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Executive summary

The Pharmaceutical Benefits Scheme (PBS) has been in operation for 61 years with some benefits first made available in June 1948. At December 2009, the PBS provided access to over 740 drugs available in more than 1,850 forms, and marketed as over 3,500 brands.

On 28 June 2007, amendments to the *National Health Act 1953* received royal assent which gave effect to a significant restructure of PBS pricing arrangements to ensure the long-term sustainability of the PBS. This restructure is referred to as PBS reform. A requirement of the legislation is that the Minister for Health and Ageing presents a report to the Parliament on the impact of the reforms.

At the time the PBS reform package was introduced, the PBS appeared to be entering a phase of lower, more stable growth, although new medicines continued to be listed and patents for over 100 drugs were expected to expire within the decade. It was considered opportune to restructure PBS pricing to achieve better value and greater price transparency, particularly for multiple brand medicines subject to market competition.

The PBS in operation

Australia's National Medicines Policy (NMP) provides the overarching framework for the operation of the PBS. The overall aim of the NMP is to meet medication and service related needs so that optimal health outcomes and economic objectives are achieved. The NMP has four central objectives:

- timely access to the medicines that Australians need, at a cost individuals and the community can afford;
- medicines that meet appropriate standards of quality, safety and efficacy;
- quality use of medicines; and
- maintaining a responsible and viable medicines industry.

Patients contribute to the cost of the supply of medicines under the PBS through co-payments, with Government meeting the cost of the medicine that exceeds the co-payment. Concessional patients (those who hold Commonwealth concession cards) are entitled to greater subsidy of their medicines and, as such, pay a lower co-payment. From 1 January 2010, the co-payments are $5.40 for concessional patients and $33.30 for general patients.

The supply of medicines to consumers involves several parties through a supply chain. The PBS recognises three specific functions in the supply of medicines—manufacturing, wholesaling and dispensing. The majority of PBS medicines are dispensed through community pharmacies which are responsible for checking and filling PBS prescriptions and advising consumers on how to use the dispensed medicines.

PBS reform

PBS reform comprised a package of measures designed to achieve better value for money from drugs that are subject to price competition. Key elements of the reform package were as follows:

- Creation of two separate formularies on the PBS. Formulary One (F1) consists of drugs where there is only one brand and Formulary Two (F2) consists of drugs where there are two or more brands listed on the PBS. F2 is further divided into two parts until 1 January 2011:
  - F2A which contains all drugs that were not subject to high levels of discounting to pharmacies on 1 October 2006; and
  - F2T which contains all drugs that were subject to high levels of discounting to pharmacies on 1 October 2006.

  Drugs on F1 move to F2A when a new brand lists.

- A series of statutory price reductions apply to F2 medicines as follows:
  - staged 2 per cent price reductions for F2A drugs on 1 August 2008, 1 August 2009 and 1 August 2010; and
  - a 25 per cent price reduction for F2T drugs on 1 August 2008.

  Five single brand drugs were placed on F2T because they were in a therapeutic group with other multiple brand drugs. Because these drugs were still on patent, it was decided that the price reduction for the drugs would be phased in instalments over the remainder of the patent life of the drugs.
- Formalisation through legislation of the 12.5 per cent price reduction policy that had been applied administratively since 1 August 2005. Under this policy, the first time a new brand of a PBS listed drug is listed on the PBS, the price of all brands of that drug is reduced by 12.5 per cent.
- Progressive introduction of a system of price disclosure for all F2 medicines from 1 August 2007 for F2A and January 2011 for other medicines on F2. Under these arrangements, any manufacturer listing a new brand of a PBS medicine is required to provide the Department of Health and Ageing with information about the prices at which it sold its new brand. Based on the information provided across a year, a 'weighted average disclosed price' (WADP) is calculated that reflects the price at which the drug is being supplied in the market. If this WADP is more than 10 per cent below the PBS price, then the PBS price is reduced to the WADP.

PBS reform included a structural adjustment package for community pharmacies and wholesalers that recognised the potential impact of the statutory price reductions listed above (through losses of trading terms and reductions in percentage mark-ups). The structural adjustment package consisted of:

- a change to the pharmacy mark-up structure, resulting in an increase in mark-ups for many medicines;

- an incentive for pharmacies to process claims using PBS Online;
- a premium-free dispensing incentive to encourage pharmacies to dispense brands of substitutable PBS medicines that cost consumers no more than the relevant co-payment; and
- an increase to the Community Service Obligation (CSO) funding pool for wholesalers that participate in that arrangement.

PBS reform also included a number of other measures that did not relate to the pricing of medicines, including:

- introduction of a guarantee of supply requirement that obliges the manufacturer listing a new brand triggering a statutory price reduction or offering a price decrease for an existing brand of a PBS item to undertake to supply that brand for 24 months;
- introduction of a streamlined authority arrangement to reduce the administrative effort of doctors to prescribe some lower risk authority-required medicines; and
- the establishment of a working group to provide strategic oversight of joint activities undertaken by the Department and Medicines Australia to enhance the PBS processes, and to consider issues relating to timely and appropriate access to effective new medicines on the PBS.

In addition to the reform measures, funding was provided for a campaign to increase consumer awareness of the safety and effectiveness of generic medicines.

Implementation of reform

All components of the reform package have commenced.

Statutory price reductions

A total of 450 PBS items across 89 F2T drugs received the full 25 per cent price reduction on 1 August 2008 and 13 items across all five single brand drugs on F2T received the first instalment of the phased price reduction. In addition, a number of drugs were subject to a partial 25 per cent price reduction because one or more components of the combination drug was listed on F2T.

On the first price reduction date of 1 August 2008, a total of 449 PBS items listed on F2A received a 2 per cent price reduction. This rose to 487 PBS items for the second 2 per cent price reduction on 1 August 2009. In addition, a number of combination drugs were subject to a partial 2 per cent price reduction on these dates because one or more components of the combination drug was listed on F2A.

There is provision under the legislation for the Minister to exempt items from statutory price reductions to ensure that access to specific PBS items is not threatened when there are no suitable alternatives. There were 45 items exempt from statutory price reductions on 1 November 2009. These items are also exempt from price disclosure requirements.

Price disclosure

The price disclosure arrangements commenced on 1 August 2007 for all drugs on F2A. Between 1 August 2007 and 1 December 2009, a total of 38 drugs became subject to price disclosure. As at December 2009, calculations had been performed on three separate occasions, with price reductions determined for seven out of 20 price disclosure groups.

The implementation of the price disclosure arrangements has been subject to some administrative issues and legal challenge. The early implementation issues serve to illustrate that the introduction of new arrangements can be complex to administer and may take some time to fully and effectively operationalise. The Department is responding to the issues that have arisen by ensuring that appropriate protocols and procedures are in place for all steps and stages of the price disclosure process. The Department is also considering the experience of the early rounds of price disclosure in the development of suitable arrangements for dispute resolution into the future, and will continue to consult the industry.

Structural adjustment package

The implementation of the PBS Online initiative from 1 July 2007 (which pays pharmacies $0.40c per prescription lodged using PBS Online) has led to a significant increase in the number of pharmacies claiming PBS benefits online. In December 2009, approximately 97 per cent of community pharmacies were using PBS Online.

The premium-free dispensing incentive was introduced on 1 August 2008 ($1.50 indexed annually) to pay pharmacies for each substitutable PBS medicine dispensed that does not have a brand premium or other special patient contribution. In the first 12 months of its implementation (1 August 2008 to 31 July 2009), the incentive was paid on over 75 million eligible prescriptions (payments totalled over $112 million). This represents over 40 per cent of the total 182 million PBS prescriptions dispensed over this period.

As part of PBS reform, dispensing fees paid to pharmacies were increased and changes were made to the mark-ups that apply to PBS medicines. These arrangements took effect on 1 August 2008.

Additional funding of $69 million over three years was added to the CSO funding pool from 1 July 2008.

Other measures

A campaign to increase consumer awareness of generic medicines was conducted by the National Prescribing Service (NPS) from June 2008 to July 2009. An evaluation of the campaign concluded that it had been successful in achieving its objective of increasing confidence and understanding about the safety and efficacy of prescription generic medicines.

From 1 August 2007, manufacturers have been subject to new guarantee of supply arrangements. The Department received 54 notifications of failure to supply between 1 August 2007 and 1 December 2009. These have had a limited impact on consumers because, in each case, there was at least one other brand of the medicine available.

The new streamlined authority process was instituted from 1 July 2007 for almost half of the medicines then listed as authority-required. The impact of the new streamlined authority process on prescribing behaviour during the first year of operation was closely monitored, and a review found no substantial changes in either total prescription volume or total PBS outlays during that period. The Government decided that further additions to the list could be considered, and a new stakeholder forum was established to provide opportunities for the medical profession and the Department to consider the operation of the arrangements on an ongoing basis.

Although the streamlined authority arrangements have reduced administrative burden for doctors, the authority system remains an important one for ensuring the appropriate prescribing of PBS listed medicines. In 2008–09 there were 178,517 requests for authority prescriptions rejected by Medicare Australia.

As part of PBS reform, the Access to Medicines Working Group (AMWG) was formed by the Department and Medicines Australia to provide strategic oversight of joint activities undertaken to enhance the PBS processes, and to consider issues relating to timely and appropriate access to effective new medicines on the PBS. The AMWG has met eight times since its establishment.

Impact of reform to date

PBS reform was originally forecast to save $580 million over the five years 2006–07 to 2010–11. The forecasts were reduced to $103 million ($110 million including the Repatriation Pharmaceutical Benefits Scheme (RPBS)) as a result of subsequent policy changes and other factors.

Savings from statutory price reduction

Expenditure on affected items in F2T in 2008–09 was $1.51 billion. The Department has estimated that without the price reduction, expenditure on these items would have been $1.77 billion. Therefore the F2T price reductions are estimated to have reduced PBS outlays by about $263 million in 2008–09.

Expenditure for the affected items on F2A in 2008–09 was $602 million. The Department has estimated that without the price reduction, expenditure on these items would have been $613 million. Therefore the F2A price reductions are estimated to have reduced PBS outlays by $11 million in 2008–09.

The first price reductions from price disclosure were due to take effect for affected F2A medicines on 1 August 2009. Due to a range of issues, this did not occur on this date. Price reductions for three drugs took effect on 1 December 2009. Data on the impact of these price reductions is not yet available.

In total, the estimated reduction in PBS outlays in 2008–09 from the statutory price reductions is $274 million.

Structural adjustment package

The uptake of PBS Online was more rapid than expected. As a result of this measure, the Government paid pharmacies a total of $145.5 million to June 2009. Government also paid pharmacies an additional $102.4 million in 2008–09 through the premium-free dispensing incentive.

As a result of the changes to the mark-ups and dispensing fees, Government paid an estimated additional total of $89.4 million to pharmacies in 2008–09.

In 2008–09, the Government paid an additional $22 million to wholesalers to support the CSO.

The total cost to Government of the structural adjustment package was $359.3 million to June 2009.

The net cost to Government on administered funds to 30 June 2009 was $85.3 million. This reflects the difference between the cost of the structural adjustment package ($359.3 million) and the estimated reduction in PBS outlays ($274 million).

Impact on consumers

The effect of medicines' price changes on consumers is limited by the operation of the PBS co-payments. Concessional patients did not experience any effect of the 1 August 2008 price changes because all PBS items were priced above the concessional co-payment ($5.30 in 2009). Consequently, concessional patients continued to pay the basic co-payment amount of $5.30 for their medicines. The price of under co-payment medicines was affected for general patients ($32.90 in 2009).

There is no evidence of any adverse impact on consumers by manufacturers offsetting statutory price reductions through increased prices, including the imposition of brand premiums. Such increases cannot occur on the same day as a price reduction; and if a company imposes a brand premium, there must be at least one brand that is not subject to a brand premium.

The combined impact of the 25 per cent and the first 2 per cent price reductions and changes to mark-ups and dispensing fees resulted in some PBS items decreasing in price and others increasing in price. In total, 398 under co-payment items decreased in

cost to non-concessional (general) patients; 688 under co-payment items increased in cost to non-concessional patients; and 1,122 under co-payment items did not change in price to non-concessional patients. The average decrease was $1.92 and the average increase was $0.64c.

The second 2 per cent statutory price reduction on 1 August 2009 also affected the price paid for PBS medicines for under co-payment drugs by non-concessional patients. Altogether, 179 items in the F2A formulary dropped in price by 2 per cent or more, by an average of $0.46c, between July and August 2009.

Impact on the supply chain

Medicines are supplied under a range of trading terms between participants in the supply chain. Because these trading terms form part of confidential commercial relationships between the participants, reliable information on the exact nature of the trading terms is not readily available. Therefore, it is not possible to accurately estimate the likely actual loss or gain from price changes for any particular part of the supply chain. The analysis in this report does not include any impact of changed trading terms.

Manufacturers

As a result of PBS reform, it is estimated that the PBS expenditure on the manufacturer component of PBS prescriptions (the PBS price excluding all mark-ups and dispensing fees, also known as the ex-manufacturer price) was reduced by $341.0 million in 2008–09.

The ex-manufacturer price does not equate directly to income for manufacturers. The extent to which reductions in the ex-manufacturer price translate to loss of income for manufacturers depends on trading terms with wholesalers and pharmacies.

Although limited, the available data shows that prescriptions for generic medicines are increasing at lower overall cost to Government, while prescriptions for innovator

medicines are reducing but at higher proportional cost to Government. Broadly, this suggests that the PBS is buying more generics at a cheaper price while maintaining access to new innovative medicines.

Wholesalers

It is estimated that PBS reform resulted in expenditure on wholesaler margins being $25.6 million lower than would have otherwise been the case. A reduction in wholesaler margin does not necessarily equate to a reduction in wholesaler income because medicines are provided to pharmacies under different trading terms. Additional funding of $22 million to CSO funding to partially offset the reduction in wholesaler margin occurred in 2008–09.

Pharmacies

Estimating the impact on pharmacies is particularly complex. Pharmacy income is derived from a number of sources, including remuneration for supplying PBS medicines, income from private prescriptions and other retail income derived from front-of-shop sales. In relation to PBS medicines supplied by pharmacies, increases in dispensing fees, changes to mark-up bands and the introduction of new incentives had an upward impact on pharmacy incomes, but statutory price reductions had a downward impact on income from mark-ups for many medicines.

