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

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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.

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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.

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Competing interests

None identified.

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