The National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2007: reform or fracture?

Ken J Harvey, Anthony H Harris and Liliana Bulfone

Reform is needed, but will the current Bill enact the best options?

Two articles in this issue of the Journal[1,2] comment on a complex but important piece of legislation put forward by the Minister for Health and Ageing — the National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2007 (the Bill).[3]

The Bill splits the Pharmaceutical Benefits Schedule into two formularies: "one part for single brand drugs [F1], the other part for drugs that have multiple brands or that are interchangeable at the patient level with drugs with multiple brands [F2]".[3] The Bill allows reference pricing of drugs within each formulary but disallows an ongoing link in the price of drugs between formularies.

The Bill institutes progressive mandatory price reduction and price disclosure by the sponsors of multiple brand (generic) medicines for drugs on F2. The aim of this is to ensure that the price the government pays for Pharmaceutical Benefits Scheme (PBS) medicines more closely reflects discounted prices paid by pharmacists and international prices for generic medicines.

A support package will be provided to help community pharmacists adjust to the new arrangements. Authority approvals will be streamlined, a public awareness campaign is promised to promote the use of generic medicines, and a working group will be established to consider issues of continued access to innovative medicines through the PBS.

The government argued in the Bill that dual delinked formularies were required to tackle a problem caused by reference pricing: price reductions imposed on multiple brand generic medicines that were being discounted to pharmacies would, in many cases, flow directly on through price linking to single brand patented medicines that were not being discounted. This was said to cause difficulties for the innovative pharmaceutical industry and to place patients at risk of losing subsidised access to many worthwhile medicines.[4]

The government believes patients will not be disadvantaged by the proposed changes, as out-of-pocket costs to patients would remain unchanged. In some cases, patients should pay less. It is estimated that the mandatory price reductions for drugs in the F2 formulary will result in patients paying between 20 cents and $4.65 less for about 400 drugs that will fall below the current copayment amount of $30.70 (for general patients), or that were already below this amount.

The articles by Searles et al[1] and Faunce[2] raise three concerns about the Bill. First, eliminating global reference pricing could result in Australia paying more for a new medicine in F1 that is no better than those already available in F2. Second, these changes appear to reflect ongoing pressure from the United States through the Medicines Working Group established by the Australia–US Free Trade Agreement to weaken the PBS system of evidence-based reference pricing. Third, mandatory price reductions and price disclosure for drugs on the F2 formulary, while saving the government money, provide little financial relief to patients and are unlikely to stimulate the Australian generic medicine industry.

Reference pricing is a means of negotiating a lower price by tying the subsidy to the differential effectiveness of the drug — its comparative clinical outcome rather than its cost of production. This principle applies both at the time of initial subsidy and later, when new competitors arrive on the scene. The proposed changes may not change the initial pricing mechanism, which will continue to use comparative effectiveness as a criterion for pricing. What they will do is lessen the "downward pressure" on single brand (patented) drug prices over time. With the new dual formulary system, there will no longer be an automatic price reduction when different drugs of similar effectiveness for the same condition are listed on the PBS at a lower price.

The problem with the current system, as Searles et al make clear, is that we are paying too much for drugs that are out of patent, where the company has already made its profit on the initial investment. We need a means to reduce the price of generic drugs in a system where fixed out-of-pocket costs to consumers and historic negotiated prices with suppliers provide no incentive to switch to generics, and where there are no competitive forces to reduce prices to government.

The Bill does provide one mechanism to do so. It will mandate price reductions to government for out-of-patent medicines over time. This will lower the cost of generic drugs in Australia — a much needed reform. The problem is that it relies on annual administrative rule changes that do little to encourage the generic medicine industry and may have the effect of maintaining high prices for patented medicines, even when similar non-patented drugs are falling in price. The unforeseen result might be that we will pay more for the health gains from many new expensive medicines over time.

Searles et al suggest one alternative — maintain a single formulary, but have closed-bid, competitively tendered contracts with generic medicine suppliers to provide key drugs outside of the PBS. Another option would be to increase competition for generic drugs (within a single or dual formulary) by allowing generic drug manufacturers to discount to government rather than wholesalers or pharmacies. A generic-brand price discount to consumers could be seen as an extension of the current brand price premium scheme — instead of consumers paying more than the regular copayment for a particular brand, they could pay a lower price if they choose a particular generic.

Using a market price signal of a copayment reduction for consumers is likely to be more effective in stimulating generic medicine use than the proposed government advertising campaign, possibly a lot cheaper, and is consistent with the aim of the National Medicines Policy to provide timely access to the medicines that Australians need, at a cost patients and the community can afford. Fine-tuning such a system so that the expected increase in market share would be enough to encourage a local industry, or

to ensure the kind of continuous price reductions that the Bill imposes, is something that the government could experiment with — without serious disruption to the system.

More public discussion on the proposed reform is expected when the legislation reaches its next stage — a Senate Committee inquiry scheduled for 15 June 2007. We suggest the Senate should consider any necessary amendments to the Bill to allow generic-brand price competition and to facilitate a copayment reduction if consumers choose a generic drug. This could increase the use of generic drugs without an expensive government advertising campaign and potentially better stimulate the Australian generic medicine industry.

