Senate Community Affairs References Committee Inquiry

Consumer Access to Pharmaceutical Benefits

Prepared by Pfizer Australia

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Pfizer

Australia

Contents

Disclosure

This submission has been prepared by Pfizer Australia – a wholly owned subsidiary of Pfizer Inc., based in New York. Pfizer Australia is this country's largest manufacturer of prescription medicines.

Wyeth is now a part of Pfizer Inc. The merger of local Wyeth and Pfizer entities is pending in Australia and is subject to completion of various local legal and regulatory obligations.

Pfizer Australia is a member of Medicines Australia – the peak industry body for the innovative medicines industry in Australia.

Pfizer is directly impacted by the Therapeutic Groups announced in 2009. In May 2009, the Government announced it would create a new Therapeutic Group (TG) for 'higher potency' HMG Co-A reductase inhibitors, i.e. Lipitor® – atorvastatin (manufactured by Pfizer) and Crestor ®– rosuvastatin (manufactured by AstraZeneca). In the Mid Year Economic and Fiscal Outlook (MYEFO) on Monday 2 November three new TGs were announced by the Minister; one of which is the Venlafaxine group which will include venlafaxine (Efexor®-XR) and desvenlafaxine (Pristiq®). Both Efexor®-XR and Pristiq® are registered to Wyeth Australia.

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Executive summary

The Australian healthcare system is underpinned by the National Medicines Policy[1] (NMP) and is based on "A *partnership for better health outcomes*". The NMP objectives include: *timely access to the medicines that Australians need, at a cost individuals and the community can afford* and *maintaining a responsible and viable medicines industry.*

In 2006 the Government and pharmaceutical industry negotiated a PBS Reform package to ensure the long-term sustainability of the PBS. The reform was built on the principle of achieving value for money to allow the funding of innovative medicines. In 2009 the impact of PBS Reform was independently verified to show the previous Government's original savings estimate of $3 billion dollars over 10 years grossly underestimated the actual savings of $5.8 billion over the same period.

While PBS Reform was negotiated with the former government (and then health minister Tony Abbott) the package of reforms and it's enabling legislation, was supported by the then opposition (and then shadow health minister Nicola Roxon).

In conflict with the principles of PBS Reform are the four new Therapeutic Groups (TG) announced in 2009 without consultation. It appears no advice was sought from key stakeholders concerning patient safety or any other implication of the proposed changes.

The Therapeutic Group Premium (TGP) policy implemented on 1 February 1998 allowed groups of medicines which deliver the same health outcomes (benefits) to be price-linked on the PBS.

It is worth noting in 1998 a TG was proposed for medicines known as SSRI's (selective serotonin reuptake inhibitors) which are commonly used for the treatment of depression. However, the SSRI TG proposal was subject to extensive consultation with stakeholders and interrogation through the Senate Estimates process. The proposal to form the SSRI TG was subsequently abandoned.

Pfizer opposes the creation of the new TGs for the following reasons:

- to protect individuals from additional risk when receiving medical treatment
- to prevent individuals having higher out of pocket costs for their essential medicines
- to maintain the integrity and sustainability of the PBS through PBS reform
- to ensure the continued delivery of health outcomes to the Australian population
- to sustain a viable innovation medicines industry

We will use the High Potency statin TG (HP statin TG), of atorvastatin (Lipitor®) and rosuvastatin (Crestor®), as a case study to illustrate the potential impact of TGs.

[1] http://www.health.gov.au/internet/main/publishing.nsf/Content/national-medicines-policydoc~national-medicines-policy-2

Access to medicines means an individual has available to them the most appropriate medicine to provide safe, efficacious and tolerable treatment at an affordable cost.

Switching a patient from one medicine to another without a valid clinical reason will inevitably lead to less compliance and poorer health outcomes. There is direct evidence that patients are significantly more likely to discontinue or be less compliant on statin therapy after switching, particularly when switching to a different statin molecule and not just a different brand of the same molecule.

This is particularly relevant to the new TGs since the majority of medicines are distinct molecules (medicines) and not different brands of the same molecule. For consumers requiring HP statins the health consequences, such as stroke, will be seen in the future. To illustrate the immediate impact even further switching an individual with a major depressive disorder from one medicine, such as an SNRI,[2] to another could result in serious deterioration of their health now.

Any treatment switch must be clinically appropriate. The PBAC (as supported in recent evidence at Senate Estimates, 10 February 2010) recommended that the equi-effective (clinically equivalent) dose of Lipitor® to Crestor® is 3:1. Consider those consumers who require the most potent dose of Crestor®, 40mg, but do not receive the treatment due to the TGP. It is possible the consumer would receive the highest potency of Lipitor® (80mg), the interchangeable medicine, as the equivalent treatment even though the clinically equivalent dose is 120mg (which is not a TGA registered dose).

The TG policy requires that medicines in a Group must be "interchangeable at a patient level" – yet the most basic analysis of dose relativities in the HP statin Group demonstrate this is not possible. This reinforces the risks for consumers and medical practitioners from a policy which was formed without consultation with the medicines' manufacturers and without sufficient consideration to the impact on comsumers.

Each medicine brought to Australia requires signficant investment to establish highly specialised technical support from early research to post-marketing surveillance. Uncertainty created by short-term cost-savings measures such as TGs will inevitably lead to fewer innovative medicines in Australia and consequentially job losses. *The time taken to develop, test and release a new medicine now averages 12 years and costs about $1 billion. These resources are too large for most healthcare organisations, research institutions or governments to provide.*[3] Pharmaceuticals as one of the keys to ensuring a nation's wellbeing has been acknowledged in the United Kingdom.[4]

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[2] SNRI Serotonin–norepinephrine reuptake inhibitor

[3] *For organisations to make investments on this scale requires a level of certainty that they will be able to cover very considerable development costs during a short period of patent exclusivity. It is vital that governments make decisions which do not add to the uncertainty of medical research. For the community, the benefits will continue forever. This was one of the underpinnings of PBS reform.* Pfizer Australia submission to the Senate Community Affairs Committee Inquiry into Gene Patents. 20 March 2009. http://www.aph.gov.au/Senate/committee/clac_ctte/gene_patents/submissions/sublist.htm

Comparator price erosion is already reducing the number of medicines available in Australia. Driving down the initial PBS listing price through TGs will further limit access to medicines in Australia.

Individual patient experience is the actual test of interchangeability

The National Health Act (1953) does not define interchangeability, NHA (1953) 101(3BA)".. whether the drug or medicinal preparation and another drug or medicinal preparation should be treated as interchangeable on an individual patient basis."

Interchangeable at "an individual patient level" may result in a person requiring treatment, irrespective of their individual characteristics, being prescribed any medicines in a TG. Individuals could also be switched from one medicine to another at any point in time and potentially also be switched back.

Pfizer has not been informed as to what clinical evidence was considered in the formation of the HP statin TG. It should be noted that the evidence submitted for the listing of a drug on the PBS is not sufficient evidence to make any recommendation on interchangeability. This requires additional evidence and a different method of analysis.

The evidence submitted for PBS listing addresses a specific research question and provides evidence specific to this. The question of interchangeability does not form the basis of a recommendation to list any drug on the PBS. This issue has been raised with the PBAC at the annual MA/PBAC meeting in 2009 and has neither been answered nor resolved.

At a minimum there is no registered equivalent dose of Lipitor® for Crestor® 40mg. And, to achieve equivalent doses of Crestor® and Lipitor® raises significant Quality Use of Medicines (QUM) issues, such as, cutting tablets, which is not acceptable.

The premise of a TG is to achieve **both** the same health outcomes and cost. An annual review of medicine cost is conducted for each TG. In contrast, neither the equi-effective dose in the community nor the health outcomes (benefits) achieved are re-assessed in a TG.

Initial calculations show consumers will not receive any savings from the HP statin TG.

The TG policy is defined by "Should the Minister determine that the drug should continue to be listed and subsidised on the PBS, the patient must pay an additional amount on top of the normal patient co-payment."[5] There is always one medicine in a TG without a TGP. The prescriber may request a TGP exemption.

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[4] Life Sciences Blueprint. July 2009. Delivering the Life Sciences Blueprint, January 2010. http://www.bis.gov.uk/Policies/innovation/business-support/ols

[5] PBPA Policies, Procedures and Methods. April 2009. Page 29.

If the consumer cannot pay the TGP and is not eligible for an exemption they will be foreced to switch to a premium-free medicine. This will have additional pathology and doctor costs plus the associated inconvenience. If the consumer is not advised of the TGP at the time of prescribing they will be forced to go back to the doctor to continue treatment with the premium free medicine or they may discontinue treatment.

The Commonwealth will fund exemptions to the TGP therefore paying the same price for the medicine. Plus there will be an increased administrative burden and cost for processing the TGP exemptions, from both Medicare and the prescribing clinician.

Lack of consultation and transparency for new therapeutic groups

Pfizer received notification of the new TG for 'higher potency' HMG Co-A reductase inhibitors (HP statins) on 28 May 2009 and was given until 4 June 2009 to respond. The timeframe of **7 calendar days** was clearly inadequate. The government provided no clearly defined question to be answered. The government's consultative process effectively excluded the companies which developed, tested and manufactured these medicines. In short, the truncated timeframe and non-transparent process for the determination of the new TGs means companies had limited capacity to challenge the decision or seek clarification.

This contrasts with the rigorous, transparent and consultative process for the listing of medicines on the PBS. Consultation and scientific rigour are the hallmarks of Australia's TGA and PBAC. They have safeguarded patients and provided confidence to medical practitioners over the past six decades.

The Terms of Reference for the inquiry, which we will address in our submission, raise many relevant questions relating to the appropriateness of this policy, particularly:

- the impact of new TGs on consumer access;
- the criteria and clinical evidence used to qualify drugs as interchangeable;
- consultation undertaken in the development of new TGs

Pfizer welcomes the opportunity provided by the Committee to submit our view on a range of other important issues captured in the Terms of Reference including:

- the impact of TGs on the classification of medicines in F1 and F2 formularies;
- the delay to price disclosure;
- the process of timing and consideration by Cabinet;

Pfizer acknowledges the decision by the Senate in February 2010 to disallow the three TGs announced in November 2009. The disallowance honours the Senate's intention to allow the Community Affairs References Committee to inquire into the measure.

Pfizer welcomes the opportunity to provide a submission to the Committee and would similarly welcome an opportunity to appear before the Committee at a public hearing should the Committee find this helpful in its deliberations.

