SENATE COMMUNITY AFFAIRS COMMITTEE

INQUIRY INTO:

NATIONAL HEALTH AMENDMENT (PHARMACEUTICAL BENEFITS SCHEME) BILL 2007

SUBMISSION BY THE AUSTRALIAN GOVERNMENT DEPARTMENT OF HEALTH AND AGEING

13 JUNE 2007

INTRODUCTION

On 16 November 2006 the Australian Government announced a package of measures to reform the pricing of drugs on the Pharmaceutical Benefits Scheme (PBS). Subject to the passage of legislation, these measures will be implemented progressively, commencing on 1 July 2007.

The nature and pricing of drugs on the PBS has changed significantly since its inception more than 50 years ago. There are now many drugs that operate in a highly competitive, commodity market.

The focus of the proposed reforms to the PBS is on the way in which the drugs that are listed on the PBS are priced for subsidy purposes over time, in particular as they enter a commodity phase of production. The focus is not on the way in which drugs are evaluated and listed, nor the way in which patients access PBS drugs.

PBS reform comprises an integrated package of measures designed to achieve price reductions in the short term for drugs that can sustain lower prices, better value for PBS listed drugs over the long term, and a smooth transition for affected stakeholders. For patients the PBS will not change, with the exception that the price of some drugs for some patients will reduce.

The key elements of the package are:

- restructuring the Schedule of Pharmaceutical Benefits into two formularies to differentiate between single (F1) and multiple (F2) brand drugs and removing price links between drugs on F1 and those on F2;
- applying mandatory price reductions to drugs on F2 (those that are subject to competition between suppliers).
- providing a structural adjustment package for pharmacy and pharmaceutical wholesalers (through amendments to the Community Pharmacy Agreement), including support for online claiming and incentives to dispense substitutable drugs that do not have additional patient charges;
- streamlining the way that doctors can access ‘authority’ approvals for prescribing certain drugs, thereby reducing red tape and giving doctors more time to spend with their patients;
- establishing a working group to consider issues related to continued access to new and innovative drugs for Australians through the PBS; and
- conducting a public awareness campaign to increase knowledge and provide assurance about generic drugs.

The National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2007 and associated regulations and legislative instruments seek to implement several key elements of the reform package, including:

- the allocation of existing PBS listed drugs to the two formularies;
- rules for allocating new PBS listings to the formularies and moving drugs from F1 to F2;
- the way in which mandatory price reductions apply to drugs on the F2 formulary;
- the requirement and timing of price disclosure for drugs on the F2 formulary;
- the criteria that specific formulations of drugs must meet in order to be exempt from mandatory price reductions; and
- requirements for guarantee of supply of brands of PBS drugs.

A summary of the key elements of the proposed amendments to the Act, including provisions in regulations and legislative instruments are at Attachment A.

The PBS reform package intends to position the PBS so that it can continue to provide subsidised access to a comprehensive range of treatments, allow for clinical choice, and be affordable for individuals and the community.

THE CURRENT FRAMEWORK FOR THE PBS

The PBS is a fundamental component of Medicare and provides timely, reliable and affordable access to necessary and cost effective drugs.

Drugs listed on the PBS

In 2005/06, 168 million PBS subsidised prescriptions were dispensed at a cost of $6.2 billion.[1] This equates to 8.2 prescriptions per capita. An estimated 72% of all prescriptions dispensed in Australia are subsidised under the PBS.

Through the PBS the Australian Government subsidises the cost of drugs that treat a wide range of medical conditions. The top five drugs by expenditure and volume are shown at Tables 1 and 2 below.

Table 1 - Top 5 PBS drugs by expenditure, 2005-06

Drug name	To treat	Expenditure
Atorvastatin	Blood cholesterol	$488 million
Simvastatin	Blood cholesterol	$308 million
Fluticasone with salmeterol	Asthma	$156 million
Esomeprazole	Ulcers	$156 million
Olanzapine	Schizophrenia and bipolar disorder	$149 million

