Editorial

Drug price reforms: the new F1–F2 bifurcation

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(Aust Prescr 2007;30:138–40)

Significant changes to the Pharmaceutical Benefits Scheme (PBS) are underway. The Australian Parliament recently passed the *National Health Amendment (Pharmaceutical Benefits Scheme) Act 2007*. At the core of this Act are new sections (85AB and 85AC) to the *National Health Act 1953*. These had the effect of dividing, from 1 August 2007, the PBS into two separate formularies – F1, which mostly contains single brand medicines, and F2, which mostly contains multiple brand, mainly generic, medicines (see box).

These complex changes aim to 'recognise the importance of world-class life-enhancing drugs to patients', protect patients from higher costs and get better value from market competition between medicines with multiple brands.[1] The changes may allow PBS and patient savings through lower priced generics, but their impact on the price of patented single-brand medicines is uncertain in our view. Chiefly this is because in future most new patented medicines will be listed in F1 with reduced reference pricing thereafter.

In Australia, overall pharmacy fees vary for products priced below the general patient co-payment ($30.70), and a Choice survey in August 2006 found a wide range in the prices pharmacies charge.[2] This was due to varied application of permissible fees under the Fourth Community Pharmacy Agreement. Australian prices for generic drugs were higher than in countries with larger markets or processes such as competitive tender. In Australia, the price a patient paid for a medicine below the general co-payment depended on the manufacturer's price, wholesale and pharmacy markups, and dispensing fees. Manufacturers could offer generic drugs to pharmacists at large discounts to the prices paid by the PBS. The government therefore considered that it had been paying too much for these medicines. In our view, this consideration unfortunately outweighed policy concerns about the importance of maintaining the full integrity of PBS reference pricing.[1,3]

PBS prices will now be influenced by which formulary a drug is in (Table 1). To add to the complexity, the criteria do not apply to single brand combination products, as they could have components in different formularies.

Drugs which are in F2 are categorised according to the size of the discounts to pharmacy as at 1 October 2006. When the discount was less than 25% the drug is in F2A. Drugs which were heavily discounted by more than 25% are in F2T. The suppliers of drugs in these categories will have to disclose to the Department of Health and Ageing the actual price at which they sell a brand to wholesalers or pharmacies. This requirement applies to new brands of F2A medicines from 1 August 2007 and to new brands of F2T medicines from 1 January 2011. The aim is to ensure that the PBS price is based on the actual supplier price to wholesalers or pharmacy.

A price reduction of 12.5% at the time of PBS listing of the first generic brand of a drug has been required since 2005, and will continue to apply. From 1 August 2008, there will be

F1 contains drugs with a single brand, however it does not contain those single brand drugs that are interchangeable on an individual patient basis with drugs that have multiple brands or single brand combination items.

F2 contains drugs with multiple brands and those single brand drugs that are interchangeable at the individual patient level with drugs that have multiple brands.

In this issue…

There are many balances in medicine. Debra Kennedy writes on balancing the use of antipsychotic drugs during pregnancy with the risk of congenital abnormalities, while Stephen Reddel describes how the benefits of immunosuppression for myasthenia gravis have to be balanced against the adverse effects.

Paul Komesaroff discusses the delicate balance between health professionals and the pharmaceutical industry. Sometimes this balance is upset and can result in promotional activity breaching the Medicines Australia Code of Conduct.

Governments have to balance health budgets and there have been recent reforms of the Pharmaceutical Benefits Scheme. Tom Faunce and Hans Lofgren give their view of the changes.