Recommendations

It is recommended that:

1. **On the basis of patient safety and to provide certainty for industry the Commonwealth government remove the legislative provisions relating to the Therapeutic Group Premium policy.**

2. **For any legislative or policy changes the Commonwealth:**

   i. **consult with all stakeholders in a consistent manner to ensure due process is followed to safeguard patients and provide integrity for Australia's PBS system**

   ii. **guarantee that consumers will not experience a negative impact to their ability to access necessary treatment**

   iii. **include any additional direct and indirect costs or savings associated with the introduction of a TG into the estimated savings**

   iv. **recognise the determination of cost and effectiveness as is a requirement as per the NHA**

   v. **ensure that prescribers, consumers and dispensers are appropriately informed and educated on the implications of any policy changes.**

3. **There is a consistent approach to transparency and consultation for the consideration of all PBS medicines.**

4. **Any new Government policies do not undermine the principles of PBS reform.**

5. **The Commonwealth collaborate with industry to implement a formal dispute resolution process for price disclosure.**

6. **The Commonwealth act on the recommendations made since 2004 to ensure timely and equitable access to all medicines on the PBS.**

7. **The Commonwealth government recognise the successful reform of the PBS through the incorporation of PBS reform savings into the budget.**

Terms of Reference

On 25 November 2009, the Senate successfully moved for the Community Affairs Committee to conduct an inquiry into Therapeutic Groups (TG)[6].

The terms of reference (TOR) for the inquiry are as follows:

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.

This submission is presented in two parts: 1) TOR a) to e) which focuses on the issues of therapeutic groups (TGs) and 2) TOR f) to h) which covers issues ranging from price disclosure to the timing of Cabinet consideration.

The desirable outcome from this inquiry is to see policy measures reviewed, and recommendations for amendments where appropriate, to ensure all parties respect the principles of PBS reform. To adhere to the principles of appropriately valuing innovation aligned with, but operationally separate from, a competitive market would primarily necessitate the removal of ongoing reference pricing which includes TGs

[6] http://www.aph.gov.au/Senate/committee/clac_ctte/consumer_access_pharm_benefits/index.htm

The sustainability of the Pharmaceutical Benefits Scheme

The Pharmaceutical Benefits Scheme (PBS) was introduced in 1948 to provide Australians with affordable and equitable access to the medicines they need. Approximately 80% of prescriptions dispensed in Australia are subsidised by the Commonwealth through the PBS.

The need for reform of the PBS to ensure sustainability of the scheme and to allow the funding of innovative medicines was recognised by Government and industry. In response, the pharmaceutical industry collaborated with the Government in 2006 to develop PBS Reform (see Appendix A). The intent of PBS Reform is encapsulated in:

The division of the Schedule into separate formularies means that the Government can implement mandatory price reductions and hence make savings on the cost of the PBS which do not directly impact on single brand medicines.[7]

In 2009 the impact of PBS reform was independently verified to show the previous Government's original estimate of $3 billion dollars of savings over 10 years grossly underestimated the actual savings of $5.8 billion over the same period.

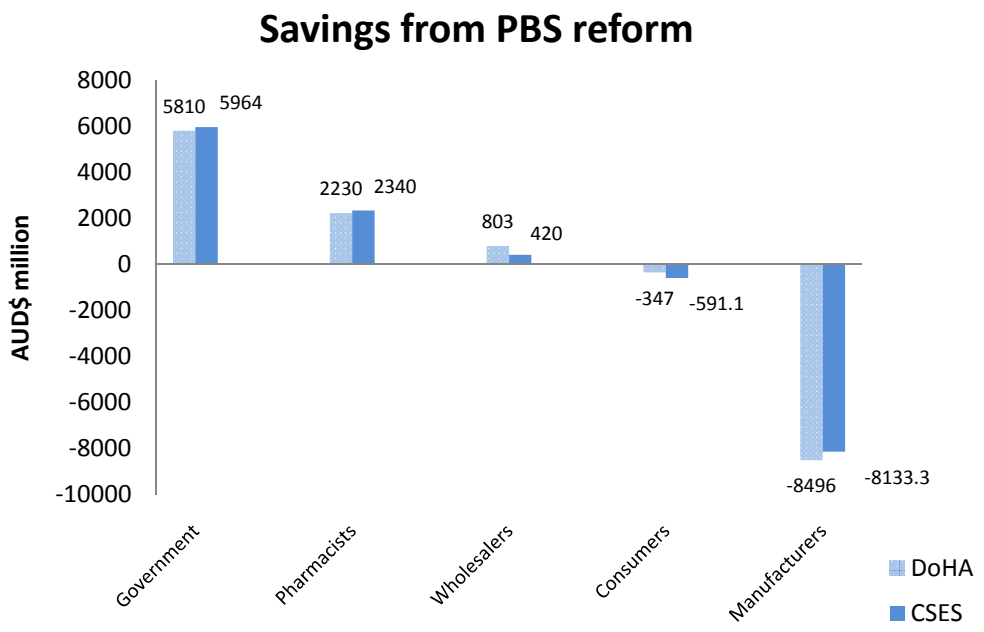

Figure 1: CSES and PwC (DoHA) modelled savings of PBS reform

NOTE: Estimates based on greatest generic competition assumptions. Detail provided in Appendix B.

[7] Buckmaster & Spooner. National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2007, Bills Digest, 31 May 2007. http://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;adv=;db=;group=;holdingType=;id=;orderBy=alphaAss;page=;query=(Dataset%3Abillslst,billhome,tariffs,billsdgs,webdisinsts,webdisinstr%20SearchCategory_Phrase%3A%22bills%20and%20legislation%22)%20Author_Phrase%3A%22buckmaster,%20luke%22%20Author_Phrase%3A%22spooner,%20diane%22;querytype=;rec=0;resCount=

Long-term fiscal policy is the key to achieving the best value for the money spent, which is exemplified by PBS Reform. The PBS is the first area of healthcare to undergo systematic reform. Benefits from the reform include ongoing access to essential medicines, direct savings to Government and consumers plus "head-room" to allow the continued funding of innovative medicines on the PBS. Further details on the savings provided by PBS reform are provided in Appendix B.

Accordingly, our key objectives for removing the four newly created TGs from the PBS are:

- to protect individuals from additional risk and confusion when receiving medical treatment
- to prevent individuals having higher out of pocket costs for their essential medicines
- to maintain the integrity and sustainability of the PBS through the PBS Reform process
- to ensure the continued delivery of health outcomes to the Australian population
- to sustain a viable innovation industry in the area of healthcare

The intent of the Therapeutic Group Premium (TGP) policy, as implemented and agreed to prior to PBS reform, is to allow the Government to pay the same amount for medicines which deliver the same health outcomes or benefits. This is achieved through an ongoing reference pricing mechanism. Prior to the proposed creation of the four TGs in 2009 there were six TGs[8] in existence. These six TGs were created prior to PBS reform and therefore are not the focus of these discussions. One of the pre PBS reform TGs is the calcium channel blocker (CCB) TG which includes the Pfizer medicine amlodipine.

Presented below are the responses to Terms of Reference a to e which are directly relevant to TGs.

We believe it is important to consider the TGP policy and the potential impacts to individual consumers within the context of the provision of pharmaceuticals in Australia.

[8] Angiotensin II Receptor Antagonists; Angiotensin Converting Enzyme (ACE) Inhibitors; Dihydropyridine-derivative calcium channel blockers – CCBs; H2-receptor antagonists; HMG Coenzyme A reductase inhibitors (statins); Proton Pump Inhibitors. http://www.health.gov.au/internet/main/publishing.nsf/Content/pbs-pbpa-policies-contents~pbs-pbpa-policies-ch2

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

Access to medicines means an individual has available to them the most appropriate medicine to provide safe, efficacious and tolerable treatment at an affordable cost. Access may be determined by:

- is the level of subsidisation sufficient so that an individual can afford to purchase their essential medicines each month?
- does the consumer and the prescriber have the appropriate information to make a fully informed decision?
- is the individual able to see their prescriber to ensure supply of the medicine?
- are there any barriers to compliance which will mean that the individual does not take their medicine as required?

We will use the High Potency statin TG (HP Statin TG) of atorvastatin (Lipitor®) and rosuvastatin (Crestor®) as a case study to illustrate the potential impact of TGs.

A TG is based on the recommendation that all medicines in the group are interchangeable at the patient level. It is difficult to ascertain the full impact of TGs on an individual's access to their medicine without knowing what interchangeable means.

It is essential that prior to the implementation of a TG the Government determines in consultation with the relevant stakeholders if medicines are interchangeable.

Impact on access to existing medicines

On 7 November 2009, Minister Roxon stated *"changes in the price paid by the Government for these medications will not affect the majority of patients as their prescriber will choose the cheaper alternative medicine."*[9] This does not reflect the dynamic interrelationship between the needs of the consumer, nor the expertise of their treating physician. Short-term savings measures such as the new TGs appear in conflict to previous Labor health policy positions.[10]

The basis of a TG is that all medicines in the group are interchangeable at the patient level. Could the TG recommendation appear in conflict with professional treatment guidelines? The disparity in the treatment of cardiovascular disease in Australia on the

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[9] Courier Mail, 7 November 2009.

[10] *We want to, and must, support changes that are aimed at increasing competition, rewarding innovation and maintaining access to medications for all Australians. Labor's fear with this package is that it is aimed at the first two, that is the increasing of competition and rewarding innovation, which is desirable, but it is not complemented by any further protections for consumers*. 2007. http://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;adv=;db=;group=;holdingType=;id=;orderBy=;page=;query=BillId_Phrase%3A%22r2801%22%20Dataset%3Ahansardr,hansards%20Title%3A%22second%20reading%22;querytype=;rec=8;resCount=

basis of National Heart Foudnation (NHF) or the PBS restrictions has already been shown.[11]

It cannot be guaranteed that the creation of the HP statin TG will not create confusion around the prescribing of high potency statins.

The impact of additional costs for medicines should be considered in the context of the current economic environment and the annual increase in the patient co-payment. "*Despite the universal cover offered by Medicare, free public hospital care and the significant subsidization of prescription medicines by the Pharmaceutical Benefits Scheme (PBS), sick Australians face some of the highest co-payment costs within the Organisation for Economic Co-operation and Development (OECD) countries (1), and have out-of-pocket costs close to those faced by Americans (2). …in 2008, 36 percent of chronically ill Australians said that they had failed to fill a prescription or skipped medication doses, did not visit a doctor when they had a medical problem or did not get recommended tests, treatment or follow-up because of cost*.[12] The impact on patient contributions will be discussed in response to TOR c.