Table 2 – Top 5 PBS drugs by volume, 2005-06

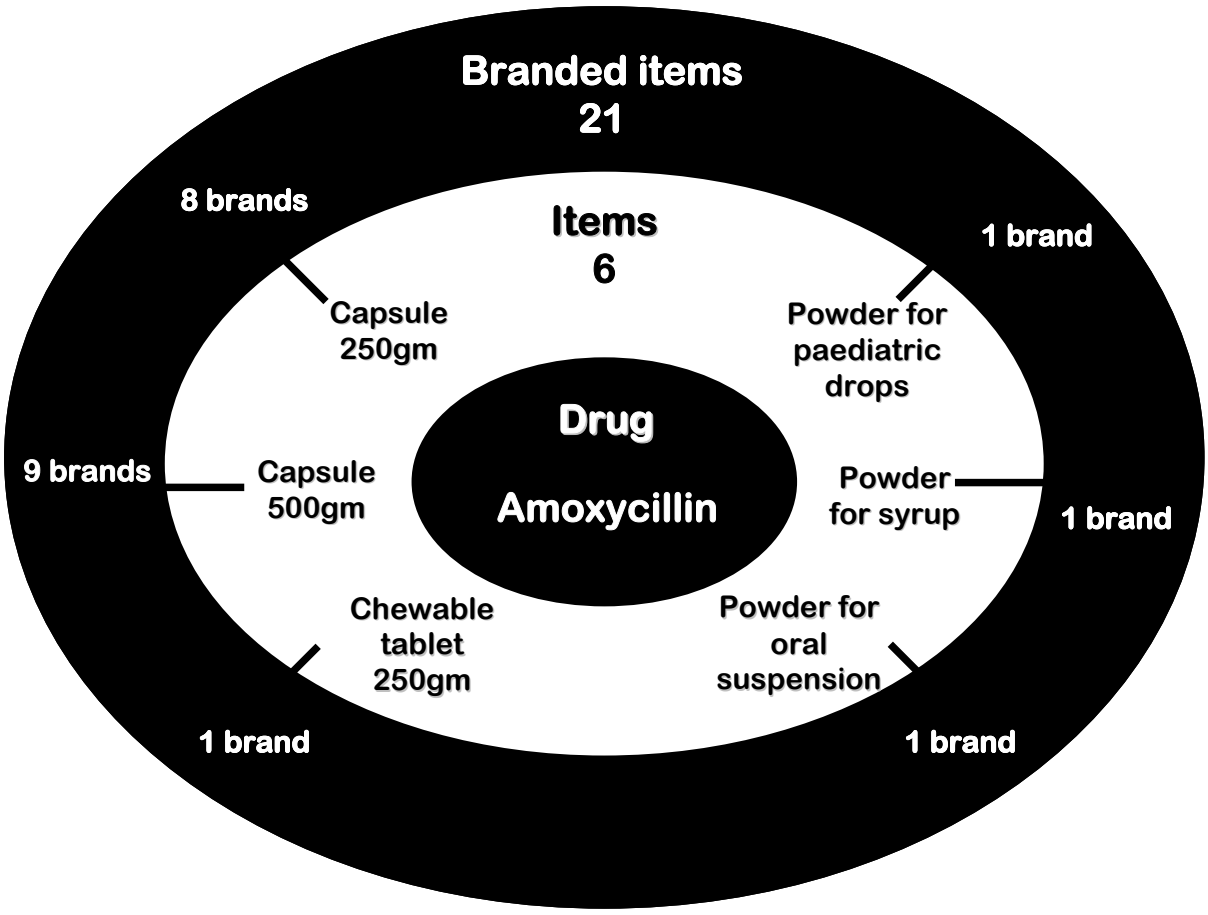
Drug name	To treat	Volume dispensed
Atorvastatin	Blood cholesterol	8.5 million
Simvastatin	Blood cholesterol	5.9 million
Omeprazole	Ulcers	3.8 million
Paracetamol	Pain	3.7 million
Esomeprazole	Ulcers	3.4 million

At 1 June 2007, there were 680 individual drugs (or molecules) listed on the PBS. Each drug generally comes in a range of different forms (such as tablets, injections) and different strengths. These are referred to as items. There are about 1600 items of the 680 individual drugs on the PBS. In addition, many drugs have multiple brands. There are about 2900 branded items currently listed on the PBS.

An example of the relationship between drugs, items and branded items is at Figure 1.

[1] An estimated further 33 million prescriptions for PBS listed drugs were dispensed at a cost less than the general patient co-payment and so do not appear in official PBS statistics as their entire cost was met by the patient.

Figure 1 – The drug amoxycillin, its items and branded items at 1 June 2007.



