2008. Medicines on F2A were not believed to be subject to price discount but were due for price cuts of 2% in each of August 2008, 2009 and 2010;
- Introduction of price disclosure for new brands of medicines on F2A after 1 August 2007. The aim of price disclosure is to align the PBS listed prices to that of the actual market price.
- Implementation of a pharmacy compensation package including:
 - a change to the mark-up and dispensing fee used to calculate the dispensed price based on the price to pharmacist in August 2008;
 - an incentive of \$1.50 for pharmacists to dispense a substitutable, premium-free medicine;
 - an incentive of \$0.40 for each prescription processed using PBS Online;
 - additional funding of \$69 million over three years for the Community Services Obligation (CSO) Funding Pool to compensate wholesalers.
- the introduction from 1 July 2007 of streamlined authority arrangements for some "Authority required" medicines.

KEY FINDINGS

Over ten years to 2017-18, the impacts of PBS reforms:

- Total savings from PBS reform measures - \$6.4 billion;
- The effect on PBS stakeholders
 - Manufacturers – projected to lose \$8.13 billion in sales revenue;
 - Wholesalers¹ – projected to lose \$591 million;
 - Pharmacists – projected to be better off by \$2.34 billion;
 - Patients - projected to save \$420 million; and
 - Government - projected to save \$5.96 billion.

ACCESS TO NEW MEDICINES

- Introduction of streamlined authorities had no significant impact on the uptake or prescribing of previously authority required medicines.
- Number of new listings on the PBS has increased significantly in the last three years. However, there is evidence to suggest that there are significant lags in the time taken to obtain medicines in Australia and that the approval lag seems to be increasing over time.

SUSTAINABILITY OF PBS IN FUTURE

- PBS reforms will keep PBS sustainable. CSES estimates that the PBS expenditure will remain between 0.6 - 0.7 percent of GDP in the time period to 2013-14 and anticipates its growth at compounded annual rate of just over 3% per annum.

¹ Excluding additional funding of \$69 million over three years for the Community Services Obligation (CSO) Funding Pool to compensate wholesalers

OTHER FINDINGS

- In terms of volume, generic manufacturers have gained market share of the PBS market and account for over third of all PBS scripts in 2007-08, while the research based manufacturers have lost nearly 15% of their market share since 2000.

KEY ASSUMPTIONS IN THIS REPORT

- Global growth in demand for PBS medicines – 3.5% per annum;
- Patent expiries based on IMS Health Patent Focus database;
- 12.5% price cuts - Entry of trigger brand one month after date of patent expiry for all medicines with annual sales of above \$5 million in 2007-08;
- Price disclosure price cuts based on attractiveness of the market for a generic entry.
- PBS reforms pharmacy compensation package (change in mark-ups and dispensing fee, \$1.50 incentive and the 40 cents PBS Online fee) continues unchanged to 2017-18.

EXECUTIVE SUMMARY

The Centre for Strategic Economic Studies (CSES) has been asked by Medicines Australia to analyse the impact of PBS reform measures announced in August 2006 on overall PBS expenditure and to report on how these reforms have affected the Government, pharmacists, wholesalers, manufacturers and other suppliers and patients.

This document is the final report of the study by CSES and includes estimates of the present and future effect of changes that have already occurred and those that will occur over the next few years.

Over recent years, the Commonwealth Government through the Department of Health and Ageing has introduced a series of changes to the way the Pharmaceutical Benefits Scheme (PBS) operates. A new policy commenced on 1 August 2005 and imposed a 12.5% mandatory price cut on the entry of the first new brand of a medicine after 1 August 2005. The policy applied only once for each medicine, including for medicines in a reference pricing group where the reduction occurred as a flow-on from another medicine.

A more complex package of changes focussing on further price cuts was discussed with the industry in May 2006 and finalised as policy in early 2007. Some of these changes required amendments to the National Health Act 1953 so the policy was designed to be implemented from 1 August 2007.

This set of changes is known as the PBS reform measures and this document presents the results of an analysis of the impact of these PBS reforms on PBS expenditure. Key changes included:

- Creation of two formularies on the PBS: F1 which consists of single brand medicines, typically protected by patent; and F2 which comprises multiple brand medicines. This division into F1 and F2 meant that medicines on F1 previously linked to medicines on F2 via a reference pricing group would no longer be affected by pricing changes in the F2 medicines.;

- Creation of two sub-formularies in F2 namely F2A and F2T: F2T contain those brands of medicines where significant discounts were being offered and were subject to a 25% price cut on 1 August 2008. Medicines on F2A contain those brands not believed to be subject to significant discounts in the market and are subject to price cuts of 2% in each of August 2008, 2009 and 2010;
- Introduction of price disclosure for new brands of medicines on F2A after 1 August 2007 and for F2T after 1 January 2011. Suppliers of new brands of medicines are obliged to disclose the actual price paid by the pharmacist as distinct from the listed PBS price

The PBS reform measures also included:

- a pharmacy compensation package which included:
 - a change to the formula used to calculate the dispensed price based on the price to pharmacist in August 2008;
 - an incentive of \$1.50 for pharmacists to dispense a substitutable, premium-free medicine;
 - an incentive of \$0.40 for each prescription processed using PBS Online;
 - additional funding of \$69 million over three years for the Community Services Obligation (CSO) Funding Pool to compensate wholesalers;
- the introduction from 1 July 2007 of streamlined authority arrangements for some "Authority required" medicines;
- a generic medicines awareness campaign; and
- the establishment of the Access to Medicines Working Group.

CHANGES IN AUGUST 2008

The analysis in this report is divided into two main sections. Firstly the impact of those changes that have already occurred, namely the price and formula changes in August 2008 and the \$1.50 dispensing incentive and the PBS Online incentive, are estimated using known changes in prices and estimated volume of use data.

This gives an estimate of the annual savings and costs arising from these changes. The on-going savings over the period 2008-09 to 2013-14 are then projected assuming a common growth rate of 3.5% per year in volume usage.

The total impact of the change in dispensing formula combined with the 25% price cuts for medicines on F2T and the 2% cuts for F2A will reduce PBS expenditure by \$1,570.4 million over the 6 years from 2008-09 to 2013-14 and by \$2,828.5 million in the period to 2017-18. Offsetting this will be an increased cost to the Government of \$887.4 million being \$414.2 million for PBS On-line incentives and \$473.2 million for the \$1.50 dispensing incentives (Table E1).

Table E1 Savings from PBS reform in August 2008, \$m

	TOTAL 2008-09 TO 2013-14	TOTAL 2008-09 TO 2017-18
Formula change and 25% and 2% price cuts	1,570.4	2,828.5
PBS On-line	-414.2	-743.5
\$1.50 dispensing incentive	-473.2	-852.3

* Positive sign indicates savings to Government and/or patients; cost to supply chain participants

The savings generated by the PBS reforms impact most strongly on manufacturers and other suppliers whose total loss over the period to 2013-14 is \$2,040.8 million and \$3,675.9 million over the longer period. This is shared almost equally among originator brands and other brands, the former losing \$989.7 million or 48.5% of the total loss. Wholesalers lose \$153.6 million and pharmacists gain \$624.0 million because of the changes to the dispensing formula offset the cuts in prices (Table E2). Altogether then the pharmacists gain \$1511.4 million being \$624.0 million from the net changes in dispensing formula and price cuts plus \$887.4 million from the PBS On-line and dispensing incentives.

The savings of \$1,570.4 million are captured mainly by the Government with \$1,427.9 million although patients benefit by \$142.5 million (Table E3).

Table E2 Impact on participants of PBS reform in August 2008, \$m

	TOTAL 2008-09 TO 2013-14	TOTAL 2008-09 TO 2017-18
Manufacturers	2,040.8	3,675.9
Wholesalers	153.6	276.7
Pharmacists	-624.0	-1,124.0
Originator manufacturers	989.7	1,782.6

* Positive sign indicates savings to Government and/or patients; cost to supply chain participants

Table E3 Savings to Government and patients of PBS reform in August 2008, \$m

	TOTAL 2008-09 TO 2013-14	TOTAL 2008-09 TO 2017-18
Government	1,427.9	2,571.9
Patients	142.5	256.6
Total	1,570.4	2,828.5

* Positive sign indicates savings to Government and/or patients; cost to supply chain participants

CHANGES FROM JULY 2009 TO JUNE 2018

The second part of the analysis is concerned with estimating the savings over the next ten years that will occur as the rest of the PBS reform changes are implemented. These include the 2% price reductions in August 2009 and August 2010 to F2A medicines and the price cuts arising from price disclosure. The estimates of the impact of these changes are necessarily more uncertain than those for the changes that have already occurred because they rely on assumptions about patent expiry, the entry of new brands, and the extent of any price discounts that may occur.

These assumptions are set out in detail in Section 3 of the report and the Appendix. In general it is assumed that those medicines experiencing patent expiry between June 2009 and May 2018 will attract a new brand if their sales were over \$5 million in 2007-08. This new entry will occur in the month after patent expiry. These medicines will also be candidates for price disclosure cuts in the future.

Aside from medicines going off-patent, there are other medicines on F2A with sales in excess of \$5 million which could also attract a new brand and be subject to price disclosure. It is assumed that these medicines and similar ones on F2T after 1 January 2011 will suffer price disclosure cuts, with the size of the cut determined by a formula related to sales size. Two versions of the extent of price cuts are modelled – conservative and competitive with the values set out in Section 3.

Having made these assumptions about which medicines will be subject to 12.5% mandatory cuts, and which will be subject to price disclosure cuts and when these price cuts will occur, the only other PBS reform to be taken into account is the continuing 2% price cuts for F2A medicines in August 2009 and August 2010. The medicines affected by these cuts are those on the F2A formulary at the time.

The savings to the PBS from PBS reform are calculated by comparing the estimated expenditure with that under a base case scenario which assumes that there are no further price cuts arising from either the 12.5% mandatory price cut policy or the PBS reform package or from any other cause. In effect this just projects prices at June 2009 forward and applies the global growth rate assumption.

Table E4 Savings from PBS reforms after June 2009, \$m

	CONSERVATIVE		COMPETITIVE	
	TOTAL 2008-09 TO 2013-14	TOTAL 2008-09 TO 2017-18	TOTAL 2008-09 TO 2013-14	TOTAL 2008-09 TO 2017-18
12.5% cuts only	1,094.7	3,493.2	1,094.7	3,493.2
PBS reforms	821.3	3,525.3	1,057.4	5,151.5
PBS reforms plus 12.5%	1,916.0	7,018.5	2,152.2	8,644.9

* Positive sign indicates savings to Government and/or patients; cost to supply chain participants

Table E4 shows the savings arising from PBS reforms and projected 12.5% price cuts.

The assumed 12.5% price cuts generate \$1,094.7 million in savings over the period from 2009-10 to 2013-14. PBS reform by itself generates savings of \$821.3 million giving a total of \$1,916.0 million from 12.5% price cuts plus all the PBS reform price cuts.

Over the longer period the savings from the 12.5% price cuts are \$3,493.2 million with a further \$3,525.3 million from PBS reform giving a total of \$7,018.5 million.

The costs to supply chain participants of the PBS reforms during the period are shown in Table E5.

The total savings of \$1,916.0 million arising from the 12.5% price cuts and PBS reform over the period from 2009-10 to 2013-14 is borne as a cost to pharmacists of \$118.6 million, to wholesalers of \$111.8 million, to manufacturers of \$1,685.6 million and to originator manufacturers of \$1,419.8 million. Over the longer period the costs are \$472.0 million, \$412.1 million, \$6,134.4 million and \$5,418.0 million respectively.

For PBS reform alone the total savings of \$821.3 million over the period from 2009-10 to 2013-14 is borne as a cost to pharmacists of \$53.8 million, to wholesalers of \$48.5 million, to manufacturers of \$719.1 million and to originators of \$544.4 million. Over the longer period the costs are \$252.4 million, \$212.4 million, \$3,060.4 million and \$2,566.0 million respectively.

Table E5 Impact of PBS reforms after June 2009, supply chain participants, \$m

	CONSERVATIVE		COMPETITIVE	
	TOTAL 2008-09 TO 2013-14	TOTAL 2008-09 TO 2017-18	TOTAL 2008-09 TO 2013-14	TOTAL 2008-09 TO 2017-18
Pharmacists	118.6	472.0	141.3	599.2
Wholesalers	111.8	412.1	125.9	514.4
Manufacturers	1,685.6	6,134.4	1,885.0	7,531.3
Originators	1,419.8	5,418.0	1,586.3	6,733.1
Total	1,916.0	7,018.5	2,152.2	8,644.9

* Positive sign indicates savings to Government and/or patients; cost to supply chain participants

The savings accruing to the Government from PBS reform are shown in Table E6.

The total savings arising from the 12.5% price cuts and PBS reform over the period from 2009-10 to 2013-14 are \$1,916.0 million while Government savings are \$1,885.5 million so that the savings to patients are \$30.6 million. Over the longer period the Government savings are \$6,911.3 million and savings to patients are \$107.2 million.

Table E6 Government savings from PBS reforms after June 2009, \$m

	CONSERVATIVE		COMPETITIVE	
	TOTAL 2008-09 TO 2013-14	TOTAL 2008-09 TO 2017-18	TOTAL 2008-09 TO 2013-14	TOTAL 2008-09 TO 2017-18
12.5% cuts only	1,085.9	3,465.4	1,085.9	3,465.4
PBS reforms	799.5	3,446.0	1,009.7	4,988.1
PBS reforms plus 12.5%	1,885.5	6,911.3	2,095.7	8,453.4

* Positive sign indicates savings to Government and/or patients; cost to supply chain participants

Just from PBS reform the total savings arising from the 12.5% price cuts and PBS reform over the period from 2009-10 to 2013-14 are \$821.3 million while Government savings are \$799.5 million so that the savings to patients are \$21.8 million. Over the longer period the Government savings are \$3,466.0 million and savings to patients are \$107.2 million.

COMBINED IMPACT OF PBS REFORMS

The two main parts of the analysis are brought together in Section 4 which combines the estimates from Sections 2 and 3. Table E7 shows the results of this exercise.

Table E7 Combined savings from all PBS reforms, \$m

	CONSERVATIVE		COMPETITIVE	
	TOTAL 2008-09 TO 2013-14	TOTAL 2008-09 TO 2017-18	TOTAL 2008-09 TO 2013-14	TOTAL 2008-09 TO 2017-18
12.5% cuts only	1,094.7	3,493.2	1,094.7	3,493.2
PBS reforms	1,504.3	4,758.0	1,740.4	6,384.2
PBS reforms plus 12.5%	2,599.0	8,251.2	2,835.2	9,877.6

* Positive sign indicates savings to Government and/or patients; cost to supply chain participants

The total savings from the 12.5% price cuts and all PBS reforms for the period to 2013-14 estimated using the assumptions outlined in this report are \$2,599.0 million with \$1,504.3 million due to PBS reform. Over the longer period to 2017-18 the savings are \$8,251.2 million and \$4,758.0 million respectively.

For the period to 2013-14, manufacturers lose \$2,759.9 million from PBS reform and \$3,726.4 million if the 12.5% cuts are included as well. Over the longer period the values are \$6,736.3 million and \$9,810.3 million respectively. Originator manufacturers account for about 56% of the losses of all manufacturers being \$1,534.1 million from PBS reform and \$2,409.5 million overall. In the period to 2017-18 they lose \$4,348.6 million and \$7,200.6 million (Table E8).

Table E8 Cost of PBS reforms to supply chain participants, \$m

	CONSERVATIVE		COMPETITIVE	
	TOTAL 2008-09 TO 2013-14	TOTAL 2008-09 TO 2017-18	TOTAL 2008-09 TO 2013-14	TOTAL 2008-09 TO 2017-18
Manufacturers				
PBS reforms	2,759.9	6,736.3	2,959.3	8,133.3
PBS reforms plus 12.5% cuts	3,726.4	9,810.3	3,925.8	11,207.3
Wholesalers				
PBS reforms	202.1	489.1	216.2	591.4
PBS reforms plus 12.5% cuts	265.4	688.8	279.5	791.1
Pharmacists				
PBS reforms	-1,457.6	-2,467.4	-1,434.9	-2,340.2
PBS reforms plus 12.5% cuts	-1,392.8	-2,247.8	-1,370.1	-2,120.6
Originator manufacturers				
PBS reforms	1,534.1	4,348.6	1,700.6	5,663.7
PBS reforms plus 12.5% cuts	2,409.5	7,200.6	2,576.0	8,515.7

* Positive sign indicates savings to Government and/or patients; cost to supply chain participants

Wholesalers lose \$202.1 million from PBS reforms and \$265.4 million overall. Taking into account the increased CSO funding reduces these losses to \$133.1 million and \$196.4 million. Over the longer period these losses are \$489.1 million and \$688.8 million, or \$420.1 million and \$619.8 million with the extra CSO funding.

Pharmacists are better off by \$1,457.6 million as a result of PBS reform and by \$1,392.8 million overall. This rises to \$2,476.4 million and \$2,247.8 million over the longer period.

The savings to the Government from the 12.5% price cuts and PBS reforms is estimated at \$2,426.0 million over the period and \$1,340.0 for just the PBS reforms. Including the extra \$69.0 million for the CSO Funding Pool reduces these estimates to \$2,357.0 million and \$1,271.0 million respectively. Over the longer period the savings to the Government from the 12.5% price cuts and PBS reforms is estimated at \$7,887.4 million and \$4,422.1 million just for PBS reforms. Again this is reduced if the CSO Funding Pool is included bringing the savings to \$7818.4 million and \$4,353.1 million (Table E9).

The savings to patients from the 12.5% cuts and PBS reform over the period to 2013-14 are \$173.0 million with \$164.3 million from PBS reform. Over the longer period they are \$363.8 million and \$335.9 million respectively. Under more competitive price disclosure assumptions this rises to \$448.1 million and \$420.1 million respectively.

Table E9 Combined Government savings from all PBS reforms, \$m

	CONSERVATIVE		COMPETITIVE	
	TOTAL 2008-09 TO 2013-14	TOTAL 2008-09 TO 2017-18	TOTAL 2008-09 TO 2013-14	TOTAL 2008-09 TO 2017-18
12.5% cuts only	1,085.9	3,465.4	1,085.9	3,465.4
PBS reforms	1,340.0	4,422.1	1,550.2	5,964.2
PBS reforms plus 12.5%	2,426.0	7,887.4	2,636.2	9,429.5

* Positive sign indicates savings to Government and/or patients; cost to supply chain participants

LISTING NEW MEDICINES ON THE PBS

For the purpose of this study it is assumed that all new medicines listed on the PBS from July 2009 to June 2014 will be single supplier medicines protected by patent and that patent expiry dates are later than June 2014. As such the PBS reforms will not affect them. Nonetheless it is useful to estimate what impact these new listings might have on PBS expenditure in light of discussions about the sustainability of the PBS.

A number of approaches to this were examined and all produced similar results, so the method finally adopted was the easiest, namely calculating what the level of expenditure is for the typical PBS medicine and applying this to net new medicines entering the PBS.

On average the size of the total PBS formulary grows by 12-13 medicines per year, although there can be significant variation from year to year, while the average cost of a medicine on the PBS is \$11.1 million.

If it is assumed that the formulary increases by 12 medicines per year and the average cost of each grows by 5% per year, then the cumulative addition to PBS expenditure above that in 2007-08 due to these new medicines is shown below. By 2013-14 the net effect of the new medicines is an additional \$949.5 million.

Table E10 Additional PBS expenditure due to new medicines, \$m

	2008-09	2009-10	2010-11	2011-12	2012-13	2013-14
All new medicines	139.6	286.2	440.1	601.7	771.3	949.5

ORIGINATORS, GENERICS AND PREMIUMS

The number of research-based manufacturers has fallen slightly since 2001 although this is most likely due to mergers within the industry. The numbers of diagnostic and other suppliers has remained relatively constant, but the number of generic suppliers has increased from 28 to 47 or by 67%. While research-based manufacturers are still in the majority, generic suppliers now account for about a third of all suppliers.

The share of research-based manufacturers in PBS scripts has fallen from 79.9% in 2000-01 to 64.5% in 2007-08 and the share in PBS expenditure has fallen from 89.7% to 81.9%. On the other hand the share of scripts by generic suppliers has increased from 19.2% to 34.7%, and of expenditure from 9.7% to 17.6%. The shares of other types of suppliers have remained relatively constant.

The shares of PBS scripts and expenditure accounted for by originator and generic brands as distinct from type of supplier are also presented. Originator brands have fallen from 73.1% of all scripts in 2000-01 to 63.2% in 2007-08, but the drop in terms of expenditure is much less – from 87.0% to 81.2%.

