SENATE COMMUNITY AFFAIRS REFERENCES COMMITTEE

INQUIRY INTO: CONSUMER ACCESS TO PHARMACEUTICAL BENEFITS

SUBMISSION OF THE AUSTRALIAN GOVERNMENT DEPARTMENT OF HEALTH AND AGEING

9 APRIL 2010

Contents

Terms of reference

On 25 November 2009 the Senate referred the following matter to the Community Affairs References Committee for inquiry and report by 30 June 2010:

Consumer access to pharmaceutical benefits and the creation of new therapeutic groups through the Pharmaceutical Benefits Scheme (PBS), including:

a) the impact of new therapeutic groups on consumer access to existing PBS drugs, vaccines and future drugs, particularly high cost drugs;

b) the criteria and clinical evidence used to qualify drugs as interchangeable at a patient level;

c) the effect of new therapeutic groups on the number and size of patient contributions;

d) consultation undertaken in the development of new therapeutic groups;

e) the impact of new therapeutic groups on the classification of medicines in F1 and F2 formularies;

f) the delay to price reductions associated with the price disclosure provisions due to take effect on 1 August 2009 and the reasons for the delay;

g) the process and timing of consideration by Cabinet of high cost drugs and vaccines; and

h) any other related matters.

1. Summary

The therapeutic group policy helps to ensure the long term sustainability of the Pharmaceutical Benefits Scheme (PBS). The policy:

- ensures that the Government pays only the same price for the same health outcome;
- results in savings to taxpayers which allows the PBS to continue to deliver new high cost drugs for the benefit of Australians. From November 2007 twelve new high cost drugs have been listed on the PBS, or their listing has been extended, at an estimated cost of $1.5 billion for the first four years;
- does not impact on what clinicians may prescribe for treatment of their patients;
- does not mean pharmacists can exchange one drug for another – any change in drugs must be prescribed by a clinician; and
- does not reduce patient access to drugs.
    - The doctor still decides on the most appropriate treatment in consultation with their patient.
    - In the vast majority of cases it results in no cost impact at all on patients because co-payments are unchanged, or reduces the amount paid by the patient for drugs that cost less than the co-payment.
    - There is a possibility of pharmaceutical companies seeking a patient paid premium for therapeutic group medicines, but no such premium was sought for any of the drugs in the four groups formed in 2009 and 2010.
    - Of the 515 brands of medicines in the six previously formed groups, six brands have therapeutic group premiums, which range in cost from $1.52 to $4.35 per script.

2. Overview of the Pharmaceutical Benefits Scheme.

The PBS provides the Australian community with reliable, timely and affordable access to over 740 drugs available in more than 1,850 forms, and marketed as over 3,500 brands. In 2008-09, around 182 million PBS-subsidised prescriptions were dispensed at a cost to the Australian Government of over $7.7 billion. This represented approximately 15 per cent of the Australian Government Health and Ageing portfolio budget.

Medicines are listed on the PBS on the advice of the independent, expert advisory body known as the Pharmaceutical Benefits Advisory Committee (PBAC) which is comprised of doctors, other health professionals and a consumer representative. The PBAC considers applications from companies for PBS listing having regard to the clinical effectiveness and cost-effectiveness (value-for-money) of medicines, in

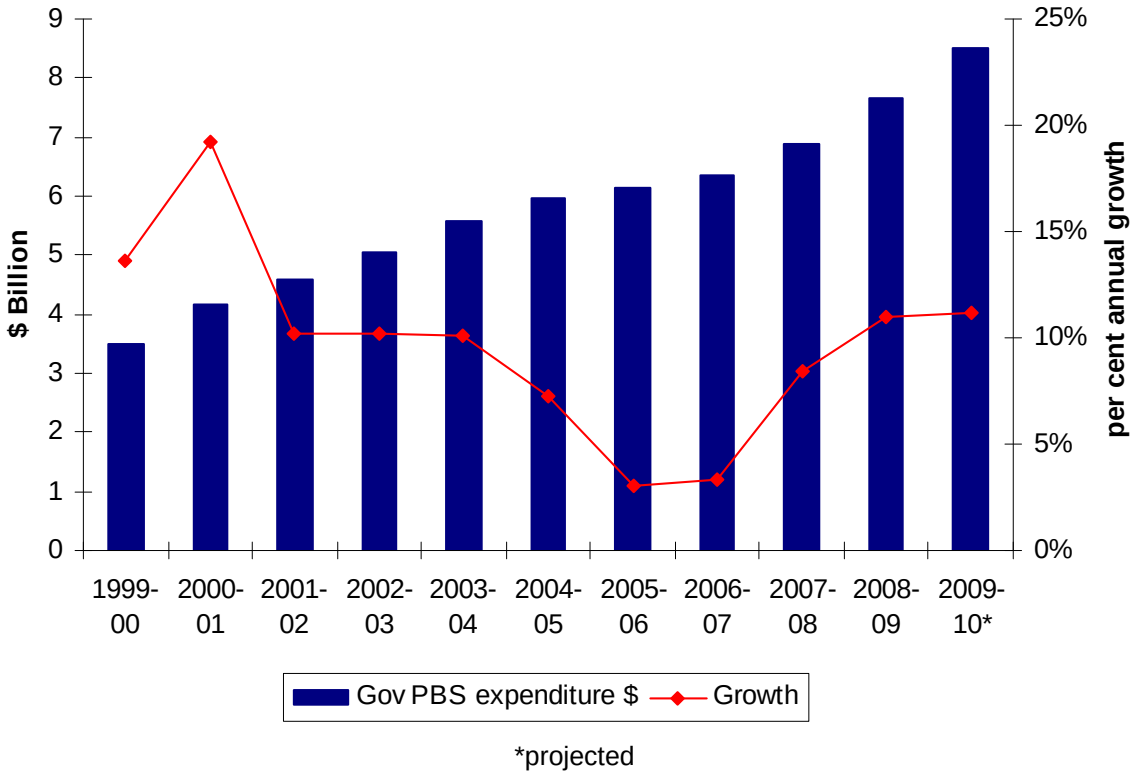
comparison with other available treatments. Companies cannot be compelled to apply for PBS listing, or to expand the scope of an existing listing.