Competing interests

Ken Harvey is a member of the Australian Labor Party (ALP) and the ALP candidate for Kooyong in the forthcoming federal election. Anthony Harris and Liliana Bulfone are part of a group at Monash University providing commentaries to the Australian Government on submissions to the Pharmaceutical Benefits Advisory Committee.

Author details

Ken J Harvey, MB BS, FRCPA, Adjunct Senior Research Fellow[1]
Anthony H Harris, MA, MSc, Deputy Director[2]
Liliana Bulfone, BPharm, MBA, GradCertHealthEco, Senior Research Fellow[2]
1 School of Public Health, La Trobe University, Melbourne, VIC.
2 Centre for Health Economics, Monash University, Melbourne, VIC.
Correspondence: ken.harvey@latrobe.edu.au

References

1 Searles A, Jefferys S, Doran E, Henry DA. Reference pricing, generic drugs and proposed changes to the Pharmaceutical Benefits Scheme. [Published online ahead of print, *Med J Aust* 13 June 2007.]
2 Faunce TA. Reference pricing for pharmaceuticals: is the Australia–United States Free Trade Agreement affecting Australia's Pharmaceutical Benefits Scheme? [Published online ahead of print, *Med J Aust* 13 June 2007.]
3 The Parliament of the Commonwealth of Australia, House of Representatives. National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2007. Explanatory memoranda. http://www.austlii.edu.au/au/legis/cth/bill_em/nhabsb2007473/ (accessed Jun 2007).
4 Hon. Tony Abbott MP, Minister for Health and Ageing. Second reading speech: National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2007, House of Representatives, Debates, 24 May 2007. http://www.aph.gov.au/hansard/reps/dailys/dr240507.pdf (accessed Jun 2007).

eMJA Rapid Online Publication 13 June 2007 ❑

Reference pricing, generic drugs and proposed changes to the Pharmaceutical Benefits Scheme

Andrew Searles, Susannah Jefferys, Evan Doran and David A Henry

ABSTRACT

- Draft legislation introduced to Parliament on 24 May 2007 proposes changes to the Pharmaceutical Benefits Scheme (PBS), including the creation of two formularies. The F1 formulary will contain single brand drugs that are not considered "interchangeable on an individual patient basis", while the F2 formulary will contain mainly older drugs (many of them generic) for which there is at least one alternative product considered to be clinically interchangeable.
- Drugs in F1 will not be compared with those in F2 for pricing purposes, even if clinical trial data show them to be equivalent (or even inferior) for the same clinical indication. This undermines the evidence-based approach to reference pricing currently used in the PBS.
- Other changes require compulsory price disclosures and price cuts for generic medicines. While positive, these amendments are unlikely to deliver generic medicine prices as low as those in other developed countries. This is important, in view of growing evidence of the unaffordability of prescription medicines in the Australian community.

eMJA RAPID ONLINE PUBLICATION 13 JUNE 2007

Australia's Pharmaceutical Benefits Scheme (PBS) needs periodic reform to retain its effectiveness against a backdrop of ongoing development of pharmaceutical products and changing markets. Any reform should be based on the timely provision of good-quality, affordable, safe and efficacious medicines to Australian patients, with minimal negative consequences for other stakeholders — this is consistent with the central objectives of the National Medicines Policy.[1]

Proposed changes to PBS processes were laid out in legislation introduced to Federal Parliament on 24 May 2007, which will amend the *National Health Act 1953* (Cwlth).[2] The proposed changes were foreshadowed in announcements by the Minister for Health and Ageing[3] but (perhaps because of their complexity) were little discussed in the media or in Parliament. Here, we focus on two of the reforms: reference pricing, and the price of generic medicines (see glossary of key terms in Box 1). Our main concerns are that the proposed changes to the PBS will lead to higher prices for drugs that offer no advantage over existing products, and will fail to provide very low-cost generic products that would ease the financial burden on patients and their families. We suggest some alternative approaches that should have been considered.

Reference pricing in Australia

In Australia, the costs of drugs that are in the same therapeutic group and are considered to have similar levels of safety and efficacy are usually reimbursed at the level of the *lowest*-cost drug in that group.[4,5] The Pharmaceutical Benefits Branch publishes detailed therapeutic relativity sheets listing drugs considered to be equivalent; these sheets also describe situations in which manufacturers can charge price premiums that have to be paid by patients.[6] Even when a premium has been granted, the relativity sheet maintains a link between the prices of the products, which remain within a single group. When new drugs appear to offer substantial clinical gains over existing products, the sponsoring companies are encouraged to submit comprehensive pharmacoeconomic analyses to the Pharmaceutical Benefits Advisory Committee (PBAC) in order to justify higher prices.[5]

Where reference pricing in Australia works well: branded and patented medicines

The success of the PBS processes (particularly reference pricing) can be measured by lower average prices for some types of pharmaceuticals in Australia compared with other developed countries.[7] This is particularly true for "me too" drugs — patented drugs that are members of an existing therapeutic class, but offer no worthwhile additional benefits. In general, countries with unrestricted determination of prices (such as the United States) have higher ex-manufacturer prices for patented and branded medicines than those in the Australian system. While some OECD (Organisation for Economic Co-operation and Development) countries limit the reference group to off-patent medicines, in Australia, a patented or branded medicine can be referenced to the lowest-cost generic product within the same therapeutic group for the purpose of price setting.