The number of PBS items with premiums rose rapidly to the year 2000, levelled off until 2004 then rose in 2005 and 2006 before stabilising again. As a percentage of all items, the number of items with premiums followed a similar pattern except that it fell in 2007 and again more strongly in 2008 and 2009.

The average premium has risen from 10.7% of base price in August 1991 to 17.3% in August 2009. It rose strongly in 1993 then remained fairly steady until 2001 but rose again in 2002 and 2003 before another steady phase up to the present.

If the average premium (as a percentage of the base price) is weighted by its importance as measured by sales in the appropriate year, the situation is somewhat different. Firstly, the premium is much less, being 4.5% in 1991-92 rising to 8.2% in 2007-08, the latest year for which sales data is available. Secondly, the experience has been more variable from year to year. From 1994-95 to 1997-98 the premium fell, before recovering to a relatively unchanged level until 2003-04. This was followed by another large fall in 2004-05 before a period of steady increase to 2007-08.

Competition among brands is probably greater for those medicines with larger sales which would explain why the average premium is lower on a weighted rather than an unweighted basis. The rise in the weighted premium since 2004-05 may reflect manufacturers of originator brands trying to maintain the absolute levels of the premium in a period where prices of popular medicines have been falling significantly.

SUSTAINABILITY OF THE PBS

In its recent Budget in May 2009, the Commonwealth Government produced estimates for both the growth in GDP and in overall budget expenses for the period 2009-10 to 2012-13.

The levels of expenditure on the more general program "Pharmaceutical services and benefits" and the calculated level of the PBS can be expressed both as a percentage of GDP and of overall Government spending. It is clear that the PBS rises as a percentage of GDP to 2010-11 but starts to fall thereafter as GDP growth picks up. As a percentage of Government spending, the PBS rises somewhat across the period partly because Government spending is not rising as fast after 2009-10. The more general program "Pharmaceutical services and benefits" also begins to fall as a percentage of GDP after 2010-11 but remains relatively steady as a percentage of Government spending.

At least to 2012-13 therefore, the Government is not indicating from its projections that there is any serious issue about the sustainability of the PBS.

This study on the impact of PBS reforms has projected PBS expenditure under a base scenario and for different combinations of measures within the PBS reform package and the 12.5% price cuts. These can all be expressed as a percentage of GDP and of overall government spending using the Government's forecasts for these two measures.

While the two base case scenarios show a rise in PBS expenditure as a percentage of GDP, if the projected 12.5% cuts are included the share begins to fall after 2010-11. Once all PBS reforms are accounted for, the PBS falls to 0.706% of GDP in 2013-14 having reached 0.744% in 2010-11. Including the projected 12.5% price cuts lowers the share to 0.678% in 2013-14.

A similar picture emerges when PBS expenditure is seen as a percentage of Government spending. However this spending begins to fall as a percentage of GDP itself after 2009-10 meaning that the share of the PBS in Government spending remains relatively unchanged once the PBS reforms and 12.5% price cuts have been taken into account.

The impact of PBS reforms and the on-going 12.5% mandatory price cuts have ensured that the sustainability of the PBS in the medium-term is not open to question.

STREAMLINED AUTHORITIES

There seems to be little evidence to suggest that the introduction of the streamlined authority arrangements have resulted in higher prescribing by doctors of these medicines.

1 INTRODUCTION

The Centre for Strategic Economic Studies (CSES) was asked by Medicines Australia to analyse the impact of PBS reform measures on overall PBS expenditure and to report on how these reforms have affected the Government, pharmacists, wholesalers, manufacturers and other suppliers and patients. In addition CSES was asked to report on (i) recent trends in the listing of medicines on the PBS, and the impact of new listings on future PBS expenditure, (ii) trends in the shares of PBS medicines held by originator and generic companies, and (iii) the sustainability of the PBS in the light of PBS reforms

This document is the final report of the study by CSES and includes estimates of the present and future effect of changes that have already occurred and those that will occur over the next ten years to 2017-18. The study benefited from valuable advice, suggestions and constructive criticism provided by the Taskforce assembled by Medicines Australia. Members are listed below and their insights with respect to the assumptions used throughout this report drew upon extensive experience in pharmacy, pharmaceutical manufacturer and supply, services to the industry and policy and program delivery within Government.

Fabian Dwyer	IMS Health General Manager Australia and New Zealand
Mendel Grobler	Pfizer Australia Director Patient Access
Sara Pantzer	Amgen Australia Head Government Relations and Policy
Brendan Shaw	Medicines Australia Executive Director - Health Policy and Research
Amish Chaturvedi	Medicines Australia Research Manager
Michael Fitzsimons	Medicines Australia Policy Manager

STRUCTURE OF THE REPORT

This introductory section provides some background to the reforms and describes them in detail. The following section discusses those changes that have already occurred and for which price data is available, including price changes in August 2008, changes to the pricing formula, the premium-free incentive and PBS Online.

The third section discusses those reforms that have not yet occurred, including further flagged price cuts and those arising from price disclosure requirements over the time period to 2017-18. The estimates of the impact of these changes are necessarily more uncertain than those for the changes that have already occurred because they rely on assumptions about patent expiry, the entry of new brands, and the extent of any price discounts that may occur.

Section four of this report brings together the estimates from sections two and three to provide consolidated projections of PBS expenditure and estimates impacts of PBS reforms on each participant - Government, pharmacists, wholesalers, manufacturers and other suppliers, and patients.

The on-going listing of new medicines on the PBS will affect the overall level of PBS expenditure even though these new medicines are unlikely to be affected directly by the PBS reform measures at least in the medium term. Estimates of how much these new medicines might add to overall expenditure are provided in Section 5. The sustainability of the PBS in the light of the findings of this study and the Government's own forecasts of PBS expenditure are assessed in Section 7.

For ease of readability, most of the detailed tables referred to in this report are included in Section 10 at the end of the document.

The projections of PBS expenditure and savings arising from PBS reform have been made for each of the ten years from 2008-09 to 2017-18 based on a set of assumptions developed in consultation with Medicines Australia. As the projections get further away from the present, they are subject to more uncertainty. This is particularly so in the latter years of the period. New medicines listed on the PBS would be expected to become more important in terms of market share of the PBS at the expense of the medicines currently available. However, these new medicines which would initially have patent protection would begin to lose this protection over time and become subject to the PBS reform and other policy changes on entry of competition from listing of new brands. The influence of this cannot be modelled in detail as the composition and the patent expiry dates of these new medicines are unknown at this time.

For these reasons, the total savings arising from PBS reform and other cause are reported for two periods – the six year period from 2008-09 to 2013-14 and the longer ten year period to 2017-18.

The key assumptions underpinning the model used to project future expenditure and the impact of the various components of PBS reform are set out in Sections 2 and 3 and the Appendix discusses the sensitivity of the results to these assumptions. A common factor for all the modelling is the assumption of a common growth rate for the underlying demand for PBS medicines.

Over the ten years to 2008-09, the average growth rate in prescriptions supplied to patients from community pharmacies was 3.5%², although there has been significant variation from year to year. In 2008-09 for instance the growth rate was 6.2% while in 2007-08 it was 1.6%. However these figures do not include those medicines available under Section 100 of the National Health Act 1953. The demand for these medicines has been growing significantly faster than for those medicines available through community pharmacies.

For the purposes of this report, a common growth rate of demand for PBS medicines of 3.5% per annum is assumed for each of the years from 2008-09 to 2017-18. It should be noted however that the projections in this report include most Section 100 medicines which could justify a somewhat higher rate of growth than 3.5%.

A further common assumption is that, in the absence of any knowledge of future Government policy in this area, the present level of patient copayments and safety net thresholds is maintained over the next ten years. A number of studies (eg Sweeny 2009) have shown that the demand for PBS medicines by patients is determined by income levels, the number of medicines available, and the levels of copayments and safety net thresholds. As copayments and safety net thresholds are assumed to be unchanged in the period to 2017-18, this means there is no influence from these on patient demand in this study, irrespective of their elasticities. Similarly, it is assumed that those agreements made between the Government and community pharmacy within the context of the Fourth Community Pharmacy Agreement (CPA) concerning pricing and other arrangements will continue within future CPAs covering the period to 2017-18.

Data on PBS expenditure and scripts for each combination of PBS item code and PBS manufacturer code from 1991-92 to 2007-08 has been provided to CSES over a number of years by DoHA and Medicare Australia. Pricing and other data for each combination of PBS item code and PBS manufacturer code has been extracted from the electronic version of the monthly PBS Schedule provided by DoHA.

² For data to 2007-08, DoHA 2009a, Expenditure and prescriptions twelve months to 30 June 2008. For 2008-09 data, Medicare Australia 2009, Medicare Australia Statistics

Findings on savings from PBS reform and 12.5% price cuts are presented in nominal dollars. This means that in any particular year these are the savings in dollar amounts that will accrue to Government or patients. Totals are expressed as sums of the savings in individual years. This is the form used by Government in reporting savings and in other similar studies of the impact of PBS reform. Alternative approaches such as using discount factors are appropriate for assisting decisions about capital investments but are not appropriate in this context.

CHANGES TO THE PBS

Over recent years, the Commonwealth Government through the Department of Health and Ageing has introduced a series of changes to the way the Pharmaceutical Benefits Scheme (PBS) operates.

On October 1, 2004, in the lead up to the Federal Election, the Coalition parties announced, as part of the funding of their *Recognising Senior Australians – Their Needs and Their Carers* policy, that if re-elected they would apply a 12.5% reduction in the price of certain PBS medicines. Under the *Charter of Budget Honesty*, the Department of Finance and Administration estimated that this measure would achieve savings of \$701.8 million over the four years from 2004-05 to 2007-08. These savings were later revised to \$740 million, and in the papers accompanying the Commonwealth Budget for 2005-06 this was further revised to be \$1,036 million over the period to 2008-09.

The administrative guidelines for the new policy (DoHA 2005) state that

“A 12.5 % price reduction will only be triggered by an application to list a new generic brand of a medicine. This includes:

- New generic medicines - these are new versions of medicines where the patent for the original medicine has expired. The new version of medicine has the same active ingredient as the original medicine.
- New pseudo generic medicines - these are new versions of medicines which are still on-patent. These may be marketed by the patent holder or by another sponsor under an arrangement with the patent holder. The new version of medicine has the same active ingredient as the original medicine.

As the PBS is based on a reference pricing system (the prices of medicines are linked if they work in the same way or have the same health outcome), the reduction will:

- Flow on to all brands of that medicine.
- Flow on to all forms and strengths of that medicine which are administered in the same way.
- Flow on to all other medicines in the same reference pricing group, which are administered in the same way.
- Be applied to combination medicines (when one medicine is combined with another medicine in the one formulation) on a pro-rata basis.
- Be applied on a pro-rata basis, based upon the PBS listed indication(s) in common between the new generic brand and the other medicines in the same reference pricing group. The pro-rata reduction will be determined by the listing recommendations of the Pharmaceutical Benefits Advisory Committee and the utilisation of the medicine in the relevant indication(s). Where there is disagreement about the pro rata reductions to apply, an assessment will be made by the Pharmaceutical Benefits Pricing Authority.”

The new policy commenced on 1 August 2005 and applied only once for each medicine, including for medicines in a reference pricing group where the reduction occurred as a flow-on from another medicine.

A more complex package of changes focussing on further price cuts was discussed with the industry in May 2006 and finalised as policy in early 2007 (DoHA 2006, DoHA 2007). Some of these changes required amendments to the *National Health Act 1953* so the policy was designed to be implemented from 1 August 2007.

This set of changes is known as the PBS reform measures and this document presents the results of an analysis of the impact of these reforms on PBS expenditure.

The reforms divided the PBS into two formularies: F1 which consists of single brand medicines, typically protected by patent; and F2 which comprises multiple brand medicines. This division into F1 and F2 meant that medicines on F1 previously linked to medicines on F2 via a reference pricing group would no longer be affected by pricing changes F2. This has had the effect of narrowing the impact of the 12.5% price cut policy only to the medicine with a new brand and not to other members of its reference pricing group.

Within F2, DoHA identified a group of medicines where the manufacturer or supplier were offering significant discounts to pharmacists from the official PBS listed price. As an interim measure, formulary F2 was split into F2A and F2T. Medicines assigned to F2T were those where some suppliers of brands were offering significant discounts and were subject to a 25% price cut on August 2008. Medicines on F2A were not believed to be subject to significant price discounts and are subject to price cuts of 2% in each of August 2008, 2009 and 2010.

Suppliers of new brands of medicines on F2A after 1 August 2007 are obliged to disclose the actual price paid by the pharmacist as distinct from the listed PBS price. Other suppliers of brands of the same medicine are invited to also disclose the actual price paid and a weighted average of these discounts is calculated based on the prices provided. If the weighted average discount is greater than 10%, a new price to pharmacist will be listed reflecting this discount.

The same policy applies to medicines on F2T for new brands listed from 1 January 2011.

The PBS reform measures also included a compensation package for community pharmacy, which included:

- a change to the formula used to calculate the dispensed price based on the price to pharmacist in August 2008;
- an incentive of \$1.50 for pharmacists to dispense a substitutable, premium-free medicine;
- an incentive of \$0.40 for each prescription processed using PBS Online; and
- additional funding of \$69 million over three years for the Community Services Obligation (CSO) Funding Pool to compensate wholesalers.

Another important change was the introduction from 1 July 2007 of streamlined authority arrangements for some PBS “Authority required” medicines.

HOW PBS PRICES ARE DETERMINED

When a new medicine is listed on the PBS, its price is determined on the basis of evidence presented to the Pharmaceutical Benefits Advisory Committee (PBAC) and as a result of negotiations between the supplier and the Pharmaceutical Benefits Pricing Authority (PBPA). The price that is determined is essentially the price at which the wholesaler provides the medicine to the pharmacist and is linked directly to the manufacturer’s ex-factory price.

Most of the PBS reform measures as well as the mandatory 12.5% price cuts and other price determinations within the PBS occur at this level of the price to pharmacist net of any price premium added by the manufacturer.

Following DoHA terminology, this price is called the

(i) *Commonwealth price to pharmacist for the manufacturer's pack (CPPMP)*.

If the manufacturer adds a premium, this CPPMP will be different from the

(ii) *Manufacturer's price to pharmacist for the manufacturer's pack (MPPMP)*

Note that the manufacturer's pack size (PS) can vary among brands within the same PBS item code. The manufacturer's pack size can also be different from the maximum quantity (MQ) that can be dispensed on a doctor's prescription.

The dispensed price is calculated by applying a known formula containing a mark-up and a dispensing fee to the price to pharmacist as specified in the Fourth Community Pharmacy Agreement. The Community Pharmacy Agreement is a five-yearly agreement negotiated between the Government and the Pharmacy Guild.

The formula for calculating the mark-up was as follows for the period up to and including July 2008

RANGE	MARK-UP
\$0.01 to \$180	10%
\$0.01 to \$180	10%
\$180.01 to \$450	\$18.00
\$450.01 to \$1000	4%
\$1000.01 to \$99999	\$40.00

The formula changed in August 2008 to be as follows

RANGE	MARK-UP
\$0.01 to \$30	15%
\$30.01 to \$45	\$4.50
\$45.01 to \$180	10%
\$180.01 to \$450	\$18
\$450.01 to \$1750	4%
\$1750.01 to \$99999	\$70

To this is added the dispensing fee. The ready prepared dispensing fee in June 2009 was \$5.99.

(iii) *Commonwealth dispensed price for maximum quantity (CDPMQ)*

This is the dispensed price calculated by using CPPMP. After deducting the patient copayment this is the amount the Commonwealth reimburses the pharmacist.

(iv) *Manufacturer's dispensed price for maximum quantity (MDPMQ)*

This is the dispensed price calculated by using MPPMP. Here the patient pays the co-payment plus any premium added by the manufacturer. After deducting these, this is also the amount the Commonwealth reimburses the pharmacist.

As an example, suppose that a medicine has a pack size of 25 tablets, the maximum quantity that can be dispensed is 50, and the CPPMP is \$40. To this the manufacturer adds a premium of \$2 so that the MPPMP is \$42. Then CDPMQ is

$\$40 * (50/25) * (100\% + \text{mark-up}) + \$5.99 = \$80 * 1.1 + \$5.99 = \$93.99$, while MDPMQ is

$\$42 * (50/25) * (100\% + \text{mark-up}) + \$5.99 = \$84 * 1.1 + \$5.99 = \$98.39$.

Note that the premium at the price to pharmacist level is \$2.00 (for the pack of 25) while at the dispensed level it is \$4.40 (\$98.39-\$93.99) (for the maximum quantity of 50).

For most medicines on the PBS, the price to pharmacist is split with the manufacturer receiving 93% of this and the wholesaler receiving 7%. This formula is set out in the Fourth Community Pharmacy Agreement. In the above example, the manufacturer would receive \$37.20 and the wholesaler \$2.80.

In summary, the policy operates at the price to pharmacist level but to assess the impact on the various participants, the modelling of the savings from policy changes must be undertaken at both the dispensed price level and the price to pharmacist level.

2. SAVINGS TO THE PBS FROM PBS REFORMS IN AUGUST 2008

This section examines the effect on PBS expenditure of those components of the PBS reform package that were introduced in August 2008. These included:

- a 25% cut in the price to pharmacist of medicines on formulary F2T;
- a 2% cut in the price to pharmacist of medicines on formulary F2A; and
- a change in the formula used to calculate the dispensed price.

In the same month there were some other changes including:

- a 12.5% cut in the price to pharmacist on entry of a new brand for 4 medicines; and
- price changes for some medicines not associated with PBS reform.

In addition, the PBS reform package provides (i) an incentive of \$1.50 for pharmacists to dispense a substitutable, premium-free medicine and (ii) an incentive of \$0.40 for each prescription processed using PBS Online.

Unlike the estimates presented in the following section, the estimates here are based on known changes to prices.

As noted above, the mark-up for calculating the dispensed price changed in August 2008 and dispensing fees were also raised. The ready prepared fee rose by 18 cents from \$5.81 to \$5.99, the extemporaneously prepared fee rose from \$7.85 to \$8.03, the water added fee from \$8.40 to \$8.52, and the dangerous drug fee from \$2.49 to \$2.71.

2.1 THE 25% AND 2% PRICE CUTS

In August 2008, those medicines with brands on PBS formulary F2T were subject to a mandatory cut in the price to pharmacist of 25%. Those medicines on PBS formulary F2A were subject to the first of the three mandatory cuts in the price to pharmacist of 2%.

In order to identify which brands were subject to these cuts, the percentage change in the Commonwealth price to pharmacist for the manufacturers pack (CPPMP) was calculated from the electronic version of the monthly PBS Schedule made available by the Department of Health and Ageing.

In most cases the identification of brands subject to the 25% cut was straightforward as the price changes were generally in the range -24.5% to -25.5%. The oral form of diazepam was subject to a mandatory cut of 12.5% arising from the introduction of a new brand in August 2008 and was then

subject to a further cut of 25%. The 25% cut on the eye ointment form of aciclovir was reversed in December 2008.

The F2T formulary contains some medicines which are single supplier but interchangeable at the patient level. For those medicines protected by patent, the 25% cut is being phased in over the remaining patent life. The medicines that seem to have been affected in this way had cuts in August 2008 as follows

Lercanidipine	a calcium channel blocker	4%
Esomeprazole	a proton pump inhibitor	4%
Lansoprazole	a proton pump inhibitor	5%
Pantoprazole	a proton pump inhibitor	4%
Rabeprazole	a proton pump inhibitor	4%

Those brands subject to the 2% mandatory cut were also reasonably easy to identify. However carvedilol which suffered a 12.5% price cut in April 2008 was not subject to a further 2% cut in August 2008.

To calculate the impact of just the 25% and 2% cuts in August 2008 and to avoid the effect of the change in the dispensing price formula it was necessary to recalculate the dispensed prices for August 2008 based on the old formula.

The difference between the new dispensed price calculated in this way and the dispensed price for July 2009 shows the impact of the 25% and 2% cuts isolated from the effect of any change in the dispensing price formula.

CSES obtains data from the Department of Health and Ageing giving the number of scripts, patient cost and government cost for each combination of item code and manufacturer code on the PBS. To obtain an estimate of the savings arising from the price cuts in August 2008, the annual data on expenditure for 2007-08 was used. Doing this provides a full year estimate of the impact of the price cuts. Data for the full year 2008-09 is unavailable from the Department

For those medicines subject to the 25% (or partial) cuts in August 2008, the total PBS expenditure for 2007-08 was multiplied by the change in the dispensed price as described above. The difference between this and the original expenditure represents the full year savings arising from these price cuts. This is estimated to be \$348.2 million.