The PBAC is committed to using sound evidence-based principles to decide which products should be subsidised through the PBS and under what circumstances. The same requirements for listing medicines on the PBS are applied in all cases to ensure consistency and fairness in the listing process.

When a medicine is listed on the PBS, certain restrictions or conditions may apply as recommended by the PBAC. Restrictions reflect that the PBAC received and considered evidence that demonstrated the medicines to be sufficiently medically effective and cost-effective in these patient groups only.

The PBS is one of the fastest-growing Government programs. As Figure 1 below demonstrates[1], the cost of the PBS has continued to grow over the past ten years, averaging growth of 9.6 per cent. In 2008-09 the cost of the PBS was 9.2 per cent higher than that in 2007-08, and in 2009-10, the PBS is expected to grow a further 10.6 per cent to an annual cost of $8.5 billion.

Figure 1: Government PBS expenditure growth: 1999-2000 to 2009-10



PBS growth is mainly driven by growing demand and the listing of new high cost medicines. The continuing trend of doctors to prescribe newer, more expensive medicines is illustrated by the fact that prescription volumes grew by 6.2 per cent in 2008-09, while the cost to the Government of the PBS increased by 9.2 per cent. PBS growth is also influenced by the prices of existing PBS medicines and how these

[1] Source: Department of Health and Ageing, Expenditure and prescriptions twelve months to 30 June 2009

change over time, the number and cost of minor new medicines added to the PBS (particularly in an environment of rapid technological innovation), population growth and ageing, the increasing prevalence of chronic disease, the level of coverage by concession cards, the number of prescriptions dispensed, the amount that patients contribute towards the cost of prescriptions and changing community expectations concerning appropriate levels of care.

Current projections for PBS expenditure are for continued steady growth beyond the forward estimates period. The *Impact of PBS Reform* Report to Parliament stated that on current projections, PBS outlays by 2018 will be higher than originally projected before structural reform. Expenditure will be in the order of $13 billion to $13.7 billion.

The 2010 Intergenerational Report, *Australia to 2050: Future Challenges*, forecast that overall health expenditure would increase from 4.0 per cent of GDP in 2009–10 to 7.1 per cent in 2049–50. It also forecast that Government spending on the PBS will increase in real terms from $443 per capita in 2012–13 to $534 per capita in 2022–23; with PBS expenditure remaining at 0.7 per cent of GDP in the medium term (to 2019-20).

Both these reports recognise that it is essential to combine increased accessibility of pharmaceuticals with practical cost reductions to maintain sustainability. Reforms such as therapeutic groups and price disclosure are essential components in the Government's commitment to maintain both maximum accessibility and sustainability of the PBS, now and into the future.

The Government's commitment to finding efficiencies allows it to invest in new innovator drugs. Major new PBS listings (those estimated to cost more than $10 million per annum in any of the first four years of listing) during 2008 and 2009 are set out in Table 1.

Table 1: Major new PBS listings for 2008 and 2009

Medicine	To treat	Projected Cost to Government
Varenicline	Smoking cessation	$76.3 million over first 4 years
Cinacalecet	Secondary Hyperparathyroidism	$165.9 million over first 4 years
Natalizumab	Relapsing-Remitting Multiple Sclerosis	$358.3 million over first 4 years
Humira	Crohn Disease	$131.8 million over first 4 years
Clopidogrel	Acute Coronary Syndrome	$74.7 million over first 4 years
Posaconazole	prophylaxis and treatment of invasive fungal infections	$39.1 million over first 4 years

Sunitinib	renal cell carcinoma	$131.0 million over first 4 years
Bevacizumab	colorectal cancer	$314.0 million over first 4 years
Lenalidomide	multiple myeloma	$104.0 million over first 4 years
Total		**$1,395 million over first 4 years from each listing**

This investment in new innovator drugs not only provides the Australian community with affordable access to medicines that deliver optimal health outcomes, but it also continues to foster and develop the Australian pharmaceutical industry. Development of the Australian pharmaceutical industry is one of the key platforms underpinning Australia's National Medicines Policy. However, this level of investment can only be sustained if measures are also undertaken to optimise the cost effectiveness of the PBS. For example, the 2010 Intergenerational Report estimated investment in new drugs will represent over $1.5 billion of the estimated $8.5 billion of PBS expenditure in 2009-10[2].

Australia's National Medicines Policy provides the overarching framework for the operation of the PBS. A central objective of the policy is "timely access to the medicines that Australians need, at a cost individuals and the community can afford". In addition, the National Medicines Policy recognises that the partners in the policy (governments, health educators, health practitioners, and other healthcare providers and suppliers, the medicines industry, healthcare consumers, and the media) should take responsibility for achieving value for money, and that a fair distribution of costs and savings between the partners should be achieved.

The formation of therapeutic groups is only one of a number of efficiency initiatives that have been implemented over the past thirteen years to help ensure the long term sustainability of the PBS. Major pricing initiatives in that time include:

- formation of therapeutic groups and introduction of the therapeutic groups pricing policy (1997);
- increasing the patient co-payment amounts (2002-03);
- increased focus on pricing medicines in specified groups by reference to the weighted average monthly treatment cost methodology (at introduction of therapeutic groups in 1997 and review of the methodology in 2003-04) ;
- administrative 12.5 per cent price reduction policy - applied when the first *new* brand of an already PBS listed medicine is listed on the PBS (2005); and
- The PBS Reforms package (2007), comprising:
    - placement of PBS listed drugs on formularies and the application of statutory price reductions;
    - legislative basis for the 12.5 per cent price reduction on first new brand listing; and
    - price disclosure related price reductions.