Reference pricing and the selective use of pharmacoeconomics is a rational approach for spending public money: higher prices are only paid for drugs that have clinical benefits not available from an alternative therapy. Reference pricing does not create a price barrier for pharmaceutical manufacturers wanting to access the Australian market; it merely rationalises government reimbursement for prescription drugs.[8] For patented and branded medicines, reference pricing works well and is not in need of reform.

The facilitation of low-priced generics

While the Australian version of reference pricing works with patented and branded products, experience here and overseas suggests that it does not create a sufficient level of price competition when numerous generic products become available within a therapeutic class (eg, statins).[8] This can lead to higher average generic medicine prices, which makes the PBS expensive for the government, and generic medicines unnecessarily expensive for patients through high copayments. While this aspect of the PBS needs reform, the policy challenge is to address this weakness in reference pricing without diminishing its ability to deliver value for money for patented and branded medicines. We do not believe the proposed reforms adequately meet this challenge.

The new F1 and F2 PBS reform proposals

The PBS reforms propose to convert the existing single formulary into two formularies: F1 and F2 (new sections 85AB and 85AC of

1 Glossary

Branded/patented medicine: This is usually the first product on the market that contains a particular molecule (eg, the Valium brand of diazepam). After expiry of the patent, the branded product usually remains on the market, but has to compete with generic products.

Product patent: A set of exclusive rights prohibiting (without permission of the patent holder) other pharmaceutical manufacturers from manufacturing and selling products that contain the same molecule. A product patent typically has a term of 20 years, although the effective product life is shorter than this due to the time required to develop the drug and bring it to market.

Generic medicine: A medicine that contains the same active molecule as a branded product and enters the market to compete with it after the branded product's patent has expired. Generic medicines are required to be bioequivalent to the branded medicine.

Reference pricing: A technique whereby the reimbursement of a group of therapeutically similar medicines is set at the level of either the lowest or average price of the group. In Australia, the reference is to the lowest price in the group. For products sold above the reference price, the patient has to pay the premium.

Copayment: A charge levied on a patient for a prescription drug subsidised by the Pharmaceutical Benefits Scheme (PBS). The maximum payment for a patient who does not have concessional status is currently A$30.70. If the dispensed price of the drug is less than A$30.70, the patient pays the full cost of the prescription.

Equivalence (clinical): A new product is considered to be equivalent to an existing product if it is shown to be no worse in comparative clinical trials. This is often referred to as a test of "non-inferiority".

Interchangeability: There is no definition of this term in the proposed legislation, despite an extensive list of key term definitions. The PBS website describes interchangeable products as "brands of a particular strength of an item where evidence of bioequivalence or therapeutic equivalence on an individual basis (or justification for not needing such data) has been accepted by the TGA [Therapeutic Goods Administration] or PBAC [Pharmaceutical Benefits Advisory Committee]".*

* http://www.health.gov.au/internet/wcms/publishing.nsf/Content/pbs-pbpa-policies-contents~pbs-pbpa-policies-glossary ◆

the National Health Act).[2] The F1 formulary will contain single brand drugs that are not deemed "interchangeable on an individual patient basis" with therapeutically equivalent products (new section 101[3BA]).[2] The F2 formulary will contain drugs for which there is at least one additional product that is considered clinically interchangeable. Most generic medicines will be in the F2 category. Reference pricing will continue within each formulary but, critically, not between F1 and F2.

The creation of the F1 and F2 formularies requires legislative amendments that place additional demands on the PBAC. The committee will now be required by the new section 101(3BA) to consider whether or not a drug is "interchangeable on an individual patient basis" and inform the Minister on this point.[2] In addition, the committee will be required to advise the Minister if a product is suitable for use by a particular patient subgroup because of its "form and manner of administration", and that no other similar product is available (new section 101[4A]).[2]

The concept of interchangeability effectively subordinates the test of "equivalence", the concept currently used successfully by the PBAC in its reference pricing determinations. Equivalence is a well accepted concept in evidence-based medicine. Interchangeability, however, is a more demanding test that is mentioned on the PBS website only in relation to bioequivalent or therapeutically equivalent versions of existing drugs in a particular form and strength.[9] The problem is that it is difficult to be certain if drugs that appear equivalent on the basis of average effects measured in comparative clinical trials will always be interchangeable at the level of an individual patient. Manufacturers are likely to allege non-interchangeability of a new product as an argument to have it listed in F1, which would mean it does not have to be compared with other clinically equivalent products in F2 for the purpose of pricing. For example, citalopram and escitalopram are currently PBS-listed on the basis of reference pricing (with generic versions of fluoxetine as the reference).[6] However, advice released on the PBS website in February 2007 indicates that, following the proposed reforms, citalopram will be listed in F2, while escitalopram will be listed in F1, meaning that a price cut to citalopram will not apply to its *S*-enantiomer![10]

Currently, the ability of reference pricing to obtain value for money depends on newly listed medicines being compared with an existing therapy, rather than placebo. Under the proposed reforms, a sponsor of a new medicine destined for the F1 formulary might submit only a placebo-controlled clinical trial for scrutiny by the PBAC, even though they have evidence comparing it with a drug already listed in F2. This could lead to a situation where Australia pays more for a new medicine that is no better, or is actually less effective, than what is already available.

