Department of Health and Ageing

The Impacts of Pharmaceutical Benefits Scheme Reform

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PricewaterhouseCoopers

Contents

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Executive Summary

This report provides financial estimates of the impacts of PBS reform, which result in savings to Government of between $3.6 billion to $5.8 billion.

This report examines the impact of Pharmaceutical Benefits Scheme (PBS) reforms in terms of:

- the net impacts on the Australian Government of additional direct expenditures and savings to Government;
- impacts on community pharmacy and pharmaceutical wholesalers;
- impacts on the pharmaceutical industry; and
- impacts on consumers who use PBS medicines.

Overall, we estimate over the ten years from 1 July 2008 to 30 June 2018, that the reforms result in savings between $3.6 billion and $5.8 billion for Government and between $0.6 billion and $0.8 billion for patients.

Overview of PBS reform

PBS reform enables the Commonwealth to obtain value from the discounting that results from competition between brands

PBS reform introduces structural changes to the pricing of PBS medicines to allow the Australian Government to obtain value from the discounting which occurs as a result of competition between brands in the supply of PBS medicines by manufacturers to pharmacy. This is irrespective of whether medicines are innovator or generic brands.

It follows a series of previous price measures introduced by the Government, such as the 12.5% price reduction policy introduced in 2005. These mandatory price reductions are triggered by the first application to list a new brand of medicine for a medicine which was previously a 'single brand' medicine.

Recent funding cost growth has been unsustainably high

PBS reform encompasses a specific range of initiatives over and above those mentioned above, designed to help ensure the sustainability of the PBS and moderate the significant growth in its funding cost, which averaged 8.9% per annum in the last six years and 9.2% in 2008-09, when the cost to Government was $7.65 billion.

The components of PBS reform include:

- the creation of F1 and F2 formularies, which removed the 'reference pricing' price links between single brand medicines that are not interchangeable with other drugs at the patient level, and all other drugs;
- the segregation of F2T and F2A subgroups, depending on the estimated trading discounts to pharmacy for particular drugs, with
  - medicines listed on F2T subject to a one-off 25% mandatory price reduction on 1 August 2008; and
  - medicines listed on F2A subject to staged price reductions of 2% per year for three years commencing on 1 August 2008.

PBS reform includes a range of measures to reduce the price of PBS listed medicines and promote more competitively priced pharmaceuticals

All drugs on the F1 and F2 formularies continue to be subject to the 12.5% price reduction policy, if triggered;

- price disclosure, to ensure that the price paid by Government for certain products listed on the PBS more closely reflects the price at which they are sold by suppliers to pharmacy;
- a three-part structural adjustment package to pharmacy to help them adjust to the new arrangements. This includes:
  - *the premium free incentive* – a fee paid to pharmacists when they dispense a premium free brand. As a result of negotiations around the Fifth Community Pharmacy Agreement, this policy has now been extended through to 30 June 2014. This payment only applies to PBS subsidised medicines (not under co-payment medicines or private scripts) and is indexed each year;
  - *the $0.40 online incentive fee*, which is an incentive of 40c for each prescription processed using PBS Online. As a result of negotiations around the Fifth Community Pharmacy Agreement, this incentive fee now expires on 30 June 2010; and
  - *increases in pharmacy mark-ups and dispensing fees* through changes in the dispensing formula. As a result of negotiations around the Fifth Community Pharmacy Agreement indexation of the dispensing fee has been frozen until 1 July 2012; and
- additional CSO funding of $69 million, which was added to the $150 million Community Services Obligation (CSO) Funding Pool established under the Fourth Community Pharmacy Agreement in 2006 to compensate pharmaceutical wholesalers for the additional cost they incur in providing the full range of PBS medicines.

Payments to pharmacy and wholesalers as part of the reforms offset some of the financial savings to Government

Modelling approach

To ensure that the measured impacts of PBS reform are genuinely incremental, a '*base case'* forecast scenario has been developed to estimate expected Government expenditure and supply chain impacts over the next 10 years in the absence of PBS reform.

This expenditure profile estimates the funding cost of the PBS and the distribution of costs and revenues across the industry that only takes into account previously announced changes that would have occurred without the specific range of measures contained in PBS reform. In particular, the base case includes the impact of the 12.5% price reduction policy and relevant aspects of the Fourth Community Pharmacy Agreement.

Against this, a '*with PBS reform'* forecast scenario has been developed that captures all specific PBS reform measures - both those that have already taken place and those that are due to take place up until 2017-18. This scenario also captures changes affecting the PBS that are measured in the base case.

The additional measures contained in the PBS reform scenario relate to further price reductions of PBS listed pharmaceuticals associated with price disclosure or mandated 25% or staggered 2% price cuts, and

Government incentives aimed at the promotion of more competitively priced pharmaceuticals and online prescription processing.

Growth in the volume of scripts written or dispensed has been forecast separately for each molecule until 2017-18, based on a structural time series model which extracts the relevant features of historic information to develop a forward looking trend.

We have estimated average annual volume growth of 3.8%, including the entry of new drugs over the forecast period. These estimated volumes are used to calculate the impact of the online incentive and the change in the dispensing fee. The forecast volumes used to calculate all other impacts of PBS reform exclude the new drugs – in effect, because we assume that newly-listed drugs will not come off patent during the projection period, the impact of the PBS reforms on these drugs will be minimal. Excluding new drugs, the annual average increase in volumes is 2.4%.

Key financial impacts

The key financial impacts estimated from the modelling are summarised below. Overall, the reforms are projected to save between $4.2 billion and $6.6 billion, depending on the impacts of price disclosure. This saving is shared by the ultimate funders of PBS, the Government and patients.

The financial impact of PBS reform on market participants will depend on changes in the trading terms that pharmacy is able to negotiate.

The expected impacts on market participants modelled in this report do not take into account any impact arising from changes in negotiated trading terms. They only estimate reductions in the components of PBS prices that are attributable to manufacturers, wholesalers, and pharmacy, and the payments to pharmacy and wholesalers that are part of PBS reform.

According to this analysis, the reduction in the manufacturers' component of PBS prices accounts for the majority of the PBS savings to government. The reduction in the wholesaler component of PBS prices is greater than the increase in the CSO for wholesalers, creating additional savings to government. The reduction in the pharmacy component of PBS prices is outweighed by the payments to pharmacy as a part of PBS reform, and pharmacy makes a net gain overall from the reforms in terms of payments from government. More detail on the impacts for each market participant follows.

Table 1: Summary of the net financial impacts 2008/09 to 2017/18 $million

	High price disclosure impacts	Low price disclosure impacts
Funders		
Saving to Government	$5,810.7	$3,619.5
Saving to patients	$802.5	$591.7
Total	$6,613.2	$4,211.1
Market Participants		
Reduction in the manufacturer component of PBS prices	-$8,496.2	-$6,390.6
Reduction in the wholesaler component of PBS prices	-$347.4	-$200.0
Impact on Government payments to pharmacy	$2,230.4	$2,379.4
Total	-$6,613.2	-$4,211.1

Key financial impacts for the Australian Government

Net financial savings to Government from PBS reform range from $3.6 billion to $5.8 billion, depending on price disclosure outcomes

The estimated net financial savings to Government as a result of PBS reform, after allowing for payments to pharmacy and wholesalers, range from $3.6 billion to $5.8 billion, depending on price disclosure outcomes (Table 2).

Table 2: Summary of the net financial impact of PBS reform on Government expenditure $million

	$million	$million
Mandatory Price Cuts		$4,648.9
2% cuts	*$142.1*	
25% cuts	*$4,506.8*	
Price disclosure – high estimate		$4,400.4
Price disclosure – low estimate		$2,209.1
Pharmacy structural adjustment package		-$2,991.2
Premium free incentive	*-$1,357.7*	
Online incentive	*-$154.9*	
Mark-up formula & dispensing fee changes	*-$1,478.7*	
Community Service Obligation		-$247.4
Total excluding price disclosure		**$1,410.4**
Total including price disclosure – high end		**$5,810.7**
Total including price disclosure – low end		**$3,619.5**

The savings from PBS reform are derived from:

- a one-off 25% mandatory price cut in the price to pharmacists of medicines on formulary F2T on 1 August 2008, which is phased in for Lercanidipine, Esomeprazole, Lansoprazole, Pantoprazole, and Rapeprazole over their remaining patent life;
- staged 2% price cuts in the price to pharmacists on formulary F2A which occurred in August 2008 and August 2009, and the final 2% cut that is yet to take effect on August 2010; and
- price disclosure.

These are partly offset by the impacts of the pharmacy structural adjustment package and the CSO for wholesalers. The net financial saving to Government, excluding price disclosure, is $1.4 billion. Price disclosure and the 25% price reductions account for the bulk of the financial savings to the PBS, as shown in Table 3. These results assume that the increase in the CSO Funding Pool and the $1.50 brand premium free incentive do not expire and continue over the forecast period.

These impacts are additional to those associated with earlier reforms which are included in the base case, such as the 12.5% cut in the price to pharmacists on entry of a new brand, risk sharing changes to the dispensing fee, and other non PBS reform price changes. The savings grow over time, as the volume of drugs impacted by the measures grows, and the impacts of price disclosure grow to offset the structural adjustment package measures.

Table 3: Savings to Government by year, by type of reform $million

	FY09	FY10	FY11	FY12	FY13	FY14	FY15	FY16	FY17	FY18	Total
Mandatory Price Cuts	$330	$387	$416	$442	$467	$492	$517	$525	$533	$541	**$4,649**
Price Disclosure (high end)	$0	$9	$38	$62	$121	$296	$578	$855	$1,117	$1,324	**$4,400**
Price Disclosure (low end)	$0	$9	$38	$49	$76	$157	$286	$415	$538	$640	**$2,209**
Pharmacy Structural Adjustment Package	-$369	-$371	-$279	-$260	-$267	-$274	-$282	-$289	-$296	-$303	**-$2,991**
CSO	-$23	-$23	-$23	-$24	-$24	-$25	-$25	-$26	-$26	-$27	**-$247**
Total (high end)	**-$61**	**$2**	**$151**	**$220**	**$296**	**$488**	**$787**	**$1,065**	**$1,327**	**$1,535**	**$5,811**
Total (low end)	**-$61**	**$2**	**$151**	**$207**	**$251**	**$350**	**$495**	**$624**	**$748**	**$851**	**$3,619**

Key financial impacts for manufacturers

Reductions in the manufacturers component of PBS prices provide savings to the PBS of between $6.4 billion to $8.5 billion, depending on the impacts of price disclosure

In this report, we estimate the impacts of PBS reform on pharmacy, wholesalers, and manufacturers which arise from changes in Government and patient expenditure on PBS drugs. Profitability and funding flows for these stakeholders is also significantly impacted by the trading terms negotiated between these various parties. The results presented in this report are limited to Government and patient expenditure only and do not reflect the impact of any changes in trading terms, which are uncertain but may be substantial.

The impact of PBS reforms is derived using the approved price to pharmacy (APP) as a starting point. Prices at different points in the supply chain are derived by deducting the known margins at each stage in the supply chain.

Under the reforms the reduction in the manufacturers' component of PBS prices is estimated to provide savings to the PBS of between $6.4 billion and $8.5 billion over the forecast period as a result of the mandatory price cuts and price disclosure (Table 4). Of this, the impact of mandatory 25% and 2% cuts represent the largest portion of the impacts on the manufacturers component of PBS prices – around $4.3 billion over the forecast period. Changes in trading terms with pharmacy are not included in these estimates, but will determine the overall impact on manufacturers.

Table 4: Impacts on manufacturers of PBS reforms $million

	FY09	FY10	FY11	FY12	FY13	FY14	FY15	FY16	FY17	FY18	Total
Mandatory 2% and 25% price reductions	-$299	-$352	-$381	-$407	-$433	-$460	-$487	-$497	-$508	-$520	**-$4,344**
Price disclosure – high estimate	-$0	-$8	-$34	-$54	-$107	-$270	-$536	-$802	-$1,063	-$1,279	**-$4,152**
Price disclosure – low estimate	-$0	-$8	-$34	-$43	-$67	-$142	-$263	-$384	-$503	-$602	**-$2,046**
Net impact – high estimate	**-$299**	**-$360**	**-$414**	**-$461**	**-$540**	**-$730**	**-$1,023**	**-$1,299**	**-$1,571**	**-$1,798**	**-$8,496**
Net impact – low estimate	**-$299**	**-$360**	**-$414**	**-$450**	**-$501**	**-$602**	**-$750**	**-$882**	**-$1,012**	**-$1,121**	**-$6,391**

Key financial impacts for pharmacy and wholesalers

Payments to pharmacy as part of PBS reform outweigh the reductions to the pharmacy component of PBS prices and net impacts on Government payments to pharmacy range from $2.2 billion to $2.4 billion over the forecast period depending on the impact of price disclosure

In contrast, PBS reform is estimated to have a positive impact on pharmacy as payments to pharmacy from the structural adjustment package outweigh the losses incurred as a result of the impact of the various price cuts and their flow-through impacts on pharmacy margins.