Pharmacy income also varies as a result of the trading terms a pharmacy is able to negotiate with manufacturers and/or wholesale suppliers. Given the size of some statutory price reductions, it is likely that the trading terms previously available to pharmacies for many medicines have changed following PBS reform. Data on these trading terms is not generally known to the Department.

From the PBS Online incentive, pharmacies received $145.5 million to June 2009. In addition, pharmacies received $102.4 million in 2008–09 through the premium-free dispensing incentive and an estimated additional $89.4 million in 2008–09 from the changes to the

dispensing fee and mark-ups. The estimated net impact of the structural adjustment package on pharmacies was $68.6 million in 2007–08 and $268.7 million in 2008-09 (note that this does not include the offsetting effect of changes to trading terms, which cannot be estimated by the Department but which will grow over time as price disclosure affects the trading terms able to be offered by manufacturers and/or wholesalers).

Prescribers

PBS reforms have had a positive impact on prescribers. Access to a wide range of subsidised medicines has been preserved and the introduction of the streamlined authority arrangements has been well received. The medical profession has noted the success of the arrangements in reducing the administrative burden on doctors, and is seeking extensions to the list of streamlined authorities drugs.

Long-term impact of reform

Long-term forecasting is difficult and requires assumptions to be made about a wide range of factors which are, by necessity, somewhat speculative. The further out the forecasting period, the more difficult the task. To assist its assessment of the long-term impact of reform, the Department commissioned PricewaterhouseCoopers (PwC) to model the future impact of the reform package on Government expenditure, the pharmaceutical industry, wholesalers, pharmacies and consumers.

Decisions taken by Government since the Department first commissioned this work are also reflected in the modelling, including those aspects of the in-principle agreement reached with the Pharmacy Guild of Australia in December 2009 that relate to pharmacy remuneration and the structural adjustment package.

PwC was asked to consider the impact of the reform package in the long term on the pharmaceutical supply chain. These estimates should be considered notional only,

because they do not take account of the impact of changed trading terms on any part of the supply chain. PwC estimates that, over the forecast period from 2008–09 to 2017–18:

- Consumers will pay between $592 million and $803 million less in patient co-payments as a result of the price reductions from PBS reform.
- The total savings to Government from the reforms will be in the range of $3.6 billion to $5.8 billion to 2018. The estimated contribution of the price disclosure component of the reforms is in the range of $2.2 billion to $4.4 billion.
- The cost to Government of the structural adjustment package will be in the order of $3.0 billion (excluding the impact of the price reductions).
- The impact of reform on direct payments from Government to pharmacies will be a nominal increase in the range of $2.2 billion to $2.4 billion (note that this is not a net impact of reform on pharmacies because it does not take account of any impact of changed trading terms will act to reduce the benefit to pharmacies).
- The impact on the wholesaler margin will be a reduction in the range of $0.2 billion to $0.3 billion.
- The impact on the manufacturer component of PBS prices will be a reduction in the range of $6.4 billion to $8.5 billion.

As noted earlier, changes to components of the PBS price does not translate directly as a loss or gain in revenue to any part of the supply chain because of trading terms that are negotiated between the participants. The estimates produced can in no way be taken to illustrate net impacts of the reforms on manufacturers, wholesalers or pharmacies.

It is important to note that the PwC modelling is based on data relating to the large subset of PBS medicines affected by the reform package (those subsidised under section 85 and section 100 of the *National Health Act 1953* and those subsidised under the RPBS). It does not include all PBS data collected by the Department[1], therefore the figures are not directly comparable to those routinely published by the Department.

1 Section 100 not processed by Medicare Australia. Highly Specialised Drugs, Doctors Bag, Safety Net Cards are excluded.

The PBS into the future

PBS reform was originally estimated to produce savings to Government of $3 billion over 10 years. PwC modelling puts the figure in the range of $3.6 billion to $5.8 billion, depending significantly on savings to be realised through price disclosure. These figures need to be set against the backdrop of projected growth in health spending and the factors that drive that growth. The Government's report, *Australia to 2050: future challenges* (the 2010 intergenerational report), released on 1 February 2010 forecasts that health spending will grow, as a percentage of GDP, from 4 per cent in 2009–10 to 7.1 per cent in 2049–50. Per capita expenditure on the PBS is expected to grow in real terms over the forecast period.

PBS expenses for 2008–09 were $7.7 billion, a growth rate of 9.2 per cent over the previous year. This compares with annual growth of 9.4 per cent in 2007–08 and average annual growth of 9.6 per cent between 1998–99 and 2008–09. In the last 10 years, average annual growth in PBS was higher than that of Gross Domestic Product (GDP) (7.2 per cent in nominal terms). Figures published as part of the Portfolio Additional Estimates forecast growth in 2009–10 to be higher than 2008–09, at about 10.6 per cent.

The forecasts for future expenditure suggest that, even with higher (than anticipated) savings likely to come from reform, PBS outlays into the future will be above the original estimates. Actual expenditure on the PBS by 2018 will be higher, after savings, than originally projected before structural reform. Based on current projections outlays in 2018 will be in the order of $13 billion even if the high end estimate of savings from reform is realised and $13.7 billion under the lower saving scenario.

As part of its analysis PwC considered the prices of drugs in Australia relative to prices paid by the National Health Service (NHS) in the UK. PwC observed that, while in some cases Australian prices are lower than those in the UK, for several of the highest volume drugs on the PBS, Australian prices are higher than in the UK. Examples include simvastatin (40 mg tablets) for which the PBS pays $44.45 (AUD) compared with $2.74 (AUD) in the UK, atorvastatin (40mg tablets) for which the PBS pays $79.05 (AUD)

compared to $48.85 (AUD) in the UK and atenolol (50mg tablets) which is $10.27 on the PBS (AUD) and $1.82 in the UK[2].

These examples point to the need to continue a responsible search for opportunities to provide the best possible medicines for Australians at the best possible prices.

Conclusion

The reforms to the PBS have been progressively implemented since the middle of 2007, with some components yet to take full effect (such as price disclosure for drugs on F2T). The indications are that the overall impact on patients has been positive and a modest reduction in government expenditure on the PBS has occurred. The impact of the reforms on different parts of the supply chain is difficult to determine.

As noted, long-term forecasting is difficult and relies heavily on a range of assumptions, the validity of which will not be known for several years. While the indications for significant savings from the reforms into the future are very positive, for the reasons outlined, the Government views these figures with cautious optimism.

It is important to protect the fundamental objective of the PBS—to provide access for Australians to safe and effective medicines at a cost the individual and community can afford. Under current arrangements, the cost of the PBS is expected to continue to grow, even taking into account the impact of the reforms; and this will put increasing pressure on the health budget. A responsible Government must keep such a large and growing program under constant review.

2 These comparisons are a 'point in time' calculation. Such comparisons depend on PBS and NHS prices and exchange rates between currencies at the time of calculation and the methodology applied to standardise supply (eg pack size) and account for dispensing fees.

2

Introduction

In November 2006, the then Minister for Health and Ageing announced a significant restructure of PBS pricing arrangements to ensure the long-term sustainability of the PBS. This restructure is referred to as PBS reform. To give effect to many of the elements of PBS reform, changes to the *National Health Act 1953* (the Act) were necessary; and these were contained within the *National Health Amendment (Pharmaceutical Benefits Scheme) Act 2007* (the Amending Act) which received royal assent on 28 June 2007 and came into effect on 1 August 2007.

Section 104B of the Act states that the Minister must prepare a report on the impacts of the reforms made by the Amending Act by 31 December 2009 and must cause a copy of that report to be laid before each House of Parliament within five sitting days after the day of the completion of the preparation of the report. This report details the impact of the Amending Act and all other aspects of PBS reform, including its impact on Government expenditure and its impact on consumers, prescribers and the pharmaceutical supply chain. The report also considers the possible future impact of PBS reform.

This report is not intended to serve as a detailed guide to PBS reform or the PBS more generally, and some aspects of the PBS and PBS reform have been simplified for readability. Readers who require a detailed understanding of specific policies are encouraged to contact the Department of Health and Ageing (the Department).

In response to a request from the Department, submissions were received from the Pharmacy Guild of Australia, Medicines Australia, the Generic Medicines Industry Association, the National Pharmaceutical Services Association and the Australian Medical Association. In addition, one manufacturer made an independent submission. These submissions were considered in the preparation of this report.

3

Background

3.1 The PBS

The Pharmaceutical Benefits Scheme (PBS), along with the Medicare Benefits Schedule and free access to public hospitals, is one of the pillars of Australia's public health system. The PBS provides Australians with access to necessary and lifesaving medicines at an affordable price.

The PBS has been in operation for 61 years with some benefits first made available in June 1948. It has evolved from supplying a limited number of 'lifesaving and disease preventing drugs free of charge to the community into a broader subsidised scheme which, as of December 2009, provides access to over 740 drugs available in more than 1,850 forms, and marketed as over 3,500 brands.

Australia's National Medicines Policy (NMP) provides the overarching framework for the operation of the PBS. The overall aim of the NMP is to meet medication and service related needs so that optimal health outcomes and economic objectives are achieved. The NMP has four central objectives:

- timely access to the medicines that Australians need, at a cost individuals and the community can afford;
- medicines that meet appropriate standards of quality, safety and efficacy;
- quality use of medicines; and
- maintaining a responsible and viable medicines industry.

All of the medicines available under the PBS are listed in the Schedule of Pharmaceutical Benefits (the Schedule). The Schedule also explains how the medicines can be used in order to be subsidised.

In 2006–07, the year that PBS reform was announced, the Australian Government spent over $6.4 billion on the PBS. In that year, the cost to Government of the PBS grew by 4.3 per cent. Over the previous 10 years (1997–98 to 2006–07), the PBS grew by an average of 9.9 per cent per annum, compared with average Gross Domestic Product (GDP) growth of 6.5 per cent (in nominal terms).

3.2 Consumers

Consumers were a key consideration in the development of PBS reform and the preparation of this report. When the intention to implement reforms to the PBS was first announced in November 2006, the then Minister for Health and Ageing stated that consumers would not be disadvantaged.

There are two types of patient categories providing different levels of subsidised access to medicines through the PBS—concessional patients and general (non-concessional) patients. To be eligible for concessional benefits under the PBS, patients must have one of the following concession cards:

- Pensioner Concession Card;
- Commonwealth Seniors Health Card; or
- Health Care Card.

Both concessional and general patients contribute to the cost of the supply of medicines under the PBS through co-payments, with Government meeting the cost of the medicine that exceeds the co-payment. However, concessional patients are entitled to greater subsidy of their medicines and, as such, pay a lower co-payment.

When PBS reform was announced, the co-payments were $4.70 for concessional patients and $29.50 for general patients. These payments are indexed each year. From 1 January 2010, the co-payments are $5.40 for concessional patients and $33.30 for general patients.

There is also a PBS safety net that operates to protect consumers from high out of pocket expenses in any calendar year. A concessional patient who reaches the safety net is not required to pay a co-payment for any further PBS medicines received in that calendar year. A general patient reaching the safety net pays the lower concessional co-payment for PBS medicines dispensed during the remainder of that calendar year.

When PBS reform was first announced, the safety net thresholds were $253.80 for concessional patients and $960.10 for general patients. From 1 January 2010, the thresholds are $324.00 for concessional patients and $1,281.30 for general patients.

In 2006–07, there were approximately 168 million prescriptions subsidised under the PBS. By 2008–09 this had risen to approximately 182 million prescriptions. In addition, approximately 22 per cent of prescriptions each year are dispensed to general patients at a cost below the PBS co-payment[3]. These prescriptions do not attract a Government subsidy and are, therefore, not currently recorded in Medicare Australia PBS claiming data, although there are plans to remedy this.

3.3 Prescribers

Consumers can only access subsidised PBS medicines if they have a valid PBS prescription from a PBS prescriber. At November 2006, only medical practitioners and participating dental practitioners were able to prescribe PBS medicines. However, since 1 January 2008, authorised optometrists have had limited prescribing rights under the PBS.

3.4 The pharmaceutical supply chain

Medicines are like many other products in that their supply to consumers involves several parties through a supply chain. There are different models of supply, but the PBS recognises three specific functions in the supply of medicines—manufacturing, wholesaling and dispensing.

3 Drug Utilisation Sub-Committee Data for 2007–08. Sourced from a sample of community pharmacies.

The dispensed price of each PBS medicine is made up of at least the following four components:

- the ex-manufacturer price—an amount that recognises the cost of the medicine itself from the manufacturer;
- a wholesaler margin—a percentage or flat fee that recognises the wholesaler's role in storing and distributing medicines to pharmacy;
- a pharmacy mark-up—a percentage or flat fee that recognises the pharmacy's role in storing medicines and making them available for consumers; and
- a dispensing fee—a fee that recognises the pharmacist's professional role in dispensing medicines to consumers.

There are also a number of other fees that apply to some items, such as a dangerous drug fee.

While the manufacturer is notionally entitled to be paid the ex-manufacturer price for the medicine and the wholesaler is entitled to be paid the full wholesaler margin, competitive pressures mean that these prices may be discounted as a way of winning or maintaining market share. While PBS medicines are ultimately funded by Government and patient co-payments, it is community pharmacies that purchase these medicines from wholesalers or manufacturers and benefit from any discounting that is available.

3.4.1 Suppliers (manufacturers)

Suppliers of PBS subsidised medicines make medicines available to community pharmacies through wholesalers or directly to pharmacies. Many suppliers import these medicines from overseas. Typically, the supplier of a medicine will also be the sponsor of the medicine for gaining Therapeutic Goods Administration (TGA) approvals and a recommendation for subsidy through the PBS.

As part of the Amending Act, suppliers were asked to accept additional responsibilities when seeking to list a new brand of a PBS medicine. These new responsibilities are discussed later in this report. Within the Act, for the purposes of the PBS, suppliers are referred to as 'Responsible Persons'.