Using the same procedure for those medicine affected by the 2% cuts gives an estimate of the full year savings of \$12.0 million.

2.2 CHANGE IN THE DISPENSED PRICE FORMULA

The impact of the change in the dispensed price formula in isolation from any other change can be calculated by using the price to pharmacist for July 2008 and calculating what the dispensed price would be if the new formula were used. Comparing this with the actual dispensed price for July 2008 shows the extent of price change due to the change in formula.

Again using actual expenditure data for 2007-08, the additional cost to the PBS is estimated at \$131.5 million.

2.3 OTHER PRICE CHANGES IN AUGUST 2008

Aside from the 25% and 2% price cuts and the change in dispensed price formula, the other changes that occurred were a 12.5% cut (or partial cut) in four medicines and price increases for some other medicines.

The impact of the 12.5% cuts alone can be assessed in a similar way to those 25% and 2% cuts already described above. The reduction in cost to the PBS is estimated at \$0.9 million.

The impact of all other changes to prices is estimated to have saved \$4.4 million.

2.4 COMBINING THE CHANGES IN AUGUST 2008

While it is useful to estimate the impact of any change in isolation, the impact of the combination of changes can also be calculated.

The difference between the dispensed price in July 2008 and August 2008 reflects the combined effect of the change in formula and the 25% and 2% price cuts. The savings arising from these effects can be modelled in the same way as before using data from 2007-08. The estimated savings are \$280.0 million.

2.5 IMPACT OVER FUTURE YEARS

Assuming that the underlying demand for PBS medicines grows by 3.5% between 2007-08 and 2008-09, the savings for 2008-09 from the 25% and 2% price cuts only would be about \$330.3 million and \$11.4 million. The numbers are slightly less than the full year estimates because the policy only began in August 2008 so there would only be an 11 month effect in 2008-09. Assuming the same 3.5% annual growth over the projection period to 2017-18, the overall net impact of PBS reform is savings of \$1,570.4 million in the period to 2013-14 and \$2,828.5 million in the time period to 2017-18 (Table 2.1).

2.6 IMPACT ON SUPPLY CHAIN PARTICIPANTS

It is possible to calculate the impact of the changes in August 2008 by considering the relationship between the dispensed price and the price to pharmacist and the mark-up rules for wholesalers.

The relationship between the dispensed price and price to pharmacist described in Section 1 was used to calculate the impact on both the pharmacist and the wholesaler.

For each of the measures presented in Table 2.1, the estimate of the impact on costs is obtained by calculating the difference between two versions of the dispensed price and multiplying this by usage data from 2007-08. If instead the difference between the two versions of the price to pharmacist is calculated (taking into account any difference between pack size and maximum quantity) and multiplied by the usage, then the impact at the wholesaler level is obtained.

The difference between the estimate at dispensed price level and at price to pharmacist level represents the impact on the pharmacist.

The impact at price to pharmacist level can then be allocated to wholesaler and manufacturer assuming a share of 93% manufacturer and 7% wholesaler.

Note that any change arising from the change in the dispensed price formula only affects the pharmacist and has no impact on the wholesaler or manufacturer.

Tables 2.2-2.4 report the impact on manufacturers, wholesalers and pharmacists of the various scenarios set out in Table 2.1.

For manufacturers, the total loss over the period to 2013-14 is \$2,040.8 million made up of losses of \$1,971.1 million from the 25% cuts and \$69.7 million from the 2% cuts. Wholesalers lose \$153.6 million. Pharmacists on the other hand gain \$624.0 million despite the impact of the 25% and 2% cuts on the price to pharmacist of medicines affected by these policies.

Table 2.5 shows the impact on manufacturers of originator brands. Their loss over the period is \$989.7 million arising overwhelmingly from the 25% and 2% price cuts.

This loss is about 48.5% of the losses by all manufacturers suggesting that originator and generic brands suffered losses in about equal amounts.

Over the longer period to 2017-18, manufacturers, wholesalers, and originator manufacturers lose some \$3,675.9 million, \$276.7 million and \$1,782.6 million respectively while pharmacists gain \$1,124.0 million.

2.7 SAVINGS FOR GOVERNMENT AND PATIENTS

Within the PBS, patients contribute a fixed copayment plus any premium towards the dispensed price of a medicine with the Government reimbursing the pharmacist for the difference. For concessional patients, the current copayment is \$5.30 while for general patients the copayment is currently \$32.90. For each patient category there are PBS safety net arrangements. Once the safety net threshold expenditure level is reached during the course of the year the copayment is reduced – general safety net patients pay the concessional copayment of \$5.30 while concessional safety net patients pay nothing.

From the point of view of how much is paid therefore, there are three categories of patients

- General non-safety net patients (GNSN) paying a copayment of \$32.90
- Concessional non-safety net and general safety net patients (CON) paying \$5.30
- Concessional safety-net patients (CSN) paying nothing

In assessing how much of the savings from PBS reform flow to the Government and the patient, it is clear that all the benefits for the last category (CSN) will flow to the Government, because the patient pays nothing under any scenario.

For the second category (CON) savings will only flow to patients where the price of the medicine falls below \$5.30. There are very few medicines in this category so savings to the patient will be small and the bulk of savings will flow to the Government.

It is only in the first category (GNSN) where there could be significant savings flowing to the patient as the prices of some medicines fall below the copayment level of \$32.90.

Modelling the impact of PBS reform on Government and patients can be done in a way similar to the modelling used to assess the impact of PBS reform overall.

The volume of medicines consumed by the GNSN and CON categories are calculated in the same way using their expenditure levels in 2007-08. However instead of calculating overall expenditure based on the dispensed price MDPMQ, Government expenditure is calculated using the Commonwealth dispensed price for maximum quantity (CDPMQ) (ie without any premium) and after deducting the relevant copayment for the GNSN and CON categories.

If the Government expenditure estimates for the GNSN and CON categories are added to the overall estimates for the CSN category, the result is the total level of Government expenditure across all patient categories.

As shown in Table 2.6, the total savings to the Government generated by the change in formula and the 25% and 2% price cuts over the period 2008-09 to 2013-14 is estimated to be \$1,427.9 million. The difference between this and the overall savings of \$1,570.4 million (Table 2.1) are \$142.5 million or 9.1% which is the savings accruing to patients.

Over the longer period to 2017-18, the savings to the Government are \$2,571.9 million with savings of \$256.6 million for patients.

2.9 COST OF PBS ON-LINE

In 2007-08, there were some 170,953,203 scripts dispensed through community pharmacies. If 98% of these were reported using PBS On-line then the cost of this program is $\$0.40 \times .98 \times 170,953,203 = \67.0 million.

Assuming an annual growth rate of 3.5% and allowing from only 11 months effect in 2008-09, the projected cost of this initiative is (in \$m)

	2008-09	2009-10	2010-11	2011-12	2012-13	TOTAL 2008-09 TO 2013-14	TOTAL 2008-09 TO 2017-18
PBS On-line, \$m	61.4	65.8	68.1	70.5	73.0		
	2013-14	2014-15	2015-16	2016-17	2017-18		
PBS On-line, \$m	75.5	78.1	80.9	83.7	86.6	414.2	743.5

The 40 cent PBS Online fee is due to cease on 30 June 2011³ and is estimated to cost \$195.3 million from 2008-09 to 2010-11.

If this measure were to continue beyond 30 June 2011, the total cost of PBS On-line from 2008-09 to 2013-14 is estimated to be \$414.2 million and from 2008-09 to 2017-18 it is \$743.5 million.

2.10 COST OF \$1.50 DISPENSING INCENTIVE

The PBS reform package provides an incentive of \$1.50 to dispense a substitutable, premium – free medicine. This incentive is due to cease on 30 June 2011².

To calculate the cost of this initiative, those items with a premium were identified by comparing the base cost to pharmacist with the manufacturer's price to pharmacist. Any item with at least one brand with a premium was deemed to be an item for which this incentive might be applicable.

There are about 443 such items.

For each of these items the number of scripts for bands without a premium in 2007-08 was identified and these totalled 47.1 million. The full year effect of the incentive is therefore $47.1 \times 1.5 = \$70.7$ million.

Assuming an annual growth rate of 3.5% and allowing from only 11 months effect in 2008-09 then the projected cost of this initiative is as shown in the next table. Here it is assumed that the share of premium-free brands remains constant within a particular item.

	2008-09	2009-10	2010-11	2011-12	2012-13	TOTAL 2008-09 TO 2013-14	TOTAL 2008-09 TO 2017-18
Projected cost, \$m	67.1	75.7	78.4	81.1	84.0		
	2013-14	2014-15	2015-16	2016-17	2017-18		
Projected cost, \$m	86.9	89.9	93.1	96.3	99.7	473.2	852.3

The \$1.50 fee for dispensing a premium – free medicine is estimated to cost \$221.2 million from 2008-09 to 2010-11.

If this measure were to continue beyond 30 June 2011, the total cost of PBS On-line from 2008-09 to 2013-14 is estimated to be \$473.2 million and from 2008-09 to 2017-18 it is estimated to be \$852.3 million.

³ Commonwealth of Australia and the Pharmacy Guild of Australia 2007

3. PBS REFORMS AND PROJECTED PBS EXPENDITURE

The following section presents results from the analysis of the impact of PBS reforms that have yet to occur on projected PBS expenditure.

It is based upon the actual prices of PBS listed medicines to June 2009 and projects monthly prices from July 2009 to June 2018 based on assumptions made about the impact of a number of factors, namely

- The entry of new brands leading to mandatory 12.5% cuts to the price to pharmacist for those medicines that qualify for such cuts.
- 2% price cuts for F2A formulary medicines in August 2009 and August 2010.
- Known cuts in price to the pharmacist for 4 medicines arising from price disclosure to take effect in August 2009 (which was subsequently deferred to 1 April 2010).
- Price disclosure arising from listing of new brands for F2A medicines after 1 August 2007 and for F2T medicines after 1 January 2011

The current formula for calculating dispensed price from the price to the pharmacist is used for the period from July 2009 to June 2018. Dispensing fees are assumed to be as at June 2009.

Demand for all medicines entering into the analysis is assumed to grow at a global growth rate of 3.5% per annum for each of the years in the period to 2017-18.

Taken into account separately is the impact of the continuing listing of new medicines at a rate of about 12 per year.

The modelling has been designed to show, as much as is practical, the impact of the individual components of the PBS reform package both individually and in combination.

The savings to the PBS from PBS reform are calculated by comparing the estimated expenditure with that under a base case scenario. Two versions of this base case scenario are presented.

“Base case scenario - no change from June 2009” assumes that there are no further price cuts arising from either the 12.5% mandatory price cut policy or the PBS reform package or from any other cause. In effect this just projects prices at June 2009 forward and applies the global growth rate assumption.

“Base case scenario – 12.5% cuts only” assumes that the 12.5% mandatory price cut policy will continue and makes some assumptions about which medicines will be affected. However it does not take into account the impact of the PBS reform package.

The modelling calculates what effect the PBS reform measures will have on the price to pharmacist net of any premium and then calculates the dispensed price based on this taking into account the pricing formula and premium mark-ups where applicable.

3.1 ASSUMPTIONS UNDERLYING THE MODELLING

3.1.1 12.5% mandatory price cuts on entry of new brand

Within either of the two base case scenarios it is necessary to make some assumptions about which medicines could be affected by the mandatory 12.5% price cut arising from the first new brand of a medicine after August 2005.

Quite a few medicines have already been affected by this policy either directly or because they were members of a Reference Pricing Group, and these have been identified by examining changes in the Commonwealth price to pharmacist for the manufacturers pack and checking this against various lists published by DoHA. Up to June 2009 there were 127 medicines that had experienced a price cut arising from this policy, although for some this affected only some forms or strengths.

Once these medicines are excluded, as well as those medicines with patent expiry dates after June 2018 and those medicines specifically exempted by DoHA from statutory price cuts, the remaining medicines which could experience a 12.5% cut can be divided into two groups.

The first of these is those medicines, mainly in formulary F1, with patent expiry dates from June 2009 to May 2018⁴.

Based on discussions with Medicines Australia and the Taskforce, it was decided to assume that those medicines with sales in excess of \$5 million in 2007-08 would attract a new brand while those with sales less than \$5 million would not. Where new brand entry is assumed, listing on the PBS occurs in the month after the month in which the patent expires. The exception to this is for those medicines within the angiotensin II receptor antagonist (A2RA) group all of which are currently patent protected. The first medicine within this group that attracts a new brand will trigger a 12.5% cut for all members of the group. However the first patent expiry is for eprosartan mesylate with an expiry date of 8/06/2010. This medicine had sales of only \$2.7 million in 2007-08 while the next candidate, telmisartan with an expiry date of 5/02/2012, had sales of \$26.5 million. The mandatory 12.5% price cut for A2RAs therefore is assumed to occur in March 2012.

Aside from medicines on F1, there is one medicine on F2T with patent expiry

⁴ Patent expiry dates are derived from the IMS Health Patent Focus database (IMS Health 2004).

during the period and with sales over \$5 million. This is the combination ofesomeprazole with clarithromycin and amoxicillin. There are no medicines on F2A that have sales over \$5 million and patent expiry dates during the period to June 2018.

There is a second group consisting of those medicines whose patents have expired but have not yet attracted a new entry. The PBS listing date for these medicines was decided by ranking all of these medicines by sales in descending order and assigning the most recent listing dates to the largest.

The modelling takes account of those changes to the PBS described in the Commonwealth Budget for 2009-10, including the creation of a new therapeutic group consisting of atorvastatin and rosuvastatin.

3.1.2 Known 2% price cuts in F2A

The PBS reform policy flags further cuts of 2% in the price to pharmacist for those medicines on F2A that are not exempt. These are modelled at August 2009 and August 2010 based on the composition of the F2A formulary at these dates. As medicines move from F1 to F2A as a result of new brand entry, the composition of F2A at any one time will depend in part on the assumptions made about which medicines will experience 12.5% cuts as a result of this new brand entry.

3.1.3 Known price cuts from price disclosure

To date price disclosure was scheduled to affect 4 medicines in August 2009 although this has been delayed to April 2010. The price cuts arising from price disclosure are as follows

Doxorubicin	Injection/intravesical	63.54%
Meloxicam	Oral	22.46%
Mitozantrone	Injection	34.42%
Ondansetron	Injection	15.37%

3.1.4 FUTURE PRICE CUTS FROM PRICE DISCLOSURE

One of the major uncertainties in the modelling of PBS reform is not being able to accurately predict which medicines will be subject to price disclosure after the entry of a new brand, when this will occur, and the extent of price cuts resulting from this price disclosure.

It is assumed that price disclosure cuts will only occur in April and August during the year. Medicines Australia has developed a schedule for price disclosure cuts estimating when price cuts are to occur, in relationship to when the new brand is listed on the PBS. This schedule is based on estimated time of entry of a trigger

brand, the data collection cycles, voluntary disclosure period and DoHA notification period. Based on the schedule, the price cut will happen at least two years after the new brand entry but could vary depending on the month of listing. The following table shows for each month in 2009, when price disclosure cuts will occur if at all. A similar schedule applied to all the other years in the period.

LISTING DATE	PRICE CUT DATE
Jan – 2009	Apr – 2011
Feb – 2009	Apr – 2011
Mar – 2009	Apr – 2011
Apr – 2009	Apr – 2011
May – 2009	Aug – 2011
Jun – 2009	Aug – 2011
Jul – 2009	Aug – 2011
Aug – 2009	Aug – 2011
Sep – 2009	Apr – 2012
Oct – 2009	Apr – 2012
Nov – 2009	Apr – 2012
Dec – 2009	Apr – 2012

Those medicines discussed in Section 3.1.1 will be subject to price disclosure because a new brand will trigger a mandatory 12.5% price cut.

However all medicines on the F2A formulary are potential candidates for price disclosure following entry of a new brand – not just those that have had a mandatory 12.5% cut. There were twenty such medicines with PBS sales over \$5 million in 2007-08. Dates for entry of a new brand and the implied price disclosure dates were allocated assuming that those with the largest sales would attract a new brand earlier than those with lesser sales.

Further assumptions are required about the size of the price cut resulting from price disclosure and the probability of this happening. Again this is an area of uncertainty but, after discussion with Medicines Australia, it was decided to determine these two aspects of price disclosure according to the level of PBS sales of the medicine in 2007-08 as follows

CATEGORY	PBS SALES 2007-08 \$M	PRICE CUT %	PROBABILITY %
1	Over 150	20	100
2	100 to 150	20	100
3	50 to 100	20	100
4	25 to 50	20	50
5	10 to 25	15	50
6	5 to 10	15	50
7	Less than 5	0	0

For example, if a medicine had sales of \$60 million in 2007-08 it would fall into category 3 and incur a price disclosure cut of 20%. On the other hand if its sales were \$22 million it would be in category 5 and would incur a price cut of 15% with a probability of 50% that the price cut will occur.

For those medicines in categories 4, 5 and 6 where the probability of a cut occurring is 50% it was decided to make the probability 100% but the cut would be half of that given in the table. Thus the medicine with sales of \$22 million in category 5 would incur a price cut of 7.5%, instead of a 15% cut with a probability of 50%. The alternative is to allocate medicines at random equally to a group which incurs a cut and one that does not. The difference in outcomes between the two procedures is not likely to be great.

An alternative more competitive assumption was also modelled to reflect market dynamics. The competitive estimates assume that the disclosure price cuts in categories 1 and 2 are 40% with a probability of 100% rather than 20% with a probability of 100%.

From 1 January 2011, medicines on F2T will also be subject to price disclosure following entry of a new brand. Given that these medicines have already had a 25% cut in August 2008 and most have had a mandatory 12.5% price cut, it was decided after discussions with Medicines Australia, that only those medicines with sales over \$100 million would be likely to attract a new brand. There are 3 such

medicines on F2T. The date of entry of a new brand is presumed to be January 2011 with a price cut arising from price disclosure of 20% in April 2013 for all three medicines.

3.2 MODELLING PROCEDURE

The only complete annual data currently available for PBS expenditure and scripts by item and manufacturer code is for the year 2007-08.

For each item and manufacturer code in this dataset, pricing data was obtained from the PBS Schedule database maintained by CSES. Data is current to June 2009 meaning that actual price data is available for the years 2007-08 and 2008-09. The modelling is based on these actual prices in particular for June 2009.

As noted earlier, all policy is based on changes in the Commonwealth price to pharmacist for the manufacturers pack (CPPMP).

Using the CPPMP in June 2009 and after accounting for price cuts, a set of monthly CPPMP prices for each combination of item and manufacturer code from July 2009 to June 2018 was calculated.

These CPPMP prices are converted into MPPMP prices by multiplying the CPPMP prices by the premium factor applicable in June 2009. This factor is the known ratio of MPPMP to CPPMP in June 2009.

These prices to the pharmacist are converted into dispensed prices by using the current formula and the current dispensing fees as at June 2009, but taking into account that for some medicines there is no mark-up or dispensing fee.

Some combinations of item and manufacturer code have experienced changes in either pack size or maximum quantity over the period to June 2009. The price calculations have also taken account of this where necessary.

The result of these calculations was a set of manufacturer's dispensed price for maximum quantity (MDPMQ) which is the actual dispensed price. The Commonwealth reimburses pharmacists based on the Commonwealth dispensed price for maximum quantity (CDPMQ) net of any copayment.

The average dispensed price was calculated for a particular year by averaging the price over the year. For 2007-08 and 2008-09 this averaging was based on the actual MDPMQ from July to June in each year. For later years it is an average of the calculated MDPMQ.

The volume of medicines consumed for each combination of item and manufacturer code in 2007-08 was obtained by dividing the total expenditure

in 2007-08 by the average MDPMQ for 2007-08. To calculate the volume for each of the years from 2008-09 to 2017-18 a global growth factor of 3.5% per annum was applied.

To estimate PBS expenditure for each of the years from 2008-09 to 2017-18, the volume estimate for each year was multiplied by the calculated average MDPMQ for that year to obtain PBS expenditure estimates. However, an adjustment was made when making these calculations. Because the expenditure data is for the year 2007-08 and the price calculations are based on prices in June 2009, there are inevitably some combinations of items and manufacturer codes that existed in 2007-08 but not in June 2009.

For these combinations, CPPMP and MDPMQ were allocated manually based on the CPPMP for the item code or on item codes for the same strength and form as the missing item code. This allocation took account of any manufacturer's premium that might be required.

Of a total PBS expenditure of \$7943.4 million in 2007-08 there were combinations of item and manufacturer codes worth \$396.2 million for which this allocation was required. In most cases this was relatively straightforward, but there remained a residual of about \$34 million which could not be incorporated into the modelling. In the results reported below this residual was added back into the results and was assumed to grow at 3.5% per annum over the period. This had no impact on the calculation of savings arising from PBS reform overall.