The PBAC may be permitted to select the comparator for a new drug that is destined for the F1 formulary. However, this will not resolve the pricing issue created by the F1–F2 proposal. The break in F1–F2 reference pricing will prevent the new F1 drug from being referenced to the lowest-priced drug in its therapeutic class if the lowest-priced drug is in F2. Further, its location in F1 will insulate it from mandatory price cuts that could be applied to its alternatives in F2.

Generic medicines and the new PBS changes

Compulsory price disclosures for generic medicines are being introduced to ensure that the reimbursement by the PBS is not above their market price. Generic medicines will be subject to mandatory price cuts, which in some cases will be up to 25% off the current price. These reforms head in the right direction but do not go far enough. The planned 25% price cut for high sales-volume generic medicines is unlikely to produce prices that approach those obtained by a number of countries, including the United Kingdom, the US and New Zealand. Box 2 compares reimbursed prices for key groups of medicines in Australia and NZ. Prices for these products in Australia would need to fall by over 44% to be equivalent to NZ prices. Even in the US, which is generally not a good model of access to affordable drugs, consumers benefit from generic drug prices that are much lower than in Australia. For instance, in 2006, the Wal-Mart retail chain introduced a generic drugs program that offers a wide range of medicines (including statins, angiotensin-converting enzyme inhibitors, and serotonin reuptake inhibitors) for a flat monthly fee of US$4.[11] In the UK, the National Health Service Purchasing and Supply Agency is able to source monthly treatment packs of simvastatin 20mg, enalapril 20mg and fluoxetine 20mg for sub-

2 Prices of selected generic drugs in Australia and New Zealand

Drug	Clinical indication	Quantity	Australia	NZ*	Price fall to match NZ†
Enalapril 10 mg	High blood pressure	30 tabs	$19.21	$6.20	68%
Fluoxetine 20 mg	Depression	28 caps	$23.50	$6.81	71%
Simvastatin 20 mg	High cholesterol	30 tabs	$47.90‡	$16.30§	66%
Metformin 500 mg	Diabetes	100 tabs	$14.20	$7.93	44%

All prices are A$ (A$1 = approximately NZ$1.12 as at 6 June 2007).
* Source: http://www.pharmac.govt.nz/interactive/. † The Australian price cut (%) required to bring Australian prices in line with those in NZ. ‡ Australian non-concessional patients pay the copayment of A$30.70. § Non-concessional patients in NZ pay a copayment capped at NZ$15.00 (A$13.41) for fully subsidised medicines. ◆

stantially less than £1 (excluding value added tax, pharmacy markups and dispensing fees).[12]

Affordability of medicines for Australian patients

Affordability of medicines for Australian patients is influenced by the size of the copayment for medicines and the operation of the PBS Safety Net. The copayment for general users has increased regularly in recent years and is currently up to A$30.70, depending on the listed price of the medication. *Choice* recently commented that working families are particularly affected by copayments because they often do not benefit from concessional prices.[13] The cost of prescriptions in Australia is a barrier to accessing health care. An international survey conducted in five countries showed that cost was a factor in not obtaining a prescription for 21% of Australians with below-average income. Surprisingly, 18% of Australians with an above-average income also cited cost as a reason for not obtaining a script.[14] A more recent survey found that just over a third of Australians reported the financial burden of prescription medicines to be moderate to extreme.[15] This burden is both unfair and unnecessary. As an example, Box 2 shows the dispensed price of fluoxetine (20 mg, 28 caps) to be A$23.50 in Australia, compared with A$6.81 in NZ. A 25% reduction in the price of simvastatin in Australia would still leave a general user paying A$30.70, compared with A$13.41 in NZ.

Alternative approaches

The central aim of reforms should be to ensure the timely provision of high-quality, safe and efficacious medicines that are affordable to the community and, most importantly, to the individual patient. However, consumers do not appear to have been included in the stakeholder reference group formed to provide feedback to government on the implementation of the PBS reforms.[10] PBS processes that work well, such as reference pricing of patented and branded products and the use of pharmacoeconomics, should be strengthened. These techniques help achieve value for money from PBS expenditure. This objective can only be achieved by maintaining a single formulary. We agree with compulsory disclosure of the price that pharmacists and wholesalers pay for drugs. We accept that in order to obtain value from the international market for generic products, delinkage of the prices of some generic and branded products is necessary.

The need to achieve lower prices for generic medicines in Australia has been highlighted,[16] and a number of approaches are possible. For example, the Australian Government could establish an alternative subsidised supply program (involving closed-bid competitive tendering) to procure selected lines of ultra-low-cost generic drugs. These products would not be included in reference pricing and would not be reimbursed through the normal PBS mechanisms, so would not be price-linked to existing products. The drugs would receive marketing approval from the Therapeutic Goods Administration in the normal way. Creating a viable market for these products would require incentives for importers (as most products will come from India and China). Pharmacists may require encouragement to dispense these products, probably in the form of a higher dispensing fee. But both pharmacists and prescribing doctors will doubtless be motivated by a desire to improve the affordability of medicines for their patients. Such a program would require an extensive promotional campaign aimed at both the public and the health profession, particularly to provide solid reassurance about the quality of the products.