[2] Pages 51 and 52 of the Intergenerational Report 2010

PricewaterhouseCoopers, when conducting independent modeling commissioned by the Department of Health and Ageing for the 2010 *Impact of PBS Reform* Report to Parliament, estimated that the 2007 package of reforms result in savings of between $3.6 billion and $5.8 billion in the ten year period from 1 July 2008 to 30 June 2018 depending on the impact of price disclosure.

The objective of reforms has been to ensure that Government pays the same price for the same health outcome, and at the best available price, without interfering with the clinical relationship between a doctor and their patient. Under the pricing policies introduced since 1997, doctors have been able to continue prescribing whichever medicines are most appropriate for their patients, while the Government has paid less for health outcomes.

3. Overview of the Therapeutic Group Policy

3(a) *Summary*

The therapeutic group policy applies to groups of drugs that are considered interchangeable at the patient level. Within these groups, in the vast majority of cases, patients can move from one drug in the group to another without any clinical or financial impact.

The aim of therapeutic groups is to ensure that Government pays the same price for the same health outcome, at the best available price, in a way that does not conflict with the Government's view that a patient's doctor is best placed to advise on the most appropriate treatment.

3(b) Discussion

Governments in many countries have policies to make sure that they spend comparable amounts on pharmaceutical products for comparable health outcomes. For example, systems that achieve this through reference pricing have been operating successfully in a number of countries, particularly in Europe, for many years. Germany first introduced reference pricing in 1989, followed by The Netherlands, Denmark, Italy and Spain. In general, under reference pricing the maximum reimbursement for one product is set by reference to the price of other comparable product/s.

In Australia, one method for providing comparable government expenditure on medicines that provide comparable health outcomes is the formation of therapeutic groups. Other methods for reference pricing medicines include payment of the same government subsidy for different brands of the same drug, and ensuring that specified groups of drugs have the same monthly treatment cost despite variations in prescribed doses.

In 2007 the then First Assistant Secretary for the Pharmaceutical Benefits Division of the Department of Health and Ageing was asked in the course of the Senate Inquiry into the PBS Reform legislation what 'interchangeable' means in the context of drugs that might be included in therapeutic groups. She said:

> *Interchangeability means that these drugs are pharmaceutically related, have the same mechanism of action and provide similar therapeutic outcomes at*

equivalent doses at the individual patient level … The Therapeutic Group Premium Policy was introduced by the Government in 1998. The policy applies within specifically defined groups of drugs which have similar safety and health outcomes. Within these groups, the drugs can be interchanged at the patient level.[3]

The clinical appropriateness of the policy is ensured by obtaining advice from the PBAC before therapeutic groups of medicines are formed. Once groups are formed the therapeutic group pricing policy is applied so that all medicines in the group are priced by reference to the lowest priced medicine in the group.

3(c) History of the Therapeutic Group Policy

The therapeutic group policy was first announced in the 1997-1998 Budget and the first four therapeutic groups, in Table 2 below, were formed in February 1998.

Table 2: Therapeutic groups formed in 1998

Group & Date	Drugs	Action of Drug
ACE Inhibitors	captopril, cilazapril (since removed – not on PBS), enalapril, fosinopril, lisinopril, perindopril, quinapril, ramipril, trandolapril	Competitive inhibitor of angiotensin I converting enzyme (the enzyme responsible for the conversion of angiotensin I to angiotensin II) - used mainly for heart conditions
Calcium Channel Blockers	amlodipine, felodipine, nifedipine (lercanidipine added since creation)	Prevents calcium from entering cells of the heart and blood vessel walls – uses include lowering blood pressure
H2 Receptor Antagonists	cimetidine, famotidine, nizatidine, ranitidine	Histamine 2 receptor antagonist – inhibits acid secretion (eg: for ulcer treatment)
HMG CoA Reductase inhibitors (Statins)	pravastatin, simvastatin	HMG-CoA reductase inhibitors lower cholesterol levels in the body

The inclusion of the drugs in these first four groups was based on the expert opinion of the PBAC that the drugs in each group are very alike and work just as well as one another for the vast majority of people. The Therapeutic Goods Administration (TGA) registration and PBS listing for drugs in the groups were not always the same. For example, enalapril maleate was the only drug in the ACE Inhibitor group with TGA registration for left ventricular dysfunction; and the drugs in the H2Receptor Antagonists did not have the same PBS listings.

Once the drugs were placed in a therapeutic group, the therapeutic group pricing policy was applied, with effect from February 1998. That is, the Government paid one level of PBS subsidy for all medicines containing the drugs within each of the four groups. This applied regardless of whether or not the drugs had the same PBS listings.

[3] Answer to a Question on Notice arising from the Community Affairs Senate Inquiry into the *National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2007*, 15 June 2007.

The initial savings estimate at the time these therapeutic groups were introduced, for the first four financial years commencing 1 February 1998, was $377.5 million.

In 2007 the then Government introduced a range of PBS Reforms, including amendments to the *National Health Act 1953* (the Act), which provides the statutory basis for the PBS. At the time of these reforms a further two new therapeutic groups, set out in Table 3, were formed and the previously administrative therapeutic group policy was provided for under statute.

Table 3: Therapeutic groups formed in 2007

Group & Date	Drugs	Action of Drug
ATRA	candesartan, eprosartan, irbesartan, olmesartan, telmisartan, valsartan	Angiotensin II receptor antagonist (mainly used to lower blood pressure)
Proton Pump Inhibitors	esomeprazole, lansoprazole, omeprazole, pantoprazole, rabeprazole	Proton Pump inhibitor (decreases gastric acid production).

Total estimated savings from therapeutic group reference pricing through application of the weighted average monthly treatment cost methodology, for the first two years following formation of those therapeutic groups in 2007, is approximately $59 million.