Over the period FY09 to FY18, PBS reforms are estimated to increase the net income to pharmacy by $2.2 billion to $2.4 billion depending on the impact of price disclosure (Table 5). Excluding price disclosure, the net impact of PBS reforms for pharmacy is $2.5 billion over the forecast period.

The pharmacy structural adjustment package accounts for the bulk of the payments to market participants as part of PBS reform, and more than offsets the estimated impacts of the mandatory price reductions and price disclosure, as shown in Table 5.

Again, these impacts reflect only Government and patient expenditure on PBS medicines. Pharmacist profitability is also impacted by the trading terms which they negotiate with manufacturers. Our estimates do not take into account any impact on pharmacists arising from changes in the trading terms they are able to negotiate.

Table 5: Impacts on pharmacy of PBS reforms $million

	FY09	FY10	FY11	FY12	FY13	FY14	FY15	FY16	FY17	FY18	Total
Brand premium free incentive	$120	$123	$126	$130	$134	$138	$142	$145	$149	$152	$1,358
Online incentive	$76	$79	$0	$0	$0	$0	$0	$0	$0	$0	$155
Changes to mark-up formula and dispensing fees	$173	$170	$153	$130	$134	$137	$140	$144	$147	$151	$1,479
Mandatory 2% and 25% price reductions	-$32	-$37	-$40	-$43	-$45	-$48	-$50	-$51	-$52	-$54	-$452
Price disclosure – high estimate	-$0	-$1	-$3	-$5	-$9	-$19	-$38	-$58	-$79	-$97	-$309
Price disclosure – low estimate	-$0	-$1	-$3	-$4	-$6	-$11	-$21	-$30	-$39	-$46	-$159
Net impact – high estimate	**$337**	**$333**	**$236**	**$212**	**$213**	**$208**	**$194**	**$179**	**$164**	**$153**	**$2,230**
Net impact – low estimate	**$337**	**$333**	**$236**	**$213**	**$217**	**$215**	**$211**	**$208**	**$205**	**$204**	**$2,379**

The reduction in the wholesaler component of PBS prices ranges from $0.2 billion to $0.3 billion between FY09 and FY18 as a result of PBS reform

The impacts of PBS reform on wholesalers are quite different. Wholesalers are affected by PBS reform because the lower agreed manufacturers' prices, as a result of the mandatory price cuts and price disclosure impact on wholesaler margins.

The $69 million increase in the CSO Funding Pool is provided to compensate CSO Distributors for the reduction in revenues they would receive as a result of the PBS pricing reforms. However, the increase in the CSO does not outweigh wholesalers' reduction in margins.

As a result, the notional net financial loss for wholesalers ranges from $0.2 billion to $0.3 billion over the forecast period depending on the impact of price disclosure. The most significant impact for wholesalers comes as a result of the mandatory price cuts (Table 6).

Table 6: Impacts on wholesalers of PBS reforms $million

	FY09	FY10	FY11	FY12	FY13	FY14	FY15	FY16	FY17	FY18	Total
Mandatory 2% and 25% price reductions	-$21	-$25	-$27	-$28	-$30	-$32	-$34	-$35	-$36	-$36	**-$304**
Price disclosure – high estimate	-$0	-$1	-$2	-$4	-$7	-$19	-$38	-$56	-$74	-$90	**-$291**
Price disclosure – low estimate	-$0	-$1	-$2	-$3	-$5	-$10	-$18	-$27	-$35	-$42	**-$143**
CSO	$23.0	$23.0	$23.5	$23.9	$24.4	$24.9	$25.4	$25.9	$26.4	$26.9	**$247.4**
Net impact – high estimate	**$2**	**-$2**	**-$6**	**-$8**	**-$13**	**-$26**	**-$46**	**-$65**	**-$84**	**-$99**	**-$347**
Net impact – low estimate	**$2**	**-$2**	**-$6**	**-$8**	**-$11**	**-$17**	**-$27**	**-$36**	**-$44**	**-$52**	**-$200**

Key financial impacts for patient contributions

Overall patients receive savings on PBS listed medicines of $0.6 billion to $0.8 billion, depending on the impact of price disclosure

Patients pay a fixed co-payment plus any brand price premium towards the dispensed price of any PBS listed medicine. Patients will benefit directly from PBS reform when it results in medicine prices that fall below the maximum co-payment threshold, which varies depending on the patient group.

For patients classified as Concession Free Safety Net + RPBS (Free Safety Net), PBS reform has no impact because they do not contribute to the cost of purchasing PBS listed medicines and any cost savings flow to Government.

Most of the benefits to patients accrue to those classified as PBS – General – Ordinary as a result of medicines falling below the maximum copayment level of $33.30. Derived mainly from mandatory price reductions and price disclosure impacts, savings for patients range from $0.6 billion to $0.8 billion, depending on the impact of price disclosure (Table 7).

Table 7: Impacts on patients of PBS reforms $ million

	FY09	FY10	FY11	FY12	FY13	FY14	FY15	FY16	FY17	FY18	Total
Mandatory 2% and 25% price reductions	$21	$27	$32	$36	$42	$48	$55	$59	$64	$69	**$452**
Price disclosure – high estimate	$0	$0	$1	$1	$3	$12	$33	$61	$100	$141	**$351**
Price disclosure – low estimate	$0	$0	$1	$1	$2	$6	$16	$26	$39	$49	**$140**
Net impact – high estimate	**$21**	**$27**	**$32**	**$37**	**$45**	**$60**	**$87**	**$120**	**$163**	**$209**	**$802**
Net impact – low estimate	**$21**	**$27**	**$32**	**$37**	**$44**	**$54**	**$70**	**$85**	**$103**	**$118**	**$592**

Key assumptions

The impacts of PBS reform have been modelled based on various assumptions regarding discounting behaviour and underlying volume and price growth.

The assumptions used that are common to both the base case and the PBS reform case are shown in Table 8.

The additional assumptions used to estimate the impact of PBS reform are shown in Table 9. One of the most uncertain aspects of PBS reform is the impact of price disclosure. This uncertainty arises because the weighted average disclosed price (WADP) is significantly influenced by the market players who opt in to price disclose. It is also uncertain what impact price disclosure will have on trading terms and incentives, which will directly impact the actual price to pharmacists, and therefore profitability, and hence the impact of price disclosure on market participants. The impacts of price disclosure estimated in this report do not take account of any impact on pharmacists arising from changes in the trading terms, which are subject to negotiation.

Assumptions regarding price disclosure are based on analysis of the timing of new entrants over the past 5 years, and the presence of competitors for molecules of varying market size, and estimates of discounts available in the market. We note that:

- Within two years of coming off patent, and weighted by expenditure, 90% of the molecules had a competitor in the market. The likelihood of having a competitor enter the market varies by market volume.
- The extent of discounting available in the market is uncertain, and can vary considerably by drug. We note that the price reductions to be applied as a result of previously announced price disclosure discounts, including those where no reduction is to be applied, are 14% on average.

- We would expect the impacts of price disclosure to be achieved gradually over time, as prices are adjusted in response to previous price disclosure impacts, market share of originators and other manufacturers change, and the WADP is re-calculated year on year. Market share of an originator brand declines over the first four years after a competitor enters the market. The market share for originators is lower overall for large volume drugs, and hence we would expect large volume drugs to achieve higher discounts.

Table 8: Key assumptions common to the base case and PBS reform case

Variable	Assumption
Average annual growth in scripts written or dispensed FY09 to FY18	3.8% (including new listings). 2.4% (excluding new listings)
New medicines listed FY09 to FY18 that do not come off patent	13 per year, with an average cost to Government and patient of $12.2 million (increasing by 5% per annum) and with volume of 260,000 scripts on average.
Timing of drugs coming off patent and entry of new brands that trigger the 12.5% price reduction policy	F1 drugs currently greater than $10 million expire at current best estimate of patent expiry date. These are known to spike in 2012-13. Other F1 drugs currently less than $10 million, or for which expiry dates are unknown, are assumed to expire over the next 6 years (one sixth of this group expire each year). New entrants emerge for 80% of low sales molecules (less than $2 million per annum), and for all molecules with annual sales over $2 million. New entrants emerge 1 month after patent expiry (except for Atorvastatin (Lipitor) which is minus 2 months as agreed with Ranbaxy) 12.5% price reduction policy takes affect at the next available April, August, or December price change point.
Indexation	2% forecast WCI9 is applied to index the dispensing fee and the community service obligation. 2.5% forecast CPI growth is applied to patient co-contributions.

Table 9: Key assumptions underpinning the PBS Reform case

Variable	Assumption
Price disclosure timing	Price disclosure discounts occur a minimum of 2 years after the price disclosure mechanism is first triggered by a new entrant, at the next April or August price adjustment date following that 2 years.
Price disclosure triggers for existing F2 formularies	Probabilities of a new competitor emerging to trigger price disclosure depend on market size are: • 100% for drugs with sales over $100 million • 75% for drugs with sales $50 million to $100 million • 40% for drugs with sales $2 million to $50 million
Price disclosure impacts – F1 drugs shifting onto F2	Price disclosure impacts are assumed to be achieved gradually over the first four years after a drug comes off patent: Discounts vary by volume of sales as per below: **High Estimate assumes the following average discounts** • 40% for molecules with sales greater than $100 million • 18% for molecules with sales between $50 million to $100 million • 16% for molecules with sales less than $50 million **Low Estimate assumes the following average discounts** • 18% for molecules with sales greater than $100 million • 9% for molecules with sales between $50 million to $100 million • 7% for molecules with sales less than $50 million
Price disclosure impacts – Current F2 drugs	Price disclosure impacts are assumed to be achieved gradually over the first four years for those drugs for which price disclosure is triggered. Discounts vary by volume of sales as per below: **High Estimate assumes the following average discounts** • 20% for molecules with sales greater than $100 million • 9% for molecules with sales between $50 million to $100 million • 7.5% for molecules with sales less than $50 million **Low Estimate assumes the following average discounts** • 15% for molecules with sales greater than $100 million • No reductions for drugs with sales below $100 million
Dispensing Fee	Fee assumed to be held constant until 30 June 2012, then indexed each year at WCI9 (2%)

Variable	Assumption
Online incentive	Utilisation assumed to be maintained at 98%, and to conclude on 30 June 2010.
Brand premium free incentive	Assumed to be maintained throughout the forecast period.
Additional CSO	The additional CSO is assumed to be $23 million per annum until 2009/10, then increase in line with WCI9 (2%).

Glossary and definitions

Abbreviation	Definition
APP	Approved price to pharmacists Approved price to pharmacists means: a if a price agreement is in relation to the brand of the PBS item – the amount in force under agreement as the amount that is taken to be the appropriate maximum price for sales of the brand of the PBS item to approved pharmacists; or b if a price determination is in force in relation to the brand of the PBS item the amount in force under the determination as the amount that is taken to be the appropriate maximum price for sales of the brand of the PBS item to approved pharmacists
Bioequivalent	Bioequivalent as determined by the Therapeutic Goods Administration
Brand	Brand of a pharmaceutical item means: a the trade name under which the person who is or will be the responsible person supplies the pharmaceutical item; or b if there is no trade name, the name of the person who is or will be the responsible person
CSO	Community Services Obligation
DoHA	Department of Health and Ageing
Drug	A drug or medicinal preparation in relation to which a declaration under subsection 85(2) of the *National Health Act 1953* is in force
DVA	Department of Veterans' Affairs
F1 formulary	F1 will contain drugs that: • Have only one brand of each form and strength listed on the PBS; and • Are not interchangeable at the patient level with a drug that has multiple brands listed on the PBS (i.e. not part of a therapeutic group that has multiple brands).
F2 formulary	F2 will contain all drugs that do not meet the criteria for F1.

Abbreviation	Definition
F2A formulary	The F2A formulary consists of all drugs listed on Part A of the F2 formulary in the *National Health (Pharmaceutical Benefits) Regulations*, or that the Minister has determined are in Part A of the F2 formulary under section 85AC of the *National Health Act 1953*. The F2A formulary ceases to exist on 1 January 2011.
GDP	gross domestic product
Generic drug	A drug that is bioequivalent to a drug that has a brand name with the same active ingredients
GoS	Guarantee of supply
Incentive	An incentive is some benefit which is offered to encourage a purchase to be made of the disclosing brand or a product range which includes the disclosing brand. These include both monetary and non-monetary benefits.
Innovator drug	The first formulation of a new drug to come on the market, which has a brand name
Mandatory brand	Any new brand that must participate in price disclosure arrangements. This includes the trigger brand and any subsequent mandatory brands.
New brand	A new brand of a drug already listed on the PBS, which is bioequivalent to a form and strength of an existing brand (or in the case of biologicals, 'biosimilar' to an existing brand, but this will not always be the case.
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefits Scheme
PBS item	A particular form and strength of a drug covered by a unique PBS item code
Responsible person	Responsible person for a brand of a pharmaceutical item means the person determined by the Minister under section 84AF of the *National Health Act 1953* to be the responsible person for the brand of the pharmaceutical item. This is a legal term and in many cases it will be referring to an entity, such as a company, rather than an individual.
RPBS	Repatriation Pharmaceutical Benefits Scheme

Abbreviation	Definition
RPG	Reference Pricing Group
Sales revenue	Sales revenue is the revenue which is generated from the sale of the disclosing brand. The methods used by the responsible person to define sales and recognise and measure revenue for price disclosure purposes should be consistent with the responsible person's financial accounting policies.
TGA	Therapeutic Goods Administration
TG	Therapeutic Group This means a group of drugs which have been determined to be interchangeable at the patient level.
The Department	The Department of Health and Ageing.
Trigger brand	The first new brand for a manner of administration for a drug that must comply with price disclosure arrangements.
WADP	Weighted average disclosed price

1 Essential features of PBS reform

Government expenditure on the PBS is currently 0.7% of gross domestic product (GDP) having grown at 8.9% per annum in the last six years and 9.2% in 2008-09, to $7.65 billion.[1]

In part this is due to an increase in prescriptions, which have grown at 2.9% per annum over the last ten years because of population growth, an ageing population and the escalation of chronic disease. In 2008-09 8.4 scripts were written per head of population.