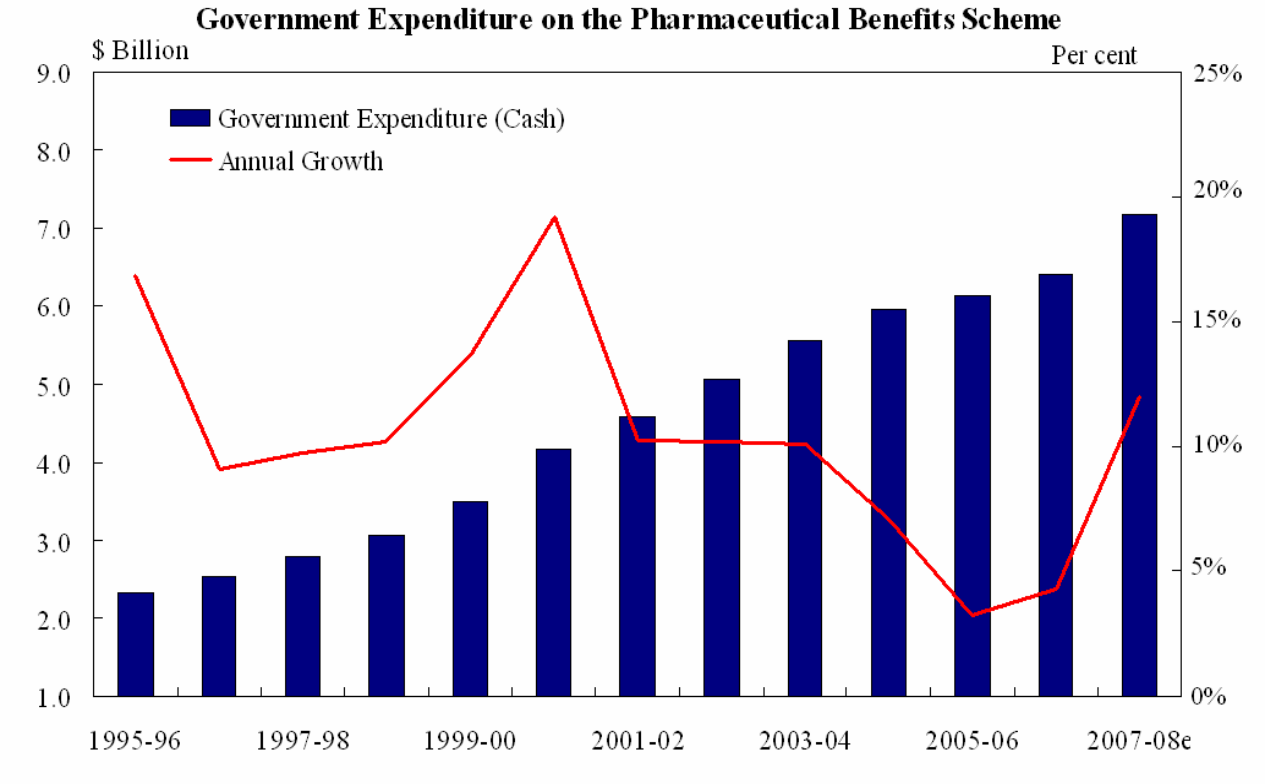
PBS expenditure

In 2006-07 PBS expenditure is expected to be $6.4 billion, rising to $7.0 billion in 2007-08. While the PBS has grown at a lesser rate in recent years, it continues to be one of the fastest growing Australian Government funded programs.

Recent slowing in the rate of PBS growth reflect a number of factors, including the impact of Australian Government measures designed to improve PBS sustainability, some long term changes in the prescribing and use of drugs for a range of common conditions, the withdrawal of some drugs from the Australian market following safety concerns, and the price of some drugs falling beneath the general patient co- payment.

Trends in PBS growth between 1995-96 and 2009-10 are shown in Figure 2.

Figure 2 - Australian Government Expenditure on the Pharmaceutical Benefits Scheme



The PBS is a demand driven program, with expenditure each year determined by a number of factors, in particular:

- the prices of listed drugs and any changes to those prices since the preceding year;
- the number of prescriptions dispensed for each drug;
- the level of patient co-payments;
- the number of drugs priced below the level of the general patient co-payment and the volume of these prescribed to general patients who have not reached the safety net; and
- the number and cost of new drugs added to the PBS each year.

Each year many new drugs are listed on the PBS and the PBS forward estimates are varied to take account of expected additional expenditure as a result. In the past year a number of high cost drugs have been listed following recommendations by the Pharmaceutical Benefits Advisory Committee (PBAC). Some examples are at Table 3.

Table 3 – Recent high cost drug listings (and extensions to listings) on the PBS

Drug name	**To treat**	**Estimated cost to PBS over first four complete years of listing**
Enbrel®, Humira® and Remicade®	Psoriatic arthritis	$31.5 million
Ezetrol® and Vytorin®	Blood cholesterol	$77.6 million
Herceptin®	Early breast cancer	$471.1 million
Alendronate once weekly formulation (Fosamax® and Alendro®)	Osteoporosis	$60.8 million
Strattera®	Attention deficit hyperactivity disorder	$101.2 million
Lucentis® and Visudyne®	Age related macular degeneration	$629.5 million

Patient payments

A fundamental principle of the PBS is that patients contribute to the cost of the drugs that they use. This occurs through the payment of co-payments, which are currently $4.90 per prescription for concessional patients and $30.70 for general patients. Concessional patients and/or their families make no further co-payments when they reach the concessional safety net threshold (currently $274.40) and the payment for general patients reduces to $4.90 once they and/or their families reach the general safety net threshold (currently $1059.00).

Australian Government expenditure on the PBS has been around 83% of the total cost of PBS prescriptions since 1995-96, with the remaining proportion met by patients. In 2005-06 the Australian Government spent $6.2 billion on PBS expenditure, with a further $1.1 billion paid through patient co-payments.

Listing of drugs on the PBS

Drugs are listed on the PBS based on a positive recommendation from the PBAC to the Minister for Health and Ageing. In assessing a submission to list a drug the PBAC is required under Section 101 (3A) and (3B) of the *National Health Act 1953* to give consideration to the effectiveness and cost of therapy involving the drug, including by comparing its effectiveness and cost with that of alternative therapies.

Where the therapy involving the use of a drug is substantially more costly than that of alternative therapies the PBAC cannot recommend its listing unless it is satisfied that, for some patients, it provides a significant improvement in efficacy or reduction of toxicity over the alternative therapy.