3.3 MODELLING RESULTS

Using the two versions of the base case scenario, Table 3.1 shows projected PBS expenditure for the period 2008-09 to 2017-18. The values for 2008-09 are based on known prices plus the assumed growth rate in demand of 3.5% per annum.

The first two lines in Table 3.1 show projected expenditure under each scenario. The next five lines report expenditure for various combinations of PBS reform including the effects of the assumed 12.5% price cuts. Expenditure under the more competitive assumptions about price disclosure cuts is given at the end of the table. It is comparable to the line immediately above it but with larger price disclosure cuts.

Table 3.2 shows the savings arising from various combinations of change. Based on these estimates, 12.5% price cuts (line 1) generate \$1,094.7 million in savings over the period from 2009-10 to 2013-14. PBS reform (line 6) by itself generates savings of \$821.3 million giving a total of \$1,916.0 million from 12.5% price cuts plus all the PBS reform price cuts in the time period to 2013-14 (line 7).

Over the longer period to 2017-18, the savings from the 12.5% price cuts are \$3,493.2 million (line1) with a further \$3,525.3 million from PBS reform (line6) giving a total of \$7,018.5 million (line 7).

Using the more competitive assumptions, in the period to 2013-14 the total savings rise to \$2,152.2 million (line9) (up \$236 million from \$1,916.0 million under conservative assumptions). Similarly, PBS reform savings rise by the same amount to \$1,057.4 million from \$821.3 million. For the longer period, the savings under competitive assumptions were up \$1626 million to \$8,644.9 million for all changes and \$5,151.5 million from PBS reforms alone.

3.4 IMPACT ON SUPPLY CHAIN PARTICIPANTS

The impact of PBS reform measures on supply chain participants over the period was calculated by considering the relationship between the dispensed price and the price to pharmacist and the mark-up rules for wholesalers.

The results in Section 3.3 are reported at the level of the dispensed price. If instead, the manufacturer's price to pharmacist is used (taking into account any difference between pack size and maximum quantity), then the impact at the wholesaler level is obtained.

The difference between the estimates of expenditure at the dispensed price level and at the price to pharmacist level represents the revenue received by pharmacists. The expenditure at price to pharmacist level was then allocated to wholesaler and manufacturer assuming a share of 93% manufacturer and 7% wholesaler.

Tables 3.3 to 3.6 show the costs to manufacturers, wholesalers, pharmacists and originator manufacturers from PBS reform during the period. The total savings of \$1,916.0 million arising from the 12.5% price cuts and PBS reform over the period from 2009-10 to 2013-14 is borne as a cost to pharmacists of \$118.6 million, to wholesalers of \$111.8 million, to manufacturers of \$1,685.6 million and to originator manufacturers of \$1,419.8 million.

Over the longer period to 2017-18, the costs to pharmacists, wholesalers, manufacturers and originator manufacturers are \$472.0 million, \$412.1 million, \$6,134.4 million and \$5,418.0 million respectively.

From PBS reforms alone the total savings to PBS of \$821.3 million is estimated over the period from 2009-10 to 2013-14 and is borne as a cost to pharmacists of \$53.8 million, to wholesalers of \$48.5 million, to manufacturers of \$719.1 million and to originators of \$544.4 million. Over the longer period the costs to each participant are \$252.4 million, \$212.4 million, \$3,060.4 million and \$2,566.0 million respectively.

3.5 SAVINGS FOR GOVERNMENT AND PATIENTS

Modelling the impact of PBS reform on Government and patients can be done in a way similar to that outlined in Section 2.6 above.

The volume of medicines consumed by the GNSN and CON categories are calculated in the same way using their expenditure levels in 2007-08. However instead of calculating overall expenditure based on the dispensed price MDPMQ, government expenditure is calculated using the Commonwealth dispensed price CDPMQ (ie without any premium) after deducting the relevant copayment for the GNSN and CON categories.

If the Government expenditure estimates for the GNSN and CON categories are added to the overall estimates for the CSN category, the result is the total level of Government expenditure across all patient categories. Table 3.7 reports these estimates of Government expenditure on the PBS over the period under the various scenarios similar to the overall expenditure estimates given in Table 3.1. Estimates for patient expenditure can be derived simply as difference between the overall expenditure and the Government expenditure.

The amount of savings flowing to the Government can be derived in the same way as before by comparing the expenditure levels for PBS reform with those of the two base case scenarios. These are shown in Table 3.8.

Comparing the results in Table 3.2 with those in Table 3.8, shows that overwhelmingly savings from PBS reform flow to the Government rather than the patient.

The total savings arising from the 12.5% price cuts and PBS reform over the period from 2009-10 to 2013-14 are \$1,916.0 million while Government savings are \$1,885.5 million so that the savings to patients are \$30.6 million. Over the longer period the Government savings are \$6,911.3 million and savings to patients are \$107.2 million.

From PBS reform alone the total savings to PBS over the period from 2009-10 to 2013-14 are \$821.3 million including Government savings of \$799.5 million and patient savings of \$21.8 million. Over the longer period to 201-18, the Government saves \$6,911.3 million while the patients gain \$107.2 million (Table 3.8).

Using more competitive assumptions about price cuts, Government savings from the 12.5% price cuts and PBS reform rise to \$2,095.7 million over the period to 2013-14 with savings from PBS reform accounting for nearly half of the savings (\$1,009.7 million). Over the longer period the savings to Government could be up to \$8,453.4 million and \$4,988.1 respectively

4. COMBINED ESTIMATES OF SAVINGS FROM PBS REFORM

The following section combines the estimates of savings to the PBS from those reforms implemented in August 2008 with those projected to occur within the years 2009-10 to 2017-18.

Table 4.1 lists all the savings arising from PBS reform under the two scenarios, ie with and without the projected 12.5% price cuts. A positive sign indicates savings to the Government (and a cost to other participants) while a negative sign indicates costs incurred by the Government (and a benefit to other participants).

The total savings from the 12.5% price cuts and all PBS reforms for the period to 2013-14 estimated using the assumptions outlined in this report are \$2,599.0 million with \$1,504.3 million from PBS reforms only. Over the longer period to 2017-18 the savings rise to \$8,251.2 million and \$4,758.0 million respectively.

Using more competitive assumptions about disclosure price cuts, the overall savings in 2013-14 rise to \$9,877.6 million and \$6,384.2 million in 2017-18.

As shown in Table 4.2, in the period to 2013-14, manufacturers lose \$2,759.9 million from PBS reform rising to \$3,726.4 million if the 12.5% cuts are included. Over the longer period the manufacturers lose \$6,736.3 million rising to \$9,810.3 million respectively. Originator manufacturers account for over half of all the losses with estimated \$1,534.1 million from PBS reforms only rising to \$2,409.5 million overall. In the period to 2017-18 originators lose \$4,348.6 million just from PBS reforms rising to \$7,200.6 million overall.

In the time period to 2013-14, wholesalers lose \$202.1 million from PBS reforms only rising to \$265.4 million overall. After taking into account the increased CSO funding wholesaler losses reduce to \$133.1 million and \$196.4 million overall. Over the longer period these losses are \$489.1 million and \$688.8 million, or \$420.1 million and \$619.8 million with the extra CSO funding.

On the other hand, pharmacists are better off by \$1,457.6 million as a result of PBS reform and by \$1,392.8 million overall in the time period to 2013-14. This rises to \$2,476.4 million and \$2,247.8 million over the longer period to 2017-18 (see Table 4.2) assuming the compensation measure continues.

As noted earlier, most of the savings generated by PBS reforms go to the Government rather than the patient. Table 4.3 shows the level of Government savings from the various components of PBS reforms under the two scenarios.

The savings to the Government from the 12.5% price cuts and PBS reforms is estimated at \$2,426.0 million in the period to 2013-14 including \$1,340.0 million from PBS reforms only. After including the extra \$69.0 million for the CSO Funding Pool Government savings reduce to \$2,357.0 million overall and \$1,271.0 million from PBS reforms only. Over the longer period the savings to the Government from the 12.5% price cuts and PBS reforms is estimated at \$7,887.4 million and \$4,422.1 million just for PBS reforms. Again this is reduced if the CSO Funding Pool is included bringing the savings to \$7818.4 million and \$4,353.1 million.

In the time period to 2013-14, under more competitive assumptions, the Government saves \$2636.2 million overall and \$1550.2 million from PBS reforms only. These savings rise to \$9429.5 million overall and \$5964.2 million from PBS reforms only.

The difference between the estimates given in Tables 4.1 and 4.4 provides the estimates of patient savings from PBS reforms. The savings to patients from the 12.5% cuts and PBS reforms over the period to 2013-14 are \$173.0 million with \$164.3 million from PBS reforms only. Over the longer period, patient savings rise to \$363.8 million overall and \$335.9 million from PBS reforms only. Under more competitive price disclosure assumptions patients save up to \$448.1 million overall and \$420.1 million from PBS reforms only.

5. NEW MEDICINES TO BE LISTED ON THE PBS

This section looks at the listing of new medicines on the PBS in order (i) to assess whether there has been any change in the availability of new medicines on a timely basis and (ii) to ascertain what impact listings of new medicines might have on future PBS expenditure.

The establishment of the Access to Medicines Working Group involving Medicines Australia, the DoHA and the TGA has provided a forum to consider issues regarding the timely and appropriate access to new medicines. The Group first met in July 2007.

5.1 AVAILABILITY OF NEW MEDICINES

Based on CSES analysis, the PBS has grown from a formulary consisting of 530 medicines in August 1991 to 727 medicines in July 2009 (Table 5.1). On average over the past 18 years the PBS has added 25.4 new medicines (including combinations) per year. At the same time an average of 13.7 medicines are removed from the formulary each year. Just looking at the past 5 years gives very similar numbers - 25.0 new medicines and 12.2 exiting medicines - suggesting that the size of the total PBS formulary grows by an average of 12-13 medicines per year, although there can be significant variation from year to year.

As shown in Table 5.1 and Figure 5.1, the number of new medicines listed over the past three years, i.e. from 2006-07 to 2008-09 has been significantly higher than the average and well above the levels of the previous 5 years. 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, CSES notes that the increase in listings begins around the time of the introduction of PBS reform measures. This suggests that the savings made available by the impact of the mandatory 12.5% price cuts and the introduction of PBS reforms have 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.

Coincidentally the number of new medicines being listed on the PBS each year is similar to the number approved by the Food and Drug Administration (FDA) in the USA. On average, the FDA has approved about 20-21 new medicines per year over the past 10 years. While not all medicines listed in the USA become available in Australia, there are also some medicines found in Australia but not in the USA. These numbers imply therefore that most new medicines will eventually become available to patients in Australia.

Importantly however, there is strong evidence that there is a significant lag in the time taken to obtain medicines in Australia.

An analysis of the 340 new medicines listed on the PBS from 1991 to May 2009, which were also approved by the FDA, shows that the average lag between FDA approval and PBS listing is 43.9 months⁵. As this average is affected by significant outliers, however a better indication is the median lag of 26.1 months. The median is determined such that half of the medicines will have lag greater than this and half will have a lag less than this. As shown in Figure 5.2 there is wide distribution of the approval lags with some medicines being available earlier in Australia than the USA while some arrive in Australia only after a number of years. The most common lags are between 9 months and 18 months.

A similar analysis over a shorter period of time of 128 medicines listed on the PBS and approved by the European Medicines Agency (EMA) showed an average lag of 23.4 months and a median lag of 13.6 months, or about half that between the FDA and the PBS.

While approval lag is partly determined by company’s decisions as to when to apply for approval first from the TGA and then the PBAC, the presence of a two-stage approval process in Australia obviously contributes to the delay in medicines becoming available.

Of concern however is the fact that the approval lag seems to be increasing. As shown in Table 5.2 and Figure 5.3, the median lag has increased in recent years particularly since 2006, rising from 19.0 months in 2002 to 43.9 months in 2008.

⁵ Data on PBS listing dates is from the CSES database derived from the monthly electronic version of the PBS Schedule. Data on FDA approvals is from FDA (2009) and for EMA approvals, EMA (2009).

5.2 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 estimates in Sections 3 and 4.

In general, it might be expected that a new medicines 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 will therefore be exempt from the effects of PBS reform at least over the period to 2013-14 and for some years beyond and hence are not expected to contribute to the savings calculated in this analysis.

However they 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.

To estimate the impact of new medicines on overall PBS expenditure, the study calculated the level of expenditure for the typical PBS medicine and applied this to additional new medicines entering the PBS.

As shown in Table 5.3, in 2007-08 total PBS expenditure was \$7,943.4 million on 717 medicines, for an average cost of \$11.1 million. The annual growth in the cost per medicine over the past 5 years has averaged 4.9%.

Assuming that the PBS formulary increases by 12 medicines per year and the average cost of each grows by 5% per year, the cumulative addition to PBS expenditure above that in 2007-08 due to new medicines would be as shown in Table 5.4. By 2013-14, it is estimated that the net effect of the new medicines would be an additional \$949.5 million per year in PBS expenditure.

	2008-09	2009-10	2010-11	2011-12	2012-13	2013-14
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All new medicines, \$m	139.6	286.2	440.1	601.7	771.3	949.5
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An alternative approach to estimating the impact of new medicines is to look at the sales profile of a typical new PBS medicine. Based on all new medicines listed on the PBS since 1992-93, the average sales profile of a new medicine is as shown in Table 5.5. For instance, for new medicines listed since 2001-02, the typical first year sales were \$3.3 million, second year sales were \$8.4 million, third year sales were \$11.2 million and sales typically flatten out by the sixth year or so.

The typical sales figure of \$14-20 million in the fifth year is somewhat larger than the \$11.1 million estimated from Table 5.3. This latter method, however does not take account of the extent to which new medicines take market share from already listed PBS medicines.

Econometric analysis of the relationship between PBS spending and the number of medicines on the formulary produced broadly similar results to those given above.

6. ORIGINATORS, GENERICS AND PREMIUMS

As the size of the PBS market has grown both in terms of the number of medicines on the formulary and in terms of the volume of medicines consumed by patients, the number of suppliers of medicines to the PBS has increased – from 125 in August 2001 to 144 in August 2009 (Table 6.1). Classifying suppliers by type is not straightforward as some perform multiple roles. Thus while research-based manufacturers mainly supply originator brand medicines some also produce either competitor or generic brands. Similarly, some suppliers that mainly sell generic brands competing with originator brands, also supply some single-supplier medicines often on licence from originator companies. In addition there are some suppliers that specialise in diagnostics where the concept of an originator brand is unclear, or in supplying single-supplier off-patent medicines.

There are two ways therefore of measuring the importance of generics within the PBS. The first is to classify suppliers according to their main business, namely research-based manufacturers, generic suppliers, diagnostic suppliers and other types of suppliers.

The second is to classify brands according to whether they are originator brands or brands competing with originator brands.

Table 6.1 shows the number of PBS suppliers in each category according to the first method. Table 6.2 gives the percentage shares of each type of supplier.

The number of research-based manufacturers has fallen slightly since 2001 although this is most likely due to mergers within the industry. The numbers of diagnostic and other suppliers has remained relatively constant, but the number of generic suppliers has increased from 28 to 47 or by 67% (Table 6.1). While research-based manufacturers are still in the majority, generic suppliers now account for about a third of all suppliers (Table 6.2).

In terms of their share within the PBS, the picture is somewhat different.

The shares of PBS scripts classified by type of supplier are shown in Table 6.3, while Table 6.4 shows the shares in PBS expenditure. The share of research-based manufacturers in PBS scripts has fallen from 79.9% in 2000-01 to 64.5% in 2007-08 (Table 6.5) and the share in PBS expenditure has fallen from 89.7% to 81.9% (Table 6). On the other hand, the share of scripts by generic suppliers has increased from 19.2% to 34.7%, and of their share of expenditure from 9.7% to 17.6%.

The shares of PBS scripts accounted for by originator and generic brands rather than type of supplier are shown in Table 6.5, while Table 6.6 shows the shares in PBS expenditure. Originator brands have fallen from 73.1% of all scripts in 2000-01 to 63.2% in 2007-08, but the drop in terms of expenditure is much less – from 87.0% to 81.2%.

Manufacturers can add a premium to the base price (ie the Commonwealth dispensed price) of their brand upon application to the DoHA. Typically these brand premiums are small in relation to the base price. The most usual type of premium is a brand premium where the manufacturer adds a premium above the dispensed price of other brands of the same medicine. Therapeutic premiums are also allowed for some single supplier brands within a small number of therapeutic groups. There are also a few cases where the manufacturer and Government cannot agree on a price and the manufacturer adds a premium called a Special Patient Contribution.

The number of brands with a premium over the period from August 1991 to August 2009 is shown in Table 6.7, as well as the number of items with one or more premiums and the overall number of items. The percentage of items with premiums is also included.

As Table 6.7 and Figures 6.1 and 6.2 demonstrate, the number of items with premiums rose rapidly to the year 2000, levelled off until 2004 then rose in 2005 and 2006 before stabilising again. As a percentage of all items, the number of items with premiums followed a similar pattern except that it fell in 2007 and again more strongly in 2008 and 2009.

In August 2009, only 17.2% of PBS items contained brands with a premium, with 82.8% of items dispensed free of any premium.

The average size of the premium as a percentage of the base price is shown in Table 6.8 and Figures 6.3 and 6.4. Two versions are presented. The first is a simple unweighted average of all brands with a premium using the values at August each year. On this measure, the average premium has risen from 10.7% of base price in August 1991 to 17.3% in August 2009. As Figure 6.3 shows, however, the average mark-up rose strongly in 1993 then remained fairly steady until 2001 but rose again in 2002 and 2003 before another steady phase until 2009.

If the average mark-up is weighted by its importance as measured by sales in the appropriate year, the situation is somewhat different. Firstly, the mark-up is much less, being 4.5% in 1991-92 rising to 8.2% in 2007-08, the latest year for which sales data is available. Secondly, the experience has been more variable from year to year. From 1994-05 to 1997-98 the average mark-up fell, before recovering to a relatively unchanged level until 2003-04. This was followed by another large fall in 2004-05 before a period of steady increase to 2007-08 (Figure 6.4).

Competition among brands is probably greater for those medicines with larger sales which would explain why the average mark-up is lower on a weighted rather than an unweighted basis. The rise in the weighted mark-up since 2004-05 may reflect manufacturers of originator brands trying to maintain the absolute levels

7. SUSTAINABILITY OF THE PBS

of the premium in a period where prices of popular medicines have been falling significantly.

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 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 recent Budget in May 2009, the Commonwealth Government produced estimates for both the growth in GDP and in overall budget expenses for the period 2009-09 to 2012-13. These are reproduced in Table 7.1. If the growth rate is applied to the level of nominal GDP in 2007-08, the actual implied levels of GDP for the period 2008-09 to 2012-13 can be obtained. The Budget papers also report on the projected level of expenditure on "Pharmaceutical services and benefits" for this period and on the components of this from 2009-10 to 2012-13. Combining the projections for "Pharmaceutical benefits—concessional", "Pharmaceutical benefits—general" and "Pharmaceutical benefits—highly specialised drugs" gives the projections reported in Table 7.1 as "PBS".

The levels of expenditure on the more general program "Pharmaceutical services and benefits" and the calculated level of the PBS can be expressed both as a percentage of GDP and of overall Government spending. These are shown in Table 7.1 and it is clear that the PBS rises as a percentage of GDP to 2010-11 but starts to fall thereafter as GDP growth picks up. As a percentage of Government spending, the PBS rises somewhat across the period partly because Government spending is not rising as fast after 2009-10. The more general program "Pharmaceutical services and benefits" also begins to fall as a percentage of

GDP after 2010-11 but remains relatively steady as a percentage of Government spending.

At least to 2012-13 therefore the Government is not indicating from its projections that there is any serious issue regarding the sustainability of the PBS.

This study on the impact of PBS reforms has also projected PBS expenditure under various scenarios and the results have already been given in Table 3.1. However these did not include the additional expenditure due to new medicines as described in Section 5 or the cost of the \$1.50 dispensing incentive or PBS Online. If these additional expenditures are added to those scenarios in Table 3.1 the results are the estimates shown in Table 7.2. Here the two base scenarios are listed as well as the outcomes from the modelling of the range of PBS reforms and the 12.5% price cuts. These can all be expressed as a percentage of GDP and of overall Government spending using the Government's forecasts for these two measures.

While the two base case scenarios show a rise in PBS expenditure as a percentage of GDP, if the projected 12.5% cuts are included the share begins to fall after 2010-11. Once all PBS reforms are accounted for, the PBS falls to 0.706% of GDP in 2013-14 having reached 0.744% in 2010-11. Including the projected 12.5% price cuts lowers the share to 0.678% in 2013-14.