The funding cost of the PBS has outstripped growth in prescriptions due to price increases associated with new technology and innovations, and strong growth in the number of concession card holders.

Finding a way to support important health care provision while making PBS expenditure sustainable into the future remains a major challenge for Government. In response to this the Government in 2006 embarked on a series of PBS reforms. This report assesses the impact of these reforms to date, as well as the likely impact over the next ten years.

Previous cost containment measures

Prior to PBS reform the major methods for containing the cost of the PBS were to agree prices with manufacturers and with pharmacy on the mark-ups they and wholesalers would receive.

The PBS attempted to negotiate the lowest price possible directly with manufacturers via the Pharmaceutical Benefits Advisory Committee (PBAC). Many medicines are on patent, so to arrive at fair prices the PBAC grouped drugs with others that treated the same health outcome to form Reference Pricing Groups (RPGs) and compared the cost effectiveness of different treatments.

Reimbursement to pharmacy and wholesalers is negotiated separately in the Community Pharmacy Agreements which fix the mark-up that pharmacy and wholesalers were to receive on the agreed prices.

In 2005, the Government introduced price measures to improve the sustainability of the PBS, such as the 12.5% price reduction policy, which is triggered by the first application to list a new brand of medicine for a medicine which was previously a ‘single brand’ medicine, be they:

- new versions of medicines where the patent for the original medicine has expired, or
- new pseudo generic medicines, which are new versions of medicines which are still on-patent, marketed by the patent holder or by another sponsor under an arrangement with the patent holder.

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[1] Department of Health and Ageing Annual Report 2008-09.

These price cuts were designed to take advantage of the advent of generic medicines which are non-innovative drugs produced to contain the same active ingredient as another drug that has come off-patent.

Initially the price cuts flowed onto all versions of the drug with the same active ingredient and *other* medicines treating the same health outcome. That is, the price cuts are applied to all drugs in a Reference Pricing Group (RPG) and the price cuts applied to all of these drugs as long as they were administered in the same way.

DoHA made special provision for drugs which were combination medicines, or where the generic drug was not licensed for all clinical applications. This means that the reduction in price for some medicines considered the weighted average of the reduced price and old price, by clinical use. In effect, for some medicines the price cut was less than the full 12.5%.

It was mandatory for any new PBS listings to offer at least a 12.5% discount to the existing PBS price for drugs in the same RPG (the 12.5% cuts could be applied a maximum of once for any RPG).

The 12.5% mandatory price cuts guaranteed that on entry to the PBS generic medicines offered a saving to the Government. Many generic manufacturers offer pharmacy and wholesalers further large discounts and favourable trading terms to incentivise pharmacy purchasing. Pharmacy and wholesalers profited from these terms of business while generic manufacturers had little incentive to offer Government discounts over 12.5%.

The essential features of PBS reform

PBS reform was introduced to allow the Government to obtain value from the discounting that occurred between competing brands, irrespective of whether they are generic or innovator brands.

The major components of PBS reform have included:

- the creation of F1 and F2 formularies, which removed the 'reference pricing' price links between single brand medicines that are not interchangeable with other drugs at the patient level, and all other drugs;
- the segregation of F2T and F2A subgroups, depending on the estimated trading discounts to pharmacy for particular drugs, with
  - medicines listed on F2T subject to a one-off 25% mandatory price reduction on 1 August 2008; and
  - medicines listed on F2A subject to staged price reductions of 2% per year for three years commencing on 1 August 2008.

  All drugs on the F1 and F2 formularies continue to be subject to the 12.5% price reduction policy, if triggered;
- price disclosure, to ensure that the price paid by government for certain products listed on the PBS more closely reflects the price at which they are sold by suppliers to pharmacy; and

- a three-part structural adjustment package to pharmacy to help them adjust to the new arrangements. This includes:
  - *the premium free incentive*– a fee paid to pharmacists when they dispense a premium free brand. As a result of negotiations around the Fifth Community Pharmacy Agreement, this policy has now been extended through to 30 June 2014. This payment only applies to PBS subsidised medicines (not under co-payment medicines or private scripts) and is indexed each year;
  - *the $0.40 online incentive fee*, which is an incentive of 40c for each prescription processed using PBS Online. As a result of negotiations around the Fifth Community Pharmacy Agreement, this incentive fee now expires on 30 June 2010; and
  - *increases in pharmacy mark-ups and dispensing fees* through changes in the dispensing formula. As a result of negotiations around the Fifth Community Pharmacy Agreement indexation of the dispensing fee has been frozen until 1 July 2012;
- additional CSO funding of $69 million, which was added to the $150 million Community Services Obligation (CSO) Funding Pool established under the Fourth Community Pharmacy Agreement in 2006 to compensate pharmaceutical wholesalers for the additional cost they incur in providing the full range of PBS medicines.

Wholesalers are eligible to access the CSO Funding Pool, which is subject to indexation, if they can demonstrate that they meet specified service standards.

The Government also committed to an education program to increase the uptake of generics.

On 1 August 2007, Guarantee of Supply (GoS) provisions were established to protect supply by requiring the suppliers of new brands of medicines listing on the PBS to guarantee to supply for a minimum period even if the listing circumstances of that brand change, such as being subject to a price reduction. Criminal penalties were imposed if suppliers failed to comply with the requirement to notify the Minister if they were unable to supply.

The GoS period for the guaranteed brand of the pharmaceutical item is up to 24 months from the date of listing. The GoS provisions are intended to deter responsible persons from supplying without a viable business model able to support their long-term participation in the market. They apply to:

- new brands that are bioequivalent to an existing brand; and
- existing brands of F2 drugs offering price reductions.

PBS reform also made the 12.5% price reduction policy a legislative requirement.

The introduction of F1 and F2 formularies

The stated purpose of the formulary split was to allow the Commonwealth to obtain savings from brand competition, and to protect single brand medicines from unsustainable price cuts.

Prior to the PBS reforms, the 12.5% price cuts on drugs flowed onto all drugs in the RPG. These included different medicines, some still on patent, and some which doctors could not substitute in treating their patients.

The new formularies tightened the flow-on effects of price cuts using two alternative definitions of drug comparability:

- bio-equivalence – occurs when different drugs contain the same active ingredient and have the same route of administration. *In effect Bio-equivalent drugs are generic substitutes.*
- interchangeable medicines are different molecules with the same mode of action and comparable efficacy. All interchangeable medicines are part of the same Therapeutic Group (TGs)[2].

If a drug has bioequivalent substitutes, or is interchangeable with other medicines that do, it is placed in F2. Otherwise the drug is included in F1. Only those drugs in F2 are now subject to the mandatory 12.5% price reduction.

The F2 category of drugs are genuinely substitutable and interchangeable at the patient level. Many of these F2 drugs are bioequivalent and are substitutable *by pharmacists* when generic substitutes are available. Because of this pharmacists and wholesalers were able prior to 2008 to negotiate significant discounts (trading terms) to the approved price to pharmacy (APP) as an incentive to purchase product, without any requirement to disclose the form or extent of any such incentive.

F2T drugs are F2 drugs that had trading discounts of greater than 25% to pharmacists as at 1 October 2006. The remainder of drugs, F2A, were drugs surveyed that attracted trading terms to pharmacy of less than 25%.

[2] Up till 2009 the TG's included the ACE inhibitors, angiotensin II receptor antagonists, calcium channel blockers, H2 receptor antagonists, proton pump inhibitors and two of the statins (pravastatin and simvastatin only) (Fact Sheet, 2009). During 2009 two new TG's were formed – the oral bisphosphonates and one of the classes of antidepressants.

Impacts of price disclosure on F2

Price disclosure may reset the approved price to pharmacy (APP) annually based on the weighted average disclosed price paid by pharmacy for interchangeable products that have the same manner of administration (for all forms and strengths of that drug). It has already commenced for some F2A products, but will not begin for any F2T products until 1 January 2011.

From this time onwards, all suppliers listing a new brand must agree to disclose the actual market price as a condition of listing. Price disclosure will only begin after a new brand is listed and will apply to those drugs in the same group that opt in, as it is not mandatory for them to do so.

The first price reductions resulting from disclosure were due to take effect from 1 August 2009, however they were delayed due to administrative issues. Three out of the four of these medicines have taken price reductions from 1 December 2009 as a result of price offers equivalent to the price disclosure reductions they were due to incur. Price disclosure on these medicines is continuing on the basis of an annual cycle.

Current arrangements for F1 formulary

The arrangements for an F1 drug are as follows:

- the Government negotiates with manufacturers (sponsors) for the drug depending on the benefits the drug provides and the manufacturers' costs. This negotiation sets the APP;
- the APP applies to the specific medicine, and may vary by clinical indication and route of administration (given by the item number);
- the pharmacy dispenses the drug at the APP plus a fixed mark-up which is determined by a formula, but is usually close to 10%; and
- the APP contains both the payment to wholesalers and the payment to manufacturers. The Fourth Community Pharmacy Agreement contains a guideline for this payment, however in reality, the price is set in the competitive marketplace of wholesalers and can vary.

Moving from F1 to F2

Drugs will move from F1 onto F2, as a general rule, when there is a listing of a new brand and a generic version of the molecule enters the market. *The generic is licensed for the specific item code* (covering clinical use, and route of administration). Thus the innovators products may remain in F1 for some item codes. If the generic is the first new brand of a medicine, it will trigger the 12.5% price reduction. Where a medicine has already been subject to a 12.5% price reduction, it will not be subject to further 12.5% price reductions.

The flow of money for PBS listed pharmaceuticals between manufacturers, wholesalers, pharmacists, patients, and the Government are outlined in Appendix A.

2 Modelling and key assumptions

To ensure that the measured impacts of PBS reform are genuinely incremental, a '*base case'* forecast scenario has been developed to estimate expected Government expenditure and supply chain impacts over the next 10 years in the absence of PBS reform.

This expenditure profile estimates the funding cost of the PBS and the distribution of costs and revenues across the industry that only takes into account previously announced changes that would have occurred without the specific range of measures contained in PBS reform. In particular, the base case includes the impact of the 12.5% price reduction policy and relevant aspects of the Fourth Community Pharmacy Agreement.

Against this, a '*with PBS reform'* forecast scenario has been developed that captures all specific PBS reform measures - both those that have already taken place and those that are due to take place up until 2017-18. This scenario also captures changes affecting the PBS that are measured in the base case.

The additional measures contained in the PBS reform scenario relate to further price reductions of PBS listed pharmaceuticals associated with price disclosure or mandated 25% or staggered 2% price cuts, and Government incentives aimed at the promotion of more competitively priced pharmaceuticals and online prescription processing.

Key elements of the base case

There have been several initiatives announced in recent years that will continue to affect the funding cost of the PBS, and that need to be modelled as part of the base case to ensure that the measured impacts of PBS reform are genuinely incremental.

Foundations of the Base case

The base case for PBS expenditure for Government involves detailed projections of volumes and prices for each drug currently in the PBS schedule. Molecules which belong to the same Therapeutic Group (TG) are further aggregated. The base case model uses the actual volume of drugs for the period 2007 to November 2009, and then projects volumes forward. The price series used for the base case and the PBS reform case are the actual 2009 November prices. For the base case, these prices are revised to subtract the impact of the two rounds of 2% price cuts on F2A drugs which occurred in August 2008 and August 2009, and the 25% price cut on F2T drugs which occurred in August 2008.

The base case also includes price adjustments that result from the 12.5% mandatory price reduction that is triggered by the first application to list a new brand of medicine for a medicine which was previously a 'single brand' medicine - generally just after patent expiry. The model groups different brands and strengths of drug by molecule.

The base case (and the impacts of PBS reform measured against it) assumes that current TGs are not changed, that no new TGs are added, and that the rules of price disclosure and other reforms do not impact the operation of the TGs. It does however include announced changes to TGs that were part of the 2009/10 Federal Budget and the creation of three new TGs on 2 November 2009, with price changes to take effect from 1 April 2010. Minister Roxon has publicly stated that the Government has the discretion as to the creation of new TGs and if it believes warranted will create new TGs.

The base case also excludes any pending measures that may be contained in the Fifth Community Pharmacy Agreement currently being negotiated.