As such, drugs are listed on the PBS following two types of evaluation findings:

- Those where the PBAC is satisfied that the drug warrants a higher price than an alternative. These are referred to as ‘cost effective’ listings.

- Those where the PBAC considers that the drug is no more effective than a PBS-listed

alternative and therefore does not warrant a higher price. These are referred to as 'cost minimisation' listings.

Pricing of drugs on the PBS

In the past, drugs listed on a cost minimisation basis have been linked for pricing purposes based on the health outcomes that they provide. This is referred to as 'reference pricing' and means that the Australian Government will pay a similar amount for each drug in a reference pricing group that provide similar health outcomes.

For example, the drugs aripiprazole, olanzapine and ziprasidone all treat schizophrenia, are price linked to each other and form a reference pricing group. If the price of one of the drugs in the group is reduced the prices of the other drugs will reduce accordingly.

Therapeutic Group Premium (TGP) groups (referred to as 'Therapeutic Groups' in the Bill) are a particular type of reference pricing group. The drugs in these groups have been specifically assessed by the PBAC as being interchangeable with each other at the individual patient level. There are currently six TGP groups:

- Angiotensin II Reductase Antagonists;
- Ace Inhibitors;
- Calcium Channel Blockers;
- HMG CoA reductase Inhibitors (statins);
- H_2 Receptor Antagonists; and
- Proton Pump Inhibitors.

As with other reference pricing groups, the price that the Australian Government pays for each drug in the group reflects the price of the lowest priced drug in that group. However, TGP groups differ from the other reference pricing groups in that, in the vast majority of cases, patients can move from one drug in the group to another without any clinical effect. This is not necessarily true of drugs in reference pricing groups, which have only been assessed as providing *similar* health outcomes.

There are currently 112 reference pricing groups (including the six TGP groups) comprising 270 of the 680 drugs listed on the PBS.

Patient paid premiums

There is currently little reference in the Act to the way in which drugs are priced and there is no ability for the Minister to apply mandatory price reductions.

The Act requires that the Minister and a supplier agree on a price. When a drug is first listed on the PBS the Pharmaceutical Benefits Pricing Authority (PBPA) provides advice to the Minister on the price of the drug, based upon the recommendations of the PBAC. When a price reduction is required for a drug that is already listed on the PBS the PBPA Secretariat and the Department inform affected companies of the new price of their drug(s) and seek their agreement to the new price.

If agreement cannot be reached, the Minister may determine that the difference between the Australian Government price and the supplier's requested price form the basis for a 'special

patient contribution' (SPC). SPCs take the following forms:

- A brand premium may apply to a drug that has multiple brands listed on the PBS. The Brand Premium Policy has been in place since 1990 and applies when there are a number of therapeutically equivalent (or 'bioequivalent') brands available. The Australian Government subsidises each brand to the level of the lowest priced brand (the 'benchmark price'). Provided at least one brand is supplied at this price, suppliers of other brands can apply a brand premium.

  In the past ten years the proportion of brands with a brand premium has been reasonably constant. At May 2007 12% of all eligible brands had a brand premium and the average brand premium was $2.76.

- A Therapeutic Group Premium (TGP) may apply to drugs in a group of drugs which the PBAC has determined are interchangeable at the patient level (a therapeutic group as described above). Provided at least one drug in the group is available at the benchmark price other drugs in the group can have a TGP. The TGP policy has been in place since 1998 when the first four groups were formed. Two additional groups were added in 2006 on the advice of the PBAC.

  At May 2007 four of the 27 drugs in TGP groups had premiums. The proportion of items in the TGP groups with a premium was 7% and the average TGP was $3.61.

In the case of both brand premiums and TGPs, there is always an alternative available to a patient at the benchmark price or a capacity to have the TGP waived if a prescriber is of the view that the patient must take a particular drug and seeks approval from Medicare Australia.

- There is another form of SPC that is used less frequently than brand premiums or TGPs. These are called 'other SPCs'. These have been applied in cases where a price reduction has been required for a single brand drug in a reference pricing group and agreement has not been able to be reached with the supplier to the new reduced price. An 'other SPC' has been granted to enable the drug to remain listed on the PBS.

  As with TGPs, exemptions for patients from paying the SPC are available if a prescriber is of the view that the patient must take a particular drug and seeks approval from Medicare Australia.

  At May 2007 nine drugs, covering 22 items, attracted an 'other SPC'.

ISSUES WITH THE CURRENT FRAMEWORK

The system of reference pricing within the PBS has worked well in an environment where there has been relatively low levels of competition between brands and low price reductions offered when new brands enter the market. However, in recent times where the Australian Government has sought to obtain better value from the competition in the multiple brand market some difficulties have become apparent.

Opportunities to obtain better value from multiple brand drugs

Comparing Australian prices for common multiple brand drugs with prices paid in other similar countries, such as the United Kingdom (UK), illustrates clearly that the Australian Government has been paying too much for these drugs. For some commonly prescribed drugs that cost the PBS hundreds of millions of dollars per annum, the Australian price can be five times or more that of the UK price. Price comparisons for some key drugs on the PBS are shown in Table 4.