In the existing TGs there are off-patent, generic alternatives of the same molecule (medicine) which are available premium-free. This is in contrast to Lipitor® (atorvastatin) or Crestor® (rosuvastatin) which are different molecules and are patent protected. A TGP for one of the HP statins would mean the consumer does not have a premium free alternative of the same medicine (molecule).

Health and QUM consequences with the implementation of the new TGs

The immediate and long-term health consequences of the TGs are translatable across all TGs where two or more unique medicines (molecules) are deemed interchangeable. The main concerns on TGs would be:

1. switching consumers from one medicine to another in a TG

At the most fundamental level switching a patient from one medicine to another without a clinical reason will lead to lower compliance and adherence leading to poorer health outcomes. There is direct evidence that patients are significantly more likely to discontinue or be less compliant on a statin after switching, particularly when switching to a different statin molecule and not just a different brand of the same molecule.[13]

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[11] 41% of patients would be eligible for statin therapy based on the NHF criteria but 55% would be eligible based on PBS restrictions (Webster et al., 2009). There are large evidence-practice gaps in the prevention of cardiovascular disease (CVD) for older Australians. A significant proportions of the at risk population are not receiving the appropriate intervention to prevent primary and secondary CVD events (Heeley et al., 2010).

[12] Hynd & Russell., 2009

[13] Switching statins reduces the likelihood that patients will be compliant by around 19% ($p<0.001$), and increases the likelihood of discontinuation by between 21–48%, compared to those who remained on their initial treatment (Thiebaud et al 2005). A recently published US database study of managed care patients (Chapman *et al*. 2009) found that patients who switched from one statin to another were 33% less likely to be adherent to treatment 6 months after switch when compared to patients who switched from a branded to generic version of the same statin ($p<0.0001$). The study also found that patients who switched from one statin to another reported a significant decrease in adherence from 78.5% to 74.7% ($p<0.001$).

These concerns around the quality use of medicines (QUM) within the TGs are applicable across the therapeutic areas encompassed by the new TGs. For example, the selected anti-depressants TG includes venlafaxine (Efexor®-XR) and desvenlafaxine (Pristiq®) which are similar but distinct compounds for the treatment of major depressive disorders.[14] This TG does not include duloxetine, the other SNRI listed on the PBS for the treatment of major depressive disorders. The consequences of switching an individual with a major depressive disorder who is stable on one medicine to another due to cost or confusion over prescribing could be tragic. The TGA is clearly cognisant of the subtleties required when switching individuals to different anti-depressants.[15]

2. commencement of therapy with either medicine in a TG without re-assessment of the individual's clinical history and risk assessment

With all medicines it is essential to take into account an individual patient's risk factors and concurrent clinical history and treatment. A review of the Product Information (PI) for both atorvastatin and rosuvastatin (see TOR b) shows the two medicines are not interchangeable for all consumers for whom HP statin therapy is prescribed.

It is difficult to definitively show that patients receiving rosuvastatin would expect the same health benefits as those patients receiving atorvastatin given the disparity in the level of evidence available for each intervention (see TOR b).

We are concerned there will significant confusion around what interchangeability means as seen at the recent Estimates for the Health & Ageing Portfolio 10 February 2010.[16] Professor Bishop concluded "*So the milligram dosage is not relevant to that discussion.*" which seems in contrast to Doctor John Primrose, Adviser to the PBAC, who clearly states "*It is a matter of getting an equivalent dose of each agent for that patient. At equivalent doses they are equally effective*."

The potential consequences of lower compliance and adherence, receiving a sub-optimal dose or discontinuing statin therapy are an increase in the risk of serious and life-threatening cardiovascular events, such as stroke.

It cannot be guaranteed that consumers will not experience a negative impact to their ability to access the medicines they need with the implementation of the new TGs

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[14] Presystemic metabolism of venlafaxine (Efexor®-XR) reduces the absolute bioavailability of venlafaxine to 42%±15%. In contrast, desvenlafaxine succinate (Pristiq®) is well absorbed, with an absolute oral bioavailability of 80%. Efexor-XR and Pristiq Product Information, www.pbs.gov.au, accessed 22 Feb 2010

[15] *Discontinuation symptoms have been reported when switching patients from other antidepressants, including venlafaxine to desvenlafaxine. Tapering of the initial antidepressant followed by a washout period may be necessary to minimise discontinuation symptoms and the possibility of drug-drug interactions from a pharmacokinetic or pharmacodynamic perspective*. Pristiq Product Information.

[16] Community Affairs, Estimates, 10/2/2010, Health & Ageing Portfolio. http://www.aph.gov.au/hansard/senate/commttee/committee_transcript.asp?MODE=YEAR&ID=80&YEAR=2010

What is the impact of TGs on access to future medicines in Australia?

Conern that TGs would limit the availability of innovative medicines in Australia was previously raised in 1997:

> *My real worry is the long-term future or the introduction of new drugs into Australia, because I think that – and development in Ausralia – because I think it will discourage the introduction of new drugs into Australia. ..And lastly, I think it sends the wrong signals to those who wish to continue to develop a pharmaceutical industry here in Australia and all its associated benefits.*[17]

If a generic rosuvastatin enters the market prior to the patent expiry of Lipitor® in May 2012, through the TG, Lipitor® will be subject to a minimum 12.5% price cut through the generic pricing policy. Bringing this date forward will inevitably reduce manufacturing and result in job losses.

It is essential for any industry to have a degree of certainty around the environment in which it operates. To date this has been achieved in the Australian pharmaceutical industry through patent protection, generic medicine policy, PBAC initiated cost-effectiveness reviews and PBS reform.

Future access to medicines: impact on comparator pricing for future medicines

A consequence of the price decreases on the PBS from measures such as TGs is the lowering of the price at which an initial recommendation for PBS listing is made. This issue, commonly termed comparator erosion, is already reducing the number of medicines available in Australia and has been acknowledged as an issue by the Access to Medicines Working Group (AMWG).[18]

The AMWG noted that in 2008 approximately 15% of cost-effectiveness submissions will have a comparator in the F2 formulary. Effectively, 15% of applications to list a new medicine on the F1 formulary will have a comparator in F2. To date there has been no position statement from the AMWG on comparator erosion.

Comparator erosion: gapabentin for the treatment of neuropathic pain

An example of the urgency around this issue of comparator erosion is clear with Pfizer's medicine for neuropathic pain, gabapentin (NEURONTIN®). NEURONTIN® for the treatment of epilepsy is PBS listed but not for the treatment of neuropathic pain.

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[17] *Prof Colin Johnston. Head of Medicine, University of Melbourne. 1998.*

[18] The AMWG, with representatives from DoHA and Medicines Australia (MA), was established to consider timely and appropriate access to effective new medicines on the PBS. In the AMWG's 2008 interim report[18]: *Both parties agree that, in principle, a subset of new medicines seeking listing on the Pharmaceutical Benefits Scheme (PBS) may be impacted in the future as a result of PBS reform. In AMWG discussions, DoHA argued the issue will be relatively contained and that the current system of evaluating medicines for listing on the PBS is sufficiently flexible to handle any issues that may arise, while MA suggested that it will be more widespread and argued that changes are needed. Both parties have discussed several options, involving substituting an F1 comparator or F1 price for evaluations where an F2 product is the comparator.*

In developing a submission to the PBAC in 2001-2002 for the neuropathic pain indication the comparator was determined to be carbamazepine, a medicine that is listed as a general item on the PBS. Carbamazepine has a much broader therapeutic indication compared to NEURONTIN®. Given the length of time since carbamazepine has been available the price was very low in relation to NEURONTIN®. In addition, given the differences in the therapeutic indications of the two products there are no head-to-head trials. This is not unusual. In order to support the appropriate price for NEURONTIN® a cost-effectiveness submission would be required. As a consequence Pfizer is unable to list NEURONTIN® on the PBS for the treatment of neuropathic pain. The issue of compator erosion and the inability to list NEURONTIN® on the PBS has the direct effect of limiting the ability to list future innovative medicines on the PBS for neuropathic pain.

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

Interchangeability is inadequately described in the NHA (1953) *(3BA) … the Committee must, .. specify whether the drug or medicinal preparation and another drug or medicinal preparation should be treated as interchangeable on an individual patient basis*.[19]

Confusion around the meaning of interchangeability is ongoing:

- *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. Medicines across F1 and F2 will no longer be price linked. These are not the same molecules.*[20]
- *…medicines that are interchangeable at the patient level are included in the F2 pricing structure group……some drugs may provide similar outcomes as other drugs but are superior in certain circumstances. In this case they should remain in F1 where their price will be protected. Failure to do this could see companies withdrawing their drug from the PBS due to lack of profitability.*[21]
- *Essentially 'biosimilar' and 'bioequivalent' refer to drugs which are interchangeable at the patient level. Bioequivalent' refers to simple molecules which are interchangeable; 'biosimilar' refers to much more complex drugs which are still interchangeable but which do not necessarily have the same molecular structure.*[22]

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[19] Interchangeability is not in the Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee. http://www.health.gov.au/internet/main/publishing.nsf/Content/pbacguidelines-index

[20] Huxtable R. Senate Standing Committee on Community Affairs RE: National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2007. 15 June 2007. http://www.aph.gov.au/hansard/senate/commttee/committee_transcript.asp?MODE=YEAR&ID=80&YEAR=2007

[21] Washer M. House of Representatives- National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2007 - Speech. 31 May 2007. http://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;adv=;db=;group=;holdingType=;id=;orderBy=;page=;query=BillId_Phrase%3A%22r2801%22%20Dataset%3Ahansardr,hansards%20Title%3A%22second%20reading%22;querytype=;rec=13;resCount=

[22] Abbott T. House of Representatives- National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2007 - Speech. 31 May 2007.

To provide or develop evidence to support or refute interchangeability the first step is to understand what interchangeability means. Can interchangeable "at an individual patient level" mean any person requiring treatment, irrespective of their individual characteristics, be prescribed any of the medicines in a TG? Or can individuals be switched from one medicine to another at any point in time and potentially also be switched back?