Data components for the base case

The key variables included in the base case are:

- scripts paid for by DoHA as well as those paid by the Department of Veterans' Affairs (DVA). DVA expenditure on pharmaceuticals in 2008-09 was approximately $450 million;
- the pharmacy dispensing fee;
- pharmacy mark-ups and wholesaler mark-ups;
- 12.5% price reductions that are triggered by the first application to list a new brand of medicine for a medicine which was previously a 'single brand' medicine, which was introduced under the 2005 amendments to the *National Health Act*;
- cost savings to the PBS from the extension of the therapeutic group premium policy and the extension of the PBS reference pricing policy to all non-exempt pharmaceutical items, estimated by the Government in the Australian Budget 2009-10 to save $113.8 million and $61.2 million over four years respectively; and
- safety nets, patient co-contributions or co-payments, incentive payments. Forecast WCI9 of 2% annually is applied to the dispensing fee and the community service obligation. Forecast CPI growth of 2.5% per annum is applied to patient co-contributions.

Volume growth in scripts written or dispensed

Growth in the volume of scripts written or dispensed has been forecast separately for each molecule (ATC5 group) until 2017-18, based on a structural time series model which extracts the relevant features of historic information from July 2005 to November 2009 to develop a forward looking trend.

The model we have used is based on an autoregressive representation of the data. This analysis captures the switching between drugs that has occurred over the past five years. It also captures emerging trends within ATC5 groups as newer medicines take the place of older ones. Further detail on the demand forecasting methodology is provided in Appendix B.

In addition to the growth rates for drugs currently on the PBS, we have assumed that 13 new molecules per year will come onto the PBS, with an average cost per molecule to government and patient of $12.2 million (increasing by 5% per annum), and volume of 260,000 scripts.

Using this methodology we have estimated average annual volume growth of 3.8%, including the entry of new drugs over the forecast period. Excluding new drugs, the annual average increase in volumes is 2.4%.

While growth rates for currently-listed molecules have been estimated separately at the ATC5 level, for presentational purposes, growth rates summarised to the ATC2 level are shown in Table 10 below.

The forecast average annual increase in volumes over the forecast period of 3.8% is below that of the substantial volume growth that has occurred over the past 18 months. Volume growth in 2008-09 was 5.8% over the previous year, of which 4.2% reflected growth in the Concession Ordinary patients. Growth in 2007-08 was comparatively weaker, up 1.2% over the previous year, before which there was negative annual volume growth in the two preceding years (partly reflecting the 24% increase in co-payments in January 2005), and 2.6% growth in 2004-05 over the previous year.

Table 10: Actual and projected volume growth by molecule

Molecule (including major drugs)	Historical growth			Projected growth								
	FY07	FY08	FY09	FY10	FY11	FY12	FY13	FY14	FY15	FY16	FY17	FY18
Lipid modifying agents (includes statins)	9.4%	9.1%	10.0%	3.9%	3.0%	2.2%	2.2%	2.2%	2.2%	2.2%	2.2%	2.2%
Renin/Angiotensin System (includes ACE inhibitors and ARB's)	-1.9%	1.8%	8.7%	2.4%	4.9%	2.2%	2.2%	2.2%	2.2%	2.0%	0.9%	0.8%
Acid related disorders (includes proton pump inhibitors and H2 antagonists)	2.3%	3.2%	12.7%	3.5%	3.5%	2.2%	2.2%	2.2%	2.2%	2.2%	2.2%	2.2%
Psychoanaleptics (includes antipsychotics)	13.1%	15.1%	17.0%	9.6%	5.0%	2.2%	2.2%	2.2%	2.2%	2.2%	2.2%	2.2%
Antineoplastics (includes chemotherapy, biologicals)	-4.8%	-1.4%	4.7%	3.6%	3.6%	2.2%	2.2%	2.2%	2.2%	2.2%	2.2%	2.2%
Analgesics (includes opiates)	0.7%	4.0%	12.4%	5.6%	3.9%	2.2%	2.2%	2.2%	2.2%	2.2%	2.2%	2.2%
Obstructive airways (includes salbutamol, ventolin)	-0.1%	5.2%	5.8%	8.1%	3.5%	2.2%	2.2%	2.2%	2.2%	2.2%	2.2%	2.2%

Molecule (including major drugs)	Historical growth			Projected growth								
	FY07	FY08	FY09	FY10	FY11	FY12	FY13	FY14	FY15	FY16	FY17	FY18
Drugs used in diabetes (includes metformin, insulins)	2.9%	-6.7%	3.8%	5.5%	5.2%	2.2%	2.2%	2.2%	2.2%	2.2%	1.8%	1.7%
Psycholeptics (includes antidepressants)	-1.8%	-3.0%	5.7%	-4.1%	2.6%	2.2%	2.2%	2.2%	2.2%	2.2%	2.2%	2.2%
Newly-listed molecules				2.4%	2.4%	2.4%	2.4%	2.4%	2.4%	2.4%	2.4%	2.4%
Total Projected Scripts (millions)	178	181	194	201	214	221	230	238	246	255	263	272

Note: Based on currently listed molecules at the ATC5 level, including Repatriation Pharmaceutical Benefits Scheme (RPBS). Does not include the emergency drug system (Doctor's Bag), Safety Net cards, or supplies to Aboriginal Medical Services.

Modelling the impact of PBS reform

The modelling scenario for the impact of PBS reform adds the following components to the base case:

- a one-off 25% mandatory price cut in the price to pharmacists of medicines on formulary F2T on 1 August 2008, which is phased in for Lercanidipine, Esomeprazole, Lansoprazole, Pantoprazole, and Rapeprazole over their remaining patent life
- staged 2% price cuts in the price to pharmacists on formulary F2A which occurred in August 2008 and August 2009, and the final 2% cut that is yet to take effect on August 2010
- price disclosure
- a three-part structural adjustment package to pharmacy to help them adjust to the new arrangements. This includes:
  - *the premium free incentive*– a fee paid to pharmacists when they dispense a premium free brand. As a result of negotiations around the Fifth Community Pharmacy Agreement, this policy has now been extended through to 30 June 2014. This payment only applies to PBS subsidised medicines (not under co-payment medicines or private scripts) and is indexed each year;
  - *the $0.40 online incentive fee*, which is an incentive of 40c for each prescription processed using PBS Online. As a result of negotiations around the Fifth Community Pharmacy Agreement, this incentive fee now expires on 30 June 2010; and
  - *increases in pharmacy mark-ups and dispensing fees* through changes in the dispensing formula. As a result of negotiations around the Fifth Community Pharmacy Agreement indexation of the dispensing fee has been frozen until 1 July 2012; and
- additional CSO funding of $69 million, which was added to the $150 million Community Services Obligation (CSO) Funding Pool

established under the Fourth Community Pharmacy Agreement in 2006 to compensate pharmaceutical wholesalers for the additional cost they incur in providing the full range of PBS medicines; and

- transitioning drugs from F1 to F2A (up to 2011, thereafter to F2) following patent expiry (subject to the patent expiry assumptions below) and subjecting them to 12.5% price cuts (estimated in the base case) and then price disclosure (part of PBS reform) when a new brand enters the market (see price disclosure trigger assumptions below).

Key assumptions

The impacts of PBS reform have been modelled based on various assumptions regarding discounting behaviour and underlying volume and price growth.

In modelling PBS reform, we have focussed on modelling the effects on molecules which are currently listed on the PBS, with some more 'high level' estimates made for drugs to be newly listed over the projection period. For currently listed drugs, we have detailed information on individual drug prices and the proportion of scripts dispensed to people with and without concession cards and safety nets. We can therefore make reasonable estimates of the flow-on impact of price changes to the various market participants, including the very specific calculation of changes in the pharmacy mark-up formula. In contrast, we have only high level estimates of the volumes of newly listed drugs, and as such, calculations of specific changes, such as the changes in the pharmacy dispensing formula, are very uncertain. As a result, for newly listed drugs, we have allowed only for the impact of changes in the dispensing fee and the online incentive. Because we assume that newly-listed drugs will not come off patent during the projection period, further impacts of the PBS reforms on these drugs will be minimal.

It is also important to note that we have made no allowance for changes in the number of people who might reach the PBS safety net thresholds. In theory, as prices are lower under PBS reform, the number of people who reach the safety net threshold each year should be lower, and hence Government payments for safety net payment should also be lower. Such an estimate would be difficult to quantify and we assume the impact is minimal.

The assumptions used that are common to both the base case and the PBS reform case are shown in Table 11.

Table 11: Key assumptions common to the Base case and PBS Reform case

Variable	Assumption
Average annual growth in scripts written or dispensed FY09 to FY18	3.8% (including new listings) 2.4% (excluding new listings)
New medicines listed FY09 to FY18 that do not come off patent	13 per year, with an average cost to government and patient of $12.2 million (increasing by 5% per annum) and with volume of 260,000 scripts on average.
Timing of drugs coming off patent and entry of new brands that trigger the 12.5% price reduction policy	F1 drugs currently greater than $10 million expire at current best estimate of patent expiry date. These are known to spike in 2012-13. Other F1 drugs currently less than $10 million, or for which expiry dates are unknown, are assumed to expire over the next 6 years (one sixth of this group expire each year). New entrants emerge for 80% of low sales molecules (less than $2 million per annum), and for all molecules with annual sales over $2 million. New entrants emerge 1 month after patent expiry (except for Atorvastatin (Lipitor) which is minus 2 months as agreed with Ranbaxy) 12.5% price reduction policy takes affect at the next available April, August, or December price change point.
Indexation	2% forecast WCI9 is applied to index the dispensing fee and the community service obligation. 2.5% forecast CPI growth is applied to patient co-contributions.

The additional assumptions used to estimate the impact of PBS reform are shown in Table 12. One of the most uncertain aspects of the PBS reforms is the impact of price disclosure.

This uncertainty arises because the weighted average disclosed price (WADP) is significantly influenced by the market players who opt in to price disclose. It is also uncertain what impact price disclosure will have on trading terms and incentives, which will directly impact the actual price to pharmacists, and therefore profitability, and hence the impact of price disclosure on market participants. The impacts of price disclosure estimated in this report do not take account of any impact on pharmacists arising from changes in the trading terms, which are subject to negotiation.

Assumptions regarding price disclosure are based on analysis of the timing of new entrants over the past five years, and the presence of competitors for molecules of varying market size, and estimates of discounts available in the market. We note that:

- Within two years of coming off patent, and weighted by expenditure, 90% of the molecules had a competitor in the market. The likelihood of having a competitor enter the market varies by market volume.
- The extent of discounting available in the market is uncertain, and can vary considerably by drug. We note that the price reduction to be applied as a result of Rounds 1 to 3 of price disclosure, including those for which no reduction is to be applied, are 14% on average.
- We would expect the impacts of price disclosure to be achieved gradually over time, as prices are adjusted in response to previous price disclosure impacts, changes in market share, and price changes from originators or other manufacturers, as the WADP is re-calculated year on year. Market share of an originator brand declines over the first four years after a competitor enters the market. The market share for originators is lower overall for large volume drugs, and hence we would expect large volume drugs to achieve higher discounts.

Table 12: Assumptions for estimating the impact of PBS Reform

Variable	Assumption
Price disclosure timing	Price disclosure discounts occur a minimum of 2 years after the price disclosure mechanism is first triggered by a new entrant, at the next April or August price adjustment date following that 2 years.
Price disclosure triggers	For F1 formulary drugs – as per 12.5% price reduction policy triggers in base case. For F2 drugs, probabilities of a new competitor emerging to trigger price disclosure depend on market size are: • 100% for drugs with sales over $100 million In addition, for high estimate only: • 75% for drugs with sales $50 million to $100 million • 40% for drugs with sales $2 million to $50 million
Price disclosure impacts – F1 drugs shifting onto F2	Price disclosure impacts are assumed to be achieved gradually over the first four years after a drug comes off patent: Discounts vary by volume of sales as per below: **High Estimate assumes the following discounts** • 40% for molecules with sales greater than $100 million • 18% for molecules with sales between $50 million to $100 million • 16% for molecules with sales less than $50 million **Low Estimate assumes the following discounts** • 18% for molecules with sales greater than $100 million • 9% for molecules with sales between $50 million to $100 million • 7% for molecules with sales less than $50 million

Variable	Assumption
Price disclosure impacts – Current F2 drugs	Price disclosure impacts are assumed to be achieved gradually over the first four years for those drugs for which price disclosure is triggered. Discounts vary by volume of sales as per below: **High Estimates assumes the following discounts** • 20% for molecules with sales greater than $100 million • 9% for molecules with sales between $50 million to $100 million • 7.5% for molecules with sales less than $50 million **Low Estimates assume the following discounts** • 15% for molecules with sales greater than $100 million
Online incentive	Utilisation assumed to be maintained at 98%, and to conclude on 30 June 2010.
Dispensing Fee	Fee assumed to be held constant until 30 June 2012, then indexed each year at WCI9 (2%)
Brand premium free incentive	Assumed to be maintained throughout the forecast period. Assumed to index in line with the WCI9 (2%).
Additional CSO	The additional CSO is assumed to be $23 million per annum until 2009/10, then increase in line with WCI9 (2%).

Appendix C provides greater detail on the price disclosure assumptions made above.