A similar picture emerges when PBS expenditure is seen as a percentage of Government spending. However this spending begins to fall as a percentage of GDP itself after 2009-10 meaning that the share of the PBS in Government spending remains relatively unchanged once the PBS reforms and 12.5% price cuts have been taken into account. The impact of PBS reforms and the on-going 12.5% mandatory price cuts have ensured that the sustainability of the PBS in the medium-term is not open to question.

8. STREAMLINED AUTHORITIES

The PBS reform package included measures to streamline the prescribing of “Authority required” PBS items. Doctors prescribing certain of those medicines for long term chronic conditions (such as diabetes and osteoporosis) were permitted to do so without first obtaining approval from Medicare Australia. The principal reason for introducing streamlined authorities was to simplify the procedure for prescribers rather than to save money. Evidence is not available to assess prescriber’s satisfaction with the new procedure so the analysis in this section concentrates on whether there has been any change in prescribing overall.

There were 209 PBS items for which the streamlined authority arrangements would apply when introduced in July 2007.

Table 8.1 below compares the use of these medicines over the period 2003-04 to 2007-08 with the use of those “Authority required” medicines excluded from the streamlining arrangements, as well as to all “Authority required” medicines and to all PBS medicines. The first part of the table examines the annual growth rate for scripts for the four categories while the second part presents the growth in expenditure.

In general “Authority required” medicines grow faster than the overall PBS in part because they are newer medicines.

The growth of the number of scripts for streamlined authority medicines in 2007-08 which was the year when they were introduced was higher than the previous year 2006-07 and 2005-06 but less than in 2003-04 and 2004-05. The higher growth in 2007-08 was similar however to higher growths within the other categories. In particular the difference in growth rates between 2007-08 and 2006-07 for streamlined and non-streamlined “Authority required” medicines was 3.3% and 3.5% respectively.

Looking at growth in expenditure, the growth rate in 2007-08 for streamlined medicines was lower than in 2006-07 while the rate for non-streamlined “Authority required” medicines was higher than in 2006-07 and higher than for streamlined medicines.

There seems to be little evidence to suggest that the introduction of the streamlined authority arrangements have resulted in higher prescribing by doctors of these medicines.

Table 8.1 Growth rates of Authority required and other PBS medicines, %

	STREAMLINED AUTHORITY REQUIRED	OTHER AUTHORITY REQUIRED	ALL AUTHORITY REQUIRED	ALL PBS
SCRIPTS				
2003-04	16.0	10.2	14.3	4.3
2004-05	16.8	8.2	14.2	2.8
2005-06	7.8	14.6	9.7	-1.1
2006-07	6.1	9.4	7.1	0.8
2007-08	9.4	13.0	10.5	1.8
EXPENDITURE				
2003-04	15.2	16.2	15.8	10.1
2004-05	17.8	21.1	19.6	7.8
2005-06	14.9	17.0	16.0	3.6
2006-07	9.3	17.0	13.5	3.2
2007-08	8.8	18.5	14.3	7.9

These findings are supported by the *Streamlined Authority Initiative Review* undertaken by the DoHA (2009b) which noted that “Overall findings indicate that there were no substantial changes relative to historical growth trends observed in either total script volume or total PBS outlays for streamlined authority medicines for the first year of operation.”

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10. TABLES AND FIGURES

TABLE 2.1 SAVINGS FROM PBS REFORM IN AUGUST 2008, \$M

	2008-09	2009-10	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18	TOTAL 2008-09 TO 2013-14	TOTAL 2008-09 TO 2017-18
25% cuts only	330.3	373.0	386.0	399.5	413.5	428.0	443.0	458.5	474.5	491.1	2,330.4	4,197.6
2% cuts only	11.4	12.9	13.3	13.8	14.3	14.8	15.3	15.8	16.4	17.0	80.5	144.9
25% and 2% cuts only	341.7	385.9	399.4	413.3	427.8	442.8	458.3	474.3	490.9	508.1	2,410.9	4,342.5
12.5% cuts only	0.8	0.9	1.0	1.0	1.0	1.1	1.1	1.2	1.2	1.2	5.9	10.6
Formula change only	-124.7	-140.8	-145.8	-150.9	-156.1	-161.6	-167.3	-173.1	-179.2	-185.4	-879.9	-1,584.9
Formula change and 25% and 2% price cuts	265.7	300.0	310.5	321.3	332.6	344.2	356.3	368.8	381.7	395.0	1,874.3	3,376.0
Formula change and 12.5% price cuts	0.8	0.9	0.9	1.0	1.0	1.0	1.1	1.1	1.1	1.2	5.6	10.0
Net other formula change	-43.9	-49.5	-51.3	-53.1	-54.9	-56.8	-58.8	-60.9	-63.0	-65.2	-309.5	-557.5
Impact of PBS reform	222.6	251.3	260.1	269.2	278.7	288.4	298.5	309.0	319.8	331.0	1,570.4	2,828.5
All changes	227.6	257.0	266.0	275.3	284.9	294.9	305.2	315.9	327.0	338.4	1,605.6	2,892.1

* Positive sign indicates savings to Government and/or patients; cost to supply chain participants

TABLE 2.2 SAVINGS FROM PBS REFORM IN AUGUST 2008 - MANUFACTURERS, \$M

	2008-09	2009-10	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18	TOTAL 2008-09 TO 2013-14	TOTAL 2008-09 TO 2017-18
25% cuts only	279.4	315.5	326.5	337.9	349.8	362.0	374.7	387.8	401.4	415.4	1,971.1	3,550.3
2% cuts only	9.9	11.2	11.5	11.9	12.4	12.8	13.2	13.7	14.2	14.7	69.7	125.5
25% and 2% cuts only	289.3	326.6	338.1	349.9	362.1	374.8	387.9	401.5	415.6	430.1	2,040.8	3,675.9
12.5% cuts only	0.7	0.8	0.9	0.9	0.9	1.0	1.0	1.0	1.1	1.1	5.3	9.5
Formula change only	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Formula change and 25% and 2% price cuts	289.3	326.6	338.1	349.9	362.1	374.8	387.9	401.5	415.6	430.1	2,040.8	3,675.9
Formula change and 12.5% price cuts	0.7	0.8	0.9	0.9	0.9	1.0	1.0	1.0	1.1	1.1	5.3	9.5
Net other formula change	-0.7	-0.8	-0.9	-0.9	-0.9	-1.0	-1.0	-1.0	-1.1	-1.1	-5.3	-9.5
Impact of PBS reform	289.3	326.6	338.1	349.9	362.1	374.8	387.9	401.5	415.6	430.1	2,040.8	3,675.9
All changes	294.0	331.9	343.6	355.6	368.0	380.9	394.2	408.0	422.3	437.1	2,074.0	3,735.8

* Positive sign indicates savings to Government and/or patients; cost to supply chain participants

TABLE 2.3 SAVINGS FROM PBS REFORM IN AUGUST 2008 - WHOLESALERS, \$M

	2008-09	2009-10	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18	TOTAL 2008-09 TO 2013-14	TOTAL 2008-09 TO 2017-18
25% cuts only	21.0	23.7	24.6	25.4	26.3	27.2	28.2	29.2	30.2	31.3	148.4	267.2
2% cuts only	0.7	0.8	0.9	0.9	0.9	1.0	1.0	1.0	1.1	1.1	5.2	9.4
25% and 2% cuts only	21.8	24.6	25.4	26.3	27.3	28.2	29.2	30.2	31.3	32.4	153.6	276.7
12.5% cuts only	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.4	0.7
Formula change only	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Formula change and 25% and 2% price cuts	21.8	24.6	25.4	26.3	27.3	28.2	29.2	30.2	31.3	32.4	153.6	276.7
Formula change and 12.5% price cuts	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.4	0.7
Net other formula change	-0.1	-0.1	-0.1	-0.1	-0.1	-0.1	-0.1	-0.1	-0.1	-0.1	-0.4	-0.7
Impact of PBS reform	21.8	24.6	25.4	26.3	27.3	28.2	29.2	30.2	31.3	32.4	153.6	276.7
All changes	22.1	25.0	25.9	26.8	27.7	28.7	29.7	30.7	31.8	32.9	156.1	281.2

* Positive sign indicates savings to Government and/or patients; cost to supply chain participants

TABLE 2.4 SAVINGS FROM PBS REFORM IN AUGUST 2008 - PHARMACISTS, \$M

	2008-09	2009-10	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18	TOTAL 2008-09 TO 2013-14	TOTAL 2008-09 TO 2017-18
25% cuts only	29.9	33.8	35.0	36.2	37.4	38.8	40.1	41.5	43.0	44.5	211.0	380.0
2% cuts only	0.8	0.9	0.9	0.9	1.0	1.0	1.0	1.1	1.1	1.2	5.5	9.9
25% and 2% cuts only	30.7	34.7	35.9	37.1	38.4	39.8	41.2	42.6	44.1	45.6	216.5	390.0
12.5% cuts only	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.3
Formula change only	-124.7	-140.8	-145.8	-150.9	-156.1	-161.6	-167.3	-173.1	-179.2	-185.4	-879.9	-1,584.9
Formula change and 25% and 2% price cuts	-45.4	-51.2	-53.0	-54.9	-56.8	-58.8	-60.8	-63.0	-65.2	-67.5	-320.1	-576.5
Formula change and 12.5% price cuts	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	-0.1	-0.2
Net other formula change	-43.1	-48.6	-50.3	-52.1	-53.9	-55.8	-57.8	-59.8	-61.9	-64.0	-303.8	-547.3
Impact of PBS reform	-88.5	-99.9	-103.4	-107.0	-110.7	-114.6	-118.6	-122.8	-127.1	-131.5	-624.0	-1,124.0
All changes	-88.5	-100.0	-103.4	-107.1	-110.8	-114.7	-118.7	-122.9	-127.2	-131.6	-624.5	-1,124.9

* Positive sign indicates savings to Government and/or patients; cost to supply chain participants

TABLE 2.5 SAVINGS FROM PBS REFORM IN AUGUST 2008 – ORIGINATOR MANUFACTURERS, \$M

	2008-09	2009-10	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18	TOTAL 2008-09 TO 2013-14	TOTAL 2008-09 TO 2017-18
25% cuts only	132.0	149.0	154.2	159.6	165.2	171.0	177.0	183.2	189.6	196.2	931.1	1,677.2
2% cuts only	7.2	8.1	8.4	8.7	9.0	9.3	9.7	10.0	10.3	10.7	50.8	91.5
25% and 2% cuts only	139.2	157.2	162.7	168.3	174.2	180.3	186.6	193.2	199.9	206.9	981.9	1,768.6
12.5% cuts only	0.7	0.8	0.9	0.9	0.9	0.9	1.0	1.0	1.0	1.1	5.1	9.2
Formula change only	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Formula change and 25% and 2% price cuts	139.2	157.2	162.7	168.3	174.2	180.3	186.6	193.2	199.9	206.9	981.9	1,768.6
Formula change and 12.5% price cuts	0.7	0.8	0.9	0.9	0.9	0.9	1.0	1.0	1.0	1.1	5.1	9.2
Net other formula change	0.4	0.4	0.4	0.5	0.5	0.5	0.5	0.5	0.5	0.6	2.6	4.7
Impact of PBS reform	140.3	158.4	163.9	169.7	175.6	181.8	188.1	194.7	201.5	208.6	989.7	1,782.6
All changes	145.2	163.9	169.7	175.6	181.7	188.1	194.7	201.5	208.6	215.9	1,024.2	1,844.8

* Positive sign indicates savings to Government and/or patients; cost to supply chain participants

TABLE 2.6 GOVERNMENT SAVINGS FROM PBS REFORM IN AUGUST 2008, \$M

	2008-09	2009-10	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18	TOTAL 2008-09 TO 2013-14	TOTAL 2008-09 TO 2017-18
25% cuts only	305.6	345.1	357.2	369.7	382.6	396.0	409.9	424.2	439.1	454.4	2,156.2	3,883.8
2% cuts only	10.9	12.3	12.7	13.2	13.6	14.1	14.6	15.1	15.6	16.2	76.8	138.3
25% and 2% cuts only	316.5	357.4	369.9	382.8	396.2	410.1	424.5	439.3	454.7	470.6	2,233.0	4,022.1
12.5% cuts only	0.8	0.9	1.0	1.0	1.0	1.1	1.1	1.2	1.2	1.2	5.9	10.6
Formula change only	-121.1	-136.7	-141.5	-146.4	-151.6	-156.9	-162.3	-168.0	-173.9	-180.0	-854.1	-1,538.3
Formula change and 25% and 2% price cuts	245.1	276.7	286.4	296.4	306.8	317.5	328.6	340.1	352.0	364.4	1,728.9	3,114.1
Formula change and 12.5% price cuts	0.8	0.9	0.9	1.0	1.0	1.0	1.1	1.1	1.1	1.2	5.6	10.0
Net other formula change	-43.5	-49.1	-50.8	-52.6	-54.4	-56.3	-58.3	-60.3	-62.4	-64.6	-306.6	-552.2
Impact of PBS reform	202.4	228.5	236.5	244.8	253.4	262.2	271.4	280.9	290.7	300.9	1,427.9	2,571.9
All changes	206.6	233.2	241.4	249.8	258.6	267.6	277.0	286.7	296.7	307.1	1,457.3	2,624.8

* Positive sign indicates savings to Government and/or patients; cost to supply chain participants

TABLE 3.1 PROJECTIONS OF PBS EXPENDITURE TO 2017-18, \$M

	2008-09	2009-10	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18
Base scenario – no change from June 2009	8,050.4	8,311.4	8,602.3	8,903.4	9,215.0	9,537.5	9,871.3	10,216.8	10,574.4	10,944.5
Base scenario – 12.5% cuts only	8,050.4	8,259.9	8,496.7	8,734.1	8,874.6	9,109.5	9,383.7	9,644.0	9,933.3	10,247.4
2% cuts in August 2009 and 2010 only plus 12.5% cuts	8,050.4	8,241.7	8,452.2	8,686.0	8,825.1	9,058.3	9,330.8	9,589.3	9,876.7	10,188.8
Price disclosure August 2009 only plus 12.5% cuts	8,050.4	8,247.7	8,483.0	8,719.9	8,859.9	9,094.3	9,367.9	9,627.7	9,916.4	10,229.9
Price disclosure after August 2009 plus 12.5% cuts	8,050.4	8,254.7	8,473.5	8,654.4	8,709.6	8,828.9	8,961.6	9,043.2	9,278.7	9,487.4
All price disclosure plus 12.5% cuts	8,050.4	8,242.5	8,459.8	8,640.2	8,694.8	8,813.6	8,945.8	9,026.9	9,261.8	9,469.9
All price disclosure plus 2% and 12.5% cuts	8,050.4	8,224.7	8,416.3	8,595.0	8,649.9	8,767.6	8,898.3	8,977.8	9,211.0	9,417.4
Competitive										
All price disclosure plus 2% and 12.5% cuts	8,050.4	8,221.7	8,404.1	8,540.3	8,576.8	8,674.5	8,700.3	8,624.3	8,832.8	8,956.9

TABLE 3.2 SAVINGS FROM PBS REFORM AND 12.5% PRICE CUTS, \$M

	2009-10	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18	TOTAL 2009-10 TO 2013-14	TOTAL 2009-10 TO 2017-18
1. 12.5% cuts only	51.5	105.6	169.3	340.3	428.0	487.6	572.8	641.1	697.1	1,094.7	3,493.2
2. 2% cuts in August 2009 and 2010 only	18.2	44.5	48.1	49.6	51.2	52.9	54.7	56.7	58.6	211.6	434.5
3. Price disclosure August 2009 only	12.2	13.7	14.2	14.7	15.2	15.8	16.3	16.9	17.5	70.1	136.6
4. Price disclosure after August 2009	5.2	23.2	79.7	165.1	280.6	422.1	600.8	654.6	760.0	553.7	2,991.3
5. All price disclosure	17.4	36.9	93.9	179.8	295.9	437.9	617.1	671.5	777.5	623.9	3,127.9
6. PBS reform	35.2	80.4	139.1	224.7	341.9	485.4	666.2	722.3	830.0	821.3	3,525.3
7. Combined 12.5% cuts and PBS reform	86.7	185.9	308.4	565.0	769.9	973.0	1,239.0	1,363.4	1,527.1	1,916.0	7,018.5
Competitive											
8. PBS reform	38.2	92.6	193.8	297.8	435.0	683.4	1,019.7	1,100.5	1,290.5	1,057.4	5,151.5
9. Combined 12.5% cuts and PBS reform	89.7	198.2	363.1	638.2	863.0	1,171.0	1,592.5	1,741.6	1,987.6	2,152.2	8,644.9

* Positive sign indicates savings to Government and/or patients; cost to supply chain participants

TABLE 3.3 SAVINGS FROM PBS REFORM AND 12.5% PRICE CUTS, MANUFACTURERS, \$M

	2009-10	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18	TOTAL 2009-10 TO 2013-14	TOTAL 2009-10 TO 2017-18
1. 12.5% cuts only	46.8	95.9	151.5	298.1	374.1	425.6	501.2	564.7	615.9	966.5	3,074.0
2. 2% cuts in August 2009 and 2010 only	16.0	39.2	42.3	43.7	45.1	46.6	48.2	49.9	51.7	186.3	382.7
3. Price disclosure August 2009 only	10.4	11.7	12.1	12.5	13.0	13.4	13.9	14.4	14.9	59.7	116.3
4. Price disclosure after August 2009	4.6	20.5	70.6	146.3	245.4	365.8	519.6	566.6	659.2	487.4	2,598.6
5. All price disclosure	15.0	32.2	82.7	158.8	258.4	379.3	533.5	581.0	674.1	547.1	2,714.9
6. PBS reform	30.6	70.3	122.0	197.8	298.4	420.5	576.1	625.1	719.6	719.1	3,060.4
7. Combined 12.5% cuts and PBS reform	77.4	166.2	273.5	495.9	672.5	846.1	1,077.4	1,189.8	1,335.6	1,685.6	6,134.4
Competitive											
8. PBS reform	33.1	80.1	168.2	260.0	377.1	588.5	880.2	950.9	1,119.3	918.5	4,457.4
9. Combined 12.5% cuts and PBS reform	79.9	176.1	319.7	558.1	751.2	1,014.1	1,381.4	1,515.6	1,735.2	1,885.0	7,531.3

* Positive sign indicates savings to Government and/or patients; cost to supply chain participants

TABLE 3.4 SAVINGS FROM PBS REFORM AND 12.5% PRICE CUTS, WHOLESALERS, \$M

	2009-10	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18	TOTAL 2009-10 TO 2013-14	TOTAL 2009-10 TO 2017-18
1. 12.5% cuts only	3.0	5.8	9.5	20.0	25.1	28.7	33.3	35.9	38.3	63.4	199.7
2. 2% cuts in August 2009 and 2010 only	1.0	2.5	2.7	2.8	2.9	3.0	3.1	3.2	3.4	12.1	24.8
3. Price disclosure August 2009 only	0.7	0.8	0.8	0.9	0.9	0.9	1.0	1.0	1.0	4.1	7.9
4. Price disclosure after August 2009	0.3	1.5	4.9	9.8	16.8	25.6	36.8	40.0	46.5	33.3	182.1
5. All price disclosure	1.1	2.3	5.7	10.6	17.7	26.5	37.8	41.0	47.5	37.3	190.1
6. PBS reform	2.1	4.8	8.2	13.1	20.2	29.2	40.6	43.8	50.4	48.5	212.4
7. Combined 12.5% cuts and PBS reform	5.1	10.6	17.7	33.1	45.3	57.9	73.9	79.8	88.7	111.8	412.1
Competitive											
8. PBS reform	2.2	5.5	11.4	17.5	25.8	41.4	63.1	68.0	79.7	62.5	314.7
9. Combined 12.5% cuts and PBS reform	5.3	11.3	20.9	37.5	50.9	70.2	96.4	103.9	118.1	125.9	514.4

* Positive sign indicates savings to Government and/or patients; cost to supply chain participants