Acknowledgements

Andrew Searles is a PhD Scholar on a 3-year Australian Research Council (ARC)-funded project, supervised by Dr Thomas Faunce and Professor David Henry; Susannah Jefferys is a Research Associate with this project. The ARC was not involved in the preparation of this paper.

Competing interests

None identified.

Author details

Andrew Searles, BEc, DipEd, MMedStat, PhD Scholar[1]
Susannah Jefferys, BA LLB(Hons), Research Associate, Globalisation and Health Project[2]
Evan Doran, BA, GradDipHealthSocSci, PhD, Lecturer[1]
David A Henry, MB ChB, MRCP, FRCP, Professor of Clinical Pharmacology[1]

1 School of Medicine and Public Health, University of Newcastle, Newcastle, NSW.
2 College of Law, Australian National University, Canberra, ACT.
Correspondence: david.henry@newcastle.edu.au

References

1 Australian Government Department of Health and Ageing. National Medicines Policy. 2000. http://www.health.gov.au/internet/wcms/Publishing.nsf/Content/National+Medicines+Policy-2 (accessed May 2007).
2 National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2007. A Bill for an Act to amend the *National Health Act 1953*, and for related purposes. http://parlinfoweb.aph.gov.au/piweb/Repository/Legis/Bills/Linked/24050700.pdf (accessed May 2007).
3 Abbott T (Minister for Health and Ageing). Press Conference – PBS reform, Commonwealth Parliamentary Offices, Sydney [transcript]. 16 Nov 2006. http://www.health.gov.au/internet/ministers/publishing.nsf/Content/health-mediarel-yr2006-ta-abb161106.htm (accessed Jan 2007).
4 Australian Government Department of Health and Ageing. Pharmaceutical benefits pricing authority policies, procedures and methods. http://www.health.gov.au/internet/wcms/publishing.nsf/Content/pbs-pbpa-policies-contents~pbs-pbpa-policies-ch2 (accessed May 2007).
5 Birkett DJ, Mitchell AS, McManus P. A cost-effectiveness approach to drug subsidy and pricing in Australia. *Health Aff (Millwood)* 2001; 20: 104-114.

6 Australian Government Department of Health and Ageing. Therapeutic relativity sheets. http://www.health.gov.au/internet/wcms/publishing.nsf/Content/health-pbs-general-pricing-therelativity.htm (accessed May 2007).
7 Australian Government Productivity Commission. International pharmaceutical price differences. Research report. Canberra: Productivity Commission, 2001. http://www.pc.gov.au/study/pbsprices/finalreport/ (accessed Jun 2007).
8 López-Casasnovas G, Puig-Junoy J. Review of the literature on reference pricing. *Health Policy* 2000; 54: 87-123.
9 Australian Government Department of Health and Ageing. PBS for health professionals. Explanatory notes. http://www.pbs.gov.au/html/healthpro/browseby/explanatory-notes?ref=section2-symbols (accessed Jun 2007).
10 Australian Government Department of Health and Ageing. Pharmaceutical Benefits Scheme (PBS) reform. http://www.health.gov.au/internet/wcms/publishing.nsf/Content/pbs_reform_02feb07.htm (accessed Jun 2007).
11 Wal-Mart. Wal-Mart/Sam's Club $4 program. http://i.walmart.com/i/if/hmp/fusion/Floridagenericdruglist.pdf (accessed May 2007).
12 NHS Purchasing and Supply Agency [website]. http://www.pasa.nhs.uk/PASAweb (accessed May 2007).
13 Choice. PBS reform. Jan 2007. http://www.choice.com.au/viewArticle.aspx?id=105587&catId=100386&tid=100008&p=1&title=PBS+reform (accessed May 2007).
14 Blendon RJ, Schoen C, DesRoches CM, et al. Inequities in health care: a five-country survey. *Health Aff (Millwood)* 2002; 21: 182-191.
15 Hunter Valley Research Foundation. Wellbeing watch: a monitor of health, wealth and happiness in the Hunter. Newcastle: HVRF, 2006. http://www.hvrf.com.au/pages/publications/wellbeing_watch.php (accessed May 2007).
16 Lofgren H. Reshaping Australian drug pricing: the dilemmas of generics medicines policy. *Aust New Zealand Health Policy* 2007; 4: 11. http://www.anzhealthpolicy.com/content/pdf/1743-8462-4-11.pdf (accessed Jun 2007).

(Received 27 May 2007, accepted 5 Jun 2007) ❑

Reference pricing for pharmaceuticals: is the Australia–United States Free Trade Agreement affecting Australia's Pharmaceutical Benefits Scheme?

Thomas A Faunce

Unless the federal government changes the course of our medicines policy with intention, Australia's pricing of patented pharmaceuticals is likely to follow inequitable US trends

Proposed amendments to the *National Health Act 1953* (Cwlth) are currently being considered by the Australian federal government. The National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2007 (the Bill) includes several changes that will limit reference pricing under the Australian Pharmaceutical Benefits Scheme (PBS). Here, I argue that these amendments have been influenced by the Australia–United States Free Trade Agreement (AUSFTA) and, further, that if US influence on Australian medicines policy continues, there are likely to be adverse consequences for all Australians, involving the erosion of scientific objectivity and equity in PBS processes and, eventually, the end of public-funded medicines.