As a point of reference as to the reasonableness of the price disclosure assumptions, Appendix D provides a comparison of a sample of drug prices in the United Kingdom (which has had a price disclosure regime in place since 2005) and Australia. The differential pricing regimes will reflect a myriad of factors, one of which would be price disclosure. The comparison is provided for illustrative purposes only.

3 Australian Government financial impacts

The financial impacts of PBS reform for the Australian Government reflect the payment arrangements for PBS medicines between government, pharmacy and patients.

The Government makes payments to pharmacy for the sale of drugs and also funds a range of safety net payments to ensure that PBS medicines are affordable and accessible for patients.

The price paid to pharmacists is set under the Community Pharmacy Agreement based on a formula which comprises the ex-manufacturer price plus allowances for the supply of PBS medicines over and above that price.

Subsidies provided for patients vary depending on patient group. For instance, Centrelink Concession and Safety Net Card holders are entitled to an additional government subsidy for PBS medicines, and Department of Veterans Affairs (DVA) Repatriation Card holders are entitled to subsidised medicines under the Repatriation Pharmaceutical Benefits Scheme (RPBS).

In addition to these payments, Government makes direct payments to wholesalers from the Community Service Obligation Funding Pool.

To provide estimates of the impact of PBS reform on government expenditure, the base case and the PBS reform case separate impacts across the supply chain to capture all aspects of the funding and payment arrangements for all PBS listed pharmaceuticals, for all patient groups.

The base case provides supply chain impacts of previously announced changes that would have occurred without the specific range of measures contained in PBS reform, in particular, the impact of the 12.5% price reduction policy and relevant aspects of the Fourth Community Pharmacy Agreement.

The PBS reform case provides supply chain impacts associated with price reductions of PBS listed medicines associated with price disclosure, and mandated 25% or staggered 2% price cuts and government incentives aimed at the promotion of more competitively priced pharmaceuticals and online prescription processing.

The financial impacts on the Australian Government reflect the combined impact of the PBS-specific savings measures and additional costs.

The savings for the Australian Government from PBS reform are derived from:

- a one-off 25% mandatory price cut in the price to pharmacists of medicines on formulary F2T on 1 August 2008, which is phased in for Lercanidipine, Esomeprazole, Lansoprazole, Pantoprazole, and Rapeprazole over their remaining patent life;

- staged 2% price cuts in the price to pharmacists on formulary F2A which occurred in August 2008 and August 2009, and the final 2% cut that is yet to take effect on August 2010; and
- price disclosure.

These savings are additional to those associated with previous price measures, such as the 12.5% price reduction policy, and cost savings from the recently announced extension of the therapeutic group premium policy and the PBS reference pricing policy to all non-exempt pharmaceutical items.

These savings are partly offset by the costs of the pharmacy structural adjustment package and the CSO for wholesalers, which include:

- the brand premium free incentive, which as a result of negotiations around the Fifth Community Pharmacy Agreement, has now been extended through to 30 June 2014;
- the $0.40 online incentive fee, which as a result of negotiations around the Fifth Community Pharmacy Agreement, now expires on 30 June 2010;
- increases in pharmacy mark-ups and dispensing fees through changes in the dispensing formula, which as a result of negotiations around the Fifth Community Pharmacy Agreement, indexation of the dispensing fee has been frozen until 1 July 2012; and
- additional CSO funding of $69 million, which was added to the $150 million Community Services Obligation (CSO) Funding Pool established under the Fourth Community Pharmacy Agreement.

In estimating impacts to government, we have assumed that these payments, with the exception of the online incentive, will continue throughout the projection period.

Key financial impacts for the Australian Government

The estimated net financial savings to Government as a result of PBS reform, after allowing for structural adjustment packages to pharmacy and wholesalers, range from $3.6 billion to $5.8 billion, depending on price disclosure outcomes (Table 13).

This includes all direct impacts on Government expenditure associated with PBS reform. Indirect expenditure impacts, such as potential changes to Government revenue as a result of reduced profitability, have not been considered.

Table 13: Summary of the net financial impact of PBS reform on Government expenditure $million

	$million	$million
Mandatory Price Cuts		$4,648.9
2% cuts	*$142.1*	
25% cuts	*$4,506.8*	
Price disclosure – high impact		$4,400.4
Price disclosure – low impact		$2,209.1
Pharmacy structural adjustment package		-$2,991.2
Brand premium free incentive	*-$1,357.7*	
Online incentive	*-$154.9*	
Mark-up formula & dispensing fee changes	*-$1,478.7*	
Community Service Obligation		-$247.4
Total excluding price disclosure		**$1,410.4**
Total including price disclosure - high PD impact		**$5,810.7**
Total including price disclosure - low PD impact		**$3,619.5**

The savings from PBS reform are derived from the one-off 25% mandatory price cut and staged 2% price cuts as well as price disclosure.

These are partly offset by the impacts of the pharmacy structural adjustment package and the CSO for wholesalers. The cost of the structural adjustment and CSO measures are equivalent to 33%-43% of the total savings to Government of PBS reform, depending on the discounts obtained from price disclosure.

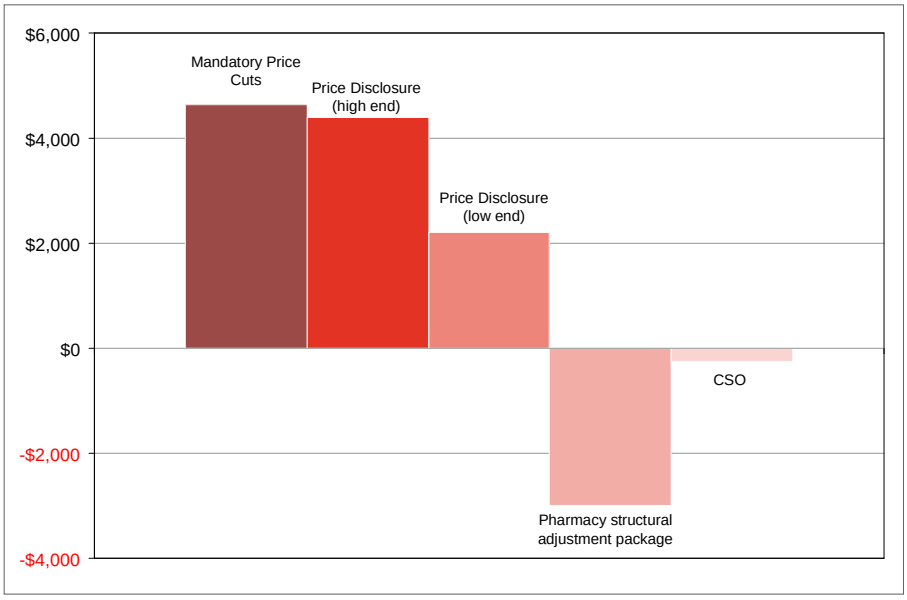
The net financial saving to Government, excluding price disclosure, is $1.4 billion. Price disclosure and the 25% price reductions account for the bulk of the financial savings to the PBS, as shown in Table 14 and Figure 1. These results assume that the increase in the CSO Funding Pool and the $1.50 brand premium free incentive do not expire and continue over the forecast period.

These impacts are additional to those associated with earlier reforms which are included in the base case, such as the 12.5% cut in the price to pharmacists on entry of a new brand, risk sharing changes to the dispensing fee, and other non PBS reform price changes. The savings grow over time, as the volume of drugs impacted by the measures grows, and the impacts of price disclosure grow to offset the structural adjustment package measures.

Table 14: Savings to Government by year, by type of reform $million

	FY09	FY10	FY11	FY12	FY13	FY14	FY15	FY16	FY17	FY18	Total
Mandatory Price Cuts	$330	$387	$416	$442	$467	$492	$517	$525	$533	$541	**$4,649**
Price Disclosure (high impact)	$0	$9	$38	$62	$121	$296	$578	$855	$1,117	$1,324	**$4,400**
Price Disclosure (low impact)	$0	$9	$38	$49	$76	$157	$286	$415	$538	$640	**$2,209**
Pharmacy Structural adjustment Package	-$369	-$371	-$279	-$260	-$267	-$274	-$282	-$289	-$296	-$303	**-$2,991**
CSO	-$23	-$23	-$23	-$24	-$24	-$25	-$25	-$26	-$26	-$27	**-$247**
Total (high PD impact)	**-$61**	**$2**	**$151**	**$220**	**$296**	**$488**	**$787**	**$1,065**	**$1,327**	**$1,535**	**$5,811**
Total (low PD impact)	**-$61**	**$2**	**$151**	**$207**	**$251**	**$350**	**$495**	**$624**	**$748**	**$851**	**$3,619**

Figure 1: Impacts of PBS reform for Government $million



4 Manufacturers' financial impacts

PBS reform has a direct impact on the price received by manufacturers for PBS listed pharmaceuticals.

Manufacturers are expected to be the most affected by PBS reform, which is intended to capture part of the discounting that manufacturers have been providing. The final impact on manufacturers will depend on changes in trading terms with pharmacy, which have not been forecast as part of this review.

In general, the price at which a new medicine is listed on the PBS is determined primarily through negotiations between the supplier of the drug and the Pharmaceutical Benefits Pricing Authority (PBPA). The PBPA in reaching an agreed price considers advice from the PBAC and alternative treatments available. The price that is set is the price for sale to community pharmacy.

The modelling undertaken for this review examines the impact of PBS reform on supply chain participants by isolating the relationship between the dispensed price and the price to pharmacists after taking into consideration the wholesaler mark-up. Removing the 7% wholesaler margin from the APP allows the model to isolate the *ex-manufacturer* price. The bulk of PBS reforms impact on prices at the point at which wholesalers provide medicines to pharmacists net of any premiums added by manufacturers.

Key financial impacts for manufacturers of pharmaceuticals

The costs for manufacturers from PBS reform are derived from:

- a one-off 25% mandatory price cut in the price to pharmacists of medicines on formulary F2T on 1 August 2008, which is phased in for Lercanidipine, Esomeprazole, Lansoprazole, Pantoprazole, and Rapeprazole over their remaining patent life;
- staged 2% price cuts in the price to pharmacists on formulary F2A which occurred in August 2008 and August 2009, and the final 2% cut that is yet to take effect on August 2010; and
- price disclosure.

These costs are additional to those associated with previous price measures, such as the 12.5% price reduction policy, and cost savings from the recently announced extension of the therapeutic group premium policy and the PBS reference pricing policy to all non-exempt pharmaceutical items.

Under the reforms the reduction in the manufacturers' component of PBS prices is estimated to provide savings of between $6.4 billion to $8.5 billion as a result of the mandatory price cuts and price disclosure (Table 15). This reflects only those impacts associated with Government and patient expenditure. The impact of any changes in trading terms will also determine the overall impact on manufacturers.

The mandatory 25% and 2% cuts have the greatest impact on manufacturers – around $4.3 billion over the forecast period.

Table 15: Impacts on manufacturers of PBS reforms $ million

	FY09	FY10	FY11	FY12	FY13	FY14	FY15	FY16	FY17	FY18	Total
Mandatory 2% and 25% price reductions	-$299	-$352	-$381	-$407	-$433	-$460	-$487	-$497	-$508	-$520	**-$4,344**
Price disclosure – high impact	-$0	-$8	-$34	-$54	-$107	-$270	-$536	-$802	-$1,063	-$1,279	**-$4,152**
Price disclosure – low impact	-$0	-$8	-$34	-$43	-$67	-$142	-$263	-$384	-$503	-$602	**-$2,046**
Net impact – high PD impact	**-$299**	**-$360**	**-$414**	**-$461**	**-$540**	**-$730**	**-$1,023**	**-$1,299**	**-$1,571**	**-$1,798**	**-$8,496**
Net impact – low PD impact	**-$299**	**-$360**	**-$414**	**-$450**	**-$501**	**-$602**	**-$750**	**-$882**	**-$1,012**	**-$1,121**	**-$6,391**

5 Pharmacy and wholesalers financial impacts

The financial impacts of PBS reform for community pharmacy and wholesalers are generated by:

- the flow-on impacts for pharmacy and wholesalers as a result of reductions in the agreed manufacturers' price; and
- the structural adjustment arrangements that the Government agreed to in order to offset the impact of PBS reform on pharmacy and wholesalers.

Flow-on impacts are created because of the way that retail pharmacy and wholesaler margins are set. The retail pharmacy margin is a combination of a specific mark-up on the approved price to pharmacist for medicines in certain price categories and a percentage mark-up on the approved price to pharmacist for other medicines. Wholesaler margins reflect the mark-up on the agreed ex-manufacturer's price of PBS medicines for the distribution of PBS medicines. Reductions in the ex-manufacturer's price reduces the dollar value of the retail margin received by pharmacy and the distribution margin.

The pharmacy and pharmaceutical wholesaler structural adjustment arrangements include incentives to dispense brand premium-free medicines, and to process prescriptions on line. It also includes increases in pharmacy mark-ups and dispensing fees as well as additional funding to pharmaceutical wholesalers in the form of a CSO Funding Pool designed to protect wholesaler margins from the new pricing arrangements.

These impacts will influence Government payments to pharmacy. However the net financial impact of PBS reform on pharmacy will depend on changes in the trading terms that pharmacy is able to negotiate.