Table 4 – Comparison of UK and Australian prices for some commonly prescribed drugs (prices as at October 2006)

Drug	**Group**	**UK price ($A)**	**Australian price**	**PBS expenditure 2005-06**
Omeprazole 20mg caps	Proton pump inhibitor	$13.71	$24.71	$8.52m
Amlodipine 10mg	Calcium channel blocker	$6.88	$28.16	$29.1m
Captopril 50mg	ACE inhibitor	$2.83	$10.53	$3.5m
Lisinopril 20mg	ACE inhibitor	$5.30	$15.71	$9.5m
Pravastatin 40mg	Statin	$9.32	$50.82	$72.4m
Simvastatin 40mg	Statin	$9.11	$52.02	$153.1m

The high prices at which these drugs are reimbursed on the PBS has contributed to a climate where many suppliers of multiple brand drugs provide them to pharmacy at heavily discounted rates.

This is not just an issue for Government but also for general patients who currently pay higher prices than necessary for drugs priced under the general co-payment (an estimated 33 million prescriptions a year).

There will be more that 100 patent expiries for PBS listed drugs over the next 10 years. PBS expenditure on these drugs was approximately $2.7 billion in 2005-06. If the pricing framework for the PBS is not changed now the value of these patent expiries to patients and the Australian Government will not be realised and discounting activity to pharmacy will continue and grow.

Structural barriers to obtaining better value from multiple brand drugs

Current reference pricing arrangements limit the capacity to pay lower prices for multiple brand drugs as any price reduction will flow directly to other drugs in the same reference pricing group. This is highly problematic when a price reduction flows to a single brand drug in a reference pricing group that is not a TGP group and therefore a suitable alternative may not be available for an individual patient. If the supplier of the single brand drug does not agree to reduce the price, the Minister must either determine that an 'other SPC' applies or the supplier may withdraw the drug from the PBS.

While all drugs in a reference pricing group provide similar health outcomes at the population level, not all treat exactly the same condition nor may they be equally suitable for an individual patient. There will be some cases where a patient cannot easily move from one drug to the next. The withdrawal from the PBS of some single brand drugs in these circumstances would therefore create difficulties for prescribers and patients.

Finding a way to significantly reduce prices and not endanger the continued listing of single brand drugs that are not interchangeable has been a key consideration in developing the PBS reform package.

PROPOSED REFORM OF THE PBS

PBS reform addresses the issues outlined above through a staged transition to new pricing arrangements and an integrated package of measures that eases the impact on the suppliers and dispensers of PBS drugs.

There will be no change to the way in which drugs are listed on the PBS. The role of the PBAC in evaluating drugs for effectiveness and cost effectiveness compared to alternative therapies remains as it is now. Rather the focus of reform is on the way drugs that are linked on the PBS will be priced over time, as they move from being a single brand to having multiple brands (generally around the time of patent expiry) when competition between brands of the same drug offers significant opportunity for lower prices.

Formularies

Subject to the passage of the Bill, from 1 August 2007 drugs on the PBS will be separated into two groups, each subject to different pricing arrangements:

- Drugs where there is only a single brand listed (F1). F1 will contain single brand drugs (both on patent and off patent) that are not interchangeable at the patient level with drugs that have multiple brands. Approximately 410 drugs will be on F1 on 1 August 2007. PBS expenditure on these drugs in 2005-06 was $3.0 billion.

- Drugs with multiple brands listed on the PBS and drugs in TGP groups that are interchangeable at the patient level with a drug that has multiple brands will form the F2 formulary. Five of the 6 therapeutic groups will be on F2. Approximately 200 drugs will be on F2 on 1 August 2007. PBS expenditure on these drugs in 2005-06 was $2.5 billion.

- Until 1 January 2011, F2 will be further separated into two groups:

    - F2A will comprise those drugs where, as at 1 October 2006, price competition between brands to pharmacy was low with discounts of less than 25 percent being provided. Approximately 90 drugs will be on F2A, with PBS expenditure of approximately $450 million in 2005-06.

    - F2T will comprise those drugs where, as at 1 October 2006, price competition between brands to pharmacy was high with discounts of 25 percent or more being provided or drugs in TGP groups that are linked to drugs with this level of discounting. Approximately 105 drugs will be on F2T, with PBS expenditure of approximately of $2.1 billion in 2005-06.

F2A and F2T will merge on 1 January 2011 to become a single F2 formulary.

Reference Pricing Groups

Drugs that are on F1 will continue to have pricing links to other F1 drugs to which they have been linked. In the event that a price reduction is offered for an F1 drug in a reference pricing group, that price reduction will flow on to other F1 drugs in that group. However, no mandatory price reductions will be required for F1 drugs.

There will be no price links between drugs on F1 and those on F2. The only reference pricing between drugs on F2 will be for those drugs in TGP groups. The numbers of drugs that will continue to be in reference pricing groups as a result of the creation of the new formularies is at Table 5.

Table 5 - Reference pricing groups before and after PBS reform.