What is reference pricing?

The PBS is an internationally respected system under which the federal government uses public funds to reimburse pharmacists (and thence manufacturers) the "health innovation" value of listed medications, as proven by scientific evidence assessed by pharmacoeconomic experts on the Pharmaceutical Benefits Advisory Committee (PBAC). This allows Australian patients to generally pay a relatively low standardised copayment (currently $30.70 for non-concessional patients) for all PBS medicines, patented and generic alike.

Under the current PBS system, once expert assessment has established that a new patented drug has better efficacy or safety than a different off-patent comparator for the same clinical indication, it is recommended by the PBAC for listing. The submission price is then further negotiated by the Pharmaceutical Benefits Pricing Authority (PBPA). If the PBAC's analysis merely establishes equal effectiveness, then, in a fundamental cost-minimisation process, the newly listed drug's initial reimbursement price is linked to the lowest in the relevant price reference group.

Reference pricing, in its most fundamental sense however, applies post-listing when new competitors (with lower prices) enter six groups presently established under the Therapeutic Group Premium (TGP) Policy. In this TGP system, the unusual criterion of "individual interchangeability" assists patients wishing to obtain an alternative to a drug in one of these groups whose price has a high additional premium. Readily expanding categories of TGP reference pricing are a fundamental institutional manifestation of the evidence-based distributional justice — seeking a fair balance between price and proven community benefit — required to underpin public expenditure on medicines under section 101(3B[a]) of the National Health Act, as well as the principle of equity of access under the Australian National Medicines Policy.[1]

What are the amendments influencing reference pricing?

The Bill proposes amendments (new sections 85AB, 85AC) to the National Health Act that will divide the current PBS formulary into two. Medicines will be listed on the F1 formulary if there are no "bioequivalent" brands or drugs in reference pricing groups subject to the TGP Policy — these will mostly be patented or "innovative" medicines. The F2 formulary will cover generic medicines.

Once adopted, specific price cuts and disclosures will be imposed *only* on F2 generic medicines. New reference pricing groups subject to the TGP (in addition to the existing six) will have to meet the additional high standard (undefined in legislation) that they are "interchangeable on an individual patient basis" (proposed sections 84AG and 101[3BA]). Reference pricing — as it now operates after PBS listing to produce "flow-on" price drops — will be problematic when the trigger drug is in the F2 formulary (although the latter's existence may cause the F1 comparator to be redefined as an F2).

What lies behind these changes?

I am concerned that at least some of the impetus for this alteration of PBS fundamentals may have come from multinational patented-pharmaceutical companies through mechanisms established by the AUSFTA.

Annex 2C of the AUSFTA,[2] which focuses on the PBS and pharmaceuticals, has led to some positive changes, including public summary documents of PBS drug-listing decisions.[3] However, it also produced a new review mechanism that is triggered after PBAC rejection decisions,[4] with increased opportunities for industry pre-hearings and consultations with technical staff, as well as a Medicines Working Group (MWG) comprising high-level officials on medicines policy from both Australia and the US.[5]

Further, in the past few months policies have been produced for full PBS cost-recovery from industry[6] — despite such "user fees" and increased liaison mechanisms being criticised as creating conflicts of interest for the US Food and Drug Administration that significantly endanger public safety.[7]

Perhaps most significantly with respect to the Bill, Annex 2C.1 of the AUSFTA emphasises the principle of valuing pharmaceutical innovation through either the operation of "competitive markets" (the US position) or by "adopting or maintaining procedures that appropriately value the objectively demonstrated therapeutic significance of a pharmaceutical" (the Australian position).[8] The potential importance to Australian medicines policy of this ambiguous definition of innovation has been highlighted in this Journal[9] and elsewhere.[10]

eMJA Rapid Online Publication 13 June 2007

United States AUSFTA negotiators' instructions on Pharmaceutical Benefits Scheme reference pricing

The US Trade Representative, the Secretary of Commerce, and the Secretary of Health and Human Services were obliged to:

> Bear in mind the negotiating objective set forth in the *Bipartisan Trade Promotion Authority Act* of 2002 to achieve the **elimination of government measures such as price controls and reference pricing** which deny full market access for United States products. In so doing, the agencies shall provide periodic and timely briefings for the Committees of the House and Senate listed above, with an interim briefing no later than 90 days after enactment to address **negotiations to establish a US–Australia Free Trade Agreement** and, as appropriate, other current negotiations.[11] [emphasis added]

AUSFTA = Australia–United States Free Trade Agreement. ◆

We should not forget that the US negotiators to the AUSFTA, who previously worked very closely with senior members of the US patented-pharmaceutical industry on the Industry Functional Advisory Committee on Intellectual Property Rights for Trade Policy Matters, had an explicit legislative mandate to seek the "elimination" of PBS reference pricing (see Box).[11] The same legislation also required the US Department of Commerce to investigate the possible future dismantling of reference pricing in OECD (Organisation for Economic Co-operation and Development) countries.[12] In December 2005, in Paris, the US sought to implement this agenda through the OECD Project on Pharmaceutical Pricing Policies and Innovation.[13]