The expected impacts on pharmacy modelled in this report do not take into account any impact arising from changes in negotiated trading terms. They only estimate reductions in the components of PBS prices that are attributable to manufacturers, wholesalers, and pharmacy, and the Government payments to pharmacy and wholesalers that are part of PBS reform.

To provide estimates of the impact of PBS reform on community pharmacy and wholesalers, the base case and the PBS reform case separate impacts across the supply chain to capture all aspects of the funding and payment arrangements for all PBS listed pharmaceuticals, for all patient groups.

The impact of PBS reform on pharmacies and wholesalers is determined by examining the relationship between the dispensed price and the price to pharmacists after taking into consideration the wholesaler mark-up. Removing the 7% wholesaler margin from the APP allows the model to isolate the *ex-manufacturer* price – the point at which wholesalers provide medicines to pharmacists net of any premiums added by manufacturers.

The dispensed price (the price received by pharmacy) is calculated by applying the agreed formula for specifying a mark-up and a dispensing fee to the price to pharmacy, which reflect negotiated outcomes between the Government and the Pharmacy Guild of Australia.

These detailed calculations of changes in formulae and mark-ups have been possible only for drugs currently listed on the PBS. For drugs to be newly-listed during the projection period, we have allowed only for the additional online incentives and dispensing fees in respect of these drugs.

Key financial impacts for community pharmacy

The net financial impact on community pharmacy is difficult to determine as it is dependent on commercial relationships between manufacturers, wholesalers and pharmacy, and how trading terms are affected in the pharmaceutical supply chain.

The direct impacts on pharmacies from PBS reform are derived from the pharmacy structural adjustment package which includes:

- the brand premium free incentive, which as a result of negotiations around the Fifth Community Pharmacy Agreement, has now been extended through to 30 June 2014;
- the $0.40 online incentive fee, which as a result of negotiations around the Fifth Community Pharmacy Agreement, now expires on 30 June 2010; and
- increases in pharmacy mark-ups and dispensing fees through changes in the dispensing formula, which as a result of negotiations around the Fifth Community Pharmacy Agreement, indexation of the dispensing fee has been frozen until 1 July 2012.

In estimating impacts to government, we have assumed that these payments, with the exception of the online incentive, will continue throughout the projection period.

These partly offset by the flow-on impacts of price reductions, namely:

- a one-off 25% mandatory price cut in the price to pharmacists of medicines on formulary F2T on 1 August 2008, which is phased in for Lercanidipine, Esomeprazole, Lansoprazole, Pantoprazole, and Rapeprazole over their remaining patent life;
- staged 2% price cuts in the price to pharmacists on formulary F2A which occurred in August 2008 and August 2009, and the final 2% cut that is yet to take effect on August 2010; and
- price disclosure.

Overall, this analysis indicates that pharmacists will be financially better off as a result of PBS reform.

PBS reform has a positive impact on the pharmacy sector because the Government incentives available from the pharmacy structural adjustment package outweigh the losses incurred as a result of changes

to the pricing of PBS medicines, and the manner in which associated price cuts flow through to pharmacy margins.

Over the period FY09 to FY18, PBS reforms are estimated to increase the net income to pharmacy by $2.2 billion to $2.4 billion depending on the impact of price disclosure (Table 16). Excluding price disclosure, the net impact of PBS reforms for pharmacy is $2.5 billion over the forecast period.

Government expenditure on the pharmacy structural adjustment package accounts for the bulk of the impacts on pharmacy, and more than offsets the estimated impacts of the mandatory price reductions and price disclosure, as shown in Table 16.

These impacts reflect only Government and patient expenditure on PBS medicines. Pharmacist profitability is also impacted by the trading terms which they negotiate with manufacturers. Our estimates do not take into account any impact on pharmacists arising from changes in the trading terms they are able to negotiate.

Table 16: Impacts on pharmacy of PBS reforms $ million

	FY09	FY10	FY11	FY12	FY13	FY14	FY15	FY16	FY17	FY18	Total
Brand premium free incentive	$120	$123	$126	$130	$134	$138	$142	$145	$149	$152	$1,358
Online incentive	$76	$79	$0	$0	$0	$0	$0	$0	$0	$0	$155
Changes to mark-up formula and dispensing fees	$173	$170	$153	$130	$134	$137	$140	$144	$147	$151	$1,479
Mandatory 2% and 25% price reductions	-$32	-$37	-$40	-$43	-$45	-$48	-$50	-$51	-$52	-$54	-$452
Price disclosure – high impact	-$0	-$1	-$3	-$5	-$9	-$19	-$38	-$58	-$79	-$97	-$309
Price disclosure – low impact	-$0	-$1	-$3	-$4	-$6	-$11	-$21	-$30	-$39	-$46	-$159
Net impact – high PD impact	**$337**	**$333**	**$236**	**$212**	**$213**	**$208**	**$194**	**$179**	**$164**	**$153**	**$2,230**
Net impact – low PD impact	**$337**	**$333**	**$236**	**$213**	**$217**	**$215**	**$211**	**$208**	**$205**	**$204**	**$2,379**

Key financial impacts for wholesalers

Wholesalers are affected by PBS reform in two ways:

- Wholesaler margins are compressed due to lower agreed manufacturers' prices as a result of the mandatory price cuts and price disclosure, which reduce the revenue available to fund the wholesale distribution of medicines; and
- the $69 million increase in the CSO Funding Pool that is provided to compensate CSO Distributors for the reduction in revenues they receive as a result of the PBS pricing reforms.

According to the modelling results, the increase in the CSO does not outweigh wholesalers' reduction in margins. As a result, the net notional financial loss for wholesalers ranges from $0.2 billion to $0.3 billion over the forecast period depending on the impact of price disclosure. The most significant impact for wholesalers comes as a result of the mandatory price cuts, i.e. $0.3 billion in total over the forecast horizon (Table 17).

Again, any changes to trading terms negotiated by wholesalers with manufacturers and pharmacy will be additional to the impacts quantified here.

Table 17: Impacts on wholesalers of PBS reforms $ million

	FY09	FY10	FY11	FY12	FY13	FY14	FY15	FY16	FY17	FY18	Total
Mandatory 2% and 25% price reductions	-$21	-$25	-$27	-$28	-$30	-$32	-$34	-$35	-$36	-$36	**-$304**
Price disclosure – high impact	-$0	-$1	-$2	-$4	-$7	-$19	-$38	-$56	-$74	-$90	**-$291**
Price disclosure – low impact	-$0	-$1	-$2	-$3	-$5	-$10	-$18	-$27	-$35	-$42	**-$143**
CSO	$23.0	$23.0	$23.5	$23.9	$24.4	$24.9	$25.4	$25.9	$26.4	$26.9	**$247.4**
Net impact – high PD impact	**$2**	**-$2**	**-$6**	**-$8**	**-$13**	**-$26**	**-$46**	**-$65**	**-$84**	**-$99**	**-$347**
Net impact – low PD impact	**$2**	**-$2**	**-$6**	**-$8**	**-$11**	**-$17**	**-$27**	**-$36**	**-$44**	**-$52**	**-$200**

6 Patient contribution financial impacts

PBS reform has an impact on the amount of money that patients must contribute towards the cost of purchasing drugs listed on the PBS, which varies depending on the category of patient. For instance, Centrelink Concession and Safety Net Card holders are entitled to an additional government subsidy for PBS medicines, and Department of Veterans Affairs (DVA) Repatriation Card holders are entitled to subsidised medicines under the Repatriation Pharmaceutical Benefits Scheme (RPBS).

Payments by patients for PBS listed pharmaceuticals, if required, include a fixed co-payment towards the full price of the drug. This co-payment is currently $5.40 for concession card holders and $33.30 for non holders.

A safety net reduces these co-payments if a patient spends more than a fixed amount. This is $324.00 for concession card holders and $1,281.30 for non-holders. If the safety net has been exceeded the patient co-payment is reduced for subsequent purchases within a year. Concession card holders make no further copayments and non-concession card holders pay $5.40 for each script.

The patient categories identified for the purposes of this analysis include:

- Concession Free Safety Net + RPBS (Free Safety Net)
- Concession Ordinary + RPBS Ordinary
- PBS – General – Safety Net, and
- PBS - General – Ordinary.

In our estimates of financial savings, we have not accounted for the fact that the number of people who reach the PBS safety net thresholds each year may decline marginally, as a result of lower PBS prices. We would expect this impact to be small.

A patient may also pay a premium for a branded product towards the dispensed price of some PBS listed medicines.

Patients will benefit directly from PBS reform when it results in medicine prices that fall below the maximum co-payment threshold, which varies depending on the patient group.

For patients classified as Concession Free Safety Net + RPBS (Free Safety Net), PBS reform has no impact because they do not contribute to the cost of purchasing PBS listed medicines and any cost savings flow to government. The following section elaborates on the modelling results for the remaining patient categories.

Key financial impacts for patient contributions

The savings for patients from PBS reform are derived from the flow-on effects of:

- a one-off 25% mandatory price cut in the price to pharmacists of medicines on formulary F2T on 1 August 2008, which is phased in for Lercanidipine, Esomeprazole, Lansoprazole, Pantoprazole, and Rapeprazole over their remaining patent life;
- staged 2% price cuts in the price to pharmacists on formulary F2A which occurred in August 2008 and August 2009, and the final 2% cut that is yet to take effect on August 2010; and
- price disclosure.

These savings are additional to those associated with previous price measures, such as the 12.5% price reduction policy, and cost savings from the recently announced extension of the therapeutic group premium policy and the PBS reference pricing policy to all non-exempt pharmaceutical items. These savings are partly offset by increases in pharmacy mark-ups through changes in the dispensing formula.

Overall patients receive savings on PBS listed medicines of $0.6 billion to $0.8 billion, depending on the impact of price disclosure.

Most of the benefits to patients accrue to those classified as PBS – General – Ordinary as a result of medicines falling below the maximum copayment level of $33.30. Derived mainly from mandatory price reductions and price disclosure impacts, savings for patients range from $591.7 million to $802.5 million, depending on the impact of price disclosure (Table 18).

In addition to the monetary savings that may accrue to patients through reduced prices, patients will also benefit in terms of continued access to cost-effective pharmaceuticals and professional pharmacy services in an environment of increasing demand.

Table 18: Impacts on patients of PBS reforms $ million

	FY09	FY10	FY11	FY12	FY13	FY14	FY15	FY16	FY17	FY18	Total
Mandatory 2% and 25% price reductions	$21	$27	$32	$36	$42	$48	$55	$59	$64	$69	**$452**
Price disclosure – high impact	$0	$0	$1	$1	$3	$12	$33	$61	$100	$141	**$351**
Price disclosure – low impact	$0	$0	$1	$1	$2	$6	$16	$26	$39	$49	**$140**
Net impact – high PD impact	**$21**	**$27**	**$32**	**$37**	**$45**	**$60**	**$87**	**$120**	**$163**	**$209**	**$802**
Net impact – low PD impact	**$21**	**$27**	**$32**	**$37**	**$44**	**$54**	**$70**	**$85**	**$103**	**$118**	**$592**

Appendix A Money flows for PBS listed pharmaceuticals

Sales of drugs in Australia include payments by patients and government to pharmacies. Pharmacies in turn pay wholesalers and manufacturers for the drugs sold. Pharmacies pay wholesalers and manufacturers prices which are negotiated in the free marketplace.

Payments by patients if required include a fixed co-payment towards the full price of the drug (which may, in some cases, cover the full cost). This co-payment is currently $5.40 for concession card holders and $33.30 for non holders.

A safety net reduces these co-payments if a patient spends more than a fixed amount. This is $324.00 for concession card holders and $1,281.30 for non-holders. If the safety net has been exceeded the patient co-payment is reduced for subsequent purchases within a year. Concession card holders make no further copayments and non-concession card holders pay $5.40 for each script.

In particular circumstances, a manufacturer may set their own higher price on PBS listed medicines. This is known as a brand premium and is payable by patients not the government. At least one brand of every pharmaceutical item must have no brand premium.

The Government pays the pharmacy the price at which the pharmaceutical was sold, minus the relevant co-payment, plus the various incentive payments to pharmacy. Under the Fourth Community Pharmacy Agreement, the Commonwealth price has been set based on a formula which comprises the ex-manufacturer price plus allowances for the supply of PBS medicines over and above that price.

Payments to pharmacy include the price pharmacy receives from government for a pharmaceutical it has sold. This should include a mark-up of close to 10% on the price the pharmacist pays for the drug. The pharmacy mark-up will vary, depending on the value of the medicine as stated in the mark-up tables.