Current Reference Pricing Groups		
	Number of groups	Number of drugs in groups
	112	270
Reference Pricing Groups after 1 August 2007		
F1	80	140
F2	5	25

Combination Drugs

A number of drugs that are listed on the PBS are a combination of one or more PBS listed drugs. To date these types of products have been priced according to the price of their component parts.

It is proposed to retain this approach to pricing combination drugs under PBS reform. These combination drugs will be listed outside the formularies, and their pricing will be based on the weighted price of their components. This will apply while there is only a single brand of the combination drug listed. If a new brand is listed the combination drug will move to F2A. Approximately 50 drugs have been identified for the combination drug list.

Movement between formularies

All drugs listed on the PBS as at 1 August 2007 will be assigned to a formulary. Generally, the only movement of drugs between formularies will be from F1 to F2. A drug will move from F1 to F2 at the time a bioequivalent or biosimilar brand of that drug is listed on the PBS (i.e. when a drug changes from being a single brand to a multiple brand). When an F1 drug moves to F2 it will become subject to the pricing arrangements that apply to F2 drugs.

Similarly, when a new bioequivalent or biosimilar brand of a drug on the combination drug list is listed, the combination drug will move to F2 and become subject to the same pricing arrangements as for other F2 drugs.

Bioequivalence and biosimilarity

Bioequivalence or biosimilarity will provide the trigger for a drug to move from F1 to F2. Bioequivalence is a test applied to non-biological drugs, and biosimilarity is a test applied to biological drugs. Both assessments are undertaken by the Therapeutic Goods Administration. When two brands of a drug are assessed as being bioequivalent or biosimilar and are indicated in the Schedule of Pharmaceutical Benefits as such (referred to as 'a' flagging), pharmacists are able to substitute the brands when dispensing. This is critical to the ability of suppliers of different brands to be able to compete.

Pricing

There is already the requirement for a 12.5 per cent price reduction when the first new brand of a drug is listed on the PBS. This policy has been in effect since August 2005. This will continue for new brands of F2 drugs and drugs that move from F1 to F2, provided a 12.5% reduction has not already applied. .

From 1 August 2008 a further reduction in the prices of drugs on F2 will be required:

- A price drop of 2 per cent a year for three years for drugs on F2A; and

- A one-off price drop of 25 per cent for drugs on F2T.

These 2%, 12.5% and 25% price reductions are mandatory price reductions required by legislation. As these reductions are mandatory they will be deemed to apply on the relevant day. This differs to the current arrangements where the Minister and a company seek to reach agreement on the new price. The deeming arrangements are proposed for the following reasons:

- As the 2% and 25% reductions will affect over 200 drugs on 1 August 2008, the administrative processes involved in reaching agreement on the new prices for each drug would be significant.

- Agreement may not be reached in some circumstances, raising the possibility that new or increased premiums are sought.

- The 12.5% price reductions can occur on 1 April, 1 August or 1 December each year. To date the 12.5% has been managed administratively rather than through legislation and at times there have been lengthy negotiations on the new prices.

For items that have patient premiums on the day that a mandatory price reduction occurs, both the price paid by the Australian Government and the patient premium will reduce by the mandatory amount. As no agreement to the new prices is sought at this time, companies will not be able to request other changes to existing premiums, or apply new premiums, at that time.

Exemptions to mandatory price reductions

The Bill provides that the Minister may determine that certain items are exempt from these mandatory price reductions, based on specified criteria (related to the unique nature of that

formulation for a specific sub-population, such as an oral solution for children where there is no other suitable alternative form of the drug). The exemption will apply while there is only one brand of that item on the PBS.

The rationale for this exemption is that these items are in a form that is critical for the treatment of specific patient groups, are generally used in low volumes and if large price reductions were required their continued availability on the PBS could be threatened. Forty-four items have been identified as appropriate for exemption from mandatory price reductions at the commencement of the new arrangements. This list has been reviewed and confirmed by the PBAC. Items may be added to the list based on the advice of the PBAC.

Price disclosure

The intent of PBS reform is to achieve 'market' prices for PBS drugs in the longer term by moving to a system of price disclosure, where the price that the Australian Government pays reflects the actual price at which the drug is being supplied to pharmacy. It is intended that data disclosed in regard to the pricing of drugs will include both price and other forms of discounts such as bonuses, rebates and related incentives.

Price disclosure will be phased in for drugs on F2:

- For F2A drugs, suppliers of any new brand listing from 1 August 2007 will be required to disclose its price as a condition of listing. Price changes based on disclosure may commence for these drugs from 1 August 2009.

- For F2T drugs, suppliers of any new brand listing from 1 January 2011 will be required to disclose its price as a condition of listing. Price changes based on disclosure may commence for these drugs from 1 August 2012.

Price disclosure requirements will be specified in the Regulations. A supplier (referred to in the Bill as a 'Responsible Person') who participates in price disclosure and who fails to comply with price disclosure requirements will commit a criminal offence, with a penalty of $33,000 for a corporation.

Further sanctions, available at the discretion of the Minister, will include delisting the brand for which disclosure requirements are not met, delisting other brands of that supplier from the PBS, or refusing to list new brands of that supplier. This course of action would take into account a range of factors, such as the number of times the company did not comply with price disclosure requirements and the reasons for non-compliance.