Without a definition of interchangeability a submission to the PBAC cannot be evaluated for interchangeability.

Evidence of the "interchangeability" of atorvastatin and rosuvastatin

Pfizer is not aware of the deliberations on the TG for HP statins (see TOR d). We are concerned by comments made during Senate estimates on 10 February 2010:

> *Very often they have in front of them very recent information which has been derived from when the drugs were listed. One of the roles of the PBAC is to regularly review all medicines that are being listed and are listed to see if they would fit within a therapeutic group.*[23]
>
> *If there is further patient information, typically it is available in things like published peer-reviewed journals and studies and the expert analysis that underpins the PBAC recommendation, and the decision is reviewed within the expert committee*.[24]
>
> *The new data that you are referring to actually would be incorporated in the TGA-product information, so that information is available to the PBAC at each of its meetings*.[25]

The Product Information does not present comparative or pharmacoeconomic analyses nor does it include any evidence from trials not conducted by the manufacturer.

It is the right of the manufacturer to be made aware of the evidence considered for any medicines on the PBS including the new TGs.

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http://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;adv=;db=;group=;holdingType=;id=;orderBy=;page=1;query=BillId_Phrase%3A%22r2801%22%20Dataset%3Ahansardr,hansards%20Title%3A%22second%20reading%22;querytype=;rec=4;resCount=

[23] Mr Andrew Stuart, First Assistant Secretary, Pharmaceutical Benefits Division. Community Affairs, Estimates, 10/2/2010, Health & Ageing Portfolio. http://www.aph.gov.au/hansard/senate/commttee/committee_transcript.asp?MODE=YEAR&ID=80&YEAR=2010

[24] Mr David Learmonth, Deputy Secretary, Department of Health & Ageing. Community Affairs, Estimates, 10/2/2010, Health & Ageing Portfolio. http://www.aph.gov.au/hansard/senate/commttee/committee_transcript.asp?MODE=YEAR&ID=80&YEAR=2010

[25] Dr John Primrose, Medical Advisor to the PBAC. Community Affairs, Estimates, 10/2/2010, Health & Ageing Portfolio. http://www.aph.gov.au/hansard/senate/commttee/committee_transcript.asp?MODE=YEAR&ID=80&YEAR=2010

If indeed new information has been considered in making this recommendation it is the right of the affected companies to be made aware of the evidence. The veracity of the evidence must be established by the manufacturer and the Commonwealth.

Evidence previously provided to the PBAC for rosuvastatin and atorvastatin

As the PBAC has previously reviewed over 70 trials for atorvastatin and rosuvastatin it is difficult, and inappropriate, to review in this forum the clinical evidence.[26] If the price of Crestor® is higher than Lipitor® but the medicines are of "equivalent" efficacy why was Crestor recommended for listing on a cost minimisation basis in 2006?[27] More recently, desvenlafaxine was recommended by the PBAC in November 2008 but there was no determination of interchangeability with venlafaxine (main comparator) or duloxetine.[28]

The PBAC recommendation to list rosuvastatin on the PBS highlights a number of areas of uncertainty around the "interchangeability" of atorvastatin and rosuvastatin.

….rosuvastatin is no worse, in terms of LDL-C lowering efficacy and safety, than atorvastatin, when compared assuming a therapeutic relativity of rosuvastatin 1 mg: atorvastatin 3 mg. which is clearly directed toward the pricing review. [29] This is clearly an approximation of the equi-effective dose as … *This analysis suggested that the rosuvastatin: atorvastatin equivalent dose ratio was greater than 1:2, but less than 1:4.*

For any changes to recommendations for PBS medicine, such as TGs, the Commonwealth must develop an implementation programme to ensure prescribers are equipped to determine the appropriate treatment including equivalent dosing.

The equivalent doses from the PBAC highlight that at a minimum these two medicines are not interchangeable for individuals requiring the higher doses. There is no registered dose of Lipitor® equivalent to 40mg Crestor®. To achieve clinically equivalent doses of Crestor® and Lipitor® consumers may be faced with the choice of filling two prescriptions or cutting their tablets, neither of which is acceptable (see Table 1).

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[26] Atorvastatin is supported by CV outcomes evidence across a wide range of patient populations, e.g. established CHD, a history of MI, ACS, previous stroke, type-2-diabetes and other CV risk factors, all clinically-relevant populations with high CV risk. (LaRosa *et al.* 2005, Pedersen *et al*. 2005, Schwartz *et al*. 2001, Cannon *et al.* 2004, Amarenco *et al*. 2006, Colhoun *et al.* 2004, Sever *et al*. 2003). A reduction in CV or cerebrovascular events in both primary and secondary prevention atorvastatin patients compared to all other statins combined has been shown (Dieleman et al. 2005). In contrast rosuvastatin has only one positive CV outcomes trial (Ridker et al., 2008)

[27] NHA (1953)101(3B)(a): …*where therapy involving the use of a particular drug or medicinal preparation, or a class of drugs and medicinal preparations, is substantially more costly than an alternative therapy or alternative therapies,… the Committee: (a) shall not recommend to the Minister that the drug, preparation or class be made available as pharmaceutical benefits or special pharmaceutical products …unless the Committee is satisfied that the first mentioned therapy, for some patients, provides a significant improvement in efficacy or reduction of toxicity over the alternative therapy or therapies;*

[28] Desvenlafaxine PSD. November 2008. http://www.health.gov.au/internet/main/publishing.nsf/Content/pbac-psd-desvenlafaxine-nov08

[29] http://www.health.gov.au/internet/main/publishing.nsf/Content/pbac-psd-rosuvastatin-july06

Table 1: Equi-effectives doses of Lipitor® and Crestor®

Rosuvastatin (Crestor®)	Atorvastatin (Lipitor®)		
Daily dose = Tablet size	Equivalent daily dose	Tablet size (No. of tablets)	Regimen required
5mg	15mg	10mg (30)	10mg + ½ x 10mg tablet
10mg	30mg	20mg (30)	10mg + 20 mg tablet
20mg	60mg	40mg (30)	3 x 20mg[1] tablets or 20mg + 40mg tablets
40mg	**No equivalent dose**	80mg (30)	**No equivalent dose**

[1] Note: for 3 x 20mg options a repeat prescription would be required in approx. 10 days which breaks the 20 day rule. The new PBS Safety Net 20 day rule means that for certain specified PBS medicine a resupply within 20 days of a previous supply, of the same medicine, will fall outside Safety Net benefits. For that supply the patient contribution will not count towards the PBS Safety Net threshold, or there the PBS Safety Net threshold has been reached, the usual patient contribution applies -not the reduced PBS Safety Net amount. Atorvastatin is one of the medicines impacted by the 20 day rule.
http://www.health.gov.au/internet/main/publishing.nsf/Content/pbs-safetynet-20day-list

A straightforward review of two of the key differentiators in the Product Information for atorvastatin and rosuvastatin (www.pbs.gov.au) shows they are not considered interchangeable for all consumers (see Appendix C). For example, only Crestor® 40mg is contraindicated for patients with severe renal impairment or of Asian heritage. Given the lack of transparency in this process there has been no opportunity for Pfizer to work with the appropriate authorities to investigate the need for exemption criteria.

In 1997 a TG was proposed for selective serotonin reuptake inhibitors (SSRIs), a group of medicines primarily for the treatment of major depressive disorders. There was significant concern around the large number of patients for whom the SSRIs were not considered interchangeable. This would have resulted in a complex set of exemptions which was considered an unacceptable risk for patient health irrespective of the associated unmanageable clinical and administrative burden, as indicated below:

> *the Therapeutic Group Premium policy to allow substitution of SSRIs [like Prozac] at best will weaken the ability of physicians to offer the best treatment for the individual but is also potentially dangerous.*[30]

At a meeting between the Royal Australian College of General Practitioners, Royal Australian and New Zealand College of Psychiatrists, Australian Medical Association and the PBAC, it was decided that the exemptions required for SSRIs were too complicated and indicated that the medicines were not interchangeable. Plus the potential risks associated with a therapeutic group for SSRIs outweighed any cost-saving of $26 million over 4 years. Consequently the SSRI TG was never implemented.

Individual patient experience is the actual test of interchangeability or not.

[30] Senator Lee.Stuart Montgomery, Professor of Psychiatry at University of London, and ex-WHO representative. House Hansard, p10616, 18 November 1997.
http://www.aph.gov.au/hansard/hansreps.htm#1997

Whilst acknowledging the similar major health outcomes that could be achieved by a particular group of medicines, patients highlighted in a practical sense that one drug is not interchangeable with another: An example of blood pressure medication – Cozar - was provided. A patient described how she couldn't use all of the other drugs due to various unpleasant side effects but could use the more modern medication due to its cleaner profile.[31]

The PBAC Guidelines do not contain the words interchangeable or interchangeability. To determine interchangeability at the patient level there are multiple complex considerations which could be explored to determine the validity of such a decision (See Appendix D).

Ongoing assessment of "interchangeability"

The premise of a TG is to achieve the same health outcomes for the same cost. The reality is a TG is designed to achieve ongoing cost savings as per the Pharmaceutical Benefits Pricing Authority (PBPA) manual.[32] There are a number of concerns with regard to WAMTC which are discussed in Appendix D.

In the HP statin TG on 1 December each year the prices for Crestor® and Lipitor® will be reviewed and adjusted to the lowest (benchmark) price based on prescribing data from general practitioners. There is potential conflict with the original recommendation by the PBAC which specifies these two medicines will provide the same health outcomes if prescribed in the ratio of 1mg Crestor to 3mg Lipitor® (known as the therapeutic relativity). Neither the adherence to the original recommendation by the PBAC on the therapeutic relativity or the delivery of the same level of health outcomes (benefits) is re-measured even though the costs are reviewed annually.

Without measuring the health benefits the Government cannot guarantee that the same health outcomes are achieved each year for each of the medicines in a TG.