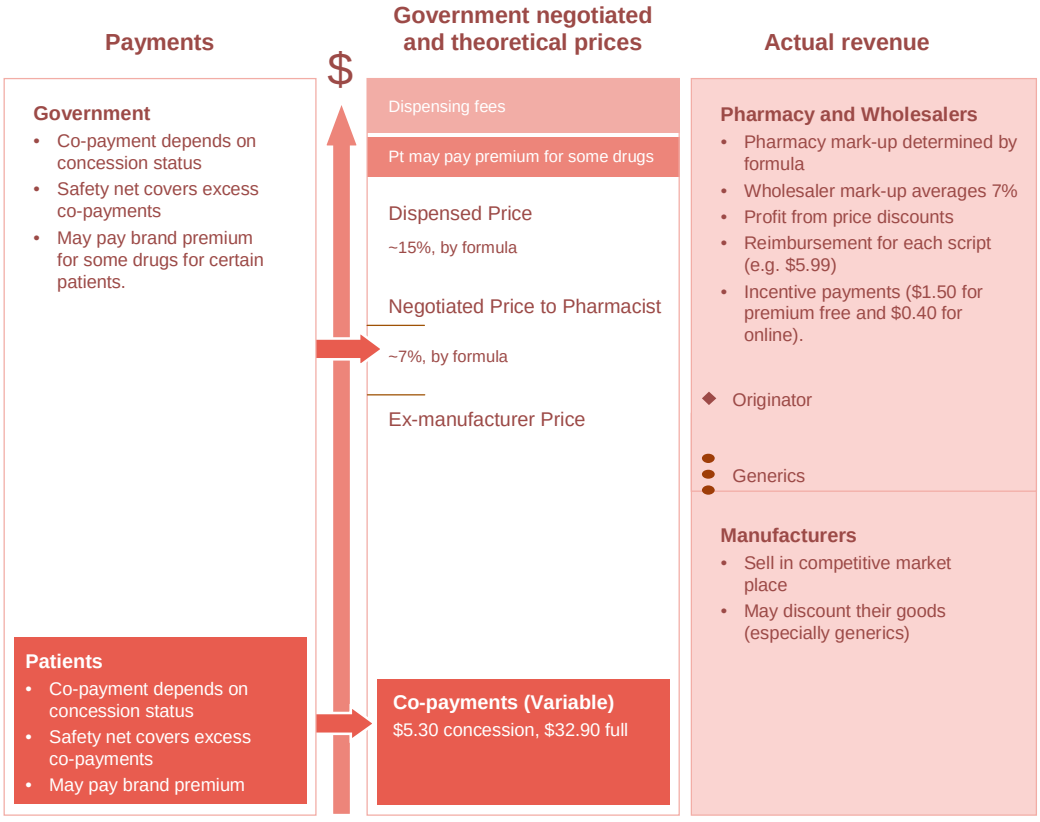
In practice, pharmacists may negotiate prices with wholesalers for the drugs they sell. This price may be cheaper than the Government negotiated price because brands compete on price to pharmacy. The different margins pharmacists make on different generic products and an innovator product form incentives for pharmacists to select and sell different medications. Pharmacists also receive a fixed reimbursement for each script dispensed (e.g. $6.42 for a standard formulation, more or less for various other formulations). Under PBS reform, pharmacists also receive incentive payments to pharmacy as previously outlined.

For wholesalers, the price wholesalers pay manufacturers and the price they charge pharmacists are set competitively. Wholesalers primarily seek to establish and maintain sales with the pharmacy, and pharmacy mark-ups are likely to be lower where they can negotiate higher sales with wholesalers. Under the Fourth Community Pharmacy Agreement, wholesale marks-ups are fixed at a maximum of 7% (which is equivalent to a 7.52% mark-up on the approved ex-manufacturers price of PBS medicines). It is understood that wholesalers often discount their margins to win pharmacy business.

Manufacturers receive a price from wholesalers for the goods sold. On F1 products this price will be close to the APP (approximately 93% of it) because wholesalers and pharmacy have little ability to choose substitutes or negotiate discounts. Some drugs may include a brand premium. It is slightly higher than the APP. However, wholesalers and pharmacies often negotiate discounts from manufacturers on F2 products. Discounts offered to pharmacy may vary for innovator and generic drugs and for different drug classes with different levels of competition.

Figure 2 illustrates the financial flows between stakeholders for the PBS.

Figure 2: Money flows in the PBS



Brand Premiums and protection of supply

After a drug moves to F2 the originator can apply for a premium if they do not accept the price they are now receiving for their product. The originator cannot do this until some date after the competitor enters the market. It must first compete in the marketplace against the new drug with a reduced APP.

From 1 August 2007, responsible persons listing a new brand of a F2 medicine on the PBS, and responsible persons for existing brands that offer a price reduction, will be required to guarantee the supply of these brands. The guarantee of supply period lasts for up to 24 months, or until another bioequivalent or biosimilar medicine lists on the PBS or becomes available at a lower price.

If there is a risk that the new drug will not be able to be supplied any longer the company (sponsor) must notify the Minister. It is a criminal offence not to notify the Minister.

Appendix B Description of demand forecasting methodology

The approach in our analysis is to use the structural time series framework promulgated by Harvey (1989).[3] These models can be described as regressions on functions of time in which the parameters are time-varying. Structural time series models are formulated in terms of unobserved components, such as trends and cycles, that have a direct interpretation. As such they are designed to focus on the salient features of series and project these into the future.

As noted, amongst other things, structural time series models provide a useful platform for analysing varying cyclicality and seasonality (and other components) of a complex form.

The structural time series model employed in this analysis is formulated in terms of a trend, seasonal, cyclical and irregular components. In the most general form of the model, all components are assumed to be stochastic and driven by serially independent Gaussian disturbances that are mutually independent. The model may be formally expressed as follows:

$$y_t = \mu_t + \psi_t + \gamma_t + \varepsilon_t, \quad \varepsilon_t \sim NID\left(0, \sigma_\varepsilon^2\right) \qquad (2)$$

where the trend, cycle, seasonal, and irregular are denoted by μ_t , ψ_t , γ_t and ε_t, respectively. In our analysis of volume growth, y_t denotes the total volume of drugs aggregated up to ATC 5 level. In other words, for each ATC 5 code a model of the form outlined in Equation (2) was developed to generate the forecasts.

The trend in Equation (2) is specified as follows:

$$\mu_t = \mu_{t-1} + \beta_{t-1} + \eta_t, \quad \eta_t \sim NID\left(0, \sigma_\eta^2\right) \qquad (3)$$

$$\beta_t = \beta_{t-1} + \varsigma, \quad \varsigma_t \sim NID\left(0, \sigma_\varsigma^2\right)$$

where μ_t is the level and β_t is the slope. The disturbances η_t and ς_t are assumed to be mutually independent.

The seasonal component is normally constructed in terms of stochastic trigonometric functions as per Harvey (1989), although dummy-variable

[3] Harvey, A.C. (1989), *Forecasting, Structural Time Series Models and the Kalman Filter*. Cambridge: Cambridge University Press.

formulations are also possible. Estimation, and signal extraction are carried out by means of the Kalman filter and associated algorithms. [4]

In this analysis we employ the trigonometric form of stochastic seasonality, where s seasons in the year is

$$\gamma_t = \sum_{j=1}^{[s/2]} \gamma_{j,t}, \quad t = 1,\ldots,T \tag{4}$$

and each $\gamma_{j,t}$ is generated by

$$\begin{bmatrix} \gamma_{j,t} \\ \gamma^*_{j,t} \end{bmatrix} = \begin{bmatrix} \cos\lambda_j & \sin\lambda_j \\ -\sin\lambda_j & \cos\lambda_j \end{bmatrix} \begin{bmatrix} \gamma_{j,t-1} \\ \gamma^*_{j,t-1} \end{bmatrix} + \begin{bmatrix} \omega_{j,t} \\ \omega^*_{j,t} \end{bmatrix} \tag{5}$$

where $\lambda_j = 2\pi j/s$ is frequency, in radians, for $j = 1,\ldots,[s/2]$ and ω_t and ω^*_t are two mutually uncorrelated white-noise disturbances with zero means and common variance σ^2_ω.

In the structural model represented by Equation (2), μ_t is the local linear trend defined by Equation (3), the irregular component, ε_t, is assumed to be random, and the disturbances in all three components are taken to be mutually uncorrelated. The signal-noise ratio associated with the seasonal, that is $q_\omega = \sigma^2_\omega / \sigma^2_\varepsilon$, determines how rapidly the seasonal changes relative to the irregular.

In all cases, the statistical specification of the cycle is described as follows:

$$\begin{bmatrix} \psi_t \\ \psi^*_t \end{bmatrix} = \rho \begin{bmatrix} \cos\lambda_c & \sin\lambda_c \\ -\sin\lambda_c & \cos\lambda_c \end{bmatrix} \begin{bmatrix} \psi_{t-1} \\ \psi^*_{t-1} \end{bmatrix} + \begin{bmatrix} \kappa_t \\ \kappa^*_t \end{bmatrix}, \quad t = 1,\ldots,T \tag{7}$$

where λ_c is the frequency, in radians, in the rage $0 < \lambda_c < \pi$, κ_t and κ^*_t are two mutually uncorrelated white noise disturbances with zero means and common variance σ^2_ψ, and ρ is a damping factor. Note, the stochastic cycle becomes a first-order autoregressive process (i.e., AR(1)) if λ_c is 0 or π.

[4] Consider Harvey, A.C. (1989), *Forecasting, Structural Time Series Models and the Kalman Filter*. Cambridge: Cambridge University Press. and Durbin and Koopman (2000)

Appendix C Modelling the impact of price disclosure

One of the most uncertain aspects of the PBS Reforms is the impact of price disclosure. This uncertainty arises because:

- price disclosure only applies to a subset of drugs. Price disclosure only applies when a new manufacturer enters the market for a particular drug – this can be either for current F2 drugs which may already have a number of manufacturers in competition or for drugs coming off patent and shifting from F1 to F2. Thus the model requires assumptions regarding the drugs which will be sufficiently attractive to attract a new competitor, and the timing of this market entry.
- the weighted average disclosed price (WADP) is based on the effective price pharmacies pay for drugs, taking into account any discounts or other incentives which manufacturers and wholesalers offer to them. This information is commercial-in-confidence and hence not readily available. Additionally, this information is subject to change – it is not clear how manufacturers, pharmacies and wholesalers will respond to the PBS Reforms and hence how prices will change in future years as the reforms mature - future price disclosure impacts are very difficult to estimate.
- calculation of the WADP will also be significantly influenced by the market players who opt in to price disclose. For drugs currently on F2, only the new market entrant needs to disclose; other manufacturers can remain out of the disclosure system. Generic manufacturers tend to offer greater discounts than originators, so this behaviour means that the full impact of price disclosure will be only gradually felt, and will be significantly influenced by the extent of discounts and market share of new market entrants relative to the originator.

Assumptions regarding drugs currently on the F1 formulary

Entry of 'trigger' brands

In choosing assumptions about new market entrants – and hence the molecules which will be subject to mandatory price cuts and price disclosure - it is important to understand that the cost of the F1 formulary is dominated by high volume drugs. As Table 19 shows, low volume drugs form a significant part of the F1 formulary – molecules with total sales of less than $2 million in 1008-09 made up 68% of F1 scripts dispensed. However, this represented just 3% of total expenditure on F1 drugs and 2% of total expenditure on the PBS.

Conversely, high volume drugs above $100 million in sales made up 2% of F1 scripts dispensed but 41% of F1 expenditure and 18% of all PBS expenditure. Thus, understanding the likely extent of competition for large-volume molecules is critical to understanding the potential impact of price disclosure.

Table 19: Market Share of F1 drugs, by market volume ($2008-09)

	% of molecules on F1	% of F1 expenditure ($)	% of total PBS expenditure ($)
Less than $2m	68%	3%	2%
$2m to $5m	17%	4%	6%
$5m to $10m	6%	5%	8%
$10m to $25m	7%	12%	11%
$25m to $50m	4%	15%	13%
$50m to $100m	3%	20%	6%
Over $100m	2%	41%	28%
Total	100%	100%	68%

To understand the likelihood of new competitors entering the market for molecules due to come off patent, we identified 43 molecules in the PBS data which came off patent over the past 5 years, and analysed the timing of any new entrants to the market.

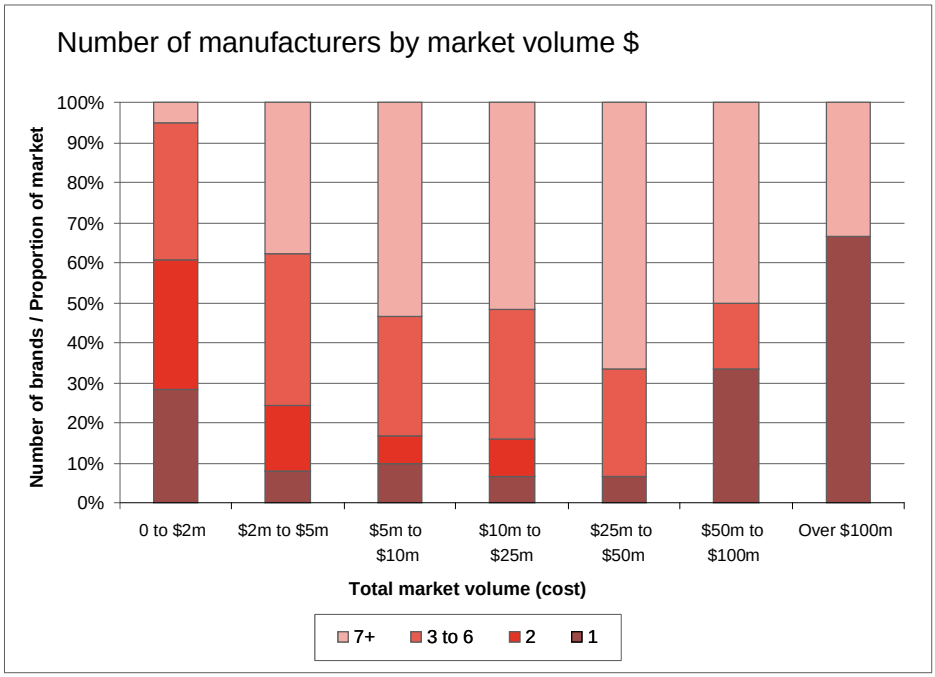
Within two years of coming off patent, and weighted by expenditure, 90% of the molecules we identified had a competitor in the market. However, as Table 20 shows, this varies by market volume, with lower volume drugs less likely to have a competitor enter the market.