TABLE 3.5 SAVINGS FROM PBS REFORM AND 12.5% PRICE CUTS, PHARMACISTS, \$M

	2009-10	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18	TOTAL 2009-10 TO 2013-14	TOTAL 2009-10 TO 2017-18
1. 12.5% cuts only	1.6	3.9	8.3	22.2	28.8	33.3	38.2	40.4	42.8	64.8	219.6
2. 2% cuts in August 2009 and 2010 only	1.2	2.8	3.0	3.1	3.2	3.3	3.4	3.5	3.6	13.2	26.9
3. Price disclosure August 2009 only	1.1	1.2	1.3	1.3	1.4	1.4	1.5	1.5	1.6	6.3	12.4
4. Price disclosure after August 2009	0.2	1.1	4.3	9.0	18.4	30.7	44.3	48.0	54.4	33.1	210.6
5. All price disclosure	1.3	2.4	5.5	10.4	19.8	32.2	45.8	49.5	56.0	39.4	222.9
6. PBS reform	2.5	5.3	8.9	13.8	23.3	35.8	49.5	53.4	60.0	53.8	252.4
7. Combined 12.5% cuts and PBS reform	4.2	9.2	17.2	36.0	52.1	69.0	87.7	93.8	102.8	118.6	472.0
Competitive											
8. PBS reform	2.9	6.9	14.2	20.4	32.1	53.5	76.5	81.7	91.4	76.5	379.6
9. Combined 12.5% cuts and PBS reform	4.6	10.8	22.5	42.6	60.9	86.8	114.7	122.2	134.3	141.3	599.2

* Positive sign indicates savings to Government and/or patients; cost to supply chain participants

TABLE 3.6 SAVINGS FROM PBS REFORM AND 12.5% PRICE CUTS, ORIGINATORS, \$M

	2009-10	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18	TOTAL 2009-10 TO 2013-14	TOTAL 2009-10 TO 2017-18
1. 12.5% cuts only	40.2	81.0	132.1	274.8	347.3	394.5	469.1	531.5	581.6	875.4	2,852.0
2. 2% cuts in August 2009 and 2010 only	12.1	29.9	32.3	33.3	34.4	35.5	36.8	38.1	39.4	142.0	291.7
3. Price disclosure August 2009 only	4.5	5.1	5.3	5.5	5.7	5.9	6.1	6.3	6.5	26.1	50.9
4. Price disclosure after August 2009	3.5	15.9	61.7	115.9	190.3	308.1	459.3	503.6	593.9	387.4	2,252.1
5. All price disclosure	8.0	21.0	67.0	121.4	196.0	314.0	465.3	509.9	600.4	413.5	2,303.1
6. PBS reform	20.0	50.2	96.8	151.0	226.4	345.3	497.8	543.4	635.1	544.4	2,566.0
7. Combined 12.5% cuts and PBS reform	60.2	131.2	228.9	425.9	573.7	739.9	966.8	1,074.9	1,216.6	1,419.8	5,418.0
Competitive											
8. PBS reform	21.5	56.1	137.3	202.3	293.8	501.6	789.8	856.8	1,022.0	710.9	3,881.1
9. Combined 12.5% cuts and PBS reform	61.6	137.1	269.4	477.1	641.1	896.1	1,258.9	1,388.3	1,603.5	1,586.3	6,733.1

* Positive sign indicates savings to Government and/or patients; cost to supply chain participants

TABLE 3.7 PROJECTIONS OF GOVERNMENT EXPENDITURE TO 2017-18, \$M

	2008-09	2009-10	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18
Base scenario – no change from June 2009	6,676.5	6,839.6	7,078.9	7,326.7	7,583.1	7,848.6	8,123.3	8,407.6	8,701.8	9,006.4
Base scenario – 12.5% cuts only	6,676.5	6,788.4	6,974.1	7,158.8	7,245.6	7,424.1	7,640.0	7,839.5	8,065.7	8,314.5
2% cuts in August 2009 and 2010 only plus 12.5% cuts	6,676.5	6,770.7	6,930.5	7,111.7	7,197.1	7,374.0	7,588.2	7,785.9	8,010.2	8,257.1
Price disclosure August 2009 only plus 12.5% cuts	6,676.5	6,776.6	6,960.7	7,144.9	7,231.3	7,409.2	7,624.6	7,823.6	8,049.3	8,297.5
Price disclosure after August 2009 plus 12.5% cuts	6,676.5	6,783.3	6,951.2	7,079.8	7,084.0	7,152.3	7,227.8	7,250.4	7,423.6	7,567.8
All price disclosure plus 12.5% cuts	6,676.5	6,771.4	6,937.8	7,065.9	7,069.7	7,137.4	7,212.5	7,234.5	7,407.2	7,550.8
All price disclosure plus 2% and 12.5% cuts	6,676.5	6,754.0	6,895.2	7,022.5	7,026.5	7,093.2	7,166.9	7,187.4	7,358.5	7,500.4
Competitive										
All price disclosure plus 2% and 12.5% cuts	6,676.5	6,751.0	6,883.7	6,974.7	6,962.3	7,009.5	6,979.0	6,849.1	6,996.0	7,057.2

TABLE 3.8 GOVERNMENT SAVINGS FROM PBS REFORM AND 12.5% PRICE CUTS, \$M

	2009-10	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18	TOTAL 2009-10 TO 2013-14	TOTAL 2009-10 TO 2017-18
1. 12.5% cuts only	51.1	104.8	167.9	337.5	424.5	483.3	568.1	636.1	691.9	1,085.9	3,465.4
2. 2% cuts in August 2009 and 2010 only	17.8	43.6	47.0	48.5	50.1	51.8	53.6	55.4	57.4	207.0	425.2
3. Price disclosure August 2009 only	11.8	13.4	13.8	14.3	14.8	15.3	15.9	16.4	17.0	68.2	132.9
4. Price disclosure after August 2009	5.1	22.9	79.0	161.6	271.8	412.1	589.1	642.1	746.7	540.5	2,930.5
5. All price disclosure	17.0	36.3	92.8	176.0	286.6	427.5	604.9	658.5	763.7	608.7	3,063.3
6. PBS reform	34.5	78.9	136.3	219.1	330.8	473.1	652.0	707.2	814.1	799.5	3,446.0
7. Combined 12.5% cuts and PBS reform	85.6	183.7	304.2	556.6	755.3	956.4	1,220.1	1,343.4	1,506.0	1,885.5	6,911.3
Competitive											
8. PBS reform	37.4	90.4	184.1	283.3	414.5	660.9	990.4	1,069.7	1,257.3	1,009.7	4,988.1
9. Combined 12.5% cuts and PBS reform	88.5	195.2	352.0	620.9	839.1	1,144.2	1,558.5	1,705.8	1,949.2	2,095.7	8,453.4

* Positive sign indicates savings to Government and/or patients; cost to supply chain participants

TABLE 4.1 SAVINGS FROM ALL PBS REFORMS AND 12.5% PRICE CUTS, \$M

	2008-09	2009-10	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18	TOTAL 2009-10 TO 2013-14	TOTAL 2009-10 TO 2017-18	
REFORMS IN AUGUST 2008													
1	25% and 2% cuts only	341.7	385.9	399.4	413.3	427.8	442.8	458.3	474.3	490.9	508.1	2,410.9	4,342.5
2	Formula change only	-124.7	-140.8	-145.8	-150.9	-156.1	-161.6	-167.3	-173.1	-179.2	-185.4	-879.9	-1,584.9
3	Impact of PBS reform	222.6	251.3	260.1	269.2	278.7	288.4	298.5	309.0	319.8	331.0	1,570.4	2,828.5
4	PBS On-line	-61.4	-65.8	-68.1	-70.5	-73	-75.5	-78.1	-80.9	-83.7	-86.6	-414.2	-743.5
5	\$1.50 dispensing incentive	-67.1	-75.7	-78.4	-81.1	-84	-86.9	-89.9	-93.1	-96.3	-99.7	-473.2	-852.3
REFORMS FROM JULY 2009 TO JUNE 2018													
6	12.5% cuts only		51.5	105.6	169.3	340.3	428.0	487.6	572.8	641.1	697.1	1,094.7	3,493.2
7	2% cuts in August 2009 and 2010 only		18.2	44.5	48.1	49.6	51.2	52.9	54.7	56.7	58.6	211.6	434.5
8	Price disclosure August 2009 only		12.2	13.7	14.2	14.7	15.2	15.8	16.3	16.9	17.5	70.1	136.6
9	Price disclosure after August 2009		5.2	23.2	79.7	165.1	280.6	422.1	600.8	654.6	760.0	553.7	2,991.3
10	All price disclosure		17.4	36.9	93.9	179.8	295.9	437.9	617.1	671.5	777.5	623.9	3,127.9
11	PBS reform		35.2	80.4	139.1	224.7	341.9	485.4	666.2	722.3	830.0	821.3	3,525.3
12	Combined 12.5% cuts and PBS reform		86.7	185.9	308.4	565.0	769.9	973.0	1,239.0	1,363.4	1,527.1	1,916.0	7,018.5
ALL REFORMS													
	All PBS reforms (3+4+5+11)	94.1	145.0	194.0	256.7	346.4	467.9	615.9	801.2	862.1	974.7	1,504.3	4,758.0
	All PBS reforms + 12.5% cuts (3+4+5+12)	94.1	196.5	299.5	426.0	686.7	895.9	1,103.5	1,374.0	1,503.2	1,671.8	2,599.0	8,251.2
MORE COMPETITIVE ASSUMPTIONS													
	All PBS reforms	94.1	148.0	206.2	311.4	419.5	561.0	813.9	1,154.7	1,240.3	1,435.2	1,740.4	6,384.2
	All PBS reforms plus 12.5% cuts	94.1	199.5	311.8	480.7	759.9	989.0	1,301.5	1,727.5	1,881.4	2,132.3	2,835.2	9,877.6

* Positive sign indicates savings to Government and/or patients; cost to supply chain participants

TABLE 4.2 COST OF PBS REFORMS TO SUPPLY CHAIN PARTICIPANTS, \$M

	2008-09	2009-10	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18	TOTAL 2009-10 TO 2013-14	TOTAL 2009-10 TO 2017-18
Manufacturers												
PBS reforms	289.3	357.2	408.4	471.9	559.9	673.2	808.4	977.6	1,040.7	1,149.7	2,759.9	6,736.3
PBS reforms plus 12.5% cuts	289.3	404.0	504.3	623.4	858.0	1,047.3	1,234.0	1,478.9	1,605.4	1,765.7	3,726.4	9,810.3
Wholesalers												
PBS reforms	21.8	26.7	30.2	34.5	40.4	48.4	58.4	70.8	75.1	82.8	202.1	489.1
PBS reforms plus 12.5% cuts	21.8	29.7	36.0	44.0	60.4	73.5	87.1	104.1	111.1	121.1	265.4	688.8
Pharmacists												
PBS reforms	-217.0	-238.9	-244.6	-249.7	-253.9	-253.7	-250.8	-247.3	-253.7	-257.8	-1,457.6	-2,467.4
PBS reforms plus 12.5% cuts	-217.0	-237.2	-240.7	-241.4	-231.7	-224.9	-217.6	-209.1	-213.3	-215.0	-1,392.8	-2,247.8
Originator manufacturers												
PBS reforms	140.3	178.4	214.1	266.5	326.6	408.2	533.4	692.5	744.9	843.7	1,534.1	4,348.6
PBS reforms plus 12.5% cuts	140.3	218.6	295.1	398.6	601.5	755.5	928.0	1,161.5	1,276.4	1,425.2	2,409.5	7,200.6

* Positive sign indicates savings to Government and/or patients; cost to supply chain participants

TABLE 4.3 GOVERNMENT SAVINGS FROM ALL PBS REFORMS AND 12.5% PRICE CUTS, \$M

	2008-09	2009-10	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18	TOTAL 2009-10 TO 2013-14	TOTAL 2009-10 TO 2017-18	
REFORMS IN AUGUST 2008													
1	25% and 2% cuts only	316.5	357.4	369.9	382.8	396.2	410.1	424.5	439.3	454.7	470.6	2,233.0	4,022.1
2	Formula change only	-121.1	-136.7	-141.5	-146.4	-151.6	-156.9	-162.3	-168.0	-173.9	-180.0	-854.1	-1,538.3
3	Impact of PBS reform	202.4	228.5	236.5	244.8	253.4	262.2	271.4	280.9	290.7	300.9	1,427.9	2,571.9
4	PBS On-line	-61.4	-65.8	-68.1	-70.5	-73	-75.5	-78.1	-80.9	-83.7	-86.6	-414.2	-743.5
5	\$1.50 dispensing incentive	-67.1	-75.7	-78.4	-81.1	-84	-86.9	-89.9	-93.1	-96.3	-99.7	-473.2	-852.3
Reforms from July 2009 to June 2018													
6	12.5% cuts only		51.1	104.8	167.9	337.5	424.5	483.3	568.1	636.1	691.9	1,085.9	3,465.4
7	2% cuts in August 2009 and 2010 only		17.8	43.6	47.0	48.5	50.1	51.8	53.6	55.4	57.4	207.0	425.2
8	Price disclosure August 2009 only		11.8	13.4	13.8	14.3	14.8	15.3	15.9	16.4	17.0	68.2	132.9
9	Price disclosure after August 2009		5.1	22.9	79.0	161.6	271.8	412.1	589.1	642.1	746.7	540.5	2,930.5
10	All price disclosure		17.0	36.3	92.8	176.0	286.6	427.5	604.9	658.5	763.7	608.7	3,063.3
11	PBS reform		34.5	78.9	136.3	219.1	330.8	473.1	652.0	707.2	814.1	799.5	3,446.0
12	Combined 12.5% cuts and PBS reform		85.6	183.7	304.2	556.6	755.3	956.4	1,220.1	1,343.4	1,506.0	1,885.5	6,911.3
ALL REFORMS													
	All PBS reforms (3+4+5+11)	73.9	121.5	168.9	229.5	315.5	430.6	576.5	758.9	817.9	928.7	1,340.0	4,422.1
	All PBS reforms + 12.5% cuts (3+4+5+12)	73.9	172.6	273.7	397.4	653.0	855.1	1,059.8	1,327.0	1,454.1	1,620.6	2,426.0	7,887.4
More competitive assumptions													
	All PBS reforms	73.9	124.4	180.4	277.3	379.7	514.3	764.3	1,097.3	1,180.4	1,371.9	1,550.2	5,964.2
	All PBS reforms plus 12.5% cuts	73.9	175.5	285.2	445.2	717.3	938.9	1,247.6	1,665.4	1,816.5	2,063.8	2,636.2	9,429.5

* Positive sign indicates savings to Government and/or patients; cost to supply chain participants

TABLE 5.1 NEW AND EXITING PBS MEDICINES, 1991-92 TO 2008-09

YEAR	NEW	EXITING	NUMBER AT JUNE
1991-92	29	9	536
1992-93	24	6	554
1993-94	24	29	549
1994-95	26	15	560
1995-96	20	23	557
1996-97	38	10	585
1997-98	34	23	596
1998-99	20	13	603
1999-00	28	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	19	16	672
2006-07	27	13	686
2007-08	26	6	706
2008-09	31	10	727
Average since 1991-92	25.4	13.7	
Average since 2004-05	25.0	12.2	

FIGURE 5.1 NEW AND EXITING PBS MEDICINES, NUMBER, 1991-92 TO 2008-09

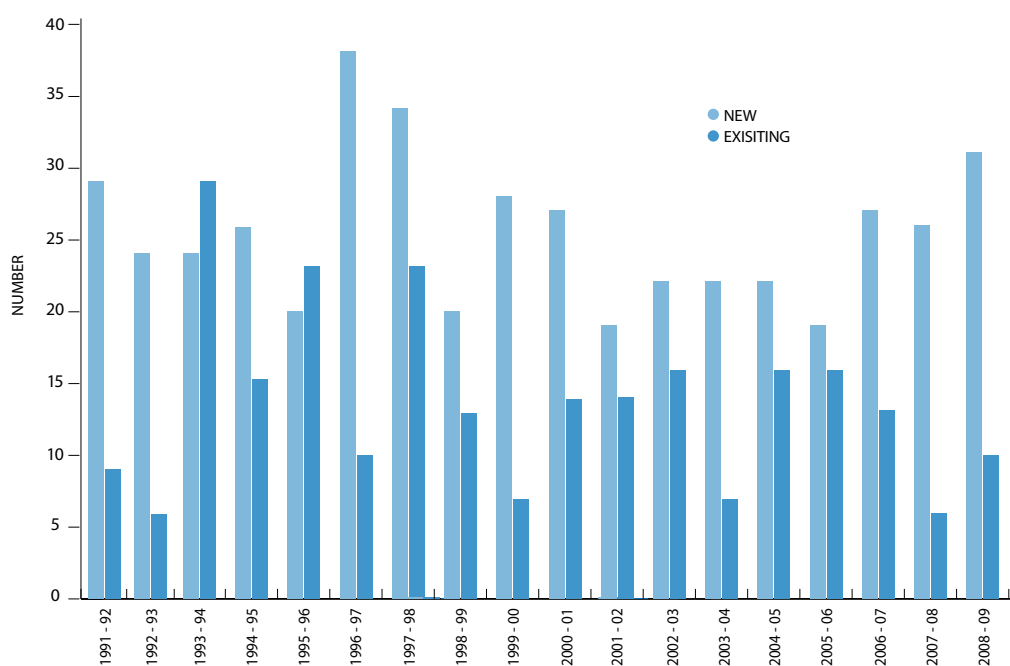


FIGURE 5.2 LAG BETWEEN FDA APPROVAL AND PBS LISTING, MONTHS

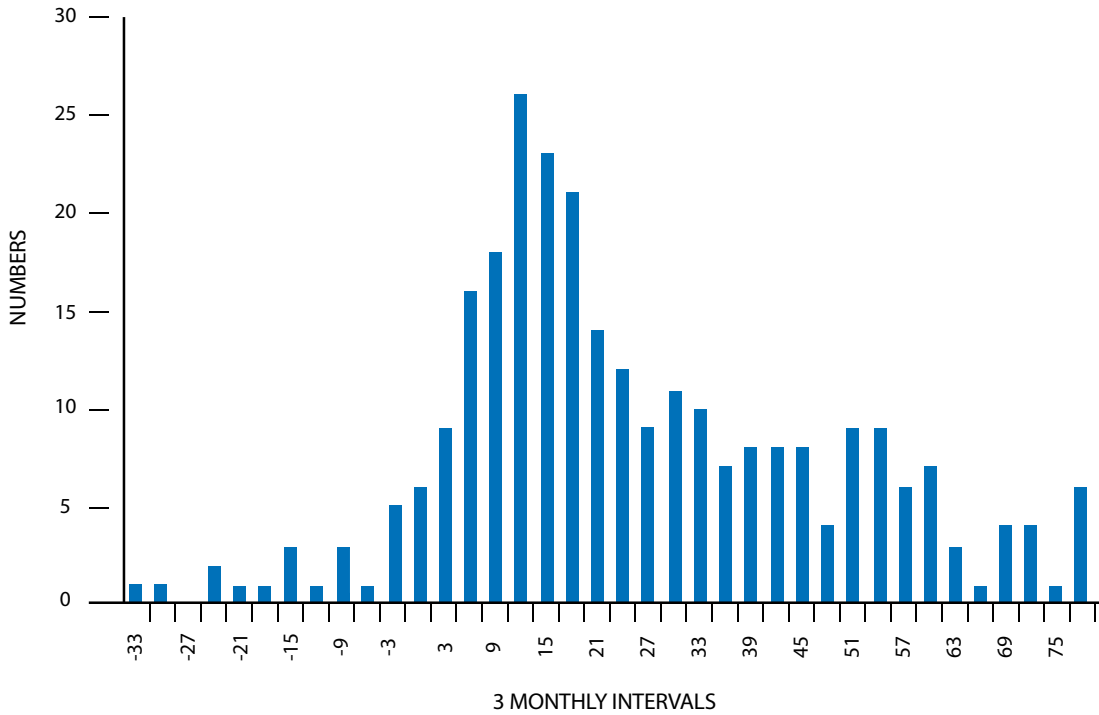


FIGURE 5.3 MEDIAN LAG BETWEEN FDA APPROVAL AND PBS LISTING, MONTHS, 1995 TO 2008

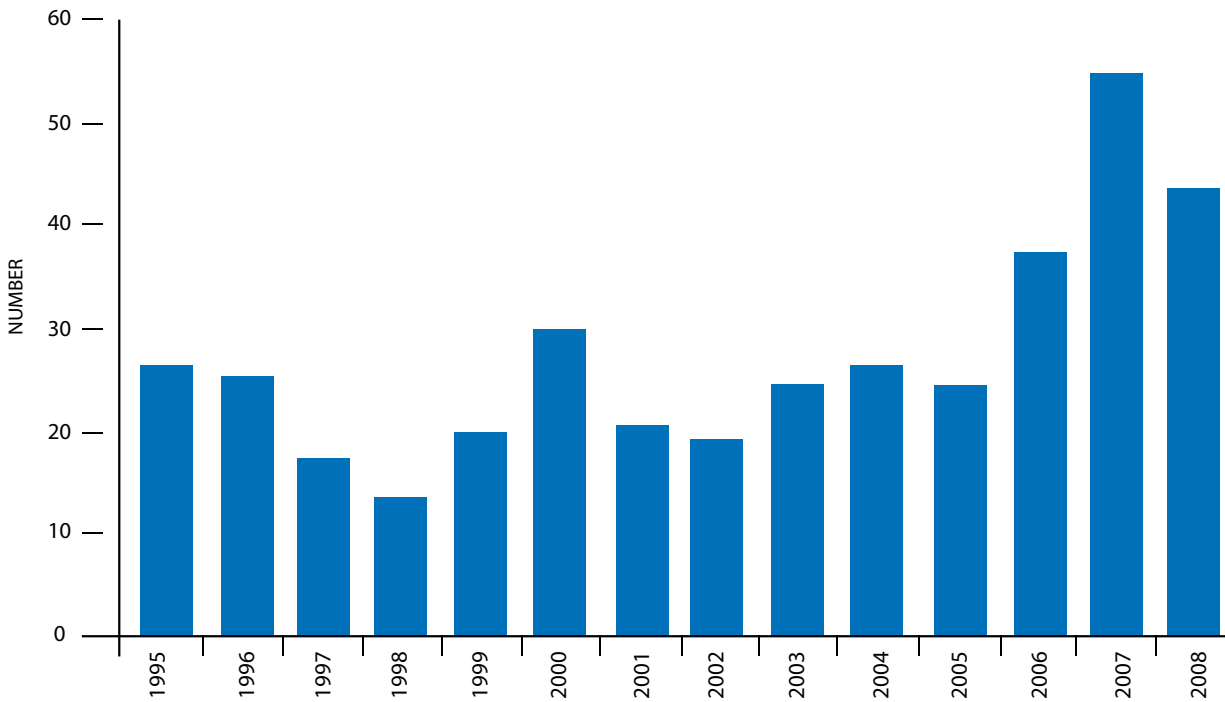


TABLE 5.2 MEDIAN LAG BETWEEN FDA APPROVAL AND PBS LISTING, MONTHS, 1995 TO 2008

YEAR	MEDIAN LAG
1995	26.5
1996	25.4
1997	17.4
1998	13.7
1999	20.3
2000	30.1
2001	20.7
2002	19.0
2003	24.9
2004	26.3
2005	24.5
2006	37.4
2007	55.2
2008	43.9

