Appendix A: Independent consultant's report—Executive Summary of the impacts of Pharmaceutical Benefits Scheme Reform (PricewaterhouseCoopers)

Department of Health and Ageing

The Impacts of Pharmaceutical Benefits Scheme Reform

February 2010

PricewaterhouseCoopers

Appendix A

Independent consultant's report—

Executive Summary of the impacts of Pharmaceutical Benefits Scheme Reform (PricewaterhouseCoopers)

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Independent consultant's report—
Executive Summary of the impacts of Pharmaceutical Benefits Scheme Reform (PricewaterhouseCoopers)

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.

  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

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

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

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.

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**

	$million	$million
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 increases 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

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.

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

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

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.

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

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 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 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 $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

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 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%)
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	F1 will contain all drugs that do not meet the criteria for F1.
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

Abbreviation	Definition
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
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
TGP	Therapeutic Group This means a group of drugs which have been determined to be interchangeable at the patient level.

Appendix A

Independent consultant's report—

Executive Summary of the impacts of Pharmaceutical Benefits Scheme Reform (PricewaterhouseCoopers)

Abbreviation	Definition
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