Suppliers are often described as either 'generic' or 'innovator' companies. Generally speaking, innovator companies are primarily concerned with the marketing of patented medicines. Generic companies generally focus on the manufacture and supply of existing medicines that are no longer on-patent. Some manufacturers supply both innovator and generic brands of medicines. Both types of suppliers make an important contribution to the availability of medicines and ongoing viability of the PBS.

Most suppliers of patented medicines in Australia are represented by Medicines Australia, while the Australian generic medicines industry is represented by the Generic Medicines Industry Association (GMiA).

There are currently approximately 170 suppliers of medicines to the PBS. In some cases, multiple suppliers may be owned by a single company.

Suppliers receive payment for PBS medicines from wholesalers and/or pharmacies.

3.4.2 Wholesalers

Most PBS medicines are distributed to community pharmacies via wholesalers. As described above, the pricing of PBS medicines includes specific provision for a wholesaler margin. In addition, some wholesalers are eligible to receive Government funding from the Community Service Obligation (CSO) funding pool. To be eligible to receive funding from the pool, wholesalers must agree to a number of service standards that aim to support access to PBS medicines; in particular, the supply of the full range of PBS medicines within 24 hours when requested. There is a particular focus on supply of low volume medicines and supply to rural and remote pharmacies. Wholesalers that participate in the CSO arrangements are referred to as CSO distributors.

There are currently three national CSO distributors (Australian Pharmaceutical Industries, Sigma and Symbion) and two state based distributors (Central Hospital Supplies which operates in Victoria and Friendly Societies Medical Association (trading as National Pharmacies) which operates in South Australia and Victoria). There are also a number of other wholesalers that do not participate in the CSO arrangements. DHL Excel participated in the CSO arrangements between 1 August 2006 and 29 October 2007.

Wholesalers receive payment for medicines from community pharmacies.

3.4.3 Community pharmacies

The majority of PBS medicines are dispensed through community pharmacies which are responsible for checking and filling PBS prescriptions and advising consumers on how to use the dispensed medicines.

The contribution of pharmacies in the supply of PBS medicines is recognised through the inclusion of a pharmacy mark-up and fees within the dispensed price of a medicine. The pharmacy mark-up varies depending on the price of the medicine dispensed.

There are more than 5,100 community pharmacies across Australia. Pharmacy ownership is governed by state and territory legislation which largely restricts community pharmacy ownership to registered pharmacists. In certain circumstances, community pharmacies may be owned by Friendly Societies. Friendly Society pharmacies are not-for-profit entities which have owned and operated pharmacies continuously since the 1840s. Friendly Society pharmacy organisations own more than 150 pharmacies throughout Australia. The Pharmacy Guild of Australia (the Guild) represents the interests of the majority of community pharmacy owners. Pharmacy remuneration is reflected in the Fourth Community Pharmacy Agreement (the Fourth Agreement) between the Guild and the Australian Government. The Fourth Agreement commenced on 1 December 2005 and expires on 30 June 2010.

PBS funding to community pharmacies flows directly from patient co-payments at the time of dispensing and Government payment after processing of claims by Medicare Australia.

3.5 Rationale for reform

Increasingly the PBS has been the subject of scrutiny as the cost of providing subsidised medicines to all Australians has escalated. As much as 80 per cent of Australia's burden of disease can be attributed to chronic conditions. As our population ages we can expect that percentage to grow. People aged 65 years and over currently make up 13.3 per cent of the population.[4] This figure is projected to reach between 23 and 25 per cent by 2056.[5]

At the same time, there has been an increase in the number and cost of new health technologies including pharmaceuticals. Together, these trends are expected to significantly increase the cost of the PBS in the future.

The stated aim of the PBS reform is 'to give Australians continued access to new and expensive medicines while ensuring that the PBS remains economically sustainable into the future.'

Prior to PBS reform, the prices of many drugs on the PBS were linked to reference drugs, with no distinction between drugs with single brands and those with multiple brands operating in a competitive market.

At the time the PBS reform package was introduced, the PBS appeared to be entering a phase of lower, more stable growth, although new medicines continued to be listed and patents for over 100 drugs were expected to expire within the decade. It was considered

4 As at 30 June 2008. ABS statistics: http://www.abs.gov.au/Ausstats/abs@.nsf/mf/3201.0

5 As at 24 March 2009. ABS statistics: http://www.abs.gov.au/AUSSTATS/abs@.nsf/Lookup/4102.0Main+Features10Marchper cent202009

opportune to restructure PBS pricing to achieve better value and greater price transparency, particularly for multiple brand medicines subject to market competition.

Under the previous PBS pricing arrangements, the price paid for multiple brand medicines was seen to be higher than the market value of the medicines. This was reflected in the differences in prices for many multiple brand medicines in Australia compared with other countries such as the United Kingdom. Much of the difference in the prices of multiple brand medicines was spent in the form of discounts and incentives to pharmacies.

To achieve better value from PBS listed drugs in the long term, it was proposed that modifications be made to the system of 'reference pricing', which linked PBS drugs that provide similar health outcomes. Under the reference pricing system, the Commonwealth paid a similar amount for each drug in a reference pricing group that provided similar health outcomes. If the price of one of the drugs in the group was reduced, the prices of the other drugs would reduce accordingly.

However, reference pricing alone did not distinguish between single brand medicines and multiple brands operating in a competitive market. So while multiple brand medicines may have been sold under different trading terms to pharmacies by suppliers, it was difficult to achieve significant savings from multiple brand medicines because any price reductions flowed on to single brand medicines. The then Minister stated:

> *In this environment, it has been difficult to impose price reductions on those multiple brand medicines which the Government knows are being discounted at pharmacies. This is because, in many cases, the reductions flow directly on, through price linking, to single brand medicines that are not being discounted. This has caused some difficulties for industry and places patients at risk of losing subsidised access to many worthwhile medicines.*[6]

6 Second Reading Speech, p.3.

By dividing the Schedule into two separate formularies with price links within each formulary, but not between them, the Commonwealth would be able to reduce the price paid for medicines operating in a competitive market while protecting patients from the possibilities of losing subsidised access to medicines.

3.6 Overview of reform

A brief overview of PBS reform is outlined below. Further detail about individual elements of the reform is presented in the discussion of implementation and impacts.

As stated above, the driving principle behind these reforms was to achieve better value for money for the PBS from drugs subject to brand competition. To achieve this, drugs on the PBS were classified into one of two formularies from 1 August 2007, based on whether they were single or multiple brands. Formulary One (F1) consists of drugs where there is only one brand and Formulary Two (F2) consists of drugs where there are two or more brands listed on the PBS. F2 is further divided into the following two parts until 1 January 2011:

- Part A (F2A) which contains all drugs that were not subject to high levels of discounting to pharmacies on 1 October 2006; and
- Part T (F2T) which contains all drugs that were subject to high levels of discounting to pharmacies on 1 October 2006.

Drugs on F1 move to F2 or F2A when a new brand lists.

PBS reform introduced a series of statutory price reductions that apply to F2 medicines as follows:

- staged 2 per cent price reductions for F2A drugs on 1 August 2008, 1 August 2009 and 1 August 2010; and
- a 25 per cent price reduction for F2T drugs on 1 August 2008.

PBS reform also legislated the 12.5 per cent price reduction policy that had been applied administratively since 1 August 2005. Under this policy, the first time a new brand of a PBS listed drug is listed on the PBS, the price of all brands of that drug is reduced by 12.5 per cent. This price reduction only flows through to other related drugs if the affected drug is listed in a therapeutic group. However, the 12.5 per cent price reduction is only applied to any drug once.

In addition to the statutory price reductions, PBS reform progressively introduced a system of price disclosure for all F2 medicines from 1 August 2007. Under price disclosure arrangements, any manufacturer listing a new brand of a PBS medicine is required to provide the Department of Health and Ageing with information about the prices at which it sold its new brand. Manufacturers of existing brands of that drug are then invited to volunteer to provide the same type of information. Based on the information provided across a year, a 'weighted average disclosed price' (WADP) is calculated that reflects the price at which the drug is being supplied in the market. If this WADP is more than 10 per cent below the PBS price, then the PBS price is reduced to the WADP.

PBS reform included a structural adjustment package for community pharmacies and wholesalers that recognised the potential impact of the statutory price reductions listed above (through losses of trading terms and reductions in percentage mark-ups). This package was designed to offset the short-term losses to community pharmacies and wholesalers, and allow them time to adjust to the new arrangements.

The structural adjustment package consisted of:

- an increase to the dispensing fee;
- a change to the pharmacy mark-up structure, resulting in an increase in mark-ups for many medicines;
- an incentive for pharmacies to process claims using PBS Online;

- a premium-free dispensing incentive to encourage pharmacies to dispense brands of substitutable PBS medicines that cost consumers no more than the relevant co-payment; and
- an increase to the CSO funding pool for wholesalers that participate in that arrangement.

PBS reform also included a number of other measures that did not relate to the pricing of medicines, including:

- introduction of a guarantee of supply requirement that obliges the manufacturer (Responsible Person) listing a new bioequivalent or biosimilar brand triggering a statutory price reduction or offering a price decrease for an existing brand of a PBS item to undertake to supply that brand for 24 months from the effective date or until another supplier triggers this same requirement;
- introduction of a streamlined authority arrangement to reduce the administrative effort of doctors to prescribe some lower risk authority-required medicines; and
- the establishment of an Access to Medicines Working Group (AMWG) to provide strategic oversight of joint activities undertaken by the Department and Medicines Australia to enhance the PBS processes, and to consider issues relating to timely and appropriate access to effective new medicines on the PBS.

In addition to the reform measures, funding was provided in the 2007–08 Budget for a campaign to increase consumer awareness of the safety and effectiveness of generic medicines.

4

Implementation of reform

This section provides more detail about the reform measures and their implementation.

4.1 Formularies

4.1.1 Establishment of formularies

On 1 August 2007, the PBS was split into two formularies as planned. In simple terms, Formulary One (F1) contains only single brand drugs while Formulary Two (F2) contains only multiple brand drugs. However, there are three exceptions to this rule that are described under *4.1.2 Exceptions to rules for placement of drugs on formularies* below.

F2 was further split into parts A and T based on the level of competition between brands; with those subject to high levels of competition between brands placed on F2T. F2A and F2T will be merged into a single formulary on 1 January 2011. These formularies are established through determinations made by the Minister as indicated by section 84AC of the Act.

The formularies set the structure for the price reductions that are described within section *4.2 Statutory price reductions*. In addition, as part of the reforms, the reference pricing link between drugs across formularies was broken. This effectively means that any price reductions that apply to drugs on F2 no longer flow through to drugs on F1 that are within the same reference pricing group. This allows the Government to achieve savings from larger price reductions, such as from price disclosure price reductions, on multiple brand medicines without threatening the viability of single brand medicines on the PBS.

4.1.2 Exceptions to rules for placement of drugs on formularies

The first exception to the rules surrounding the split of drugs between formularies relates to the placement of five single brand drugs (esomeprazole, lansoprazole,

pantoprazole, rabeprazole and lercanidipine) on F2T. While F2 predominantly consists of multiple brand drugs, these drugs were placed on F2T because they were in a therapeutic group with other multiple brand drugs. Therapeutic groups are specifically defined groups of drugs which have similar safety and health outcomes. The Government subsidises all drugs within a therapeutic group to the level of the lowest priced drug. Slightly different pricing rules apply to these five drugs compared with other F2T drugs. This is described further in section *4.2 Statutory price reductions*.

The second exception to the rules surrounding the split of drugs between formularies relates to the treatment of combination drugs. Combination drugs are medicines that contain two or more drugs. Combination drugs that are subject to competition between brands are placed on F2, but single brand combination drugs are placed on a separate combination drugs list. This combination drugs list is not included within legislative instruments, but is managed administratively by the Department.

The final exception to the rules surrounding the split of drugs between formularies relates to the treatment of co-marketed items. In some cases, manufacturers may choose to jointly release a new medicine for commercial reasons. For example, this may occur when two companies jointly develop a new medicine. For the purposes of the formularies, the Minister may determine that two or more brands (the co-marketed brands) of a pharmaceutical item (the co-marketed item) are to be treated as a single brand. To be considered as co-marketed brands, these brands must be included on the Australian Register of Therapeutic Goods within four months of each other, and must be the first and only brands of that drug to be listed on the PBS. Drugs with co-marketed brands, therefore, are initially placed on F1.

There are currently three drugs with co-marketed brands on the PBS—clopidogrel, irbesartan and the combination of clopidogrel and aspirin.

At the establishment of the formularies on 1 August 2007, there were 414 drugs on F1, 99 drugs on F2A, 99 drugs on F2T and 48 drugs on the combination drugs list.

4.1.3 Movement of drugs between formularies

Under the reforms, any drug listed on F1 or the combination drugs list will move to F2 upon listing of a new bioequivalent or biosimilar brand or if a new bioequivalent or biosimilar brand of another drug in the same therapeutic group is listed where all drugs in the therapeutic group are listed on F1. The only movement of drugs between formularies is from F1 to F2A. Once a drug moves to F2A it cannot move back to F1 or the combination drugs list, except in very specific circumstances.

A further amendment to the Act was necessary to clarify the operation of co-marketing in cases where a manufacturer of the co-marketed brands lists a new PBS item in a different form or strength with the same drug. In these circumstances, the new listing does not cause the drug to move between formularies. For example, where the manufacturer of a co-marketed 40mg tablet lists a 20mg tablet of the same drug under the same brand name, this would not cause the drug to move from F1 to F2. This amendment received royal assent on 25 June 2008.

Between 1 August 2007 and 1 August 2009, 13 drugs moved from F1 to F2A, and one drug moved from the combination drugs list to F2A. The number of drugs on each formulary from 1 August 2007 to 1 August 2009 is presented in Table 1.

Table 1: Number of drugs on each formulary on 1 August 2007, 2008 and 2009

Formulary	1 August 2007	1 August 2008	1 August 2009
F1	414	440	454
F2A	99	104	113
F2T	99	99	99
Combination drugs	48	47	52
Total	**660**	**690**	**718**

A complete listing of the drugs on each formulary is available at http://www.pbs.gov.au/html/industry/static/pricing_matters/pricing_of_pbs_items/formulary_allocations

4.2 Statutory price reductions

An important element of PBS reform is statutory price reductions.