The legislative amendments provided consistency with the pre-existing pricing policy for drugs in therapeutic groups by ensuring that new statutory price reductions apply to all drugs within a therapeutic group regardless of whether they are in the F1 (single brand drugs) or F2 (drugs subject to competition) formulary.

This was achieved by providing in the Act, for the first time, that therapeutic groups are formed by determination in a legislative instrument made by the Minister[4]. Formation of groups had previously been an administrative process.

Under the Act the Minister can form a therapeutic group only after obtaining advice from the PBAC in relation to the proposed determination[5]. Further, when deciding on the drugs that comprise a group the Minister may have regard to any PBAC advice to the effect that a drug should, or should not, be treated as interchangeable on an individual patient basis with another listed drug[6]. The PBAC has corresponding functions for providing the advice about formation of groups and interchangeability of drugs[7].

Inclusion of provisions in the Act for creating therapeutic groups supports the intention that new therapeutic groups may be formed to implement the government policy of paying comparable amounts for drugs that provide comparable health outcomes. This was clearly reflected in the Department of Health and Ageing submission to the Senate Committee Inquiry into the PBS Reform legislation in June 2007, which referred to the PBAC role in the formation of new therapeutic groups[8].

[4] Unless otherwise noted, references to the Minister in this submission are also references to their delegate, because all of the powers of the Minister under the Act in relation to creation of therapeutic groups have been delegated to Departmental officers.
[5] See subsection 84AG(1A) of the *National Health Act 1953*.
[6] See subsection 84AG(3) of the *National Health Act 1953*
[7] See subsections 101(4AA), 101(3BA) and 101(3) of the *National Health Act 1953.*
[8] Department of Health and Ageing Submission: 13 June 2007, to the Senate Community Affairs Committee Inquiry into the National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2007, at page 15.

Since those provisions surrounding formation of new therapeutic groups were included in the Act in 2007 a seventh therapeutic group was formed in September 2009 following its announcement in the 2009-10 Budget.

Group & Date	Drugs	Action of Drug
Statins-HP	Atorvastatin, rosuvastatin	Higher potency HMG-CoA reductase inhibitors lower cholesterol levels in the body

Lower prices flowing from formation of this group come into effect on 1 April 2010. It was estimated the measure would generate savings of around $114 million over the next four years.

A further three new therapeutic groups, set out in Table 4 and announced in the 2009-10 Mid Year Economic & Fiscal Outlook, were formed with effect from 21 January 2010. The price changes flowing from formation of these groups were intended to come into effect on 1 April 2010.

Table 4: Therapeutic groups formed in 2010

. Group & Date	Drugs	Action of Drug
Venlafaxine	venlafaxine, desvenlafaxine	Anti-depressants (venlafaxine and its PBS listed derivative drug)
Bisphosphonates - osteoporosis	alendronic acid, alendronic acid with calcium, risedronic acid, risedronic acid with colecalciferol, risedronic acid with colecalciferol and calcium – but only oral forms of these drugs are in this group in the circumstances listed on the PBS for treating osteoporosis	These oral bisphosphonates treat problems with bone density
Bisphosphonates - Paget disease	alendronic acid, risedronic acid, tiludronic acid – but only oral forms of these drugs are in this group in the circumstances listed on the PBS for treating Paget disease of bone	These oral bisphosphonates treat Paget disease of bone

However, the formation of these three groups was disallowed by the Senate on 11 March 2010, resulting in lost savings of approximately $48.2 million over the four years starting 2009-10.

4. Response to the Terms of Reference

4(a) The impact of new therapeutic groups on consumer access to existing PBS drugs, vaccines and future drugs, particularly high cost drugs

4(a)(i) Overview of patient access under therapeutic group policy

Placing a drug in a therapeutic group does not change a patient's access to a medicine. The listing details for a PBS medicine and restrictions surrounding when it may be prescribed on the PBS are not changed by formation of a therapeutic group. There is no impact on what clinicians may decide, in consultation with their patient, to prescribe.

Drugs in therapeutic groups are not interchangeable by pharmacists – the PBS prescriber must write a different script before a patient could be supplied a different drug in the group.

Access issues related to the cost to patients for supply of medicines in therapeutic groups are dealt with later in this submission.

4(a)(ii) Vaccines & High Cost Drugs

There are no therapeutic groups for vaccines.

There are no differences in consumer access arrangements for high cost and other PBS listed drugs in therapeutic groups. A high cost drug is, in this context, a drug for which the cost to Government is estimated to be more than $10 million in any of the first four years of listing on the PBS or extension to listing. As discussed elsewhere in this submission, it is a Government requirement that listings or extension to listings for high cost drugs be considered by Cabinet. This process reflects the high total cost to Government of subsidising the drug, and does not necessarily mean the cost of each supply of the drug is high.

4(a)(iii) Future Listings

Drugs listed on the PBS in the future may be included in a new or existing therapeutic group at the time of listing. The impact of inclusion in a therapeutic group on those drugs will be the same as for drugs in existing therapeutic groups. That is, the PBS listing price will reflect the therapeutic group pricing policy, and the medicines will be available to patients at whichever is the lower cost to the patient of the dispensed price to consumers and the applicable co-payment (unless a pharmaceutical company has requested a therapeutic group premium).

Following the 2007 PBS Reforms, the PBAC is required under the Act to consider whether any new drug it recommends for listing on the PBS should be treated as interchangeable on an individual patient basis with another PBS listed drug[9]. The inclusion of advice on interchangeability of a drug in the PBAC recommendation for listing is not advice that a therapeutic group should be formed. The Minister may subsequently determine that a drug will either be included in an existing therapeutic group, or form part of a new group. The PBAC advice on interchangeability may be taken into account when the Minister makes that decision.

[9] Subsection 101(3BA) of the *National Health Act 1953*

4(b) The criteria and clinical evidence used to qualify drugs as interchangeable at a patient level

As noted earlier in this submission[10], the Minister takes into account advice from the PBAC about whether relevant drugs are interchangeable at the individual patient level before making a decision about including them in a therapeutic group.