Table 20: Percent of identified molecules with at least 1 new entrant after 2 years off patent

	%
Less than $2m	100%
$2m to $5m	74%
$5m to $10m	100%
$10m to $25m	79%
$25m to $50m	100%
$50m to $100m	100%
Over $100m	100%
Weighted average	90%

A similar message comes from analysis of drugs on the F2 formularies. Figure 3 below shows for molecules with different market volumes, the number of manufacturers in the market.

Figure 3: Number of manufacturers by market volume ($) – F2



Around a third of molecules with less than $2 million in annual sales have only one manufacturer in the market place, and it is typical to have only 2 or 3 manufacturers competing in this sector.

Conversely, for molecules with $2 million to $50 million in annual sales, almost all molecules have more than one manufacturer competing in the marketplace, and a third of molecules have 7 or more manufacturers competing for market share. There are only a handful of molecules with over $50 million in sales annually, and these have either extensive competition (5 or more brands in the marketplace) or none – the reason for this is that many of these molecules are still on patent[5].

Clearly, competition is much greater for the larger turnover brands, but it is important to note that some limited competition still exists in the smaller markets.

[5] The four drugs on F2 which had over $50 million in sales but only one manufacturer were: simvastatin and ezetimibe combination, rabeprazole, pantoprazole and esomeprazole, and simvastatin and ezetimibe.

We have therefore assumed that the following molecules will be subject to competition from a new market entrant on patent expiry:

- An 80% chance that low market molecules (less than $2 million per annum) will be subject to new market entrants.
- All molecules with annual sales over $2 million.

Price disclosure discounts

The extent of discounting offered by generic manufacturers is not publicly available information. However, anecdotal evidence indicates that originators tend to offer little or no discount to pharmacists on their drugs, whereas the extent of discount for generics may be in the vicinity of 50% and higher (up to 65%) for larger volume pharmacies.

To understand how price disclosure may impact, we have analysed how the market share of originators and generics has changed over time after patent expiry. Using the same 43 molecules which came off patent and shifted into F2 over the past 5 years, we analysed growth in market share of generics over that time. We have analysed this by market volume to understand the extent to which price disclosure may impact different volume drugs differently.

Table 21 shows that for molecules with sales over $100 million, market share of the originator quickly drops to 61% in the first year after patent expiry and continues to decline to around 22% after Year 4. For molecules in the $50 million to $100 million sales range, the originator loses market share quickly at first, although the overall decline after 4 years is not as dramatic (around 40% market share after 4 years). For smaller markets, less than $50 million sales, market share drops to around 50% after four years and the decline is far more gradual.

Table 21: Proportion of scripts sold by originator brand, molecules shifting off patent, by market volume ($2008-09)

	Year 1	Year 2	Year 3	Year 4
Less than $50m	94%	65%	56%	48%
$50m to $100m	65%	54%	39%	39%
Over $100m	61%	52%	27%	22%

These results are broadly consistent with what is now occurring across the F2 formularies in general. Across all F2 drugs, 43% of all scripts in 2008-09 were sold by the originator and 57% by other manufacturers.

Our price disclosure discount assumptions have been derived by assuming that:

- Market share of originators and generics will reflect that shown above;
- Originators offer no discount, while new market entrants offer discounts of up to 40% initially for markets over $100 million and 20% for other markets; and
- All market participants will price disclose.

A high end and low end assumption has been derived based on assumptions about the discounts which could be expected in the market place and the speed with which new entrants gain market share.

Assumptions regarding drugs currently on the F2 formularies

Entry of 'trigger' brands

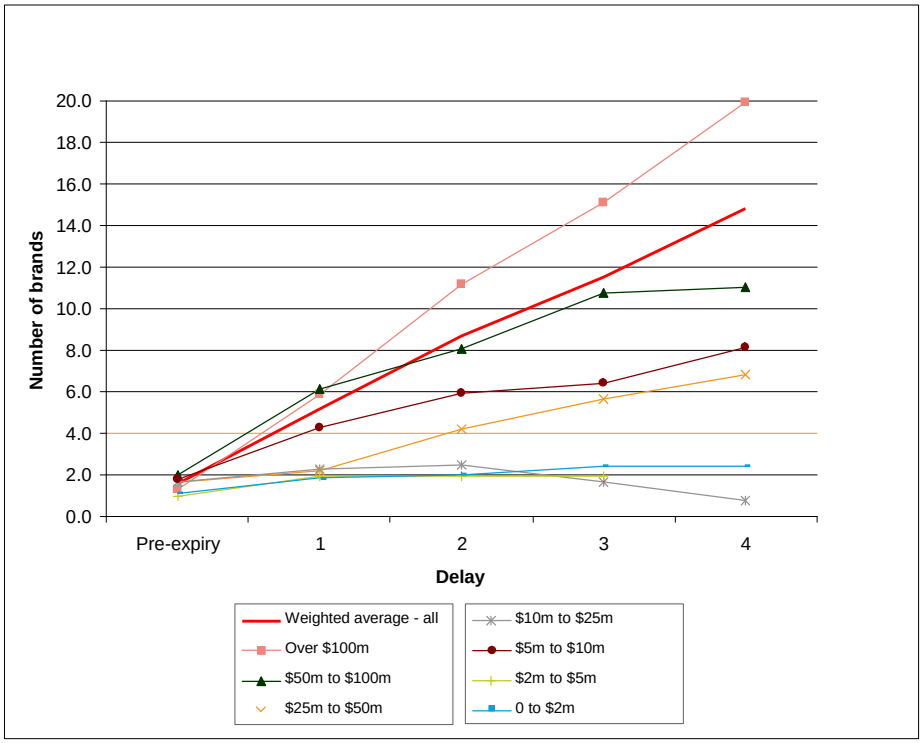
To understand the likelihood of new competitors entering the markets on the F2 formulary, we identified 43 molecules in the PBS data which came off patent over the past 5 years, and analysed the timing of any new entrants to the market.

Figure 4 shows the average number of manufacturers in the market place for each molecule, by delay (years) since the molecule's patent expired. Averages are calculated as a weighted average, and hence the overall average (shown by the dark red line) is heavily weighted toward the over $100 million market drugs (pink line - squares).

Prior to patent expiry, most molecules have only 1 manufacturer, however by one year after patent expiry, the number of manufacturers for each molecule has increased to 5.2 on average. The average number of manufacturers continues to increase each year for the large volume markets greater than $100 million. The average number of manufacturers per brand for this group increases from 5.8 in the first year after patent expiry to 19.9 in Year 4. The number of manufacturers in the $50 million to $100 million and $25 to $100 million markets also grows over this period, although to a lesser extent. There is little change after Year 3.

For smaller volume molecules less than $25 million per annum, the average number of manufacturers changes little after delay 1.

Figure 4: Number of manufacturers by market volume ($) and delay – drugs shifting off patent only.



For drugs currently on the F2 formulary, the important point is that new entrants come into the market, even some years after a drug is off patent and has transferred to the F2 formulary, so our assumptions allow for some limited further competition. We note that the fact that a number of large volume molecules, including Atorvastatin, are coming off patent soon, may make the Australian market attractive for generic manufacturers not previously providing drugs in Australia. They would likely need to offer a range of drugs to negotiate with wholesalers and pharmacies, and this may trigger further competition in the F2 markets.

We have therefore assumed that:

- For molecules with greater than $100 million in market volume, competitors will continue to enter the market in 2010/11 onwards, and trigger price disclosure. By implication, drugs such as Simvastatin are assumed to attract a new generic manufacturer.

For our high estimate impact of price disclosure, we have further assumed that:

- For molecules with between $50 million and $100 million in market volume, there will be some limited further competition. We have assumed that there is a 75% probability that a new manufacturer will enter those markets.
- Similarly, for molecules with less than $50 million in market volume, we have assumed a 40% probability of a new manufacturer entering the market.

Table 22 shows the proportion of molecules coming off patent which have a new manufacturer enter the market each year. Even in Year 4, drugs over $100 million in turnover are attracting new manufacturers, whereas in the lower-volume markets, new entrants are few after Year 3.

Table 22: Proportion of drugs shifting off patent which have a new competitor in each year after patent expiry, by market volume ($2008-09)

	Year 1	Year 2	Year 3	Year 4
Less than $50m	82%	41%	40%	28%
$50m to $100m	100%	76%	79%	35%
Over $100m	74%	79%	100%	100%

The price disclosure discount assumptions for F2 have been derived by assuming that:

- Market share of originators and generics will reflect that shown in Table 21
- Only the new market entrant and the originator price disclose. The new market entrant is assumed to achieve 10% to 13% market share. (We note that there may be other generic providers in the market place also, though they need not price disclose).
- Originators offer no discount, while new market entrants offer discounts of up to 20% initially;

A high end and low end assumption has been derived based on assumptions about the discounts which could be expected in the market place and markets which generic manufacturers will find sufficiently attractive to enter.

Appendix D International comparison of selected drug prices

Medicine price comparisons for drugs available in the Australian and UK markets for the highest volume drugs on the PBS are shown in the table below.

The UK prices are based on those reported by the National Health Service in the Electronic Drug Tariff January 2010. These prices are converted into Australian dollars based on the average exchange rate in 2009, which was 0.504442.

This comparison should be treated with caution. Prices in different markets reflect a large range of factors, from market size to distribution networks. There are also differences in product forms, strengths, and pack sizes that are made available in different markets.

The comparison shows that for many of the highest volume drugs on the PBS, Australian prices are higher than those available in the UK. It also shows that in some cases Australian prices are lower than those available in UK, reflecting the differences in the two markets and the diverse influences on in-country prices for medicines.

Table 23: Price comparisons between the UK and Australia for the 10 top volume drugs on the PBS

Drug	Form and strength	UK price per pack	UK price in AUD	Commonwealth Dispensed Price for Maximum Quantity	Difference in Australian prices
Atenolol	Tab 50 mg	£0.92	$1.82	$10.27	1016.3%
Atorvastatin	Lipitor_Tab 10mg	£13.00	$25.77	$42.70	65.7%
	Lipitor_Tab 20mg	£24.64	$48.85	$58.00	18.7%
	Lipitor_Tab 40mg	£24.64	$48.85	$79.05	61.8%
	Lipitor_Tab 80mg	£28.21	$55.92	$110.25	97.1%
Esomeprazole	Nexium_Tab 20mg	£18.50	$36.67	$38.54	5.1%
	Nexium_Tab 40mg	£25.19	$49.94	$58.67	17.5%
Irbesartan	Aprovel_Tab 75mg	£9.89	$19.61	$21.11	7.7%
	Aprovel_Tab 150mg	£12.08	$23.95	$25.15	5.0%

Drug	Form and strength	UK price per pack	UK price in AUD	Commonwealth Dispensed Price for Maximum Quantity	Difference in Australian prices
	Aprovel_Tab 300mg	£16.25	$32.21	$30.24	-6.1%
Metformin Hydrochloride	Glucophage_Tab 500mg	£6.58	$13.04	$13.09	0.4%
	Metformin HCl_Tab 850mg	£1.38	$2.74	$13.09	378.5%
Pantoprazole	Tab E/C 20mg	£9.45	$18.73	$22.37	19.4%
	Tab E/C 40mg	£16.43	$32.57	$39.14	20.2%
Paracetamol	Paracet_Tab 500mg	£1.58	$3.13	$8.42	168.8%
Rosuvastatin Calcium	Crestor_Tab 5mg	£18.03	$35.74	$51.18	43.2%
	Crestor_Tab 10mg	£18.03	$35.74	$69.91	95.6%
	Crestor_Tab 20mg	£26.02	$51.58	$96.43	86.9%
	Crestor_Tab 40mg	£29.69	$58.86	$134.44	128.4%
Perindopril Arginine	Coversyl_Tab 2.5mg	£9.09	$18.02	$12.73	-29.4%
	Coversyl_Tab 5mg	£10.22	$20.26	$18.14	-10.5%
	Coversyl_Tab 10mg	£11.36	$22.52	$24.34	8.1%
Simvastatin	Tab 10mg	£0.91	$1.80	$25.04	1288.0%
	Tab 20mg	£1.00	$1.98	$33.2	1574.7%
	Tab 40mg	£1.38	$2.74	$44.45	1524.8%
	Tab 80mg	£2.96	$5.87	$59.42	912.6%