Australian AUSFTA negotiators provided reassurances about the Annex 2C.1 innovation principle before a Senate Select Committee on 21 June 2004:

> … we went into these negotiations with an absolutely clear mandate to protect and preserve the fundamentals of the PBS. That is what this agreement does … there is nothing in the commitments that we have entered into in Annex 2C or the exchange of letters on the PBS that requires legislative change.[14]

However, when the AUSFTA MWG met for the first time in Washington, DC on 13 January 2006, Australia's Minister for Trade, Mark Vaile, stated that:

> … the core principle that we both agree on in this area … is recognising the value of innovation …[15]

To my way of thinking, this represents a restatement of Australia's position on objective, evidence-based assessment of health innovation, in accord with the National Medicines Policy.

Documents obtained under a Freedom of Information application (organised by Pat Ranald, Australian Fair Trade and Investment Network, 2007) reveal almost nothing of what was said at the first AUSFTA MWG meeting. One disclosed document, presumably discussed, was an opinion editorial in *The Australian*, which argued that: "Truly innovative cures should be referenced against innovation in other classes, rather than against generics"[16] — an approach that seems to reflect the US "competitive markets" method of valuing innovation. The second meeting of the MWG on 30 April 2007 discussed the new F1 category, which had now been structured along the same lines proposed in the editorial the MWG had discussed at their previous meeting (International Trade Law Symposium, Canberra, 4 May 2007, personal communication). The official Australian Government website only disclosed that the MWG "discussions were constructive and informative".[17]

I believe this evidence suggesting a possible, non-transparent link between the definition of innovation in AUSFTA Annex 2C.1, the MWG, and the new F1 PBS category, with its sequestration from post-listing reference pricing against generic medicines, has disturbing implications for sovereignty over Australian public health policy.

The PBS beyond Australia

In its recent free trade negotiations with the US, the South Korean Government demanded a process similar to Australia's current system of evidence-based cost-effectiveness and reference pricing.[18] Article 5.2 of the Republic of Korea–United States Free Trade Agreement, after recognising each nation's differing approach to medicines policy, indicates that if South Korea establishes a reimbursement system for pharmaceuticals or medical devices where the amount paid is not based on "competitive market-derived prices", then it has to "appropriately recognize the value of patented pharmaceutical products" (Article 5.2 [b][i]). Article 5.1 (c) and (e) respectively mention PBS-type "sound economic incentives" as a method of facilitating access to patented medicines and PBAC-style "transparent and accountable" procedures as a means of promoting health innovation. However, Article 5.7 creates a Medicines and Medical Devices Committee, similar to the AUSFTA MWG. Will the parallels continue?

The end of public-funded medicines?

In Australia, it is likely that creating an F1 PBS category where patented drugs are insulated from post-listing reference pricing against generics and required price drops may, in the short term, tempt governments to increase the extent of patient cost-sharing (perhaps through differential means-tested copayments) for high-cost patented medicines. If the proposed amendments are adopted, the incentives for pharmaceutical products to remain within the price-protected F1 class are likely to lead to much more aggressive pharmaceutical patent battles in Australia (taking advantage of intellectual property changes introduced by Chapter 17 of the AUSFTA) that could delay the introduction of cheaper generic medicines.[19] The consequent widening discrepancy between initial listing prices for patented medicines and their therapeutically equivalent generic comparators may become unconscionable.

The evolving higher prices for F1 patented medicines could also provide additional arguments for patented-pharmaceutical industry lobbyists to claim that the PBS is "unsustainable" and that we need to move to a privately financed prepaid insurance system, such as medical savings accounts (a form of medicines superannuation).[20]

If, however, a future Australian government wants to retain public funding of patented medicines and contain PBS expenditure, it could remove, or rigorously define according to established PBAC records, the criteria of "interchangeable on an individual patient basis". It also needs to be clarified that this concept will not interfere with the initial choice of cost-effectiveness comparator, initial cost-minimisation, or the creation of therapeutic relativity sheets that are used by the PBPA to assess post-listing industry requests for price rises. Without such clarification, and a robust mechanism for shifting F1 drugs to the F2, the proposed changes

to the PBS threaten a shift away from the fundamentally evidence-based method of valuing the health innovation of a patented pharmaceutical after listing. They may, instead, push it more towards valuing F1 products through the operation of markets that are nominally competitive, but readily distorted by collusion and advertising.

Much will depend on whether the government protects and supports the independence of officials involved in pharmacoeconomic analysis and vigorous price negotiations with patented pharmaceutical manufacturers (both at first listing and over time), in the MWG and, if necessary, in AUSFTA Chapter 21 dispute resolution procedures.

My concern is that the haste with which this legislation is progressing might lead to this policy choice being delegated to technical experts in finance, or working groups with private interests, rather than being made part of a systematic public debate about the kind of health care system all Australians want to have, and the trade-offs they are prepared to make against strategic objectives of trade or international public policy.

If the Australian regulatory and policy environment for medicines continues to further resemble the inequitable US system, we will similarly have unaffordable innovative products and worse health outcomes (despite low-cost generics) for citizens lacking private insurance with extensive coverage.