The percentage price reduction on each affected PBS item is calculated on the approved price to the pharmacist. This approved price is the ex-manufacturer price plus the wholesaler mark-up. The ex-manufacturer price, the wholesaler margin and pharmacy mark-up are then recalculated to ensure consistency with the remuneration arrangements set out in the Fourth Community Pharmacy Agreement (the Fourth Agreement).

For drugs on the combination drug list, the price reduction on each PBS item applies to each component of the drug in the proportion of the price attributable to that component. For example, a drug that consists of a component drug on F1 and a component drug on F2T would have a 25 per cent price reduction on 1 August 2008 for the part of the price that is attributable to the F2T component drug.

Section 99ACC of the Act provides for circumstances in which the Minister has similar powers to vary the extent of price reductions applying to single brand combination items at the time a statutory price reduction applies to one or more of its component drugs.

Under section 84AH of the Act, the Minister is able to determine that some PBS items are exempt from statutory price reductions to ensure that access to specific PBS items is not threatened when there are no suitable alternatives. To ensure ongoing access in these circumstances, the Minister may determine an item is exempt if:

- there is only one listed brand of that item; and
- the item is not bioequivalent or biosimilar with any other item; and
- the Minister is satisfied, having regard to advice from the Pharmaceutical Benefits Advisory Committee (PBAC), that it is the only suitable item with that drug for a particular subgroup of a patient population.

There were 45 items exempt from statutory price reductions on 1 November 2009. These items are also exempt from price disclosure requirements.

4.2.1 New brand listings—12.5 per cent price reductions

As part of PBS reform, the 12.5 per cent price reduction policy that had operated as an administrative policy since 1 August 2005, was legislated. Under this policy, the price of a drug is reduced by 12.5 per cent when the first new brand of that drug lists on the PBS.

Previously, these price reductions flowed through to all other drugs that were in the same reference pricing group as that drug. However, since the establishment of the formularies, these price reductions no longer flow through to F1 drugs. A drug cannot be subject to the 12.5 per cent price reduction more than once.

A total of 27 PBS items received a 12.5 per cent price reduction between 1 August 2007 and 1 August 2009.

4.2.2 F2T—25 per cent price reductions

The most financially significant aspect of PBS reform in the short term was the 25 per cent price reduction that applied to some drugs on 1 August 2008. This price reduction applied to the approved price to the pharmacist of all drugs on F2T, and was originally forecast to generate gross savings of over $1.5 billion in the years between 2007–08 and 2010–11. This forecast was subsequently reduced as the result of a number of factors, including:

- a decision to reclassify the high volume drug alendronic acid from F2T to F2A prior to the formularies coming into effect on 1 August 2007; and
- a manufacturer offering a voluntary price reduction of 20 per cent for the high volume F2T drug simvastatin, which took effect prior to 1 August 2008.

As described earlier, five single brand drugs were placed on F2T because they were in a therapeutic group with other multiple brand drugs. Because these drugs were still on patent, the then Government decided that the price reduction for these five drugs

could be phased in instalments over the remainder of the patent life of the drugs. The details of the period over which these price reductions would be phased in were placed in the National Health (Pharmaceutical Benefits) Regulations 1960 (the Regulations).

During consultations with industry following the announcement of PBS reform, it became clear that there was not an agreed basis for the relevant patent expiry for all of these drugs. To address this issue, the then Government entered into negotiations with the affected manufacturers to extend the period under which the reductions would be phased in. The Regulations were subsequently amended to reflect these changes. The schedule of price reductions for these drugs is detailed in Table 2.

The extension to phased price reductions was forecast to reduce PBS outlays by $103 million ($110 million including Repatriation Pharmaceutical Benefits Scheme savings) over the period to 2010–11.

A total of 450 PBS items across 89 F2T drugs received the full 25 per cent price reduction on 1 August 2008, and 13 items across all five single brand drugs on F2T received the first instalment of the phased price reduction as per Table 2 below. In addition, a number of drugs were subject to a partial 25 per cent price reduction because one or more components of the combination drug was listed on F2T.

Table 2: Schedule of phased price reductions for single brand drugs on F2T

Drug	Reduction day	Percentage reduction
Esomeprazole,	1 August 2008	4 per cent
Pantoprazole,	1 August 2011	7 per cent
	1 August 2014	7 per cent
Rabeprazole and Lercanidipine	1 August 2018	7 per cent
Lansoprazole	1 August 2008	5 per cent
	1 August 2009	5 per cent
	1 August 2010	15 per cent

In the development of PBS reform, it was recognised that pharmacies could face decreased value of some stock on hand (or on order) as a result of the 25 per cent statutory price reductions. Accordingly, an annex to the Fourth Agreement, appended in March 2007, stated that pharmaceutical wholesalers and suppliers would be required to begin to provide products listed on the F2T formulary of the PBS at the new reduced price two weeks before the reductions were to take effect. However, this requirement could not be included in the amendments to the Act because it would have required two different PBS prices to operate for different segments of the industry at the same time. As a result, the Commonwealth had no legal mechanism by which to require pharmaceutical suppliers to meet this commitment.

The Department consulted extensively with stakeholders about the issue, but the size of the F2T price reductions and the range of medicines affected meant that some manufacturers were not willing to commit to their usual practice of reducing prices in the month leading up to a price reduction. Pharmaceutical wholesalers indicated they were unwilling to absorb the loss associated with supplying medicines at a lower price from 18 July 2008; however they indicated that if manufacturers were to reduce prices early, they would pass the reduction on to pharmacies.

To ensure an effective transition, it was agreed (by Government, the Pharmacy Guild of Australia and all CSO distributors) that $11 million of the additional $22 million in CSO funding allocated for 2008–09 should be paid to CSO distributors in July 2008, rather than over 11 months from 1 August 2008. This would assist CSO distributors in managing their cash-flows, allowing for early price reductions to pharmacies. This one-off payment occurred on 4 July 2008.

Changes made to pharmacy remuneration arrangements to compensate for the impact of PBS reforms are discussed in section *4.4 Changes to pharmacy and wholesaler remuneration arrangements*.

4.2.3 F2A—2 per cent staged price reductions

As part of PBS reform, drugs on F2A are subject to a series of 2 per cent price reductions on 1 August 2008, 1 August 2009 and 1 August 2010. These drugs do not, however, receive a 2 per cent statutory price reduction in the same year as they receive a 12.5 per cent statutory price reduction. PBS items that have been subject to a price disclosure price reduction are not subject to further 2 per cent price reductions.

On the first price reduction date of 1 August 2008, a total of 449 PBS items listed on F2A received a 2 per cent price reduction. This rose to 487 PBS items for the second 2 per cent price reduction on 1 August 2009. In addition, a number of combination drugs were subject to a partial 2 per cent price reduction on these dates because one or more components of the combination drug was listed on F2A.

4.3 Price disclosure

Price disclosure is perhaps the most complex aspect of PBS reform. Unlike many other aspects, it is not expected to have a significant impact on PBS growth until well into the future. However, it is expected that this impact will grow to be more significant over time than other aspects of the reforms.

4.3.1 Summary of price disclosure arrangements

Under price disclosure arrangements, manufacturers are now required, as part of the process of listing a new brand of an existing PBS item, to agree to provide information to the Department about the price at which they sell their brand/s in the market. All other manufacturers of brands of PBS items that have the same drug and the same manner of administration[7] (referred to below as a price disclosure group), are also given the opportunity to volunteer to provide the same information for their brand/s.

7 Manner of administration refers to the route by which the drug enters the body. Common examples of manner of administration include: oral and injection.

The specific information they provide is:

- sales revenue for the brand/s (provided on a monthly basis);
- sales volume for the brand/s (provided on a monthly basis); and
- the value of any incentives or discounts that have been provided down the supply chain that have not already been reduced from the sales revenue (provided on an annual basis).

This requirement commenced on 1 August 2007 for all drugs on F2A. Drugs on F2T will not be subject to the price disclosure arrangements until F2T and F2A are merged on 1 January 2011.

Based on the information provided, the Department then determines a 'weighted average disclosed price' (WADP) for each PBS item in that price disclosure group. If the WADP is at least 10 per cent below the PBS price, the PBS price is reduced to the WADP. The specific calculations performed to determine this price are detailed within the National Health (Pharmaceutical Benefits) Regulations 1960. This process is repeated each year for each price disclosure group.

There is a significant lag time (usually about two years) between the time a new brand lists and when a price disclosure price reduction occurs. This is due to a number of factors, including:

- a requirement that all calculations be based on at least one full year of data for at least one brand of a drug;
- a requirement for price disclosure reductions to be announced at least six months prior to their implementation; and
- a requirement that price disclosure price reductions only occur on 1 April or 1 August of any given year.

Exempt items are exempt from price disclosure arrangements.

4.3.2 Results of price disclosure calculations

Between 1 August 2007 and 1 December 2009, a total of 38 drugs became subject to price disclosure. Two of those drugs became subject to price disclosure with respect to more than one manner of administration.

As at December 2009, calculations had been performed on three separate occasions, with price reductions determined for seven out of 20 price disclosure groups. Price reductions for four of these groups were scheduled to take effect on 1 August 2009, with the remainder scheduled for 1 April 2010.

Table 3 presents the results of each calculated price reduction along with the status of each reduction. Status is discussed further in section *4.3.3 Issues in the implementation of price reductions.*

Table 3: Results of price disclosure calculations and status of price reductions

Drug	Manner of administration	Calculated price reduction	Scheduled date for price reduction	Status
Doxorubicin	Injection/ intravesical	63.54 per cent	1 August 2009	Superseded by voluntary price reduction on 1 December 2009
Meloxicam	Injection	22.46 per cent later adjusted to 14.57 per cent	1 August 2009	No first round price reduction will take place
Mitozantrone	Injection	34.43 per cent	1 August 2009	Superseded by voluntary price reduction on 1 December 2009
Ondansetron	Injection	15.37 per cent	1 August 2009	Superseded by voluntary price reduction on 1 December 2009
Fluconazole	Oral	55.26 per cent	1 April 2010	On track
Vancomycin	Injection	71.80 per cent	1 April 2010	On track
Carvedilol	Oral	27.29 per cent	1 April 2010	On track

Note: Only drugs subject to a price reduction have been included.

4.3.3 Issues in the implementation of price reductions

The implementation of the price disclosure arrangements has been subject to some administrative issues and legal challenge. As a result, the price disclosure price reductions that were due on 1 August 2009 did not occur. Delays in price reductions for doxorubicin, mitozantrone and ondansetron were short term. In each of these cases, a manufacturer made a lower price offer equal to the price that would have been achieved through the price disclosure price reductions. These price reductions came into effect on 1 December 2009, three months after the date the price disclosure price reductions were due.

The three price reductions due to be implemented on 1 April 2010 are expected to be implemented as planned.

The early implementation issues (which include errors by both the Department and industry) serve to illustrate that the introduction of new arrangements can be complex to administer and may take some time to fully and effectively operationalise. The Department is responding to the issues that have arisen by ensuring that appropriate protocols and procedures are in place for all steps and stages of the price disclosure process.

4.3.4 Dispute resolution and audit arrangements

There is no legislative requirement for a formal dispute resolution process to be in place in relation to price disclosure. However, manufacturers have expressed concern that they are unable to independently verify the data provided by other manufacturers, and therefore the calculations performed to determine price reductions. This is because the data provided by manufacturers is provided on a commercial-in-confidence basis and cannot be provided to other manufacturers.

To address these concerns, the Department has employed a number of strategies. These include developing a number of quality assurance measures to reduce the likelihood of incorrect data being entered into the system; providing a copy of the calculation tool

to manufacturers; forming an informal audit and dispute resolution working group with industry; and engaging KPMG as consultants to develop options for dispute resolution and audit arrangements. Industry organisations have provided their views to the Department on the options for dispute resolution.

The Department is considering the experience of the early rounds of price disclosure in the development of suitable arrangements for dispute resolution into the future, and will continue to consult with industry on this matter.

4.4 Changes to pharmacy and wholesaler remuneration arrangements

4.4.1 PBS Online incentive

PBS Online is a system developed by Medicare Australia providing streamlined online claiming and claim verification to pharmacies. PBS Online provides online checks including eligibility and concessional entitlement validation (CEV) during dispensing of PBS medicines to ensure only those patients who hold valid concession cards receive concessional benefits. On 1 July 2007 an incentive of $0.40c for each prescription processed using PBS Online was introduced to encourage pharmacies to sign up to, and use PBS Online for submitting claims to the PBS.

As part of the Fourth Agreement, pharmacists received $0.10c per concessional prescription from 1 December 2006 until 30 June 2007. As part of the PBS reform package, community pharmacies which registered for PBS Online prior to 1 July 2007 continued to receive $0.10c per concessional prescription until 31 December 2007, or until they began using PBS Online.

In addition to the incentive itself, a PBS Online Software Vendor Assistance Initiative was introduced to ensure pharmacy software vendors were able to manage the increased demand for access to PBS Online via their dispensing software. As part of this initiative, software vendors are paid a one-off installation payment (up to $2,000 per pharmacy) and 24 monthly support payments (up to $200 per month) for each pharmacy they

bring online. Payments are based on pharmacies' prescription volume (as measured by claimable prescription volume using Medicare Australia records), with a tiered payment structure to recognise the greater complexity of installing and supporting PBS Online in pharmacies with larger prescription volumes.

The implementation of these initiatives has led to a significant increase in the number of pharmacies claiming PBS benefits online. Prior to the implementation of these initiatives, 365 pharmacies were using PBS Online and it was expected that the number of pharmacies using PBS Online would gradually increase to 4,600 by 30 June 2012. However, as a result of these PBS reform incentives, by December 2009 there were 5,040 community pharmacies using PBS Online. This represents approximately 97 per cent of community pharmacies.