The Act specifically provides for the PBAC to give advice before therapeutic groups are formed, and relevant advice about interchangeability of listed drugs. This is supplemented by the PBAC function to provide advice as requested about the operation of the PBS.

In general terms, interchangeability means that drugs are pharmaceutically related, have the same mechanism of action and provide similar therapeutic outcomes at equivalent doses at the individual patient level. The policy applies within specifically defined groups of drugs which have similar safety and health outcomes. This is a specific application of the general policy position that the Government should fund the same health outcomes at the same price.

The question of interchangeability of drugs in therapeutic groups differs from a finding by the Therapeutic Goods Administration that generic brands of a drug are sufficiently bioequivalent to be treated as identical. Those identical or bioequivalent brands of drugs listed on the PBS are subject to a reference pricing policy. The 1997 therapeutic groups Budget measure extended the reference pricing policy to drugs that are not required to be identical. The Budget announcement in 1997 made it clear that the new policy meant specified medicines with very similar clinical activity would have the same pricing consequences as had previously been in place for drugs with identical chemical make-up. This means drugs in therapeutic groups are not identical, but are sufficiently similar that they can be treated as interchangeable for the purposes of PBS pricing policies.

The question about whether drugs are sufficiently similar for inclusion in a therapeutic group requires clinical judgment. Most of the PBAC members are medical professionals, and they bring a considerable depth of clinical expertise and breadth of knowledge to their advisory role. Attachment A sets out current PBAC membership and the areas of expertise of the medical professionals on the Committee.

Material available to the PBAC members when considering interchangeability includes published peer-reviewed journals and studies, submissions by pharmaceutical companies and others, product information documents for the relevant drugs, and the expert analysis that underpins the PBAC deliberations.

The submissions from pharmaceutical companies for PBAC listing recommendations include comparisons with other drugs, including details about similarity of action, clinical effect and similarity or differences in safety. For example, desvenlafaxine was PBS listed on 1 February 2009, following consideration by the PBAC at its November 2008 meeting. The detailed submission by the relevant pharmaceutical company itself compared desvenlafaxine to the listed drug venlafaxine.

The PBAC gave advice that each of the four therapeutic groups formed in 2009 and 2010 should be formed, and that the relevant medicines are interchangeable at an individual patient level. That advice was initially provided for the Statins HP and the Venlafaxine Groups in March 2009, and for the two Bisphosphonates Groups in

[10] See 3(a) and 3(b)

June 2009. Further PBAC advice, received in January 2010, is referred to later in this submission[11].

4(c) The effect of new therapeutic groups on the number and size of patient contributions;

4(c)(i) Summary

The four most recently formed therapeutic groups would not have resulted in any impact on the amount paid by patients. This is because patients would continue to pay their PBS co-payment amount for supply of the medicines. It is likely that in the future, as a result of formation of the therapeutic groups, some of the medicines would have dropped in price below the general patient co-payment amount. This would mean a lower cost to patients.

The pharmaceutical companies that supply the drugs in the four recently formed therapeutic groups had not requested patient paid premiums, which can result in higher patient prices for specified brands of medicines. This meant that there would have been no additional cost to patients for access to these drugs on the PBS, including for the three groups disallowed by the Senate on 11 March 2010.

Of the six therapeutic groups that were formed prior to 2009, which presently covers 29 different PBS listed drugs, and a total of 515 brands of medicines available on the PBS, there are currently 6 brands of medicines with therapeutic group premiums, ranging in a cost to patients from $1.52 to $4.35 per script on top of the usual co-payment.

4(c)(ii) Discussion

Drugs within a therapeutic group continue to attract the same concessional or general patient co-payment, and their purchase counts towards a patient's safety net in the usual way.

There can, in some instances, be an impact on the cost of a medicine to a patient. The first is when the cost of a drug is reduced to a price less than the general co-payment fee as a result of its inclusion in a therapeutic group. There are a number of drugs in therapeutic groups that cost less than the general co-payment amount, and price reductions within those groups result in a lower cost to general patients.

The second instance when price to the patient will be impacted is when a patient is asked to make a contribution to the cost of the drug by the manufacturer, in the form of a therapeutic group premium. This only occurs if a pharmaceutical company does not agree to accept the PBS price that applies under the therapeutic group pricing policy.

A therapeutic group premium only applies to a particular brand of drug, and it has been quite rare for a premium to be applied. If a doctor prescribes a particular brand of medicine that has a therapeutic group premium, the patient will pay the premium in

[11] See 4(d)

addition to their co-payment. However, if the doctor, in consultation with the patient determines that another brand of drug is equally suitable to prescribe, that drug can be prescribed by the doctor, resulting in no additional cost to the patient. It should be noted that the drugs in therapeutic groups cannot be substituted or interchanged by pharmacists – any change must be prescribed by the clinician.

Patient access is further protected through the therapeutic group policy's upfront recognition that it might sometimes be clinically inappropriate for a patient to be prescribed a different medicine in the therapeutic group in order to avoid a therapeutic group premium. The Act therefore provides for the Commonwealth to pay the patient premium in certain circumstances. For therapeutic group medicines, the Commonwealth currently pays any patient premium where the prescriber obtains an authority from Medicare Australia based on specified criteria. At present, the specified criteria are:

- the patient suffers adverse effects when taking all of the drugs in the group that have no therapeutic group patient premium;
- the patient experiences drug interaction issues when taking all of the drugs in the group that have no therapeutic group patient premium;
- it is expected the patient would experience drug interaction issues if they took any of the drugs in the group that have no therapeutic group patient premium; and
- transferring the patient to a drug in the therapeutic group that has no therapeutic group premium would cause patient confusion resulting in problems with compliance.