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

If the implementation of a TG determines that a medicine is no longer financially viable "*Should the Minister determine that the drug should continue to be listed and subsidised on the PBS, the patient must pay an additional amount on top of the normal patient co-payment*."[33] The TGP is an out of pocket cost to the individual in addition to the patient co-payment each time the medicine is dispensed. The TGP does not contribute to the Safety Net.[34]

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[31] *Colvin, Mark. Transcript; Interview with Colin Johnson & Kay Moody by Camille Funnell. PM Program. 1997*
[32] Pharmaceutical Benefits Pricing Authority Policies, Procedures and Methods. April 2009. Page 17. http://www6.health.gov.au/internet/main/publishing.nsf/Content/health-pbs-general-pricing-pbpamethods.htm-copy2
[33] Pharmaceutical Benefits Pricing Authority Policies, Procedures and Methods. April 2009. Page 29. http://www6.health.gov.au/internet/main/publishing.nsf/Content/health-pbs-general-pricing-pbpamethods.htm-copy2
[34] Currently consumers pay a co-payment of $5.40 (Concessional) or $33.30 (General) for each prescription dispensed. Co-payments contribute toward the Safety Net to ensure consumers have a capped contribution

There is always at least one drug within each group of drugs available without a premium. A doctor may request an exemption from the TGP for their patients through Authority prescription provisions.[35] The negative impact of a price increase on an individual's ability to access medicines in Australia has been shown.[36]

What is the impact of the new HP statin TG on costs to consumers?

There are no direct cost savings to the consumer with this measure.[37] The TGP is only one of the potential additional costs the consumer may be faced with. If the consumer switches to the premium-free medicine they may be required to have additional pathology monitoring with extra doctor visits.

Additional costs to consumers from TGs

In addition to the TGP if the consumer switches medicines there may be extra costs due to additional visits to the GP. If the consumer is advised of the TGP at the pharmacy they will have the following choices:

- to pay the additional cost of the TGP
- go back to the prescribing doctor to be assessed for their suitability to receive the premium free medicine
- go back to the prescribing doctor to request an exemption from the TGP
- not have their prescription filled as they cannot afford the costs involved with the options above.

The 1997 TGPs for the anti-hypertension and ulcer medications resulted in 7% of consumers switching therapy due to the new charge. The rate of switching was higher in older patients. For around half the patients the switch was suggested by the pharmacist. Approximately 26% reported additional visits to their doctor due to the switch. For a consumer who does not get free GP treatment the rebate is currently $34 a visit.

Approximately 900,000 people in Australia receive atorvastatin therefore 7% represents around 63,000 individuals.

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for medicines. A TGP is additional out-of-pocket cost on top of the co-payment and does not count toward the Safety Net total. Current TGPs range from $1.52 to $4.66.

[35] Exemptions due to: adverse effects occur with all of the base-priced drugs; drug interactions occur with all of the base-priced drugs; drug interactions are expected to occur with all of the base-priced drugs; or the transfer to a base-priced drug would cause patient confusion resulting in problems with compliance. www.pbs.gov.au

[36] The increase in the patient co-payment on 1 January in 2005 was associated with a significant decrease in dispensing volumes for both general (2%) and concessional (5%) prescriptions of selected PBS medicines. The impact is also greater for those people with asymptomatic conditions. (Hynd et al., 2008)

[37] Even if the price of the medicines were reduced to below the general co-payment of $33.30 pharmacists can impose an additional fee of up to $3.79 (to a total of no more than the co-payment).
On current figures from Medicare Australia, 71% of atorvastatin patients and 62% of rosuvastatin patients are concessional patients. Price cuts to be applied will not reduce the PBS price below the concessional co-payment of $5.40. Potential savings would only be possible in those on the lowest doses. Less than 5% of general patients (co-payment $33.30) are on the lowest dose of Lipitor (10mg) (PBS cost $42.70). Only if the Government were to achieve a price reduction of 23% with the HP statin TG would fewer than 5% of people on Lipitor pay a lower price. Initial calculations indicate this is an unrealistic price reduction.

Direct cost implications to the Commonwealth

Clearly, the Government will have to fund any exemptions to the TGP which will mean they are effectively paying the same price as before the creation of the TG. In addition, there will be an increased administrative burden and cost associated with processing the exemptions to TGPs, from both Medicare and the prescribing clinician.

There are approximately 900,000 patients receiving atorvastatin on the PBS. If 7% switched their current statin therapy the cost to the Government from GP visits and lipid-monitoring alone could be around $5 million. This does not include the costs for visits to specialists or additional visits to GPs.

The Commonwealth must include the additional direct and indirect costs associated with the introduction of a TG into the estimated savings.

d) consultation undertaken in the development of new therapeutic groups

On 13 May 2009, the Government announced it would create a new TG for 'higher potency' HMG Co-A reductase inhibitors, i.e. Lipitor® – atorvastatin (manufactured by Pfizer) and Crestor® – rosuvastatin (manufactured by AstraZeneca). The Government announced the savings from this new TG would be $114 million over four years. Pfizer had not received any correspondence on this matter prior to the Budget announcement.

Pfizer received official notification on 28 May 2009 (dated 25 May 2009). The recommendation was given at the March 2009 PBAC meeting. The government provided no clearly defined question to be answered.

Pfizer was given the opportunity to provide a written response to this letter by 4 June 2009, a total of **7 days** from date of receipt on 28 May 2009. This timeframe is totally inadequate. Also, the advice from the PBAC was clearly inadequate to allow Pfizer a meaningful response.[38][39]

The determination[40] by the Minister (or delegate) was made on 28 August 2009, and tabled in the Senate on 7 September 2009.

The government's consultative process effectively excluded the companies which developed, tested and manufactured these medicines. In short, the truncated timeframe and non-transparent process for the determination of the new TGs means companies had limited the capacity to challenge the decision or seek clarification.

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[38] ***ATORVASTATIN CALCIUM, Lipitor®, Pfizer Pty Ltd and ROSUVASTATIN CALCIUM, Crestor®, AstraZeneca Pty Ltd.*** *In accordance with Subsection 101(4AA) of the National Health Act 1953, PBAC advises the Minister that the two drugs atorvastatin and rosuvastatin should together comprise a new therapeutic group. In doing so, and in accordance with Subsection 101(3BA), PBAC also advises that the Committee is of the opinion that these two drugs are interchangeable on an individual patient basis.*

[39] When Lipitor was considered by the PBAC in March 2007 the evaluation report by the Pharmaceutical Evaluation Section was 130 pages long and the minutes from the PBAC meeting were 9 pages.

[40] http://www.comlaw.gov.au/comlaw%5Cmanagement.nsf/lookupindexpagesbyid/IP200943505?OpenDocument

Our exclusion from the process has compromised our right to challenge decisions by, for example, presenting evidence that disproves the assumptions made regarding interchangeability. Procedural fairness cannot be selectively applied.

Was the PBAC asked to consider the validity of a HP statin TG or did the PBAC advise the Minister that a HP statin TG would be appropriate in accordance with the NHA (1953) 84AG?.[41]

The advice provided to date is inadequate. The Government has refused to provide any information regarding the methodologies used to make its determination, even when the determination is contradictory to a previous determination. Pfizer has repeatedly requested information from both the PBAC and the Minister regarding the justification for the determination that medicines it is placing in TGs are 'interchangeable at the patient level.'

The justification for the PBAC recommendations has not been provided to industry, nor has industry had a real opportunity to refute or challenge this advice – this is in stark contrast to the onus on industry to comprehensively prove safety and efficacy claims for the listing of new medicines on the PBS.

There must be a consistent approach to transparency and consultation for all PBS medicines.

Our expectations on transparency and consultation are based on the precedents set by:

- consultation on PBS reform
- the process for the consideration of a medicine by the PBAC
- the communication of the recommendations made by the PBAC
- the requirements of the United States Australia Free Trade Agreement

Further details are provided in Appendix E and Appendix F.

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

The decision to form a TG effectively dissolves the boundary between F1 and F2. All medicines in the TG will be moved to F2 (either by determination or in principle for ongoing pricing purposes) regardless of patent status once one member of the group is exposed to generic competition.

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[41] *(1) The Minister may, by legislative instrument, determine: (a) one or more therapeutic groups ; and (b) that 2 or more listed drugs are in the same therapeutic group. (1A) If the Minister proposes to make a determination under paragraph (1)(a), the Minister must obtain the advice in writing of the Pharmaceutical Benefits Advisory Committee in relation to the proposed determination. (2) A determination for the purposes of paragraph (1)(b) may specify the circumstances in which a listed drug is, or is not, in a therapeutic group . (3) In making a determination for the purposes of paragraph (1)(b), the Minister may have regard to advice (if any) given (whether before or after the commencement of this section) to the Minister by the Pharmaceutical Benefits Advisory Committee to the effect that a drug or medicinal preparation should, or should not, be treated as interchangeable on an individual patient basis with another drug or medicinal preparation.*

This means on-patent medicines may be forced to take mandatory price cuts before the expiration of that product's patent – the true trigger of the generic pricing policy. In addition, given the unpredictability of how, when or why a TG is formed companies have little advance warning of when their medicines will be adversely affected.

The HP statin TG of atorvastatin and rosuvastatin reference prices the two F1 medicines from 1 April 2010. The entry of a generic rosuvastatin prior to patent expiry for Lipitor® will have two consequences. Lipitor® will be forced to take a minimum 12.5% price cut whilst still patent protected and will likely be re-classified as an F2 medicine.

In terms of the classification of medicines as F1 or F2 it is at the Minister's determination whether a medicine is listed as F1 or F2. The criteria for classification as either an F1 or F2 medicines appears to be based on whether or not another brand of the same medicine already exists on the PBS. The premise appears to be that when the criteria for the eligibility for inclusion on F1 no longer apply e.g. the inclusion of a generic brand on the PBS, a medicine will automatically be shifted to F2.

The NHA (1953) 85AB(2) states "*The Minister may only determine that the drug is on F1 if the drug satisfies all the criteria for F1*."

But 85AB(4b) states a drug can be included in F1 if "*there are no brands of pharmaceutical items that: (i) have another listed drug that is in the same therapeutic group as the drug; and (ii) are bioequivalent or biosimilar.* It would appear that based on this definition Lipitor® could remain in F1 as it fulfils part (i) but not part (ii); Crestor® (rosuvastatin) and Lipitor® (atorvastatin) are neither *bioequivalent or biosimilar.*

This is another example of how the creation of the HP statin TG has created a great deal of uncertainty for the sponsor company.

One of the key principles of PBS reform was to create two separate formularies, F1 and F2. The Commonwealth must ensure that any new policies do not undermine the principles of PBS reform.

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*

A core initiative of PBS reform is the delivery of savings to the Commonwealth from price disclosure, a mechanism which permits the Commonwealth to determine the actual selling price of medicines. The first round of price cuts from price disclosure was delayed from 1 August 2009 to 1 August 2010 due to administrative problems.