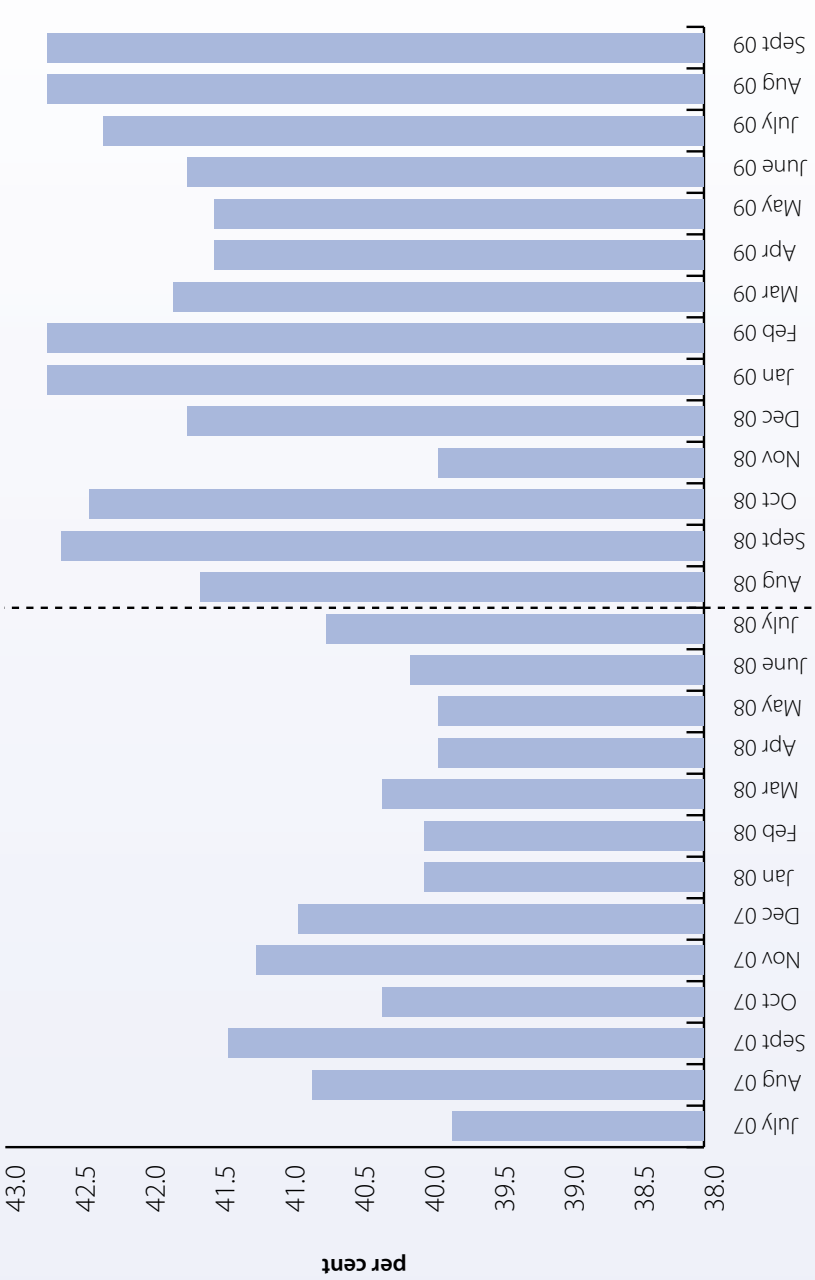
4.4.2 Premium-free dispensing incentive

A premium-free dispensing incentive was introduced on 1 August 2008 to encourage pharmacists to dispense medicines that cost consumers no more than the applicable co-payment. Under this incentive, pharmacies are paid $1.50 for each substitutable PBS medicine dispensed that does not have a brand premium or other special patient contribution. This incentive was indexed to $1.53 on 1 August 2009.

In the first 12 months after its implementation (1 August 2008 to 31 July 2009), the incentive was paid on over 75 million eligible prescriptions. As Figure 1 shows, there are variations in monthly dispensing patterns across any year. This variation is evident both before and after the introduction of the incentive. However, there is, overall, a higher level of premium-free dispensing from July 2008, when the incentive commenced.

It should be noted that Figure 1 only represents the proportion of eligible PBS prescriptions dispensed and not the total proportion of PBS brands that are premium-free. To be eligible for the incentive, a brand must attract a Government subsidy and must be substitutable with another equivalent brand of that medicine. At 1 September 2009, approximately 85 per cent of all substitutable brands were premium-free.

Figure 1: Percentage of PBS prescriptions eligible for premium-free dispensing incentive



Note—The incentive commenced on 1 August 2008. For the purpose of this figure, prescriptions dispensed prior to this date are assessed on the basis of whether they would have been eligible for the incentive if it had been in place at that time.

4.4.3 Changes to pharmacy mark-ups and dispensing fees

As part of the structural adjustment package within PBS reform, changes were made to the mark-ups that apply to PBS medicines from 1 August 2008. The changes resulted in an increase from four to six mark-up bands as illustrated in Table 4. While some PBS items now attract a lower mark-up as a result of statutory price reductions, the mark-up that applied was not reduced at any price point.

As part of the same PBS reform package, the former Government and the Pharmacy Guild of Australia agreed that the Fourth Agreement would provide for the $0.15c increase to the dispensing fee, with a commitment to review the estimates prior to the increase occurring on 1 August 2008. Following this review, the Department and the Guild agreed to an $0.18c increase to the dispensing fee, which came into effect on 1 August 2008.

Table 4: Comparison of pharmacy mark-ups before and after 1 August 2008

Approved price to pharmacist	Pre –August 2008 pharmacy mark-up	August 2008 pharmacy mark-up
Up to and including $30.00	10 per cent	15 per cent
$30.001 to $45.00		$4.50
$45.01 to $180.00		10 per cent
$180.01 to $450.00	$18.00	$18.00
$450.01 to $750.00	4 per cent	4 per cent
$750.01 to $1,000.00		
$1,000.01 to $1,750.00	$40.00	
Over $1,750.00		$70.00

4.4.5 Increase to CSO funding pool

The final part of the structural adjustment package is focused on wholesalers through an increase in funding for the CSO funding pool. This increase recognised the impact of the reduction in wholesaler margins as a result of statutory price reductions.

The Fourth Agreement between the Australian Government and Pharmacy Guild of Australia established a $150 million per annum CSO funding pool, indexed annually, to operate from 1 July 2006 to 30 June 2010. The CSO funding pool is paid to eligible pharmaceutical wholesalers (CSO distributors) that provide timely delivery of the full range of PBS medicines to pharmacies.

The CSO funding pool is a capped amount, with all funds fully expended each year. An amount equating to approximately 96 per cent of the pool is allocated to the national pool. Approximately 3 per cent is allocated to the state pool, with the remainder allocated to the CSO Administration Agency.

Under PBS reform, additional funding of $69 million over three years was added to the CSO funding pool from 1 July 2008. This was to compensate pharmaceutical wholesalers for the reduction in income resulting from the statutory price reductions under PBS reform.

The increase to CSO funding has been implemented as planned, with one minor exception; namely the early payment of $11 million in funding during 2008–09. As discussed in section *4.2 Statutory price reductions*, this early payment was made to address the potential supply issue with drugs that were subject to statutory price reductions on 1 August 2008.

The remainder of the additional $22 million allocated for 2008–09 was paid in monthly instalments of $1 million, in each of the 11 months from August 2008 to June 2009. Adjustments were made through a reconciliation process undertaken at the end of 2008–09 to ensure that CSO distributors were paid what they would have been entitled to receive if the full $22 million was spread evenly over the original 11 months.

For the remaining two financial years, payments will be made in equal instalments each month. At the conclusion of each financial year payment, reconciliations are conducted by the CSO Administration Agency.

4.5 Other changes

4.5.1 Generic medicines awareness campaign

While not part of the PBS reform package announced in November 2006, a generic medicines awareness campaign was implemented. The then Government decided to add $20 million in funding for the campaign; however this amount was later reduced to $5.1 million as part of the 2008–09 Budget.

The Department commissioned the National Prescribing Service (NPS) to develop and deliver the campaign, *Generic medicines are an equal choice*, which ran from June 2008 to July 2009. The campaign was targeted at people aged over 50, people with chronic conditions and their carers. It was implemented in three phases. Phase one consisted of re-screening an updated version of the NPS 2007 generic medicines television advertisements to remind consumers they had a choice between 'branded' and generic medicines. Phase two consisted of screening new television advertisements which were supported by additional advertising, promotional and public awareness activities. Phase three consisted of a roll-out of information and education for people from culturally and linguistically diverse backgrounds.

The NPS evaluated the campaign in July 2009. Notable observations from the evaluation included:

- a 29 per cent increase in generic medicines awareness following the phase one advertisements;
- a 5 per cent increase (from the already high 72 per cent) in the percentage of consumers who reported feeling confident about using generic medicines after phase two;

- orders for over 50,400 printed resources;
- over 8,550 visits to the generic medicines web pages; and
- 78 per cent of pharmacists reported that they found the pharmacy toolkit useful.

The NPS concluded that the campaign was successful in achieving its objective of increasing confidence and understanding about the safety and efficacy of prescription generic medicines.

4.5.2 Guarantee of supply

The listing of a new brand of an existing PBS item, or the offering of a lower PBS price for a brand, can have a number of effects on manufacturers of other brands of that medicine. These impacts can include a reduction in price of the medicine through the 12.5 per cent price reduction policy, movement of a drug from F1 to F2, and the triggering of price disclosure arrangements. All of these changes occur on the understanding that the medicine is now subject to a greater level of brand competition.

However, in some cases the new brand may be unable to be supplied to market as planned or may be withdrawn from the market within a short timeframe. The guarantee of supply requirements aim to deter suppliers from disadvantaging other manufacturers by listing on the PBS or making a lower price offer if they are not confident of their ability to supply the brand in the longer term.

From 1 August 2007, manufacturers listing a new brand of an F2 medicine on the PBS, or offering a price reduction, have been required to guarantee the supply of these brands. The guarantee of supply period is for 24 months or until such time as a substitutable brand of that medicine lists on the PBS or becomes available at a lower price.

Interruptions to supply are also disruptive for patients, prescribers and pharmacists. The provisions try to give the Government as much notice as possible about supply failures in order to minimise the impact on patients, prescribers and pharmacists. The guarantee

of supply requirements and sanctions for failing to comply with the requirements are set out in Division 3C of Part VII of the *National Health Act 1953*.

There were over 200 brands of PBS items that had a guarantee of supply requirement on 1 December 2009. Over 300 additional brands of PBS items have previously had a guarantee of supply requirement, but later lost that requirement due to the listing of a new substitutable brand.

The Department received 54 notifications of failure to supply between 1 August 2007 and 1 December 2009. The majority of these failures to supply were for periods of three months or less. These failures to supply had a limited impact on consumers because, in each case, there was at least one other brand of the medicine available.

4.5.3 Streamlined authorities

The PBS authority system requires doctors to gain approval for some PBS listed medicines prior to prescribing. This is to manage the risk of these medicines being prescribed beyond the use for which they have been restricted for subsidy under the PBS.

As part of PBS reform, a new streamlined authority process was instituted from 1 July 2007 for almost half of the medicines then listed as 'authority-required'. The objective was to reduce the administrative burden on prescribers, allowing them more time for patient care. Under this system, prescribers are no longer required to call Medicare Australia to seek authority to prescribe an authority-required (streamlined) medicine. Instead, prescribers must enter a four digit streamlined authority code onto the PBS prescription form. This code is listed with the corresponding restriction for the authority-required (streamlined) medicine. Pharmacists must not dispense an authority-required (streamlined) medicine without the four digit code.

Authority-required (streamlined) medicines are limited to those authority-required medicines that treat chronic and stable long-term conditions with stable dosage

regimens, and those that are less susceptible to risk of misuse or increased prescribing outside of restrictions. In addition, a set of criteria was developed for excluding items from the streamlined authority process.

The impact of the new streamlined authority process on prescribing behaviour during the first year of operation was monitored through the Streamlined Authority Monitoring Group (SAMG) comprising representatives of the Department of Health and Ageing, the Australian Medical Association and Medicare Australia.

In its review of the first 12 months of the arrangements, the SAMG agreed that the initiative was successful in reducing the administrative burden on medical practitioners without negative impacts on PBS expenditure. Overall findings were that there were no substantial changes (relative to historical growth trends observed) in either total prescription volume or total PBS outlays for streamlined authority medicines for the first year of operation. The small changes observed were generally within overall PBS growth trends for the same 12-month period.

The review noted that there was a reduction in the usefulness of utilisation data for PBS authority medicines because current procedures do not enable utilisation across different restrictions to be discerned in the data captured for medicines dispensed as streamlined authorities. This is being addressed by Medicare Australia and the Department.

Following the SAMG review, the Government decided that considering drugs for listing as streamlined authorities would form part of the routine assessment of drugs by the Department and PBAC. In addition, the routine monitoring of the streamlined authorities was made the responsibility of the Drug Utilisation Sub-Committee (DUSC) of the PBAC.

A new stakeholder group was also formed to provide an ongoing forum for the medical profession to raise issues and express views on the operation of the arrangements. The Department invited the Australian Medical Association, the Royal Australian College of General Practitioners, Australian Divisions of General Practice, the NPS and the PBAC to

participate in this group. The group met in March and November 2009. As a result of these meetings, additional drugs have been put forward to PBAC to consider adding to the streamlined authorities list.

Although the streamlined authority arrangements have reduced administrative burden for doctors, and extensions to the list are being considered, the authority system remains an important one for ensuring the appropriate prescribing of PBS listed medicines. In 2008–09 there were 178,517 requests for authority prescriptions rejected by Medicare Australia.

The reasons for rejection included:

- where the patient does not meet the criteria of the restriction, therefore is not eligible for the particular PBS subsidised medicine;
- where another authority prescription for the same item has previously been approved and adequate supplies should still exist for the patient; and
- where the prescriber decides during the phone call not to proceed with the authority request.

Ongoing monitoring has been undertaken by DUSC, which continues to work with the NPS, the Department and medical groups to monitor drug usage and examine possible reasons for any changes in utilization.

4.5.4 Access to Medicines Working Group

As part of PBS reform, the Access to Medicines Working Group (AMWG) was formed by the Department and Medicines Australia to provide strategic oversight of joint activities undertaken to enhance the PBS processes, and to consider issues relating to timely and appropriate access to effective new medicines on the PBS.