The legal instruments that provide arrangements for exemption from payment of a therapeutic group premium can be amended as required. Appropriate arrangements can therefore be made as required to deal with patient access issues that might arise if pharmaceutical companies impose patient premiums on brands of medicines in therapeutic groups.

4(d) Consultation undertaken in the development of new therapeutic groups

When the therapeutic group policy was first announced in 1997, the government consulted stakeholders, including medical professionals and affected companies, about the implementation of the new policy. Advice from the PBAC was then taken into account when a decision was made about forming the proposed groups.

The Government consulted about formation of the two new groups during broader consultation related to PBS Reform in 2007.

The new Statins-HP group was announced in the 2009-10 Budget. The Department of Health and Ageing wrote to affected companies shortly after the Budget announcement, seeking comments concerning implementation of the measure. The department then undertook a lengthy consultation process from May to August 2009 with the most affected company (including meetings and correspondence) before the Minister's delegate formed the groups with effect from 1 September 2009. During the

consultation process no submission was received to the effect that the affected drugs were not interchangeable.

The three further new therapeutic groups were first announced in the Mid Year Economic & Fiscal Outlook on 2 November 2009. The proposed groups were the venlafaxine and venlafaxine derivative antidepressants group, the oral bisphosphonates osteoporosis group and the oral bisphosphonates Paget disease of bone group. As part of the Government's budget process the PBAC responded, in March and June 2009, to requests for advice about the proposal to form these groups. The process for consultation and decision-making for these three groups is outlined below.

2 November 2009	Intention to make the groups published in the Mid Year Economic & Fiscal Outlook 2009.
2 & 9 November 2009	Letters to affected companies and to peak industry bodies announcing the intention to form the new groups, and to affected companies advising pricing implications. Comments sought from affected companies.
16 November to 3 December 2009	Letters from affected companies, a peak industry body, and some medical professionals, which included comments about clinical issues surrounding interchangeability of the relevant drugs and about the decision-making process.
3 December 2009	Letter from the department to the PBAC asking it to consider the clinical issues raised in the comments received in response to the invitation to comment.
3 December 2009	Letter to affected companies stating advice is likely to be sought from the PBAC on comments on clinical issues and asking that any further comments be provided to the PBAC by 16 December 2009 so that advice on the clinical issues raised could be provided to the decision-maker in early January 2010.
3 -16 December 2009	Further comments received from affected companies and some medical professionals.
22 December 2009	Indicative pricing letters sent to companies that may be offered lower prices if the new therapeutic groups are formed in January 2010.
8 – 12 January 2010	The PBAC considered the material submitted in accordance with the consultation process before giving advice confirming its view that the groups should be formed and that the relevant medicines are interchangeable on an individual patient basis.
19 January 2010	The delegate considered the advice from the PBAC, and the other comments and submissions provided in accordance with the consultation process and made the instrument forming the therapeutic groups (which commenced 21 January 2010).
20 January 2010	January 2010 PBAC advice sent to affected companies

20 January 2010 to 18 February 2010	Price offer letters sent to companies affected by lower pricing as a result of formation of the therapeutic groups. Negotiations with companies about pricing.
18 February 2010	All new prices agreed, with no therapeutic group premiums.

4(e) The impact of new therapeutic groups on the classification of medicines in F1 and F2 formularies

As a result of the 2007 PBS Reforms, the Act provides that drugs listed on the PBS may be placed in either the F1 or F2 formulary, depending on whether they meet the criteria set out in the Act for inclusion in F1[12].

The Act specifically provides that a drug in a therapeutic group with another drug that has brand competition cannot be in the F1 formulary[13]. This means that when any F1 single brand drug is placed in a therapeutic group with an F2 drug that has brand competition, it moves into F2.

In the case of the therapeutic groups formed with effect from 21 January 2010, there were two single brand F1 drugs that were placed into the oral bisphosphonates groups with the F2 drug alendronic acid. Therefore, at the time the therapeutic groups were formed those two drugs (risedronic acid and tiludronic acid) no longer met the criteria for the F1 formulary. As a result, a legal instrument was made determining that those two drugs moved to the F2A formulary. That instrument was disallowed on 11 March 2010 by the Senate.

4(f) The delay to price reductions associated with the price disclosure provisions due to take effect on 1 August 2009 and the reasons for the delay

4(f)(i) Background

Price disclosure is a key component of the 2007 PBS Reforms, which commenced in August 2007. The price disclosure arrangements will progressively reduce the prices of some PBS medicines which are subject to competition, ensuring better value for money from these medicines.

Since its introduction, 38 drugs have been required to provide price disclosure information. As a result, 62 brands of 11 drugs have been identified for price reductions of between 13 per cent and 71 per cent. This includes five drugs scheduled for reductions as a result of the fourth round of price disclosure calculations, which are on target for 1 August 2010 reductions, delivering reductions of between 13 per cent and 41 per cent.

The provisions related to price disclosure currently apply only to drugs on the F2A formulary. The Act provides for the first potential price reductions for drugs on F2T in August 2012.

[12] Section 85AB of the Act

[13] Paragraph 85AB(4)(b) of the Act

Under price disclosure the weighted average disclosed price is determined across all brands of the same drug with the same manner of administration. This is based on 12 months of sales and incentives data supplied by companies.

The price of all brands containing the drug are reduced to the calculated weighted average disclosed prices if the difference between the current PBS ex-manufacturer price and the weighted average disclosed price is 10 per cent or more.

The price disclosure related reductions will bring the PBS prices of medicines down to, but not below, the average market prices at which they are sold to pharmacies.

4(f)(ii) Delays in price reductions

Four of the nine drugs in the first round of price disclosure were scheduled for price disclosure related price reductions on 1 August 2009, which did not occur on that date due to legal technical difficulties.

Notices were issued to affected companies in December 2008 advising them of the new reduced prices intended to take effect on 1 August 2009. Those new reduced prices were based on the calculation of the weighted average price at which the relevant drugs were being sold to pharmacists, using data supplied to the Commonwealth by affected companies.