However, in-line with our commitment to the integrity of PBS reform, and therefore price disclosure; Pfizer implemented voluntary price reductions of between 15.4% and 63.5%[42] to wholesalers on 1 November 2009; these price cuts were equivalent to the price disclosure reductions. This timeframe is 8 months prior to the revised implementation date.

It is essential with any reform initiative that all stakeholders are confident the system is robust. Where disputes cannot be managed at an administrative level there must be agreed dispute resolution processes in place.

The Commonwealth must collaborate with industry to implement a formal dispute resolution process for price disclosure.

What is disappointing is that the Commonwealth will not include the savings from price disclosure in the estimates to Treasury. We recognise that savings from price disclosure are subject to variation and are not guaranteed. However, with the savings already delivered from price disclosure ranging from approximately 15% to 70% a mechanism to allow inclusion of conservative estimates into the Budget should be considered.

The Government should execute a mechanism to allow inclusion of the savings from price disclosure into the forward Budget estimates.

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

Access to medicines must be timely. Access to medicines which are purportedly of high cost to the Commonwealth take longer to be listed on the PBS due to the need for approval by Cabinet.

A common criticism is that the Cabinet threshold of $10 million per annum (in any of the first 4 years of PBS listing) has been unchanged for significant period of time and does not reflect the current perception of the impact of high cost medicines.[43]

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[42] Price reductions were applied to the following Pfizer products: ondansetron, mitozantrone and adriamycin. The products subject to price disclosure on 1 August 2009, those with a listing date of first mandatory of 1 August 2007, are listed at: http://www.pbs.gov.au/html/industry/static/pricing_matters/price_disclosure/drugs_currently_under_price_disclosure

[43] Productivity Commission Research Report. Annual Review of Regulatory Burdens on Business: Manufacturing and Distributive Trades. August 2008. http://www.pbs.gov.au/html/industry/static/pricing_matters/price_disclosure/drugs_currently_under_price_disclosure

But perhaps most importantly, if a medicine is deemed cost-effective by the PBAC why is Cabinet approval necessary? In 2008 patients with renal cell carcinoma waited 10 months after the PBAC recommendation for listing of sunitinib (Sutent®) on the PBS. For the treatment of gastrointestinal stromal tumours (GIST) Sutent® was listed 5 months after PBAC recommendation in July 2009. Are consumers who require medicines deemed to be of high cost experiencing a delay in access to subsidised treatment in comparison to consumers who require medicines that are deemed to be not of high cost?

In 2004, for the release of the Post-PBAC Review report Tony Abbott, then Minister of Health, stated: *While listing times - average listing times - have reduced quite substantially since 1995, from ten months, on average then, to about five months on average now, it is important that we do better, and that's what this report is all about.*[44]

In 2010 we still do not see this change for all medicines.

Finally, it is essential to consider the implications of the concurrent expectation that a Deed of agreement (previously referred to as a risk-sharing arrangement) is required. Given the level of control around these high cost medicines through strict Authority prescribing rules it should be argued that Deeds are increasingly outmoded and represent an unnecessary administrative burden. Sutent® for GIST was subject to a Deed of agreement even though the treatment is for less than 100 people and the Authority restriction clearly defines the treatment population (see www.pbs.gov.au).The real need is to ensure the use of the medicines is within the confines of the PBS listing which would be enhanced through more explicit measures to ensure Quality Use of Medicines.

The Commonwealth must prioritise the implementation of efficiencies in the PBS listing process, from reducing unnecessary administrative burden to implementing QUM programmes thereby streamlining the Cabinet review process and removing the need for deeds of agreement.

[44] http://www.health.gov.au/internet/ministers/publishing.nsf/Content/health-mediarel-yr2004-ta-abb270704.htm?OpenDocument&yr=2004&mth=7

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Weighted Average Monthly Treatment Cost (WAMTC) User's Manual, April 2009. http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pbs-general-pricing-wamtc

Appendix A: PBS and PBS reform

PBS Reform was designed to allow the appropriate valuation of innovative medicines whilst delivering savings to the Government through competitive market forces for off-patent medicines, allowing ongoing access to medicines for the Australian population at an affordable cost.

The majority of the savings for the Government will be through price disclosure, a mechanism based on market competition amongst off-patent products; price disclosure essentially redistributes the savings previously delivered to pharmacists and wholesalers.

A key objective of PBS Reform was to provide business confidence in a predictable and stable pricing market, a premise undermined by legislative provisions that permit the Minister for Health and Ageing, at any point in time and without consultation with affected parties, to form TGs between different medicines. This is particularly important in the Australian context as the majority of innovator pharmaceutical companies are local subsidiaries of international companies.

The reforms comprise a range of inter-connected measures on the following 5 key themes:

Changes to the pricing of PBS listed medicines

- PBS medicines to be listed on two separate formularies:
- Formulary 1 (F1) will comprise single brand (essentially patented) medicines.
- Formulary 2 (F2) will comprise multiple brand medicines and any single brand medicines interchangeable with multiple brand medicines at the patient level.
- No ongoing price links across medicines listed on F1 and those listed on F2.
- Reference pricing will continue to apply:
    - between medicines linked within reference pricing groups on F1
    - within Therapeutic Group Premium (TGP) groups and across different brands of the same medicine listed on F2.

F1 is a market for single brand medicines where efficient price setting and control is achieved through rigorous cost-effectiveness evaluation and initial prices are set by reference to other molecules. F2 is a market for multiple brand medicines where competition at the molecule level determines price – each molecule is encouraged to find its own competitive market price to extract maximum savings for the Government. PBS reform (primarily through price disclosure) capitalises on the fact that the competitive drivers in single brand medicines are the relative effectiveness of different molecules while those for multiple brand medicines are commodity-like competition between brands of the same molecule.

Price cuts for medicines on F2

- Price reductions for all F2A of 2% per year for three years from 1 August 2008.
- One-off 25% mandatory price reduction for F2T medicines will apply 1 August 2008
- Price disclosure - Suppliers listing a new brand on or after:
- 1 August 2007 on F2A disclose actual market price as a condition of listing.
- 1 January 2011 on F2T disclose actual market price as a condition of listing.

F1 medicines entering F2 after 1 August 2007 will as a general rule join F2A

The 12.5% price reduction policy will continue to apply, where relevant.

Price disclosure

For medicines subject to disclosure the responsible person must supply the total sales volume and revenue for their medicine. DoHA calculates the difference between the disclosed price (the ex-manufacturer price as calculated directly from the PBS list price) and the price the manufacturer sells at (the "true" ex-manufacturer price) and adjusts the medicine price should there be more than a 10% difference, effectively capturing the savings previously delivered to the pharmacists and the wholesalers.

Pharmacy and pharmaceutical wholesaler compensation arrangements;

Pharmacists were provided the following assistance to adjust to the new arrangements;

- $1.50 (indexed) incentive to dispense a substitutable, premium-free PBS medicine.
- An incentive of 40c for each prescription processed using PBS Online; and
- Increases in pharmacy mark ups and dispensing fees.
- An additional $69 million over three years will be added to the Community Services Obligation (CSO) Funding Pool to compensate wholesalers for the new pricing arrangements.

Streamlined authority approvals for some medicines

Establishment of an access to medicines working group

Generic medicines awareness campaign

Appendix B: Impact of PBS reform

Dr Lesley Russell, Menzies Centre for Health Policy, 2009.

If the PBS plus RPBS had grown at the same rate post 2004-05 as the average rate up until that time, then it would now cost $9.33 billion a year. So on that basis alone, without savings from generics, the government has saved $5.4 billion, considerably more than the $1.9 billion the previous Treasures Peter Costello predicted in 2002-03 Budget papers"[45]

Examining the future of the PBS, Access Economics, 1 October 2009[46]

PBS is no longer a strong driver in health care spending

Moderation of PBS growth has been achieved largely due to PBS reform and increasing patient co-payments (2008-9 patient co-payments totalled $2.8 billion).

Generic pressures will create new pressures on the pharmaceutical industry to reduce the cost of medications in the future (p.42). Over 100 drugs will experience patent expiry over the next 10 years.

Access Economics poses:

The question is not merely "how much will the PBS cost?', but more equally "what will the PBS achieve for the cost?"

In terms of the broader government finances picture, the results in this report underscore the need for more careful modelling of future spending pressure and the danger of treating temporary surges in commodities and associated government revenue as permanent.

The Impact of PBS Reforms on PBS Expenditure and Savings. The Centre for Strategic Economic Studies (CSES), October 2009. [47]

The CSES report, commissioned by Medicines Australia, projects the Government will achieve savings between $8.25 billion and $9.88 billion in the period 2008-09 to 2017-18 depending on the competitiveness of the PBS. The majority of savings are delivered through PBS Reform initiatives ($4.76 to $6.38 billion to 2017-18).

The magnitude of the savings from PBS reform was verified in the report from the Department of Health & Ageing (DoHA) (Impact of the PBS Reform) as illustrated in Figure B1.

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[45] http://www.pharmainfocus.com.au/news.asp?newsid=2996
[46] http://www.accesseconomics.com.au/publicationsreports/showreport.php?id=218
[47] http://www.medicinesaustralia.com.au/pages/page61.asp

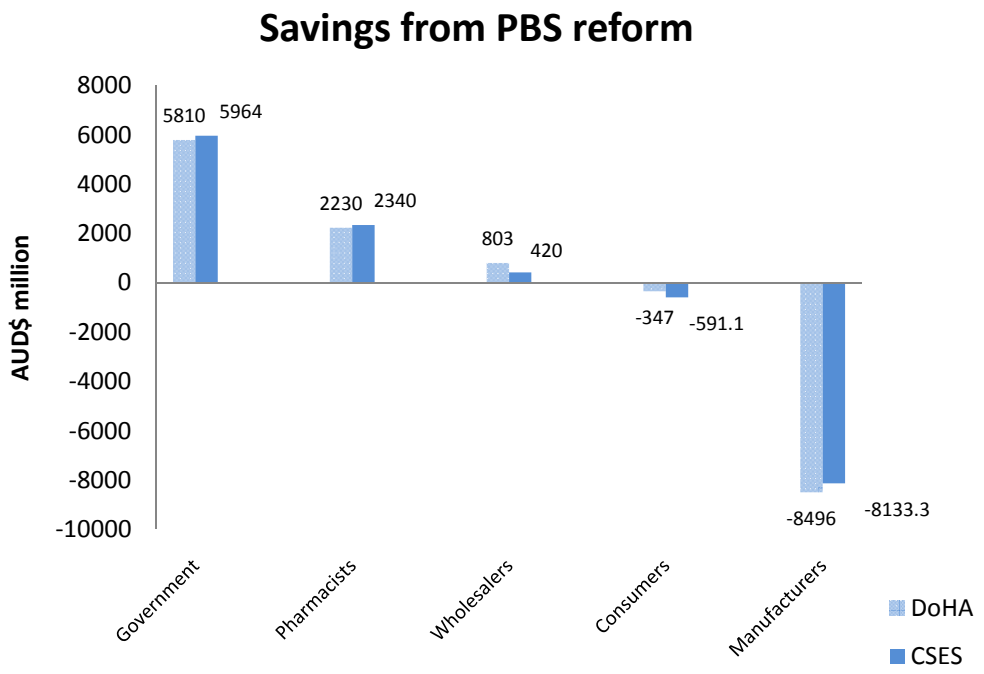

Figure B1: CSES and PwC modelled savings of PBS reform

NOTE: Estimates based on highest generic competition assumptions from both reports

A breakdown of the savings by stakeholder clearly shows the greatest gains are achieved by consumers, both directly at the point of payment, as tax payers and also with the continued availability of new medicines.