Guarantee of supply

It is proposed to introduce provisions to protect patients, prescribers and the industry from unnecessary disruptions to the supply of PBS drugs.

From 1 August 2007 suppliers of new brands of drugs listed on the PBS or suppliers who offer a price reduction will be required to guarantee supply. The guarantee of supply period will be for a minimum of 24 months or until a new brand is listed, or a new lower price offer is made and accepted by the Minister, whichever is the sooner.

If during the guarantee of supply period, the supplier forms the belief that they will fail to supply or be unable to supply, or if they do actually fail to supply or are unable to supply, they must notify the Minister, in writing. If they fail to do this they may be subject to a penalty of $33,000, for a corporation.

Should the supplier fail to comply with the guarantee of supply requirements the sanctions include delisting that brand or other brands from the PBS, or refusing to list new brands of that supplier.

The role of the PBAC

As noted earlier, the Bill does not change the current role of the PBAC in regard to the evaluation of drugs. PBAC responsibilities in this regard are established in Section 101 (3A) and (3B) of the Act. The provisions of PBS reform extend the role of the PBAC to provide advice to the Minister in regard to the following matters:

- items to be added to the list of items that are exempt from mandatory price reductions; and
- the formation of new TGP groups and the addition of drugs to existing TGP groups.

In addition the PBAC will provide advice on drugs that may be appropriate for the new streamlined authority arrangements described below.

Community pharmacy

As part of the PBS reform package, pharmacy is being provided support to adjust to the new arrangements through several measures as follows:

- A 40c incentive payment for each prescription processed using PBS online, to take effect from 1 July 2007.
- Increases to mark ups and dispensing fees provided to pharmacy for dispensing a PBS listed drug, to take effect from 1 August 2008.
- A payment of $1.50 each time a brand is dispensed which is available to patients at no more than the standard patient co-payment and for which multiple substitutable brands are listed on the PBS, to take effect from 1 August 2008.

The amendments to the Pharmacy Agreement also provide additional funding of $69 million over three years for the Community Service Obligation (CSO) Funding Pool, to assist participating pharmaceutical wholesalers to adjust to the new arrangements.

Streamlined Authorities

A proportion of drugs listed on the PBS require a prescriber to gain an authority from Medicare Australia prior to it being prescribed. The authority requirements of the PBS ensure that drugs that may be high cost or high risk, or where there is potential for inappropriate use, are used properly. One hundred and eighty four of the 615 drugs listed under Section 85 of the Act have authority requirements.

While the numbers of drugs with authority requirements will not change under PBS reform, a

new approach to administering these requirements for a subset of these is intended to be introduced from 1 July 2007. For 85 drugs a phone call to Medicare Australia will no longer be necessary. Doctors will instead record a streamlined authority code on the prescription. This is expected to reduce the numbers of phone calls that prescribers need to make to Medicare Australia by around 30%.

The streamlined authority arrangements will only apply to those drugs listed under Section 85 of the Act (i.e. it will not apply to those drugs listed under Section 100 of the Act) and will also only apply to drugs for the treatment of long-term chronic conditions. Drugs for short-term use and those that may be subject to abuse or misuse are not included in the new arrangements.

Further information on the new authority arrangements is shown in Table 6.

Table 6 – Impact of the streamlined authority arrangements

	Drugs		**Items**	
	Number	**%**	**Number**	**%**
Number of drugs listed under S85 of the Act	615		1858	
Subset of these with an authority requirement	184	38%	473	28%
Authority required drugs/items that will no longer require a pre-approval phone call	85	46%	206	55%

Generic drugs

The 2007/08 Budget provided funding of $20 million for a community education campaign to ensure that consumers and health professionals are aware of the safety, health and economic benefits of generic drugs. The campaign will focus in particular on high users of the PBS and will increase awareness that:

- all drugs in Australia, including generics, meet the same high standards of safety and effectiveness;
- generic drugs may save consumers money; and
- generic drugs help maintain the affordability of the PBS into the future.

Access to Medicines Working Group

The Department of Health and Ageing and Medicines Australia are working together to consider issues relating to timely and appropriate access to effective new drugs on the PBS through the Access to Medicines Working Group (AMWG). The work of the AMWG will complement other projects currently being progressed between Medicines Australia, the PBAC and the Department such as the outcomes of the joint policy conference convened in July 2006 and the development of key performance indicators as part of the review of post-PBAC processes.

The group will provide advice and recommendations to the Minister for Health and Ageing for the consideration of the Australian Government.

Impact on patients

PBS reform does not alter the way in which patients access the PBS. Patients will continue to have access to a choice of drugs and drugs will continue to be listed on the advice of the PBAC provided they are clinically and cost effective. No reduction in the range or number of drugs is expected.

Patients will continue to pay only the standard co-payment contribution. For some drugs that are cheaper than $30.70, patients may pay less.

There are also future benefits for patients. It is less likely under the new arrangements that other SPCs' will be required or that single brand drugs will be withdrawn from the PBS.