The AMWG has met eight times since its establishment. A communiqué is published after each meeting, and can be found at: http://www.health.gov.au/amwg

The AMWG's current priorities include streamlining the process for listing new medicines; improving post marketing data collection; identifying strategies to value incremental innovation; improving transparency of the PBAC decision making processes; engaging industry in policy development; and identifying uncertainties that hinder decision making.

Achievements in these areas include:

- trialling two pilots aimed at reducing resubmissions: (a) an early and extended evaluation of complex PBAC submissions; and (b) enhanced pre-PBAC submission meetings with sponsors to identify areas of uncertainties and suggested solutions—these pilots will be evaluated by the AMWG at the end of 2010;
- holding an industry orientated seminar on PBAC decision making processes on 30 July 2009—work is underway to hold a similar education session for consumers; and
- publishing the PBAC agenda six weeks prior to each PBAC meeting to facilitate public feedback on the medicines being considered and the impact of the medical condition on patients, their carers/family and the community.

5

Impact on Government expenditure

This section presents data relating to the impact of reform on PBS outlays to date. It includes the savings attributable to price reductions and to the costs associated with the structural adjustment package.

Some elements of the reform package commenced in 2007, while others did not take effect until much later. As the first price reductions took effect in August 2008, data is only available in relation to these measures for one financial year, 2008–09. The longer-term impact of reform is considered in section *9 Long-term impact of reform*.

5.1 Original forecasts

PBS reform was originally forecast to save $580 million over the five years 2006–07 to 2010–11 and $3 billion over 10 years. This consisted of a net increase in expenditure in 2006–07 and 2007–08 (because of the structural adjustment package), with net savings to be generated in 2008–09 and beyond. Table 5 below shows the forecasts for savings from PBS reform published at Additional Estimates in 2006.

Table 5: Original forecasts ($ million)—impact of PBS reform*

	2006–07	2007–08	2008–09	2009–10	4 yr total
(a) Pharmaceutical Benefits Scheme reform—achieving better value	2.3	8.2	-485.7	-595.2	
(b) Pharmaceutical Benefits Scheme reform—pharmacy and pharmaceutical wholesaler structural adjustment package	4.1	24.6	330.4	358.4	
Derived impact (a) plus (b)	6.4	32.8	-155.3	-236.8	-352.9

Note: negative values indicate savings to Government.

* Adapted from Health and Ageing Portfolio Additional Estimates Statement 2006–07. Includes RPBS and additional expenses for the Department of Veterans' Affairs and Medicare Australia.

The forecasts for savings to the PBS were reduced to $103 million ($110 million if RPBS is included) as a result of subsequent policy changes as well as other factors.

The policy changes that affected savings forecasts came from the following decisions: to extend the phasing of price reductions for single brand F2 medicines; and to place six F2T medicines on the F2A formulary (which made them subject to 2 per cent rather than 25 per cent price reductions). The drugs reclassified to F2A were iron polymaltose, leflunomide, levodopa with carbidopa, meloxicam, sumatriptan and alendronate.

The other factors that affected forecast savings were a higher than expected uptake of PBS Online and a voluntary price reduction for simvastatin. The voluntary price reduction for simvastatin reduced the base price for savings generated from the 25 per cent price reduction on 1 August 2008. So while there was a very significant saving to Government from the price reduction, the amount of that saving attributable to PBS reform was reduced.

These factors transformed the original forecast saving over the period 2006–07 to 2008–09 from an overall saving to an overall increase in expenditure.

5.2 Impact of price reductions on expenditure

Reform measures that were intended to reduce PBS outlays were:

- 25 per cent statutory price reduction on F2T medicines (commencing 1 August 2008);
- three staged 2 per cent price reductions on F2A medicines (on 1 August 2008, 1 August 2009 and 1 August 2010); and
- price disclosure (first reductions to take effect 1 August 2009 for F2A and 1 August 2012 for F2T).

5.2.1 Impact of 25 per cent statutory price reduction on F2T

As outlined in section *4.2.2 F2T—25 per cent price reductions*, a total of 450 items across 89 F2T drugs received the full 25 per cent price reduction on 1 August 2008, and 13 items across all five single brand drugs on F2T received the first instalment of the phased price reduction.

Expenditure on these items in 2008–09 was $1.51 billion. Based on observed prescription volumes alone (ie. assuming no interaction with other elements of the reform package), the Department has estimated that without the price reduction, expenditure on these items would have been $1.77 billion. Therefore this measure is estimated to have reduced PBS outlays by $263 million in 2008–09.

5.2.2 Impact of 2 per cent statutory price reduction on F2A

On the first price reduction date of 1 August 2008, a total of 449 PBS items on F2A received a 2 per cent price reduction. The second price reduction took effect on 1 August 2009, which is outside the period for which data is available.

Expenditure for the affected items in 2008–09 was $602 million. Based on observed prescription volumes alone (ie. assuming no interaction with other elements of the reform package), the Department has estimated that without the price reduction, expenditure on these items would have been $613 million. Therefore this measure is estimated to have reduced PBS outlays by $11 million in 2008–09.

5.2.3 Impact of price disclosure reductions

The first price reductions from price disclosure were due to take effect for affected F2A medicines on 1 August 2009. As described in section *4.3 Price disclosure*, these price reductions did not take effect on this date due to a range of issues.

Price reductions for three drugs (doxorubicin, mitozantrone and ondansetron) took effect on 1 December 2009. Data on the impact of these price reductions is not yet available.

5.2.4 Total impact of reductions to date

The estimated reductions in PBS outlays in 2008–09 from the 25 per cent and 2 per cent statutory price reductions were $274 million.

5.3 Impact of structural adjustment package

Measures that were intended to assist pharmacies and wholesalers to adjust to the new arrangements included:

- PBS Online incentive;
- premium-free dispensing incentive;
- changes to pharmacy mark-ups and dispensing fees; and
- increases to the CSO funding pool.

5.3.1 Incentive payments

The PBS Online incentive commenced on 1 July 2007 and pays pharmacies $0.40c for each prescription processed using PBS Online. As discussed previously (section *4.4.1 PBS Online incentive*) the uptake of PBS Online was more rapid than expected. As a result of this measure, the Government has paid pharmacies a total of $145.5 million to June 2009. This comprises $68.6 million in 2007–08 and $76.9 million in 2008–09.

Government also paid pharmacies an additional $102.4 million in 2008–09 through the premium-free dispensing incentive. Under this incentive, a pharmacy is paid $1.50 (indexed annually) for each substitutable medicine dispensed without a brand premium or other special patient contribution.

5.3.2 Changes to pharmacy mark-ups and dispensing fees

Changes to the mark-ups that apply to PBS medicines commenced on 1 August 2008. These changes are detailed in section *4.4.3 Changes to pharmacy mark-ups and dispensing fees.*

As a result of these changes, Government paid an estimated additional $89.4 million to pharmacy in 2008–09. This is a net impact, resulting from the downward effect of reduced prices on pharmacy mark-ups and the upward impact of changes to the pharmacy mark-up table and the increase to the dispensing fee.

5.3.3 Increases to the CSO funding pool

Section *4.4.5 Increase to CSO funding pool* describes the implementation of increased funding for the CSO pool. In 2008–09, the Government paid $22 million to wholesalers to support the CSO.

5.3.4 Total impacts of the structural adjustment package

The total cost to Government of the structural adjustment package was $359.3 million to June 2009.

5.4 Impact of reform measures on expenditure to June 2009

The net impact of the reform measures is a function of the savings produced by the price reductions, the offsetting costs of the structural adjustment package and other costs to Government (such as funding to make systems changes at Medicare Australia and Departmental costs associated with the administration of the new arrangements).

Table 6 below shows the impact on administered funding (savings to PBS outlays and costs of the structural adjustment package only), from implementation of the first measures in July 2007 to June 2009. Estimates of the financial impact into the future are provided in section *9 Long-term impact of reform*.

Table 6: Impact of PBS reform to June 2009 on administered* funds ($ million)

	2007–08	2008–09	Total
Savings from price reductions		274.0	274.0
Costs of structural adjustment	-68.6	-290.7	-359.3
Net impact on Government outlays			-85.3

Note: negative figures denote cost to Government.

* does not include Departmental costs such as staffing, administration and systems costs.

6

Impact on consumers

6.1 Financial impacts

6.1.1 Impact of price reductions and structural adjustment package on the price of medicines for consumers

The combined impact of price reductions and changes to mark-ups and dispensing fees had opposing effects on the prices of drugs on 1 August 2008. While statutory price reductions exerted a downwards pressure on prices, changes to mark-ups and dispensing fees exerted an upwards pressure. The result was that some PBS items decreased in price while others increased in price.

The effect of these price changes on consumers was limited by the operation of the PBS co-payments. Concessional patients were shielded from the 1 August 2008 price changes because all PBS items were priced above the concessional co-payment ($5.30 in 2009). The price of under co-payment medicines was affected for general patients ($32.90 in 2009).

In total, 398 under co-payment PBS items decreased in cost for non-concessional (general) patients; 688 under co-payment PBS items increased in cost for non-concessional patients; and 1,122 under co-payment PBS items did not change in price for non-concessional patients. The average decrease was $1.92 and the average increase was $0.64c. The largest decrease was $5.58 for the combination product containing tablets with 5mg ramipril and 5mg felodipine, and the largest increase was $4.86 for 30mg codeine phosphate tablets. The overall average price change on 1 August 2008 for non-concessional patients across all PBS items was a reduction of $0.15c.

The second 2 per cent statutory price reduction on 1 August 2009 also affected the price paid for PBS medicines for under co-payment drugs by non-concessional patients.

However, this impact was small, with 119 PBS items in the F2A formulary having reduced their price by 2 per cent or $0.44c on average. A further 60 items dropped in price by more than 2 per cent; however this may reflect other factors such as voluntary price reductions. Altogether, 179 items in the F2A formulary dropped in price by 2 per cent or more, by an average of $0.46c, between July and August 2009. Only one F2A item, escitalopram oxalate—oral solution 10mg (base) per mL, 28ml—increased in price to the consumer, by $4.89.

6.1.2 Impact of PBS reform on brand premiums and other special patient contributions

As the price of many medicines was reduced as part of PBS reform, some manufacturers may have considered introducing or increasing brand premiums and other special patient contributions to make up the difference between prices. Existing PBS policy ensures that there will always be at least one brand available of each PBS item that does not have a brand premium.

Price increases including the imposition of brand premiums are not permitted on the day of a statutory price reduction. On this date brand premiums must be reduced by the same percentage as the approved price to the pharmacist on that date. However, it is possible for manufacturers to increase the price or introduce these premiums at a later date.

The premium-free dispensing incentive that commenced on 1 August 2008 encourages pharmacies to dispense medicines without these premiums, and it may influence manufacturers in their decisions about whether to introduce or remove premiums. As discussed in section *4.4.2 Premium-free dispensing incentive,* the percentage of prescriptions dispensed without a premium has continued to increase since the introduction of PBS reforms.

6.1.3 Non-financial impacts

There is evidence that the reforms have not adversely affected the availability of medicines on the PBS. As shown in Table 7, the numbers of drugs, PBS items, forms and strengths, and branded products have increased between August 2006 and 1 September 2009. The increase between 2008 and 2009 is likely to reflect an existing trend rather than the impact of reform.

Table 7: Availability of PBS drugs, items, forms and strengths and branded products 1 August 2006–1 September 2009

	Date			
	1-Aug-06	1-Sep-07	1-Sep-08	1-Sep-09
Drugs	673	694	717	741
Change from previous date		21	23	24
Items	2,299	2,377	2,501	2,742
Change from previous date		78	124	241
Forms and strengths	1,639	1,706	1,754	1,844
Change from previous date		67	48	90
Branded products	2,849	3,093	3,275	3,519
Change from previous date		244	182	244

Also, PBS reforms have not negatively impacted on community access to medicines. The number of approved pharmacies, including those owned by Friendly Societies, continued to increase steadily over time, from 4,976 at June 2007 just prior to the 2007 reforms, to more than 5,100 at December 2009.

7

Impact on the supply chain

This part of the report considers the impact of PBS reform on the supply chain for the financial years 2007–08 and 2008–09. All estimates include only the impact of prescriptions that received a PBS subsidy. Under co-payment data has not been considered.

Medicines are supplied under a range of trading terms between participants in the supply chain. Because these trading terms form part of confidential commercial relationships between the participants, reliable information on the exact nature of the trading terms is not readily available. Therefore, it is not possible to accurately estimate the likely actual loss or gain from price changes for any particular part of the supply chain. The analysis below does not include any impact of changed trading terms.

7.1 Impact on manufacturers

7.1.1 Reduction in manufacturer component of PBS price

The largest effect of PBS reform on manufacturers is the reduction in the PBS price paid for F2 medicines. As a result of PBS reform, it is estimated that the PBS expenditure on the manufacturer component of PBS prescriptions (the PBS price excluding all mark-ups and dispensing fees, also called the ex-manufacturer price) was reduced by $341.0 million in 2008–09, the first year of statutory price reductions.

The ex-manufacturer price does not equate directly to income for manufacturers. This is because many medicines are provided under a range of trading terms to pharmacies, which effectively means that manufacturers receive a lower price for some of these medicines already. The extent to which reductions in the ex-manufacturer price translate to reduction in income for manufacturers depends on these trading terms.

In addition, the impact is not spread uniformly across all manufacturers. For example, those with more brands of PBS listed drugs on F2T and to a lesser extent F2A, will be

more affected on a price per unit basis than those with more brands listed on F1. This would tend to suggest that innovator manufacturers are likely to be less affected than generic manufacturers. However, such assumptions do not take into account any possible changes in dispensing patterns as a result of PBS reform. Nor do they take into account any differences in discounting behaviours between generic and innovator companies.