A criticism of the estimated savings is a lack of guarantee of price cuts from price disclosure or generic competition. Pfizer has already seen the significant savings to the Commonwealth from two years of price disclosure (see Table B1). In addition, an arrangement (details of which are in the public domain) for a generic atorvastatin to be available in Australia at the time of Lipitor® patent expiry shows that the largest medicine on the PBS will be subject to immediate generic competition.

Table B1: Weighed average price disclosure price reductions

Molecule	1st round price disclosure 01 Aug 2009	2nd round price disclosure 01 Aug 2010
Doxorubicin	63.54%	34.62%
Mitozantrone	34.42%	13.33%
Ondansetron	15.37%	17.61%

Savings delivered to the Government through PBS Reform are almost double the savings anticipated and based on the initial rounds of price disclosure price cuts the savings may be even greater.

The 2010 intergenerational report, Australia to 2050: future challenges January 2010. Treasury, Australian Government.[48]

Ageing and health pressures are projected to result in an increase in total government spending from 22.4% of GDP in 2015–16 to 27.1% of GDP by 2049–50. The current GDP fiscal gap (spending greater than revenue) is 2.75%, which is an improvement on the 3.25% of GDP fiscal gap projected in the previous IGR. The IGR2010 states:

By acting early, the Government's fiscal strategy will reduce the size of the adjustment costs required in the long run.

Australian government spending on health

Pharmaceutical spending remains a significant share of the health budget, $410 per capita in 2009-10 to $500 in 2019-20. However, the PBS as per cent of GDP is unchanged at 0.7% from 2009-10 to 2019-20 (See Figure B2). This is consistent with the estimates of from CSES which reported PBS spending of 0.67% of GDP in 2009-10 and 0.69% in 2011-12.[49] This is in comparison to the IGR2 (2007)[50] which reported the PBS would cost 0.8% of GDP in 2011-12 increasing to 1.0% in 2016-17 and 1.5% in 2026-27.

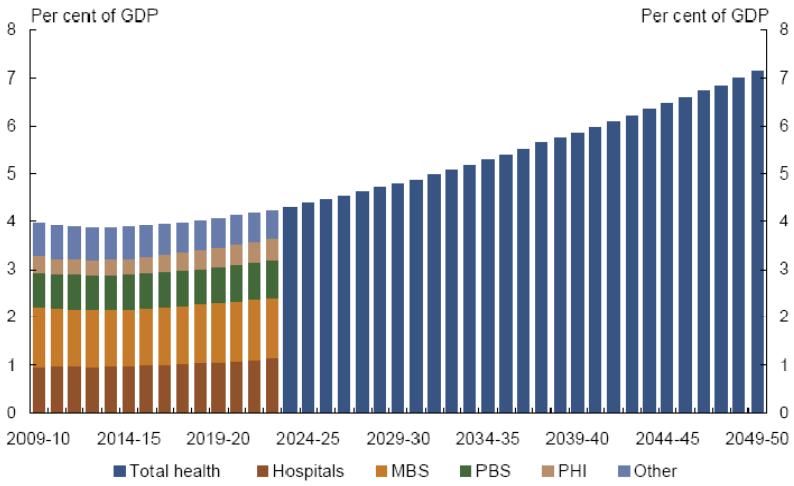

Figure B2: Projected Australian government health spending

Higher productivity is the key

Australia's productivity performance has slowed in the recent past, averaging only 1.4% in the past decade compared with 2.1% in the 1990s. The IGR2010 has assumed that the current 30-year historical average of 1.6% will continue. If productivity growth were increased to 2% per annum, the economy would be over 15% larger in 2049–50.

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[48] The 2010 intergenerational report. http://www.treasury.gov.au/igr/igr2010/
[49] The impact of PBS reforms on PBS expenditure and savings, Centre for Strategic Economic Studies, October 2009.
[50] InterGENERATIONAL report 2, 2007. http://www.treasury.gov.au/igr/

There is scope for Australia to improve its labour force participation rates, especially through policies that target improvements in education, health and attachment to the labour market. *For those wishing to continue working, key factors influencing workforce participation include: health outcomes; educational attainment; the tax-transfer system; cultural attitudes; workplace flexibility; and access to retraining and support services.*

The IGR2010 underlines the need for healthcare reform. *Simply cutting the health budget in order to achieve fiscal sustainability would not be appropriate. Rather, adjusting spending to obtain better value for money is necessary. This requires a more responsive and better coordinated health system. Health reform is required so that every health dollar will buy more and better quality health services.* [51]

The Impact of the PBS Reform - Report to the Parliament. Department of Health and Ageing, February 2010. [52]

The Impact of the PBS Reform report includes an independent assessment by PricewaterhouseCoopers (PwC). The savings from PBS reform, as discussed, are similar to those reported by CSES (See Figure 1). The Commonwealth will save almost $6 billion over 10 years with no negative effect on health outcomes delivered. In contrast the savings of $162 million over 4 years from the introduction of the four new TGs does not appear to justify the uncertainty created for consumers, clinicians and industry.

Future cost of the PBS

The greatest difference seen between the DoHA report and the CSES report is the projection of the future cost of the PBS (See Chapter 10 DoHA report). The estimates from DoHA suggest that the future PBS cost will be between $13 and 13.7 billion by 2018. This is in comparison to a projected cost of the PBS in 2018 of under $13 billion "before reform" (p.74).

CSES predicts the Government expenditure on the PBS would have been $9 billion in 2017-18 without PBS reform. With PBS reform the expected Government expenditure will between $7 and 7.5 billion in 2017-18 depending on the degree of competition in the market. The estimates for the total cost of the PBS are based on detailed information around the historical value of new medicines, savings due to PBS reform including price disclosure and price reductions with the entry of generic molecules.

Given the alignment of the impact of the savings measures from the PwC and CSES reports it is concerning to see a significant disparity in the estimates of future PBS expenditure. There is limited detail in the DoHA report so it is not possible to replicate the projections that total PBS expenditure will be $13 to 13.7billion in 2017-2018.

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[51] The impact of PBS reforms on PBS expenditure and savings, Centre for Strategic Economic Studies, October 2009.
[52] The Impact of the PBS Reform. February 2010.
http://www.health.gov.au/internet/main/publishing.nsf/Content/pbs-reform-report

Appendix C: Comparison of key elements of Lipitor® and Crestor® Product Information

Table C1: Comparison of the Contraindications and Precautions from the Product Information for atorvastatin and rosuvastatin

	Atorvastatin	Rosuvastatin
Contraindications	Active liver disease or unexplained persistent elevations of serum transaminases. Pregnancy and lactation (See PRECAUTIONS). Women of childbearing potential, unless on an effective contraceptive and highly unlikely to conceive.	Patients with active liver disease, or unexplained persistent elevations in serum transaminases. During pregnancy, in nursing mothers and in women of childbearing potential, unless they are taking adequate contraceptive precautions. **CRESTOR 40mg** is contraindicated in patients with pre-disposing factors for myopathy/rhabdomyolysis. Such factors include: − hypothyroidism − personal or family history of hereditary muscular disorders − previous history of muscular toxicity with another HMG-CoA reductase inhibitor or fibrate − alcohol abuse − situations where an increase in rosuvastatin plasma levels may occur − severe renal impairment (CrCl <30 mL/min) − Asian patients − concomitant use of fibrates.
Precautions	As with other drugs in this class, rhabdomyolysis with acute renal failure has been reported. LIPITOR therapy should be temporarily withheld or discontinued in any patient with an acute, serious condition suggestive of a myopathy or having a risk factor predisposing to the development of renal failure secondary to rhabdomyolysis, (e.g. severe acute infection, hypotension, major surgery, trauma, severe metabolic, endocrine and electrolyte disorders, and uncontrolled seizures).	The risk of myopathy during treatment with rosuvastatin may be increased with concurrent administration of other lipid-lowering therapies or cyclosporin. The benefit of further alterations in lipid levels by the combined use of rosuvastatin with fibrates or niacin should be carefully weighed against the potential risks of this combination. Combination therapy with rosuvastatin and gemfibrozil should generally be avoided. Rosuvastatin therapy should also be temporarily withheld in any patient with an acute, serious condition suggestive of myopathy or predisposing to the development of renal failure secondary to rhabdomyolysis (e.g., sepsis, hypotension, major surgery, trauma, severe metabolic, endocrine and electrolyte disorders, or uncontrolled seizures).

Appendix D: Assessment of interchangeability

Averages are compared to averages (mean to mean, median to median, etc) with a range of statistical tests. The inferences made are applicable to groups of individuals and populations as this is the methodological and theoretical basis of the calculation. Safety is not subject to a test of non inferiority – rather the test is that on balance the population rates of safety are of comparable magnitude.