Competing interests

I am Director of an Australian Research Council (ARC) grant investigating the impact of international trade agreements on Australian medicines policy. The ARC was not involved in writing this paper.

Author details

Thomas A Faunce, BA LLB, BMed, PhD, Senior Lecturer

Medical School and College of Law, Australian National University, Canberra, ACT.

Correspondence: Thomas.Faunce@anu.edu.au

References

1 Australian Government Department of Health and Ageing. National Medicines Policy. 2000. http://www.health.gov.au/internet/wcms/Publishing.nsf/Content/nmp-objectives-policy.htm/$FILE/nmp2000.pdf (accessed Apr 2007).

2 Australian Government Department of Foreign Affairs and Trade. Australia–United States Free Trade Agreement. 2004. http://www.dfat.gov.au/trade/negotiations/us.html (accessed Mar 2007).

3 Australian Government Department of Health and Ageing. PBAC outcomes and public summary documents. http://www.health.gov.au/internet/wcms/publishing.nsf/Content/pbac-outcomes-and-public-summary-documents (accessed Jun 2007).

4 Australian Government. Independent Review (PBS). http://www.independentreviewpbs.gov.au (accessed Jun 2007).

5 US Department of Health and Human Services. Australia–US Medicines Working Group holds first meeting. 2006. http://www.globalhealth.gov/Australia_meds_011406.shtml (accessed Jan 2006; no longer available).

6 Australian Government Department of Health and Ageing. PBS Latest News. PBS cost recovery consultations are happening. http://www.pbs.gov.au/html/healthpro/news/article?id=NEWS-2007-04-18-Cost_Recovery.xml (accessed Jun 2007).

7 Ray WA, Stein CM. Reform of drug regulation — beyond an independent drug-safety board. *N Engl J Med* 2006; 354: 194-201.

8 Lopert R (Medical Adviser, Pharmaceutical Benefits Branch, Department of Health and Ageing). Senate Select Committee on the Free Trade Agreement between Australia and the United States of America. Canberra: Official Committee Hansard, Monday 21 June 2004: FTA 24. http://www.aph.gov.au/Senate/committee/freetrade_ctte/hearings/ (accessed Feb 2007).

9 Harvey KJ, Faunce TA, Lokuge B, Drahos P. Will the Australia–United States Free Trade Agreement undermine the Pharmaceutical Benefits Scheme? *Med J Aust* 2004; 181: 256-259.

10 Faunce T, Doran E, Henry D, et al. Assessing the impact of the Australia–United States Free Trade Agreement on Australian and global medicines policy. *Global Health* 2005; 1: 15.

11 Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (US) 21 USC conference agreement House Report 108-391 Title XI – Access to Pharmaceuticals. Bipartisan Trade Promotion Authority Act of 2002 (US), 107-210 §2102 (b) (8) (D).

12 US Department of Commerce International Trade Administration. Pharmaceutical price controls in OECD countries: implications for US consumers, pricing, research and development, and innovation. Washington, DC: ITA, 2004. http://www.ita.doc.gov/td/chemicals/drugpricingstudy.pdf (accessed Apr 2006).

13 Scherer P (Head Health Division). Delegates to the OECD Group on Health. Pharmaceutical pricing policy [letter]. Organisation for Economic Co-Operation and Development. 20 Sep 2005.

14 Deady S (Special Negotiator, Office of Trade Negotiations, Department of Foreign Affairs and Trade). Senate Select Committee on the Free Trade Agreement between Australia and the United States of America. Canberra: Official Committee Hansard, Monday 21 June 2004: FTA 12, FTA 16. http://www.aph.gov.au/Senate/committee/freetrade_ctte/hearings/ (accessed Feb 2007).

15 Vaile M (Deputy Prime Minister and Minister for Trade). Joint press conference at the office of the United States Trade Representative, Washington, DC. 7 Mar 2006. http://www.trademinister.gov.au/transcripts/2006/060306_us_jt.html (accessed Jun 2007).

16 Laming A. Let's overhaul the Pharmaceutical Benefits Scheme. *The Australian* 2006; 10 Jan: 10.

17 Australian Government Department of Health and Ageing. AUSFTA – Medicines Working Group – 2007 meeting statement. http://www.health.gov.au/internet/wcms/publishing.nsf/Content/health-ausfta-statement-2007 (accessed Jun 2007).

18 Office of the US Trade Representative. Proposed United States–Korea FTA texts. Chapter Five. Pharmaceuticals and medical devices. http://www.ustr.gov/Trade_Agreements/Bilateral/Republic_of_Korea_FTA/Draft_Text/Section_Index.html (accessed May 2007).

19 Faunce TA, Lexchin J. Linkage pharmaceutical evergreening in Canada and Australia. *Aust New Zealand Health Policy* 2007; 4: 8. http://www.anzhealthpolicy.com/content/4/1/8 (accessed Jun 2007).

20 Delaat W (Chairman of Medicines Australia). National Press Club speech 2005. *Pharma in Focus* 2005; 8 Aug. http://www.pharmainfocus.com.au/news.asp?newsid=825 (accessed Jun 2007).

(Received 26 May 2007, accepted 5 Jun 2007) ❑