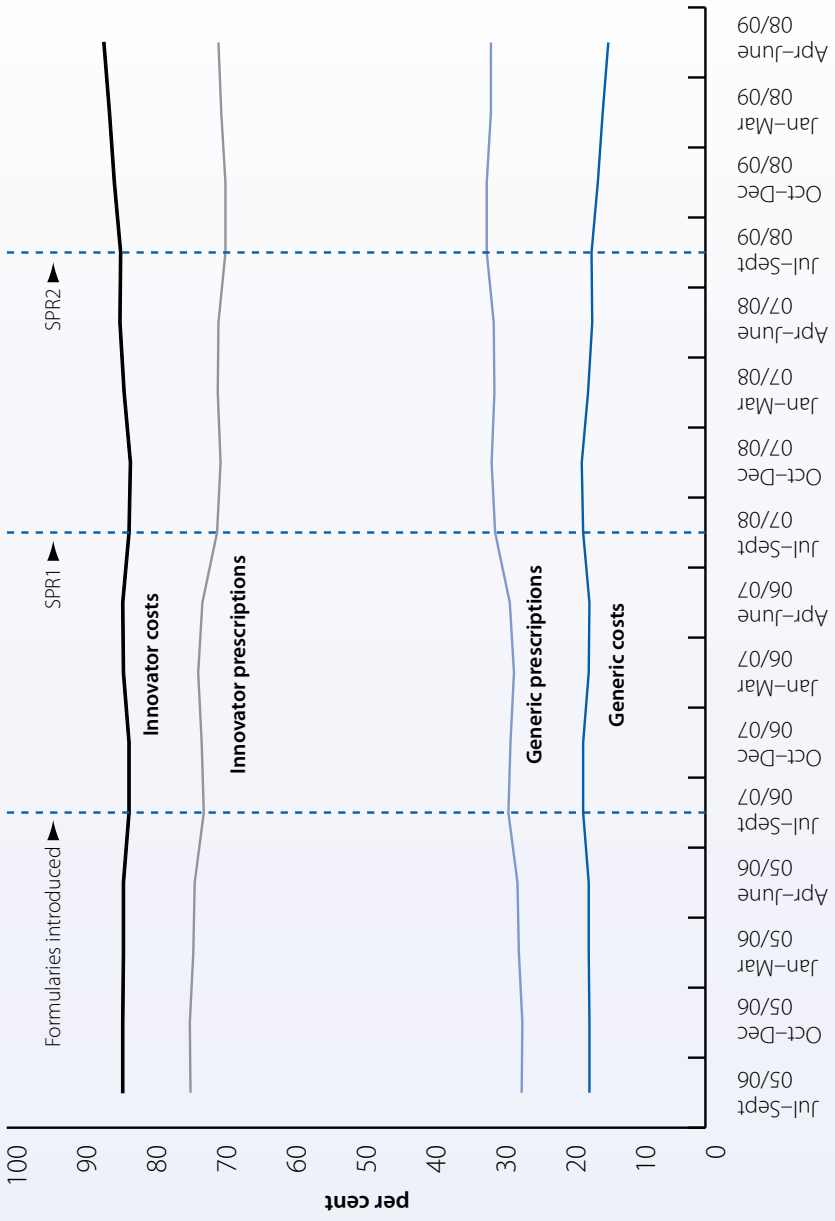
7.1.2 Impact on generic and innovator brands

In Figure 2, analysis of data from the first quarter of 2005–06 to the last quarter of 2008–09 shows the relative contribution of generic and innovator companies in terms of cost to Government and PBS prescription volumes. The figure shows the impact of the introduction of formularies and the first two stages of statutory price reductions. The data shows that the proportional share of PBS cost to Government of medicines manufactured by generic manufacturers has trended downwards, while the proportional share of PBS prescriptions has increased. Conversely, innovator prescription volumes have decreased slightly since August 2008, while the proportional share of PBS cost to Government is trending upwards. These figures should be taken as a guide only. They are likely to underestimate the generic market share of the PBS, as some generics with leading market share in the first quarter of 2005–06 may have been deemed as innovators[8].

In general, the data suggests that the PBS is buying more generics at a cheaper price while maintaining access to new innovative medicines. More generic prescriptions at overall lower cost to Government is an indication that the community will gain better value from PBS expenditure over time, particularly as medicines become subject to competition.

8 The methodology involves the Department deeming all brands of single brand drugs and the highest market share brand of all multiple brand drugs at the start of a sampling period as innovator brands. The sampling period selected commenced in Quarter 1 of 2005–06.

Figure 2: Share of cost to Government and PBS prescription volumes by innovator and generic companies 2005–06 to 2008–09



*SPR = Statutory price reduction

7.2 Impact on wholesalers

It is estimated that the PBS reform resulted in expenditure on wholesaler margins being $25.6 million lower than would have otherwise been the case. This is because the majority of PBS items have a wholesaler margin that is 7.52 per cent of the ex-manufacturer price. As the price of medicines reduces through statutory price reductions, so too does the wholesaler margin. Wholesalers operate in a competitive market and routinely provide discounts to pharmacies on what Government pays in respect of a wholesaler margin. Therefore, any reduction in the wholesaler margin may not translate to an equivalent reduction in wholesaler income.

Additional funding of $22 million to CSO funding occurred in 2008–09 to partially offset the reduction in wholesaler margin.

7.3 Impact on pharmacies

Estimating the impact on pharmacies is particularly complex. Pharmacy income is derived from a number of sources, including remuneration for supplying PBS medicines, income from private prescriptions and other retail income derived from front-of-shop sales. In relation to PBS medicines supplied by pharmacies, increases in dispensing fees, changes to mark-up bands and the introduction of new incentives had an upward impact on pharmacy incomes; however statutory price reductions had a downward impact on income from mark-ups for many medicines.

Pharmacy income may also vary as a result of the trading terms a pharmacy is able to negotiate with manufacturers and/or wholesale suppliers. As described previously, the commercial relationships between manufacturers, wholesalers and pharmacies also affect how the impact of reforms is distributed amongst the supply chain. Given the size of some statutory price reductions, it is likely that the trading terms previously available to pharmacies for many medicines would have changed following PBS reform.

The following sections outline the impacts on remuneration for supply of PBS medicines. It does not take into account other impacts such as changes in trading terms, because the Government does not have access to this information.

7.3.1 Incentive payments

As discussed previously (section *4.4 Changes to pharmacy and wholesaler remuneration arrangements* and section *5.3.1 Incentive payments*), the uptake of PBS Online, the system providing streamlined online claiming and claim verification to pharmacies, was more rapid than expected. In the period from introduction to June 2009, pharmacies received $145.5 million from this incentive.

In addition, pharmacies received $102.4 million in 2008–09 through the premium-free dispensing incentive (see sections *4.4.2 Premium-free dispensing incentive* and *5.3.1 Incentive payments*).

7.3.2 Mark-ups and dispensing fees

The net impact of PBS reform on mark-ups and dispensing fees (as discussed in section *5.3.2 Changes to pharmacy mark-ups and dispensing fees*) was an estimated increase of $89.4 million in 2008–09. This impact consists of the downwards effect of reduced price on pharmacy mark-ups and the upwards impact of changes to the pharmacy mark-up table and the $0.18c increase to the dispensing fee.

7.3.3 Impact of the structural adjustment package

The estimated net impact of the structural adjustment package on pharmacies was additional payments of $68.6 million in 2007–08 and $268.7 million in 2008-09.

In addition, the $22 million in increased CSO funding paid to wholesalers in 2008–09 is part of the structural adjustment package.

8

Impact on prescribers

The focus of PBS reform was on achieving greater value for the Government for medicines subject to competition. While PBS reforms may have had little direct impact on prescribers, the overall impact has been positive. Access to a wide range of subsidised medicines has continued, with the number of PBS drugs, forms and strengths between 2008 and 2009, increasing overall.

The medical profession has noted the success of the streamlined authority program in reducing administrative burden on doctors, and it is continuing to seek extensions to the drug list of streamlined authorities. Further information about the streamlined authorities arrangement is at section *4.5.3 Streamlined authorities*.

9

Long-term impact of reform

Although limited data is available on the impact of PBS reform, early indications are that the price reductions will have the effect of reducing Government outlays for PBS subsidised medicines without adversely affecting patient access to a wide range of cost effective medicines. Savings to Government to date have been significantly reduced by the payments made through the structural adjustment package.

The positive impact on PBS outlays will need to continue well into the future if the PBS is to remain sustainable in the longer term. To assist its assessment of the impact of reform, the Department commissioned PricewaterhouseCoopers (PwC) to model the future impact of the reform package on Government expenditure, the pharmaceutical industry, wholesalers, pharmacies and consumers.

Long-term forecasting requires assumptions to be made about a wide range of factors, including prescribing behaviour and trends, commercial decisions by pharmaceutical companies (such as when and what drugs come off patent, what generic drugs are introduced and at what price reduction), listing recommendations by the PBAC and decisions by Government. These assumptions are, by necessity, somewhat speculative; and the further out the forecasting period, the more that varying assumptions affect estimates. With this in mind, the results of the PwC work have been considered and key features are presented below. An executive summary of the work undertaken by PwC is appended to this report (Appendix A).

9.1 Estimates of savings to Government from reform

9.1.1 Forecast savings into the future

PwC modelled the forecast savings to PBS outlays by component reform measure. The tables below present the results. It is important to note that the PwC modelling is

based on data relating to the subset of PBS medicines affected by the reform package (those subsidised under section 85 of the *National Health Act 1953*, some subsidised under section 100[9] and those subsidised under the RPBS). It does not include all PBS data collected by the Department[10], therefore the figures are not directly comparable to those published elsewhere by the Department.

Decisions taken by Government since this work was first commissioned are also reflected in the modelling. Specifically, in relation to the in-principle agreement between the Commonwealth and the Pharmacy Guild of Australia for the next Community Pharmacy Agreement, PwC's work recognised:

- cessation of the PBS Online incentive on 30 June 2010;
- continuation of the premium-free incentive to 2014. For the purposes of the modelling, the incentive is assumed to continue to 2018, which will be in the timeframe of the Sixth Agreement (noting that this will be subject to negotiation between the Government and the Guild);
- continuation of the additional CSO funding to 2014. For the purposes of the modelling, the additional CSO is assumed to continue to 2018, which will be in the timeframe of the Sixth Agreement (noting that this will be subject to negotiation between the Government and the Guild); and
- no indexation of dispensing fees for two years.

As shown in Table 8 , PwC estimates that the saving to Government from the 2 and 25 per cent price reductions will be in the order of $4.6 billion to 2018. The estimated impacts of price disclosure and the structural adjustment package are presented in Table 9 and Table 10 respectively.

9 Section 100 not processed by Medicare Australia were not included

10 Section 100 not processed by Medicare Australia, Highly Specialised Drugs, Doctors Bag, Safety Net Cards are excluded.

Table 8: PwC estimated savings to Government from 2 and 25 per cent price reductions to 2018 ($ million)

	FY09	FY10	FY11	FY12	FY13	FY14	FY15	FY16	FY17	FY18	total
Estim. saving	330	387	416	442	467	492	517	525	533	541	4649

There is significant uncertainty about the likely impact of price disclosure because of commercial factors such as patent expiry, investment decisions by manufacturers and trading terms to pharmacies. Because these factors are difficult to predict, and in some cases unknown, PwC was asked to consider the range of impacts that could be considered reasonable. Table 9 below shows PwC's high and low end forecasts for the impact of price disclosure.

Table 9: PwC range of estimated savings to Government from price disclosure to 2018 ($ million)

	FY09	FY10	FY11	FY12	FY13	FY14	FY15	FY16	FY17	FY18	total
High end	0	9	38	62	121	296	578	855	1117	1324	4400
Low end	0	9	38	49	76	157	286	415	538	640	2209

Table 10 below shows PwC's estimate of the cost to Government of the structural adjustment package to 2018 (assuming for modelling purposes that components agreed in-principle for the Fifth Agreement extend to the Sixth Agreement). The estimate does not include the impact of the statutory price reductions and price disclosure. The total cost to Government of the structural adjustment package is estimated to be in the order to $3 billion over the period.

Table 10: PwC estimate of cost to Government of structural adjustment package (excluding the impact of price reductions) to 2018 ($ million)

	FY09	FY10	FY11	FY12	FY13	FY14	FY15	FY16	FY17	FY18	total
Total	-369	-371	-279	-260	-267	-274	-282	-289	-296	-303	-2991

PwC has estimated that the total savings to Government (price reductions offset by structural adjustment package) over the forecast period will be in the range of $3.6 billion to $5.8 billion.

Table 11: PwC range (high and low*) of estimated net savings to Government from reform to 2018 ($ million)

	FY09	FY10	FY11	FY12	FY13	FY14	FY15	FY16	FY17	FY18	total
High	-61	2	151	220	296	488	787	1065	1327	1535	5811
Low	-61	2	151	207	251	350	495	624	748	851	3619

* varies according to range of estimated price disclosure impacts

9.2 Estimated longer-term impact on the pharmaceutical supply chain

As noted in section *3.4 The pharmaceutical supply chain* medicines are supplied under a range of trading terms between participants in the supply chain. These trading terms form part of confidential commercial relationships, and reliable information about them is not readily available. Therefore, it is not possible to accurately estimate the likely actual loss or gain from price changes for any particular part of the supply chain.

Price reductions are applied to the approved price to pharmacies, which affects both the ex-manufacturer price and the wholesaler margin. Because the pharmacy mark-up is linked to the approved price to the pharmacy, there is also a flow on to the pharmacy

mark-up. The actual impact on each part of the supply chain depends on trading terms:

- The extent to which a reduction in the ex-manufacturer price translates into a loss to the manufacturer depends on a range of factors, including the price at which the manufacturer sells the product to the wholesaler or pharmacy.
- The extent to which a reduction in the wholesaler component translates to a loss to the wholesaler depends on the price at which the wholesaler purchases the product from the manufacturer, and the price at which it then sells the product to the pharmacy.
- The extent to which a reduction in the approved price to the pharmacist translates into a loss for the pharmacy depends on the price at which the product is purchased by the pharmacy.

Where manufacturers sell to wholesalers (or directly to pharmacies) at discounted prices, a price reduction may result in either or both of:

- a reduction in the discount provided to wholesalers (or directly to the pharmacy); or
- a reduction in the price at which the product is sold to wholesalers (or directly to the pharmacy).