Noninferiority means that, in terms of effectiveness, the proposed drug is no worse than its main comparator. It is used to support a claim of equivalence because it is ***not adequate to demonstrate the absence of a statistically significant difference between the treatments to claim equivalence****; such a lack of a significant difference might occur when the trials are too small to demonstrate a real difference in the effects of the interventions. (Subsection B.8).*

For example, the test for comparison is often whether a sample mean is comparable to another sample mean on the basis of their respective population means. No conclusion is made regarding individuals in either the sample or the population of samples or even less, the population of funding interest. The only question that can be answered regarding the interchangeability of two products is:

- limited to a representative patient (in terms of the samples studied) and
- is the a priori probability of an outcome before their initial administration of one of the compounds and only whether there will be non inferiority of one of those compounds compared to the other i.e. there is no two way non inferiority test or test for equivalence.

There are therefore necessary steps required in order to make inferences or conclusions on an individual patient basis and these are:

- the assessment of the individual patient for representativeness (this is done in a general sense in submissions)
- the exclusion of non superiority (or the performance of two way non inferiority) and
- the assessment of evidence that patients can be switched and that the outcomes assessed previously will be unaffected.

Safety is not subject to a test of non inferiority – rather the test is that on balance the population rates of safety are of comparable in magnitude. This approach is influenced by a number of factors including the lack of power to test safety for non inferiority, the sheer number of multiple comparisons that would need to be performed and the difficulty in deriving standard measures of safety.

Ongoing assessment of "interchangeability"

The premise of a TG is to achieve the same health outcomes for the same cost. The reality is a TG is designed to achieve ongoing cost savings as per the Pharmaceutical Benefits Pricing Authority (PBPA) which states: *WAMTC methodology is automatically applied to drugs that form Therapeutic Groups whether or not they are in F1*.[53]

In the HP statin TG on 1 December each year the prices for Crestor® and Lipitor® will be reviewed and adjusted to the lowest (benchmark) price based on prescribing data from general practitioners. There is potential conflict with the original recommendation by the PBAC which specifies these two medicines will provide the same health outcomes if prescribed in the ratio of 1mg Crestor® to 3mg Lipitor® (known as the therapeutic relativity). Neither the adherence to original recommendation by the PBAC on the therapeutic relativity or the delivery of the same level of health outcomes (benefits) is re-measured even though the costs are reviewed annually.

Issues with WAMTC reference pricing

WAMTC methodology is a type of reference pricing applied to particular groups of PBS medicines. *The WAMTC methodology is intended to account for different usage practices in the market place compared with the formal clinical trial situation. …As an example, if drug A is listed on a cost minimisation basis versus drug B with 45 mg = 60 mg, but as used in clinical practice the average daily doses are 47 mg and 59 mg then the price for drug A should be lower and for drug B higher than based on the 45 mg = 60 mg comparison."*[54]

The limitations around the WAMTC methodology include:

- it is based on actual dosage prescribing in a proportion of the GP community only. It does not capture specialist prescribing
- data does not necessarily come from similar patient populations and
- it does not take into account health outcomes or the approved relativities to deliver the health outcomes as recommended by the PBAC.

It is also clear that assigning any patient contribution to these medicines may differ with the re-evaluation of the prices through annual WAMTC reviews. For example, it says that the benchmark drug cannot have an associated patient contribution – does the converse hold if the drug has a special patient contribution it cannot be the benchmark drug and therefore undermines the true principles of reference pricing? This is another area with limited guidance as the NHA is not explicit on pricing matters such as WAMTC and the benchmark drug determination. These are constructs of the PBPA manual.

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[53] Pharmaceutical Benefits Pricing Authority Policies, Procedures and Methods. April 2009. Page 17. http://www6.health.gov.au/internet/main/publishing.nsf/Content/health-pbs-general-pricing-pbpamethods.htm-copy2

[54] Weighted Average Monthly Treatment Cost (WAMTC) User's Manual, April 2009. http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pbs-general-pricing-wamtc

Appendix E: Consultation and transparency

The expectations of the industry and undoubtebly other external stakeholders is based on the premise that underpins the majority of intereactions with the PBAC. PBAC is conscious of the need to be as open as possible in its proceedings, consistent with the secrecy provisions of the Act. It therefore provides to sponsors all relevant documents and evaluations considered by the committee (P.8, PBAC Guidelines Vr. 4.3).

The Australia United States Free Trade Agreement (FTA) provides very clear direction regarding the need for both countries to "*promote timely and affordable access to innovative pharmaceuticals*" and to "*recognize the value of innovative pharmaceuticals through the operation of competitive markets or by adopting or maintaining procedure that appropriately value the objectively demonstrated therapeutic significance of a pharmaceutical*." The creation of TGs in 2009 is clearly inconsistent with these principles.

Consultation on PBS Reform

The PBS Reform package was developed with the consultation of industry prior to implementation from 1 August 2007. Medicines Australia, as the industry representative body, proposed a number of solutions in response to the DoHA consultation document: *PBS Reform – a guide to the legislation.*

MA proposed that whilst there was an understanding the legislation would remain unchanged in regard to the discretionary power of the health minister to form TGs there was considerable information provided to allow the determination to follow a due process, a process that is aligned with the current PBAC process. Furthermore, MA, and therefore pharmaceutical companies, understood new TGs would not be implemented.

Consideration of a medicine by the PBAC and transparency

The NHA 1953(101) does not mandate timelines for review however the PBAC Guidelines detail the timelines of consideration of medicines and also the transparency measures and communication responsibilities of the PBAC, generally through the PBAC Secretariat.

PBAC is conscious of the need to be as open as possible in its proceedings, consistent with the secrecy provisions of the Act. It therefore provides to sponsors all relevant documents and evaluations considered by the committee. It allows up to two sets of written pre-PBAC consultation documents from each sponsor as well as a hearing before the committee. (p.8, Section 1.4) [55]

[55] http://www.health.gov.au/internet/main/publishing.nsf/content/pbacguidelines-index

The timeframes for communication of any deliberations around a sponsor's medicine or a medicine that will impact on the use of the sponsor's medicine are clear (See Box 1.3).

Box 1.3 Timeline of PBAC procedures

Action or event	Time relative to PBAC meeting
• TGA delegate's overview/advice to ADEC and/or ADEC resolution and/or TGA registration granted	
• Cut-off date for major submissions to department	17 weeks before
• Cut-off date for minor submissions to department	11 weeks before
• Departmental papers to sponsors	6 weeks before
• Sponsor's pre-subcommittee response to department	5 weeks before
• Meeting of subcommittees	4 weeks before
• Subcommittee papers to sponsors	2 weeks before
• Sponsor's pre-PBAC response to department	1 week before
• PBAC meeting	
• Verbal advice to sponsor	half a week after
• Written advice to sponsor	3 weeks after
• Publication of PBAC outcomes on departmental website	6 weeks after
• PBAC ratified minutes to sponsor	10 weeks after
• Publication of public summary document on departmental website	16 weeks after
• Publication of public summary document (first time rejections)	18 weeks after

A number of initiatives to increase the transparency around PBAC recommendations have been introduced including Public Summary Documents, to provide detail on the decision-making criteria and evidence, which were introduced in 2004 and the PBAC meeting agenda and opportunity for consumer submissions to the PBAC which were intrdouced in 2008.

Requirements of the Australia United States Free Trade Agreement

The Australia United States FTA is clear in the recognition that the Government of each country must be transparent in decision making. See Appendix F for further details.

The process relating to the creation of the new TGs has been conducted in secret by the Australian Government.

Companies have been provided with an opportunity to comment, only after the PBAC had made its recommendation to Government, thereby denying the PBAC the opportunity to consider any arguments or clinical data presented by companies. The opportunity to comment is therefore not a contributing factor to the decision making process. This is not in the interests of patients or in the interests of industry certainty.

Appendix F: Australia United States Free Trade Agreement

Key elements of Australia United States Free Trade Agreement for pharmaceuticals

Annex 2-C - Pharmaceuticals

1. Agreed Principles

The Parties are committed to facilitating high quality health care and continued improvements in public health for their nationals. In pursuing these objectives, the Parties are committed to the following principles:

(a) the important role played by innovative pharmaceutical products in delivering high quality health care;

(b) the importance of research and development in the pharmaceutical industry and of appropriate government support, including through intellectual property protection and other policies;

(c) the need to promote timely and affordable access to innovative pharmaceuticals through transparent, expeditious, and accountable procedures, without impeding a Party's ability to apply appropriate standards of quality, safety, and efficacy; and

(d) the need to recognize the value of innovative pharmaceuticals through the operation of competitive markets or by adopting or maintaining procedures that appropriately value the objectively demonstrated therapeutic significance of a pharmaceutical.

2. Transparency[2c-1]

To the extent that a Party's federal healthcare authorities operate or maintain procedures for listing new pharmaceuticals or indications for reimbursement purposes, or for setting the amount of reimbursement for pharmaceuticals, under its federal healthcare programs, it shall:

(a) ensure that consideration of all formal proposals for listing are completed within a specified time;

(b) disclose procedural rules, methodologies, principles, and guidelines used to assess a proposal;

(c) afford applicants timely opportunities to provide comments at relevant points in the process;

(d) provide applicants with detailed written information regarding the basis for recommendations or determinations regarding the listing of new pharmaceuticals or for setting the amount of reimbursement by federal healthcare authorities;

(e) provide written information to the public regarding its recommendations or determinations, while protecting information considered to be confidential under the Party's law; and

(f) make available an independent review process that may be invoked at the request of an applicant directly affected by a recommendation or determination.

3. Medicines Working Group

(a) The Parties hereby establish a Medicines Working Group.

(b) The objective of the Working Group shall be to promote discussion and mutual understanding of issues relating to this Annex (except those issues covered in paragraph 4), including the importance of pharmaceutical research and development to continued improvement of healthcare outcomes.[2C-2]

(c) The Working Group shall comprise officials of federal government agencies responsible for federal healthcare programs and other appropriate federal government officials.

4. Regulatory Cooperation

The Parties shall seek to advance the existing dialogue between the Australian Therapeutic Goods Administration and the U.S. Food and Drug Administration with a view to making innovative medical products more quickly available to their nationals.

5. Dissemination of Information

Each Party shall permit a pharmaceutical manufacturer to disseminate to health professionals and consumers through the manufacturer's Internet site registered in the territory of the Party, and on other Internet sites registered in the territory of the Party linked to that site, truthful and not misleading information regarding its pharmaceuticals that are approved for sale in the Party's territory as is permitted to be disseminated under the Party's laws, regulations, and procedures, provided that the information includes a balance of risks and benefits and encompasses all indications for which the Party's competent regulatory authorities have approved the marketing of the pharmaceuticals.

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