A company asserted (correctly) that certain pre-conditions under the Act had not been met before the December 2008 price reduction notices were issued. Companies were advised that no price disclosure related reduction would occur on 1 August 2009.

A new determination setting out new weighted average disclosed prices was made on 30 July 2009 to take effect on 31 July 2009. The weighted average disclosed prices determined for the four original drugs were based on the price information disclosed to the Commonwealth in the first round of price disclosure. Weighted average disclosed prices for other drugs, arising from the second round of price disclosure, were also included in this determination. Related price disclosure reduction notices were reissued to companies for the original four drugs on 31 July 2009, with the price reductions for all four drugs intended to take effect from 1 April 2010.

Three of those original four drugs then had their prices reduced from 1 December 2009 as a result of a price offer from one of the affected pharmaceutical companies. The price offer reduced the prices to that which would have occurred from 1 April 2010.

In light of new data (for the original price disclosure round) which was disclosed by one company in the course of a dispute resolution process surrounding the first round of price disclosure, an amended determination for new weighted average disclosed prices was made on 28 September 2009 for the outstanding drug, meloxicam. On 30 September 2009 new notices were issued to companies that supply the drug meloxicam. This was to give effect to a price change, from 1 April 2010, based on the corrected information from one of the companies that supplies meloxicam.

As a result of a clerical error, a further amending weighted average disclosed price determination was made on 1 October 2009 to correctly amend the prices set out in the July 2009 determination in respect of meloxicam medicines.

One company challenged the September/October price reduction notices for meloxicam, saying they did not meet all the preconditions under the Act for the price reductions scheduled for 1 April 2010. The issues related to the now complex interlinking of two price disclosure rounds and amendments accounting for the new

data received by the Commonwealth. Following receipt of legal advice the Department of Health and Ageing conceded that the September/October notices in relation to the drug meloxicam were invalid.

As price disclosure for each drug continues on an annual cycle, companies supplying meloxicam were, in January 2010, issued notices as part of the 1 August 2010 reductions based on meloxicam's second data collection cycle. Those reductions will represent the first price disclosure related reductions for the drug meloxicam. The scheduled reductions have occurred, or are proceeding as planned, for all other drugs.

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 of Health and Ageing is responding to the issues that have arisen by ensuring that the appropriate protocols and procedures are in place for all steps and stages of the price disclosure process. These processes have been formalised and documented to ensure accuracy and consistency throughout the program. All price disclosure legislative instruments will, in the future be reviewed by lawyers, and all calculations will be reviewed by an officer from another section of the department.

4(g) The process and timing of consideration by Cabinet of high cost drugs and vaccines

4(g)(i) Background

Before a drug can be subsidised through the PBS, it needs a recommendation to that effect from the PBAC. Recommendations for pricing of new drugs and extension to listings of current drugs following positive PBAC recommendations are made by the Pharmaceutical Benefits Pricing Authority. If it is estimated that a proposed new listing or an extension to listing will cost the Australian Government more than $10 million in any of the first four full years of listing, a submission is presented to the Cabinet for their consideration.

4(g)(ii) Cabinet Process & timing

The Department of Health and Ageing adheres to timelines and procedures as directed by the Department of the Prime Minister and Cabinet when proposing high cost drugs and vaccines for listing on the PBS and National Immunisation Program (NIP).

The average length of time between PBAC recommendation and Cabinet consideration since November 2007 is 7.1 months.

5. Conclusion

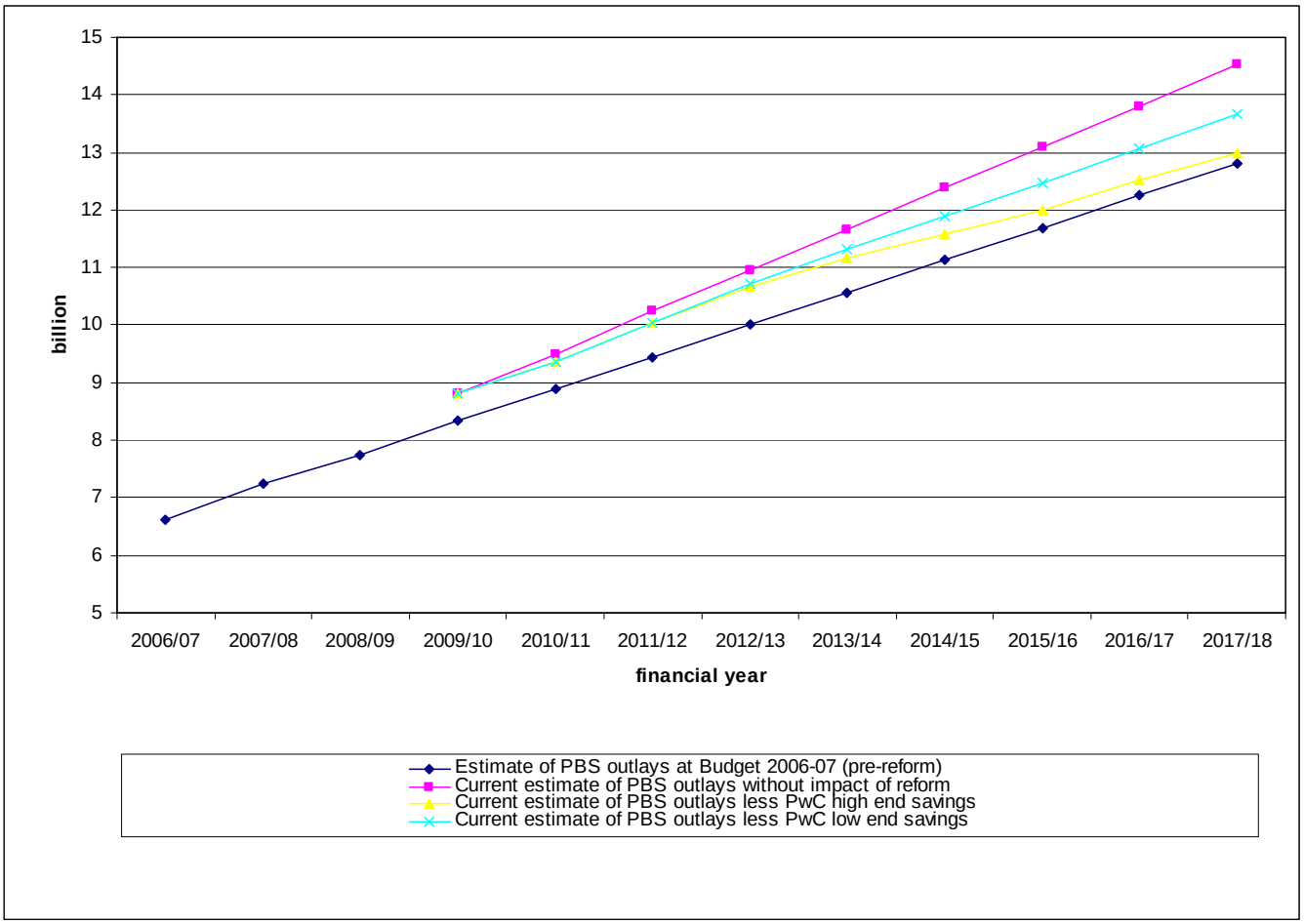
It is important that the fundamental objective of the PBS, to provide access for Australians to safe and effective medicines at a cost the individual and community can afford, is protected. The 2010 *Impact of PBS Reform* Report to Parliament stated:

> *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. (p14)

This PBS continued growth, is illustrated in Figure 2 below[14]. A responsible government must, therefore, keep such a large and growing program under constant review.

Figure 2: Pre-reform estimates of approximate PBS outlays (without reform) compared with current estimates of approximate PBS outlays (without reform) and PricewaterhouseCoopers estimated savings



It is in this context that the Government recently formed four new therapeutic groups. Three of those groups have been disallowed on 11 March 2010 by the Senate, resulting in a loss of savings of $48.2 million over the four years commencing 2009-10.

The formation of the four recent therapeutic groups did not impact on which drugs a clinician could prescribe their patient, did not allow pharmacists to exchange the drugs, did not change which medicines could be accessed on the PBS or alter the cost of the medicines to patients.

[14] Source: Figure 3, 2010 Impact of PBS Reform Report to Parliament

Attachment A

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE MEMBERSHIP

As at March 2010 the following medical professionals are members of the PBAC:

Emeritus Professor Lloyd Sansom AO (Chair) is the former Head of School of Pharmacy and Medical Sciences at the University of South Australia. He has been Chair of the PBAC since 2001.

Dr Jim Buttery is Research Development Director, NHMRC Centre for Clinical Research Excellence in Child and Adolescent Immunisation and a consultant paediatrician and Infectious disease physician at the Royal Children's Hospital, Victoria.

Professor Terry Campbell is Professor of Medicine at University of New South Wales and Head of the Department of Medicine, St Vincent's Hospital, Sydney.

Professor Jennifer Doust is Professor of Public Health at Bond University and Fellow of The Royal Australian College of General Practitioners (RACGP). She is a general practitioner.

Professor Albert Frauman is the Professor of Clinical Pharmacology and Therapeutics at the University of Melbourne and Director of the Department of Clinical Pharmacology and Therapeutics at Austin Health. He is an endocrinologist and clinical pharmacologist.

Adjunct Professor Michael Frommer is Adjunct Professor at the School of Public Health, The University of Sydney and Director of the Sydney Health Projects Group.

Professor David Isaacs is Clinical Professor at the University of Sydney. He is a paediatrician at the Department of Immunology and Infectious Diseases, based at The Children's Hospital at Westmead in Sydney.

Professor Claire Jackson is Professor in General Practice & Primary Health Care at the University of Queensland and Director, Mater Centre for Integrated Health Care and General Practice, Mater Hospital, South Brisbane.

Professor David G LeCouteur is a geriatrician, clinical pharmacologist and general physician. He is Professor of Geriatric Medicine at the University of Sydney, Director of the Centre for Education and Research on Ageing (CERA), Director of the Biogerontology Laboratory of the ANZAC Research Institute and Senior Staff Specialist Physician at the Concord RG Hospital in Sydney.

Associate Professor Geoff McColl is a rheumatologist and Clinical Dean at the Royal Melbourne Hospital/Western Hospital Clinical School and Senior Lecturer, University of Melbourne Department of Medicine.

Dr Karen Peachey is a community pharmacist from Queensland with an interest in pharmacoepidemiology and aged care.

Dr Andrew Roberts is a practising Clinical Haematologist and medical researcher. Dr Roberts is an NHMRC Practitioner Fellow, Div of Cancer and Haematology at The Walter and Eliza Hall Institute of Medical Research.

Dr Rashmi Sharma is a general practitioner and President of the ACT Division of General Practice.

Professor Robyn Ward is Professor of Medicine at Prince of Wales Clinical School, UNSW, and Senior Staff Specialist in Medical Oncology and Family Cancer Services at St Vincent's Hospital.

Dr Frances Wilson is Senior Staff Specialist in Psychiatry and Clinical Director, Adult Psychiatry Unit, at Westmead Hospital.

The members that are not medical professionals are as follows:

Mr Mitchell Messer is the consumer representative on the PBAC and a long term advocate of consumer health issues. He is the immediate past-Chair of the Consumers' Health Forum of Australia Inc.

Associate Professor Rosalie Viney is a health economist at the Centre for Health Economics Research and Evaluation, University of Technology, Sydney. She is Chair of the PBAC Economics Sub-Committee.