CONCLUSION

These reforms are intended to establish a basis for achieving better prices in the long term for medicines listed on the PBS. At a time when patents for many drugs are due to expire, the reforms remove some of the barriers to getting the best value from drugs that operate in a competitive market, while ensuring that necessary, single brand drugs remain accessible and listed on the PBS.

The reforms are expected to achieve a gross saving of $580 million in the coming four years, with savings of up to $3 billion expected in the next ten years.

For patients, the PBS will remain largely unchanged, continuing to provide access through community pharmacy to a wide range of drugs that are clinically and cost effective and continuing to support the continued listing of new, effective drugs.

ATTACHMENT A

SUMMARY OF LEGISLATIVE AMENDMENTS

Amendments to the *National Health Act 1953*

The proposed amendments to the Act are as follows:

Separation of PBS drugs into 2 formularies

- The Minister will determine the placement of PBS drugs on F1 or F2, consistent with criteria set out in the Act. The listing of individual drugs on the formularies will be prescribed in the Regulations at the commencement of the legislation and subsequent changes will be made by Ministerial determinations in legislative instruments, according to the criteria in the Act.
- Certain drugs, which are a combination of two or more drugs (at least one of which is PBS-listed), will be listed outside the formularies, and the pricing of these combination items will be based on the weighted price of their component drugs (as is current practice). This will apply while there is only a single brand of the combination product listed.

Mandatory price reductions for F2 drugs

- Statutory price reductions (2%, 25%, 12.5%) will apply to drugs on F2. These price reductions will be 'deemed' to apply if a drug is to continue to be listed on the PBS. However, if price reductions greater than the statutory amounts are offered, the Minister and the companies will either agree on a price or the Minister will determine the price that is to apply.
- The Minister may determine that certain items are exempt from statutory price reductions, based on criteria set out in the Act (related to the unique nature of that formulation for a specific sub-population, such as an oral solution for children where there is no other suitable alternative form of the drug) in order that they are not withdrawn from the PBS by the company, due to lack of profitability.

Price Disclosure

- Companies listing new brands of drugs on the PBS from 1 August 2007 (for F2A) or 1 January 2011 (for the merged F2) will be required to disclose the prices at which they actually supply their drugs to wholesalers or pharmacies. Other companies that have brands of that drug with the same manner of administration already listed on the PBS may voluntarily participate in disclosure but once they elect to do so they may not revoke this election.

- Based on disclosed pricing information, the Minister will determine, in accordance with the Regulations, the weighted average disclosed price of the drug. If the difference between the current price and the weighted average disclosed price is 10% or more, the price of the drug will reduce to that disclosed price.

- A company failing to comply with price disclosure requirements will commit a criminal offence, with a penalty of $33,000 for a corporation.

- In addition, the Minister may delist that brand or other brands from the PBS or refuse to list new brands of that company. In deciding to take these actions the Minister may take into account a range of factors, such as the number of times the company did not comply with price disclosure requirements and the reasons for non-compliance.

Guarantee of supply

- From 1 August 2007 any new brand listing on F2, plus any brand of a drug on F2 that offers a price reduction, will be required to guarantee supply of that drug. The guarantee of supply period will be 24 months, or until another new brand is listed, or until a further price reduction is offered for another already listed drug.

- Companies will be required to notify the Minister if they form the belief that they will be unable to supply or will fail to supply or have failed to supply or are unable to supply. A criminal penalty will apply for failure to notify of $33,000 for a corporation.

- In a situation where a failure to supply or inability to supply occurs, the Minister may delist that brand or other brands from the PBS or refuse to list new brands of that company. In deciding to take these actions the Minister may take into account a range of factors, such as the number of times a supply failed and the reasons for the failures.

- If the Minister delists a brand that failed to supply, the Minister will have the discretion to increase the price of any brands that suffered a price reduction as a result of the listing of the brand that failed to supply. The Minister may also move the drug from F2 to F1 or revoke any voluntary price disclosure elections from other companies with other brands of that drug.

Regulations and Legislative Instruments

A number of elements of the reforms are managed through regulations and legislative instruments:

- The two formularies (F1 and F2) will be established through regulations. Changes to the formularies will be made by Ministerial determination. New determinations will be made each time a new drug or new brand of a drug is listed which cause a drug to move from F1 to F2. The criteria which the Minister is to use in making and amending the formularies will be in legislation.

- Exempt items which are unique formulations of drugs that serve a specific demographic sub-population, and there is no suitable alternative formulation of the drug for that sub-population, will be established through Ministerial determination, subject to criteria set out in the legislation. These unique formulations will be exempt from mandatory price

reductions and from price disclosure, so long as there is only one brand of the item listed. New drugs can be added to the unique formulations list by Ministerial determination. The list of unique formulations was provided to industry on 23 March 2007.

- Drugs that are subject to the new streamlined authority provisions will be listed in the legislative instruments. The commencement list of streamlined authority drugs has been considered by the Pharmaceutical Benefits Advisory Committee.

- The method for collecting and analysing data for price disclosure purposes will be provided in the Regulations.