Similarly, any reduction in commercial prices that flows through to wholesalers may result in either or both of:

- a reduction in the discount provided to the pharmacy; or
- a reduction in the price at which the product is sold to the pharmacy.

The price disclosure arrangements acknowledge that substantial discounting on the price to the pharmacy occurs. The arrangements are intended to bring the price Government pays closer to the price paid by the pharmacy.

PwC was asked to consider the impact (in terms of Government payments) of the reform package in the long term on the pharmaceutical supply chain. The table below shows PwC's estimated high and low range impacts (depending on estimated price reductions through price disclosure) on the wholesaler margin, the manufacturer component and payments to the pharmacy. For the reasons presented above, these estimates should be considered notional only. They relate to payments made by Government and do not take account of the impact of changed trading terms on any part of the supply chain; and thus can in no way be taken to illustrate the net effect on pharmacies, manufacturers and wholesalers.

Table 12: PwC estimate of the impact of reform on wholesaler margins, payments to pharmacies and ex-manufacturer price to 2018 ($ million)—excluding any impact of changed trading terms

	FY09	FY10	FY11	FY12	FY13	FY14	FY15	FY16	FY17	FY18	total
Wholesaler margins											
High end	2	-2	-6	-8	-13	-26	-46	-65	-84	-99	-347
Low end	2	-2	-6	-8	-11	-17	-27	-36	-44	-52	-200
Pharmacy payments—mark-ups and dispensing fees											
High end	337	333	236	212	213	208	194	179	164	153	2230
Low end	337	333	236	213	217	215	211	208	205	204	2379
Ex-manufacturer price											
High end	-299	-360	-414	-461	-540	-730	-1023	-1299	-1571	-1798	-8496
Low end	-299	-360	-414	-450	-501	-602	-750	-882	-1012	-1121	-6391

As shown in Table 12, PwC estimates that the notional impact of the reform package on the wholesaler margin will be a reduction in the range of $0.2 billion to $0.3 billion over the period. Payments to pharmacies are estimated to increase in the range of $2.2 billion to $2.4 billion over the forecast period (note that this does not equate to a net gain to pharmacies because it does not take account of the offsetting effects of changed trading terms). The notional manufacturer impact is estimated to be a decrease in the range of $6.4 billion to $8.5 billion over the forecast period.

9.3 Estimated longer-term impact on consumers

The available data suggests that the reforms have had overall positive impact on consumers. More specifically, new drugs continue to be listed on the PBS which improves access and choice for consumers, and the price reductions meant that some drugs have fallen below the level of the patient co-payment.

Into the future, it is expected that non-concessional patients will continue to benefit from the reduced prices that have already come into effect. They will also benefit from a further round of small price reductions on 1 August 2010. In addition, these consumers will benefit from any price disclosure price reductions to F2 medicines that are below, or will fall below the general co-payment. As there are no further increases to dispensing fees or mark-ups associated with PBS reform, there will be no future increases to patient charges as a result of PBS reform.

PwC was asked to model the impact of the reforms on consumers. In so doing, PwC considered the contributions patients make to the cost of PBS subsidised medicines. As shown in Table 13, PwC estimates that consumers will pay between $592 million and $802 million less in patient co-payments as a result of the price reductions from PBS reform.

Table 13: PwC estimate of savings to consumers from PBS reform to 2018 ($ million)

	FY09	FY10	FY11	FY12	FY13	FY14	FY15	FY16	FY17	FY18	total
High end	21	27	32	37	45	60	87	120	163	209	802
Low end	21	27	32	37	44	54	70	85	103	118	592

9.4 Estimated longer-term impact on prescribers

The future impact of PBS reform on prescribers is expected to be small. Prescribers will continue to benefit from the streamlined authority arrangements that are in place and from any further additions to the list of streamlined authorities medicines that are being considered by the Department's streamlined authorities stakeholder forum (see *4.5.3 Streamlined authorities*).

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The PBS into the future

As modelling presented in section *9. Long-term impact of reform* shows, there is a strong likelihood that the reform measures introduced from 2007 will continue to have a positive impact on PBS outlays. More specifically, the price reductions already in place and those that are likely to come from the price disclosure arrangements will mean that Government will pay less for some drugs into the future; and the community generally will gain better value from Commonwealth expenditure under the PBS.

However, even with the effect of reform to date, PBS expenditure is expected to continue to grow into the future.

10.1 PBS growth

As noted in section *3.5 Rationale for reform*, at the time the reforms were announced, the PBS appeared to be entering a period of lower, more stable growth. In 2006–07, growth in the PBS was 4.3 per cent, after a decade in which the PBS had grown by an average of 9.9 per cent per year. New drugs were continuing to be listed, and it was recognised that patents for more than 100 drugs were due to expire within the decade. It was considered opportune to re-structure the pricing arrangements for the PBS to ensure that the benefits of the competition that would follow patent expiry were captured for the taxpayer. The reform package was expected to reduce expenditure and constrain growth without limiting the capacity for new (and often more expensive) drugs to be added to the PBS.

However, despite the changes made to date and their apparent positive impact on outlays, the PBS continues to grow quite strongly.

PBS expenditure growth is influenced by many different factors, including:

- the number of prescriptions dispensed;
- the prices of existing PBS medicines and how these change over time;

- the number and cost of new medicines added to the PBS;
- the amount that patients contribute towards the cost of prescriptions; and
- the number of prescriptions that cost less than the general patient co-payment (as only prescriptions that cost more than the general patient co-payment contribute to Government expenditure).

In addition, the health profile of the community and demographic factors affect prescribing and medicines use. Every year the Government receives recommendations from the PBAC regarding the listing of new drugs on the PBS, and decides whether to accept these recommendations and make new drugs available to the community.

PBS expenses for 2008–09 were $7.7 billion, a growth rate of 9.2 per cent over the previous year. This compares with annual growth of 9.4 per cent in 2007–08 and average annual growth of 9.6 per cent between 1998–99 and 2008–09. In the last 10 years, average annual growth in PBS was higher than that of GDP (7.2 per cent in nominal terms).

PBS growth over 2008–09 was driven by higher than expected demand and the listing on the PBS of several new high cost medicines. In 2008–09, about 182 million PBS subsidised prescriptions were dispensed, a 6.2 per cent increase from 2007–08. In the period between June 2008 and June 2009, seven medicines collectively worth over $800 million over the four years from 2008–09 were listed or had extensions to listings.

Growth in 2009–10 is expected to be higher than 2008–09 at about 10.6 per cent. This estimate includes the effect of statutory price reductions already in place and Departmental estimates of the impact of future price reductions.

The impact of price disclosure is difficult for Government forecasts to reflect. Price disclosure was introduced because of evidence that medicines are being sold to pharmacies at much cheaper prices than Government pays; yet Government had no mechanism to gain access to reliable information about trading terms and no capacity

to forecast commercial decisions that may be made by pharmaceutical companies in the future. Patent expiry is difficult to predict (as it is frequently subject to legal challenge), as are decisions of pharmaceutical companies regarding which drugs to invest in and the timing of such investments. For these reasons, forecasts about the impact of price disclosure are necessarily challenging to construct and subject to assumptions.

As discussed in section *5.1 Original forecasts* , PBS reform was originally estimated to produce savings to Government of $3 billion over 10 years. Recent estimates produced by PwC put the figure in the range of $3.6 billion to $5.8 billion, depending significantly on savings to be realised through price disclosure.

These figures need to be set against the backdrop of projected growth in health spending and the factors that drive that growth. The Government's report, *Australia to 2050: future challenges* (the 2010 intergenerational report), released on 1 February 2010, attributes steady growth in health spending since the 1990s to factors that include "… increasing use of doctors, tests and pharmaceuticals and decisions to subsidise the introduction of new technologies or list new drugs on the Pharmaceutical Benefits Scheme (p52)". The report forecasts that health spending will grow, as a percentage of GDP, from 4 per cent in 2009–10 to 7.1 per cent in 2049–50. Per capita expenditure on the PBS is expected to grow in real terms over the forecast period.

Current projections for PBS expenditure are for steady growth over the forward estimates period. If these figures are extrapolated over the next ten years, outlays in 2018 will be in the order of $13 billion even if the high end estimate of savings from reform is realised and $13.7 billion under the lower estimated savings scenario. This compares with the estimate before reform of under $13 billion in 2018.

Figure 3 (page 76) compares projected PBS expenditure at the time the reforms were announced with current projections of PBS outlays, and subtracts from the latter the PwC estimates (high and low) of savings. This figure illustrates that, even with higher

(than anticipated) savings likely to come from reform, PBS outlays into the future will be above the original estimates. Actual expenditure on the PBS by 2018 will be higher, after savings, than originally projected before structural reform.

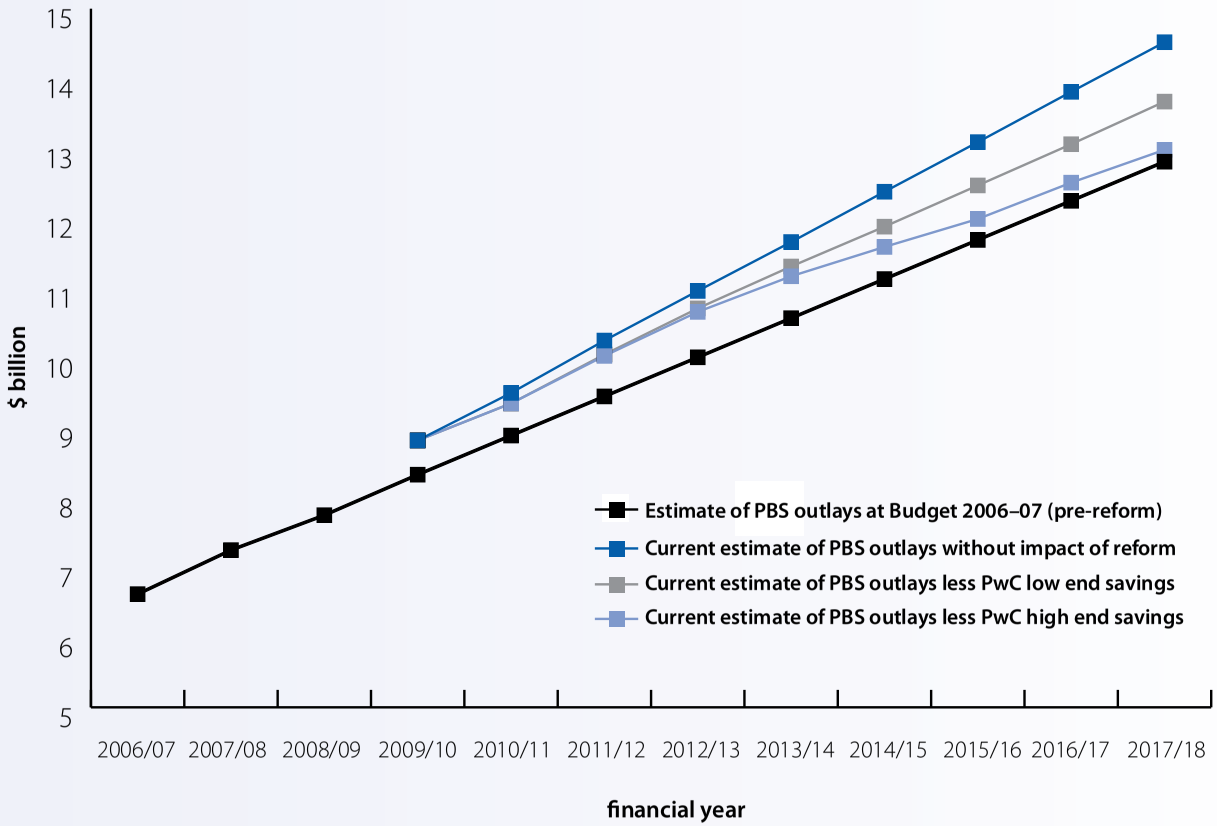
As part of its analysis, PwC considered the prices of drugs in Australia relative to prices paid by the National Health Service (NHS) in the UK. PwC observed that, while in some cases Australian prices are lower than those in the UK, for many of the highest volume drugs on the PBS, Australian prices are higher than those in the UK. For example, one of the highest volume drugs on the PBS is simvastatin. Simvastatin (40 mg tablets) costs the PBS $44.45 (AUD) compared with $2.74 (AUD) in the UK.

Other examples of commonly used medicines are atorvastatin (40mg tablets) for which the PBS pays $79.05 (AUD) compared to $48.85 (AUD) in the UK, and atenolol (50mg tablets) which is $10.27 on the PBS (AUD) compared to $1.82 in the UK[11]. Further information is provided at Appendix B.

These examples point to the need to continue a responsible search for opportunities to provide the best possible medicines for Australians at the best possible price.

11 These comparisons are a 'point in time' calculation. Such comparisons depend on PBS and NHS prices and exchange rates between currencies at the time of calculation and the methodology applied to standardise supply (eg pack size) and account for dispensing fees.

Figure 3: Pre-reform estimates of approximate PBS outlays (without reform) compared with current estimates of approximate PBS outlays (without reform) and PwC estimated savings



10.2 Conclusion

The reforms to the PBS have been progressively implemented since the middle of 2007, with some components yet to take full effect (such as price disclosure for drugs on F2T). The indications are that:

- The overall impact on patients has been positive, with more medicines staying the same or reducing in price than increasing, and new medicines continuing to be listed on the PBS.
- A modest reduction has occurred in Government expenditure on the PBS. Given the offsetting effect of the structural adjustment package, the net impact to date is an increase in Government expenditure.
- The impact of the reforms on the different parts of the supply chain is difficult to determine, given that the participants operate in commercial relationships that include a range of trading terms.

As noted elsewhere in this report, long-term forecasting is difficult and relies heavily on a range of assumptions, the validity of which will not be known until several years hence. While there are very positive indications for significant savings from the reforms into the future, for the reasons outlined, the Government views these figures with cautious optimism.

It is important that the fundamental objective of the PBS—to provide access for Australians to safe and effective medicines at a cost the individual and community can afford—is protected. Under current arrangements, the cost of the PBS is expected to continue to grow, even taking into account the impact of the reforms; and this will put increasing pressure on the health budget. A responsible Government must keep such a large and growing program under constant review.