TABLE 5.3 PBS EXPENDITURE PER MEDICINE, 1991-92 TO 2007-08

YEAR	NUMBER OF MEDICINES	PBS EXPENDITURE \$M	PBS EXP PER MEDICINE \$M	GROWTH RATE %
1991-92	542	1,430.0	2.6	
1992-93	550	1,809.5	3.3	24.7
1993-94	564	2,137.5	3.8	15.2
1994-95	575	2,403.4	4.2	10.3
1995-96	582	2,765.3	4.8	13.7
1996-97	599	3,017.0	5.0	6.0
1997-98	629	3,287.7	5.2	3.8
1998-99	627	3,602.9	5.7	9.9
1999-00	631	4,083.3	6.5	12.6
2000-01	654	4,826.8	7.4	14.1
2001-02	656	5,305.1	8.1	9.6
2002-03	663	5,795.2	8.7	8.1
2003-04	670	6,381.0	9.5	9.0
2004-05	685	6,879.7	10.0	5.5
2005-06	687	7,129.7	10.4	3.3
2006-07	698	7,325.3	10.5	1.1
2007-08	717	7,943.4	11.1	5.6

TABLE 5.4 GROSS PBS EXPENDITURE ON NEW MEDICINES, \$M

	2008-09	2009-10	2010-11	2011-12	2012-13	2013-14
New in 2008-09	139.6	146.6	153.9	161.6	169.7	178.2
New in 2009-10		139.6	146.6	153.9	161.6	169.7
New in 2010-11			139.6	146.6	153.9	161.6
New in 2011-12				139.6	146.6	153.9
New in 2012-13					139.6	146.6
New in 2013-14						139.6
All new medicines	139.6	286.2	440.1	601.7	771.3	949.5

TABLE 5.5 AVERAGE PBS EXPENDITURE OF A NEW MEDICINE BY YEAR ON PBS, \$M

	SINCE 1992-93	SINCE 1998-99	SINCE 2001-02	SINCE 2002-03	SINCE 2003-04
First	3.0	4.0	3.3	3.5	3.3
Second	7.1	9.1	8.4	8.7	7.7
Third	9.5	12.2	11.2	11.3	8.8
Fourth	11.6	14.9	14.6	14.2	10.3
Fifth	13.4	17.6	19.9	20.5	17.8
Sixth	14.3	18.6	23.6	27.0	na
Seventh	14.2	16.4	18.2	na	na
Eighth	14.7	16.4	na	na	na
Ninth	14.4	13.4	na	na	na
Tenth	14.8	9.7	na	na	na

TABLE 6.1 SUPPLIERS TO THE PBS, NUMBERS AT AUGUST

AUGUST	RESEARCH	GENERIC	DIAGNOSTIC	OTHER	TOTAL
1991	69	15	3	5	92
1992	71	16	4	5	96
1993	76	17	4	6	103
1994	78	18	4	5	105
1995	81	17	4	5	107
1996	83	15	3	7	108
1997	79	17	3	9	108
1998	84	18	3	10	115
1999	83	20	4	10	117
2000	82	24	5	10	121
2001	81	28	5	11	125
2002	79	31	6	12	128
2003	80	31	5	12	128
2004	80	32	6	12	130
2005	79	34	8	13	134
2006	79	36	7	13	135
2007	76	40	10	12	138
2008	77	43	9	11	140
2009	77	47	10	10	144

TABLE 6.2 SUPPLIERS TO THE PBS, PERCENTAGE SHARES

AUGUST	RESEARCH	GENERIC	DIAGNOSTIC	SUPPLIER	TOTAL
1991	75.0	16.3	3.3	5.4	100.0
1992	74.0	16.7	4.2	5.2	100.0
1993	73.8	16.5	3.9	5.8	100.0
1994	74.3	17.1	3.8	4.8	100.0
1995	75.7	15.9	3.7	4.7	100.0
1996	76.9	13.9	2.8	6.5	100.0
1997	73.1	15.7	2.8	8.3	100.0
1998	73.0	15.7	2.6	8.7	100.0
1999	70.9	17.1	3.4	8.5	100.0
2000	67.8	19.8	4.1	8.3	100.0
2001	64.8	22.4	4.0	8.8	100.0
2002	61.7	24.2	4.7	9.4	100.0
2003	62.5	24.2	3.9	9.4	100.0
2004	61.5	24.6	4.6	9.2	100.0
2005	59.0	25.4	6.0	9.7	100.0
2006	58.5	26.7	5.2	9.6	100.0
2007	55.1	29.0	7.2	8.7	100.0
2008	55.0	30.7	6.4	7.9	100.0
2009	53.5	32.6	6.9	6.9	100.0

TABLE 6.3 PBS SCRIPTS BY TYPE OF SUPPLIER

	GENERIC	RESEARCH	OTHER	TOTAL	GENERIC	RESEARCH	OTHER
	MILLION	MILLION	MILLION	MILLION	%	%	%
1991-92	9.1	82.7	0.9	92.7	9.8	89.2	0.9
1992-93	11.3	92.8	0.7	104.8	10.8	88.5	0.7
1993-94	13.5	99.6	0.6	113.7	11.8	87.6	0.6
1994-95	12.3	104.6	0.6	117.5	10.5	89.0	0.5
1995-96	11.4	111.9	0.5	123.7	9.2	90.4	0.4
1996-97	13.8	109.2	0.3	123.3	11.2	88.6	0.2
1997-98	17.7	106.8	0.3	124.8	14.2	85.6	0.2
1998-99	21.1	107.6	0.3	129.0	16.4	83.4	0.2
1999-00	25.0	112.3	1.0	138.3	18.1	81.2	0.8
2000-01	28.5	118.5	1.3	148.3	19.2	79.9	0.9
2001-02	33.6	120.3	1.3	155.2	21.6	77.5	0.9
2002-03	38.6	118.7	1.3	158.6	24.3	74.8	0.8
2003-04	42.9	121.2	1.4	165.5	25.9	73.2	0.8
2004-05	47.9	120.8	1.4	170.1	28.2	71.0	0.8
2005-06	55.1	111.7	1.4	168.2	32.7	66.4	0.8
2006-07	57.3	110.8	1.3	169.5	33.8	65.4	0.8
2007-08	59.9	111.3	1.3	172.4	34.7	64.5	0.7

TABLE 6.4 PBS EXPENDITURE BY TYPE OF SUPPLIER

	GENERIC	RESEARCH	OTHER	TOTAL	GENERIC	RESEARCH	OTHER
	\$M	\$M	\$M	\$M	%	%	%
1991-92	85.4	1,329.8	14.8	1,430.0	6.0	93.0	1.0
1992-93	132.7	1,664.5	12.3	1,809.5	7.3	92.0	0.7
1993-94	162.5	1,963.2	11.9	2,137.5	7.6	91.8	0.6
1994-95	172.7	2,217.5	13.1	2,403.4	7.2	92.3	0.5
1995-96	182.0	2,572.1	11.2	2,765.3	6.6	93.0	0.4
1996-97	231.4	2,778.7	6.9	3,017.0	7.7	92.1	0.2
1997-98	307.6	2,971.7	8.4	3,287.7	9.4	90.4	0.3
1998-99	344.3	3,249.3	9.3	3,602.9	9.6	90.2	0.3
1999-00	384.6	3,679.8	19.0	4,083.3	9.4	90.1	0.5
2000-01	468.7	4,328.2	29.9	4,826.8	9.7	89.7	0.6
2001-02	605.0	4,666.2	34.0	5,305.1	11.4	88.0	0.6
2002-03	731.7	5,027.4	36.2	5,795.2	12.6	86.8	0.6
2003-04	842.4	5,500.9	37.7	6,381.0	13.2	86.2	0.6
2004-05	1,002.1	5,836.8	40.9	6,879.7	14.6	84.8	0.6
2005-06	1,276.0	5,812.4	41.3	7,129.7	17.9	81.5	0.6
2006-07	1,343.7	5,977.2	40.4	7,361.2	18.3	81.2	0.5
2007-08	1,395.3	6,507.2	40.4	7,942.9	17.6	81.9	0.5

TABLE 6.5 PBS SCRIPTS BY ORIGINATOR OR GENERIC BRANDS, MILLIONS, 1991-92 TO 2007-08

	GENERIC	ORIGINATOR	TOTAL	ORIGINATOR, %
1991-92	19.5	73.1	92.7	78.9
1992-93	22.1	82.8	104.8	79.0
1993-94	24.1	89.6	113.7	78.8
1994-95	25.1	92.4	117.5	78.7
1995-96	26.8	97.0	123.7	78.4
1996-97	27.9	95.3	123.3	77.3
1997-98	29.9	94.9	124.8	76.0
1998-99	33.6	95.5	129.0	74.0
1999-00	36.9	101.4	138.3	73.3
2000-01	39.8	108.5	148.3	73.1
2001-02	43.9	111.4	155.2	71.7
2002-03	46.5	112.1	158.6	70.7
2003-04	51.1	114.4	165.5	69.1
2004-05	55.6	114.5	170.1	67.3
2005-06	59.9	108.3	168.2	64.4
2006-07	61.4	108.1	169.5	63.8
2007-08	63.4	109.0	172.4	63.2

TABLE 6.6 PBS EXPENDITURE BY ORIGINATOR OR GENERIC BRANDS, \$M, 1991-92 TO 2007-08

	GENERIC	ORIGINATOR	TOTAL	ORIGINATOR, %
1991-92	184.6	1,245.4	1,430.0	87.1
1992-93	221.8	1,587.8	1,809.5	87.7
1993-94	257.2	1,880.3	2,137.5	88.0
1994-95	283.4	2,120.0	2,403.4	88.2
1995-96	321.5	2,443.8	2,765.3	88.4
1996-97	359.5	2,657.5	3,017.0	88.1
1997-98	410.5	2,877.2	3,287.7	87.5
1998-99	478.3	3,124.6	3,602.9	86.7
1999-00	548.9	3,534.4	4,083.3	86.6
2000-01	625.6	4,201.2	4,826.8	87.0
2001-02	739.6	4,565.5	5,305.1	86.1
2002-03	839.0	4,956.3	5,795.2	85.5
2003-04	944.6	5,436.4	6,381.0	85.2
2004-05	1,090.1	5,789.6	6,879.7	84.2
2005-06	1,342.8	5,786.9	7,129.7	81.2
2006-07	1,419.0	5,942.2	7,361.2	80.7
2007-08	1,494.4	6,448.5	7,942.9	81.2

TABLE 6.7 PREMIUMS FOR PBS ITEMS, NUMBER, 1991 TO 2009

AUGUST	BRANDS WITH PREMIUM	ITEMS WITH PREMIUM	ALL ITEMS	%
1991	115	99	1,335	7.4
1992	164	132	1,331	9.9
1993	188	157	1,374	11.4
1994	198	166	1,382	12.0
1995	233	205	1,595	12.9
1996	249	225	1,605	14.0
1997	265	246	1,664	14.8
1998	331	300	1,750	17.1
1999	354	318	1,814	17.5
2000	467	393	1,888	20.8
2001	420	368	1,958	18.8
2002	411	371	2,099	17.7
2003	416	382	2,075	18.4
2004	416	386	2,143	18.0
2005	454	422	2,220	19.0
2006	532	486	2,305	21.1
2007	517	483	2,368	20.4
2008	484	451	2,500	18.0
2009	504	472	2,743	17.2

TABLE 6.8 AVERAGE PREMIUM MARK-UP ON BASE PRICE, %, 1991 TO 2009

AUGUST	UNWEIGHTED	WEIGHTED
1991	10.7	4.5
1992	10.7	5.8
1993	13.8	6.8
1994	14.7	7.7
1995	14.0	7.2
1996	14.1	6.2
1997	13.7	3.9
1998	13.0	7.1
1999	13.9	5.9
2000	12.4	7.0
2001	14.8	6.8
2002	16.5	7.5
2003	17.8	8.8
2004	16.7	5.4
2005	16.0	6.2
2006	16.5	7.7
2007	16.9	8.2
2008	16.4	na
2009	17.3	na

FIGURE 6.1 PBS ITEMS WITH A PREMIUM, NUMBER, AT AUGUST, 1991 TO 2009

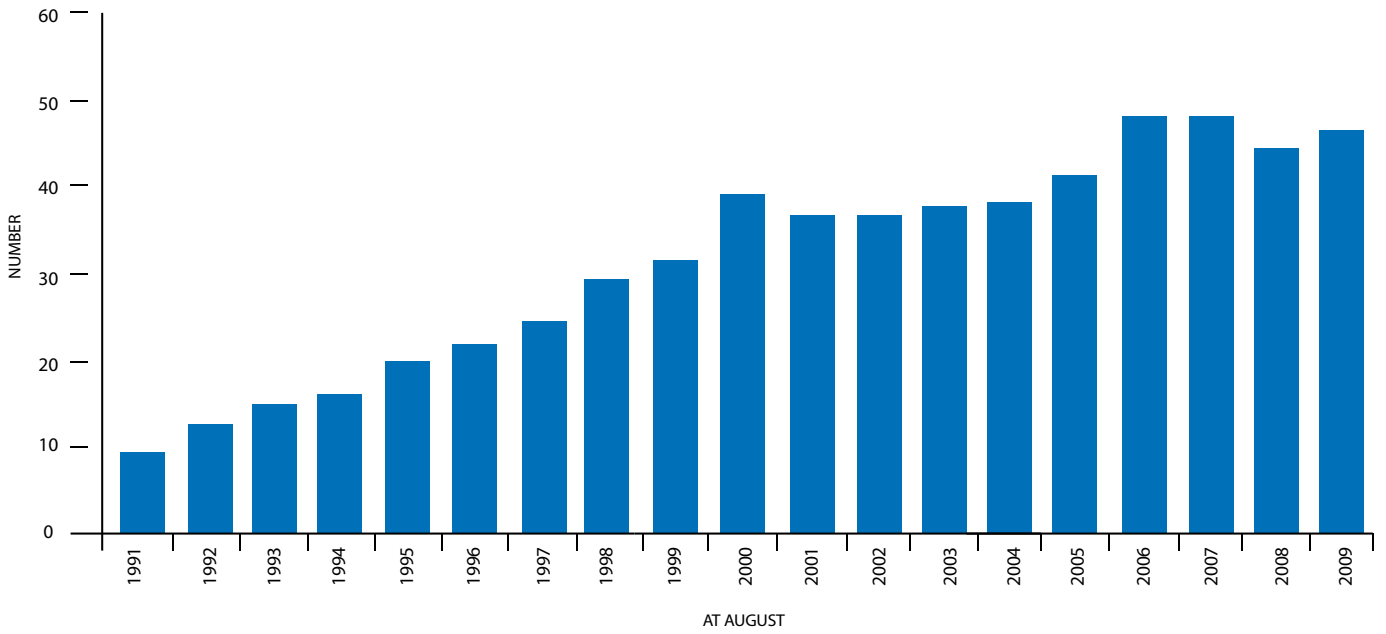


FIGURE 6.2 PBS ITEMS WITH A PREMIUM AS PERCENTAGE OF ALL ITEMS, AT AUGUST, 1991 TO 2009

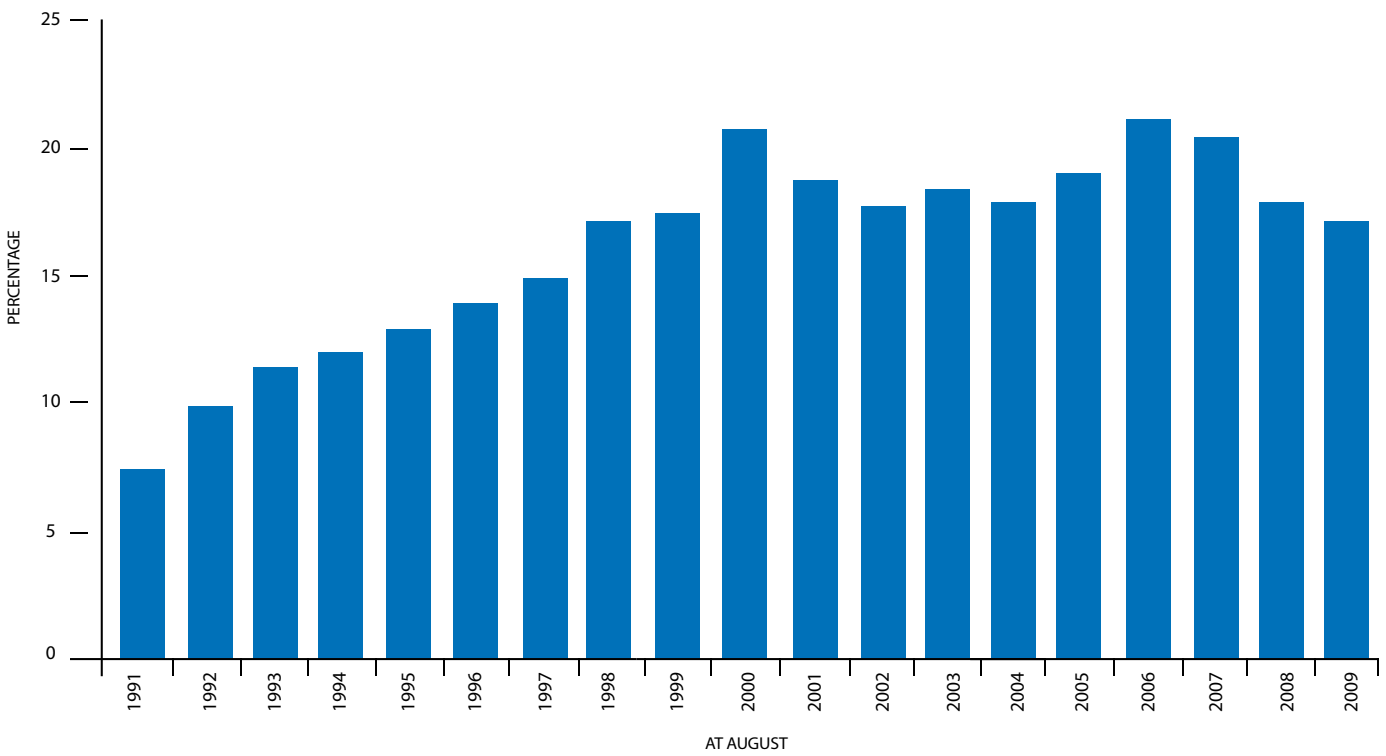


FIGURE 6.3 AVERAGE PREMIUM MARK-UP, UNWEIGHTED, %, 1991 TO 2009

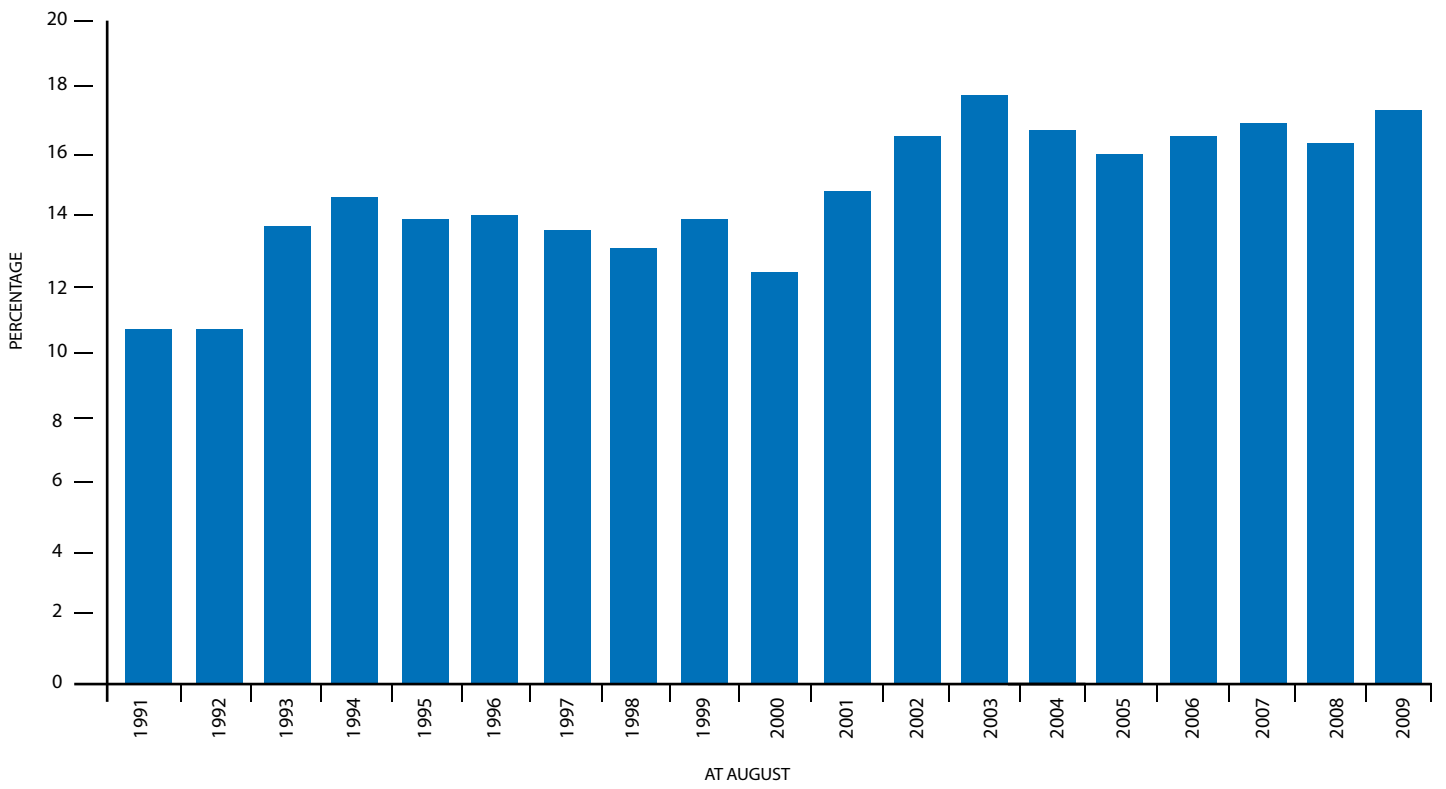


FIGURE 6.4 AVERAGE PREMIUM MARK-UP, WEIGHTED, %, 1991 TO 2009

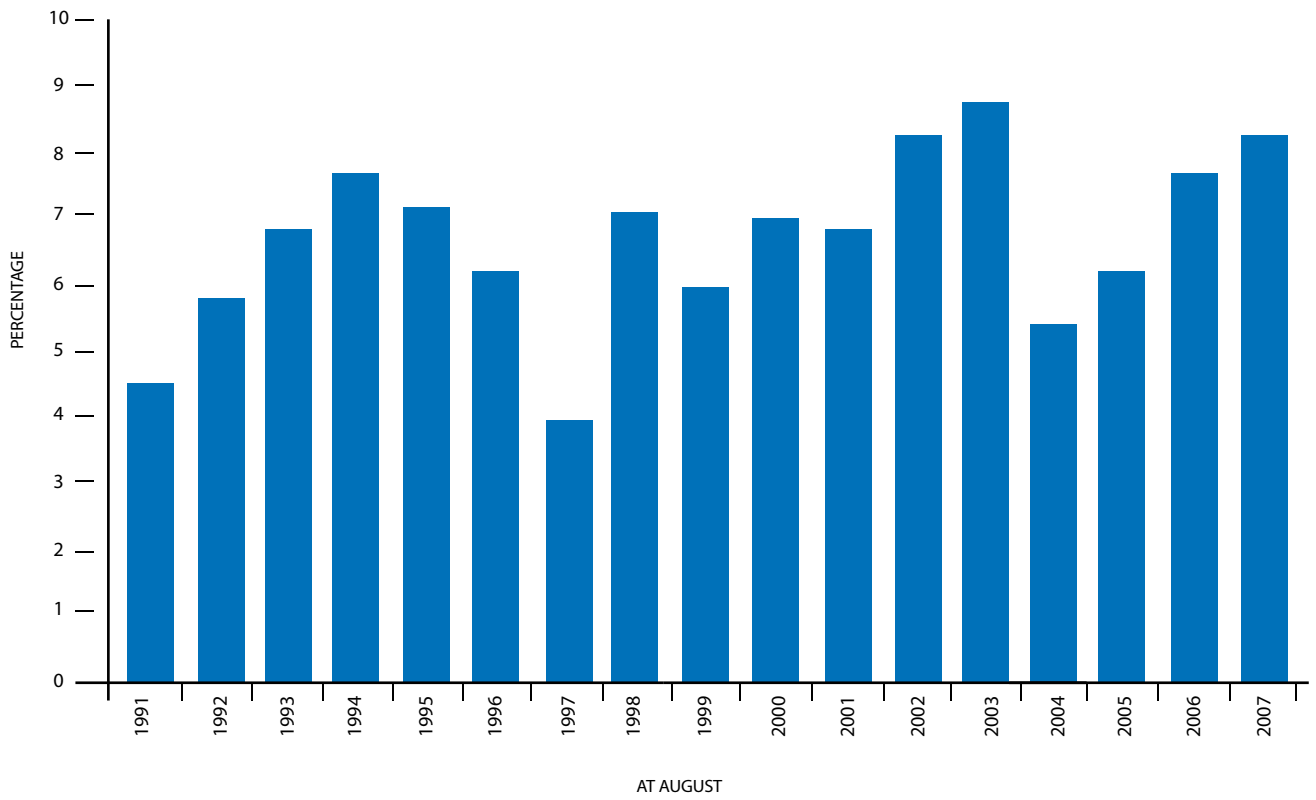


TABLE 7.1 GOVERNMENT PROJECTIONS OF GDP, GENERAL GOVERNMENT SECTOR PAYMENTS, PHARMACEUTICAL BENEFITS

	2007-08	2008-09	2009-10	2010-11	2011-12	2012-13	2013-14*
GDP growth rate, %		5.75	-1.5	3.75	6.25	6.75	5.0
Nominal GDP, \$m	1,132,172	1,197,272	1,179,313	1,223,537	1,300,008	1,387,759	1,457,147
Government payments, \$m	271,843	318,295	336,644	342,448	351,982	365,480	378,858
Payments as % GDP	24.0	26.6	28.5	28.0	27.1	26.3†	26.0
PBS**, \$m			7,870	8,400	8,913	9,377	
Pharmaceutical services and benefits, \$m	8,593	9,322	9,873	10,440	10,926	11,092	
PBS as % GDP	0.000	0.000	0.667	0.687	0.686	0.676	
Pharmaceutical services and benefits as %GDP	0.759	0.779	0.837	0.853	0.840	0.799	
PBS as % payments	0.000	0.000	2.338	2.453	2.532	2.566	
Pharmaceutical services and benefits as % payments	3.161	2.929	2.933	3.049	3.104	3.035	

* CSES Estimates

** Concessional, general and HSD only

Source: Treasury 2009, Budget Strategy and Outlook, Budget Paper No 1

TABLE 7.2 PROJECTIONS OF PBS EXPENDITURE AS % OF GDP AND GENERAL GOVERNMENT SECTOR PAYMENTS

	2007-08	2008-09	2009-10	2010-11	2011-12	2012-13	2013-14*
Nominal GDP, \$m	1,132,172	1,197,272	1,179,313	1,223,537	1,300,008	1,387,759	1,457,147
Government payments, \$m	271,843	318,295	336,644	342,448	351,982	365,480	378,858
Projections of PBS expenditure, \$m							
Base scenario – no change from June 2009	7,943.4	8,318.5	8,739.1	9,188.9	9,656.7	10,143.3	10,649.4
Base scenario – 12.5% cuts only	7,943.4	8,318.5	8,687.6	9,083.3	9,487.4	9,802.9	10,221.1
All PBS reforms	7,943.4	8,318.5	8,703.3	9,106.3	9,509.5	9,903.6	10,285.8
All PBS reforms plus 12.5% cuts	7,943.4	8,318.5	8,652.4	9,002.9	9,348.3	9,578.2	9,879.5
Projections of PBS as % of GDP, %							
Base scenario – no change from June 2009	0.702	0.695	0.741	0.751	0.743	0.731	0.731
Base scenario – 12.5% cuts only	0.702	0.695	0.737	0.742	0.730	0.706	0.701
All PBS reforms	0.702	0.695	0.738	0.744	0.731	0.714	0.706
All PBS reforms plus 12.5% cuts	0.702	0.695	0.734	0.736	0.719	0.690	0.678
Projections of PBS as % of government payments, %							
Base scenario – no change from June 2009	2.922	2.613	2.596	2.683	2.744	2.775	2.811
Base scenario – 12.5% cuts only	2.922	2.613	2.581	2.652	2.695	2.682	2.698
All PBS reforms	2.922	2.613	2.585	2.659	2.702	2.710	2.715
All PBS reforms plus 12.5% cuts	2.922	2.613	2.570	2.629	2.656	2.621	2.608

* CSES Estimates

Source: Treasury 2009, Budget Strategy and Outlook, Budget Paper No 1

APPENDIX:

SUMMARY OF MODELLING ASSUMPTIONS AND SENSITIVITY ANALYSIS

1. PBS REFORMS MODELLING ASSUMPTIONS AND RATIONALE

In charting the modelling assumptions to address uncertainties surrounding the future impacts of the PBS reforms, CSES and the Task force lead by Medicines Australia and industry experts performed information 'gap' analysis on the available information. The key unknowns were:

- Future demand for PBS medicines;
- Price disclosure particularly regarding the size and extent of price discounting in the market;
- Composition of F1 and F2 formulary over time; and
- New medicines listed on PBS over time.

The available information provided a starting point for addressing uncertainties surrounding these unknowns.

(i) Future demand for PBS medicines

Historical evidence around the average growth rate in prescriptions supplied to patients from community pharmacies over the last ten years was used to calculate the future demand for PBS medicines which was estimated at 3.5% per annum. This view of future growth was supported by IMS perspective on the Australian pharmaceutical market (not split by PBS vs non-PBS) trends for the last 5 years:

- on average annual 1.5% growth from new product introductions each year for the last 5 years;
- on average annual 6.5% volume growth of products each year for the last 5 years;
- on average an annual 1.5% decline for the last 5 years due to price decreases;
- on average annual growth of 7.8% for each year over the last 5 years.

Also, IMS Health expects total pharmaceutical market sales growth (PBS and non-PBS) of 3.5% for 2009 and over the next 2 to 3 years expects to see significant

product patent expiries which will keep growth at around the 3 to 4% level.

(ii) Composition of F1 and F2 formulary overtime

Based on broader consultation it was agreed that the composition of the F1 and F2 formularies over time would require assumptions around:

- Patent expiries;
- Timing of listing of trigger brands on the PBS;
- Movement of F1 members to F2A formulary;
- Timing of entry into price disclosure data collection cycle; and
- Final dates of disclosure price cut.

Patent expiries of current F1 members in the time period to 2017-18 were found from the IMS Patent Focus database. Based on market intelligence and historical evidence these dates provide a reasonable estimate of when a generic brand was likely to list on the PBS triggering the 12.5% price cut. However, assumptions had to be made about when and how soon the trigger brand will list on the PBS triggering price cut and movement of F1 member to F2A formulary.

Historically, generic listing on PBS is based on the attractiveness⁶ of the market. To estimate trigger dates, assumptions were made about the likelihood of generic entry. Based on market information and available historical evidence, it was concluded that bigger the volume of sales in the lead up to patent expiry higher the likelihood of generic entry triggering a price cut.

A threshold of \$5 million was considered appropriate for generic companies to consider a market attractive for entry. The rationale for this was based on premise that brands below \$5 million will not attract generics as the business cost would be prohibitive.

Based on these assumptions, all medicines on F1 formulary and F2 formulary that had not taken a 12.5% price cut and had annual sales of \$5 million dollars or more were considered candidates for future generic competition. Based on the current environment and with incentives in place to dispense generics over branded medicines, it was further agreed that a generic entry would occur sooner rather later. This was assumed to be in the month after the month in which the patent expires for the purposes of modelling the impact.

⁶ Attractiveness is based on overall sales and market size of a particular product at the time of patent expiry.

Timing of entry into price disclosure data collection cycle was established using the Pharmaceutical Benefits Scheme Price Disclosure Procedural and Operational Guidelines, issued by DoHA in July 2007. According to these guidelines, there are three annual data collection cycles. The data collection cycle that applies is the first data collection cycle after the listing of the brand that triggered disclosure. These cycles have start dates of:

- 1 January
- 1 May
- 1 September

Further according to guidelines, DoHA must notify industry six months before a price cut due to price disclosure will occur. The price change will occur at one of the two dates:

- 1 April
- 1 August

Based on these guidelines and the estimated trigger dates, a schedule of possible dates for price disclosure cuts was developed. Key elements of the schedule were

- trigger dates based on patent expiry dates;
- calculated real lag between listing on F2A and entry into a subsequent data collection cycles;
- 60 days allowance for voluntary disclosure post data collection;
- six months allowance for notification of price cut; and
- calculated real lag between when a price cut can occur based on the above mentioned dates.

Based on the schedule, the price cuts were expected to happen at least two years after the new brand entry but could vary depending on the month of listing.

(iii) Price disclosure-size and extent of price discounting in the market

The Taskforce in broader consultation with the industry estimated the size of the price disclosure cuts. Based on market intelligence and the broader industry view of anticipated market behaviour it was agreed that the size of discounting in the market will depend on the market size i.e. bigger the market size, higher the likelihood of discounting to gain or maintain market share.

A probabilistic model categorised by sales value in 2007-08 was used to estimate the size and likelihood of the disclosure price cuts. A probabilistic model was favoured over a deterministic model as the likelihood that the magnitude of price cut is subject to uncertainty. As yet there is little evidence to estimate the size of price disclosure price cuts.

The following tables provide key assumptions around the price disclosure used in modelling the impact. In the tables the range refers to PBS sales in 2007-08 and probability determines whether a particular size of cut occurs

- Existing F2A medicines
(excluding those medicines that have not taken 12.5% price cut)

CATEGORY	RANGE \$M	SIZE OF CUT	PROBABILITY
1	Over 150	20%	100%
2	100 to 150	20%	100%
3	50 to 100	20%	100%
4	25 to 50	20%	50%
5	10 to 25	15%	50%
6	5 to 10	15%	50%
7	1 to 5	No cuts	-
8	Less than 1	No cuts	-

- Existing F2T medicines
(excluding those medicines that have not taken 12.5% price cut)

CATEGORY	RANGE \$M	SIZE OF CUT	PROBABILITY
1	Over 150	15%	100%
2	100 to 150	15%	100%
3-8	Below 100	No cuts	

- A2RA (Angiotensin II receptors antagonist)
When they move from F1 to F2A, all are subject to a 12.5% cut.
- A new TGP for covering atorvastatin and rosuvastatin has recently been established.

(iv) *New medicines listed on PBS over time*

In broader consultation with the industry, it was acknowledged that new medicines 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. It was therefore agreed that most new entrants will therefore be exempt from the effects of PBS reform at least until 2016-17 hence would have marginal impacts on the reforms savings in the time period to 2017-18. For this purpose, new medicines were kept out of the reforms savings estimates in the modelling.

However it was recognised that new medicines will add to the overall PBS expenditure in future, so to predict the course of PBS expenditure over the next five years, impact of new medicines was estimated to 2013-14. CSES estimated the following based on historical data available.

- Number of new items added to the PBS formulary in the last five years – estimated at 25
- Number of medicines removed from the formulary each year – estimated at 13.
- Cost per medicine in 2007-08 – estimated at \$11.1 million per medicine
- Net increase in total PBS formulary – estimated 12-13 medicines per year

This information was then used to estimate the net effect of the new medicines on PBS expenditure in the time period to 2013-14.

2. SENSITIVITY ANALYSIS

Two main areas of uncertainty were subjected to further sensitivity analysis.

(i) *Price disclosure – size and extent of price discounting in the market was a key area of uncertainty.*

Two sets of assumptions were considered based on the market intelligence and broader consultation on the extent of anticipated price discounting in the market:

		CONSERVATIVE	COMPETITIVE	
CATEGORY	PBS SALES 2007-08 \$M	PRICE CUT %	PRICE CUT %	PROBABILITY
1	Over 150 million	20%	40.%	100
2	100 to 150 million	20%	40.%	100
3	50 to 100 million	20.%	20.%	100
4	25 to 50 million	20.%	20.%	50
5	10 to 25 million	15.%	15.%	50
6	5 to 10 million	15.%	15.%	50
7	Less than 5 million	0	0	0

Upper and lower values of the net savings under the two assumptions are summarised below. The lower values are the conservative best estimates using a lower percentage of price cuts anticipated by most originators. However, there is a feeling in the market that the rate of cuts could be much higher depending on how aggressively generics behave to capture a larger market share. It is also anticipated that the originators will respond aggressively to retain their share of the market. The upper value (competitive estimates) reflects this sentiment.

From the sensitivity analysis, it is clear that the Government would be better off by about \$210 million over the period to 2013-14 rising to \$1.5 billion in the ten years to 2017-18 if the market competition gets more aggressive.

Estimated net Government savings, \$ millions

	2008-09	2009-10	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18
Conservative (Lower value)	73.9	121.5	168.9	229.5	315.5	430.6	576.5	758.9	817.9	928.7
Competitive (Upper value)	73.9	124.4	180.4	277.3	379.7	514.3	764.3	1,097.3	1,180.4	1,371.9

(ii) Pharmacy compensation package – continuation of \$1.50 premium free fee and the 40 cents

The modelling assumes that the pharmacy compensation package continues unchanged across the time period to 2017-18. However, it is known that the revised compensation package that came into force on 1 August 2008 actually continues only until 30 June 2011 according to the Fourth Community Pharmacy Agreement. Beyond 30 June 2011 there are diverging views as to whether the Government will continue to provide compensation on the same terms or will negotiate a different arrangement. Historically, changes made during the course of an agreement are generally rolled into the next agreement.

Upper and lower values of the net savings to Government under the two assumptions are summarised below. The lower values are the best estimates of Government savings if the \$1.50 premium free fee and the 40 cents PBS Online fee are continued across the projected time period to 2017-18. The upper value shows the best estimates if the Government decides to stop incentivising the pharmacist for dispensing premium free items and for using PBS Online. According to available statistic, nearly all the pharmacies (99%) in Australia are now using PBS Online. From the sensitivity analysis, it is clear that the Government would be better off by about \$471 million over the period to 2013-14 rising to \$1.12 billion in the ten years to 2017-18.

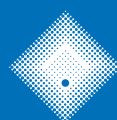
Effect of pharmacy compensation package on estimated net Government savings, \$ millions

	2008-09	2009-10	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18
With extension (Lower value)	\$73.9	\$121.5	\$168.9	\$229.5	\$315.5	\$430.6	\$576.5	\$758.9	\$817.9	\$928.7
Without extension (Upper value)	\$73.9	\$121.5	\$168.9	\$381.1	\$472.5	\$593.0	\$744.5	\$932.9	\$997.9	\$1,115.0

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