Table 1

Examples of drugs in the new Pharmaceutical Benefits Scheme formularies *

F1	F2A	F2T
atorvastatin	fluvastatin	simvastatin
bisoprolol	carvedilol	metoprolol
cefuroxime	cephazolin	cephalexin
celecoxib	ketoprofen	naproxen
doxorubicin (pegylated liposomal)	doxorubicin	–
levobunolol	betaxolol	timolol
olanzapine	clozapine	–
reboxetine	–	citalopram, fluvoxamine
salmeterol	–	salbutamol
ticarcillin with clavulanic acid	–	amoxycillin with clavulanic acid
zolmitriptan	sumatriptan	–
–	oxazepam	diazepam

* as at 2007 Sep 11

further compulsory price reductions for F2 drugs: a drop of 2% per year for three years for drugs in F2A, and a one-off price reduction of 25% for drugs in F2T (on 1 August 2008). There are no mandatory price cuts for drugs in F1. There will be compensation for wholesalers and pharmacists for the loss of income from statutory F2 price reductions. For example, from 1 August 2008 pharmacists will receive $1.50 each time they dispense a substitutable brand that costs the patient no more than the co-payment.

Many generic drugs are already priced below the general patient co-payment, and the price reductions to drugs in F2 are expected to result in more drugs falling under the co-payment. The Pharmacy Guild of Australia estimates that the price of more than 400 brands, below the general PBS co-payment, will fall.[4] Complete price and volume data will not be available for drugs once they fall below the general PBS co-payment. Although the Drug Utilisation Sub-Committee of the Pharmaceutical Benefits Advisory Committee (PBAC) receives some data, prescriptions for these drugs do not appear in official statistics of PBS expenditure.

The Minister for Health and Ageing has stated that the role of the PBAC, in assessing cost-effectiveness and cost minimisation and then advising the Minister on the listing of drugs on the PBS, is not affected by the legislation.[5] Yet the responsibilities of the PBAC will be formally extended to include advice to the Minister on exemptions from mandatory price reductions. It will also advise on whether drugs are 'interchangeable on an individual patient basis', a standard more uncertain than the previous, more evidence-based, 'equivalence' tests used to determine Therapeutic Group Premiums for reference pricing. Drugs appearing 'equivalent' on average effects measured in clinical trials, for example, may not be 'interchangeable' for an individual patient.[3] For example, while citalopram and escitalopram were in the same reference pricing group, escitalopram was initially included in F1 and citalopram was in F2T.[6]

The principle of reference pricing, that drugs with identical or similar clinical outcomes should have similar prices, is integral to the architecture of the PBS and the respect it has achieved internationally. In our view, the separation of listed drugs into two groups (F1 and F2), however this is implemented, weakens the role and fiscal benefits of referencing pricing in the PBS.

Although there will be reference pricing within F1, an effect of the changes is to insulate high priced single brand (patented) F1 drugs from price cuts and from the reference pricing that applied under previous PBS processes.[3] Once a new drug is listed on the PBS as F1, its price will not be linked to the price of any similar drug in F2. F1 drugs are not interchangeable at the individual patient level with drugs that have multiple brands, so the manufacturers may be able to retain their original PBS price until the listing of a bioequivalent brand satisfies the new standards for a shift to F2. Reductions in F2 drug prices will not affect F1 prices, even where the therapeutic effect of an F2 medicine is similar though not necessarily 'interchangeable at the individual patient level'.

It is our opinion that the creation of the F1 category will, over time, result in higher prices for some patented drugs than would have been the case under previous PBS arrangements. The government's rationale for this change appears to be that failure to make such changes could result in large 'special patient contributions' or the withdrawal of single-source products from the PBS.[5]

The government, Medicines Australia, the Consumers' Health Forum and several professional groups view the F1–F2 changes as a means of achieving lower prices and greater transparency in the generics market.[6] However, the expectation of price reductions flowing to consumers is premised on trust in effective competition among retail pharmacies. If direct benefits to

patients from lower generic medicines prices or government support for an Australian generics industry had been the primary policy objectives, then more broadly framed legislation could have included pharmacy rewards for meeting generic dispensing targets, an incentive period of market exclusivity for the first generic market entrant, and financial incentives for patients who elect to be dispensed a generic, or for patients whose doctors are prepared to prescribe generic drugs. The role of the patented pharmaceutical industry in promoting and framing these changes is also controversial[7], particularly if the new system allows price reductions to be deferred for some products.

References

1. Department of Health and Ageing. Strengthening your PBS – preparing for the future. Canberra; 2007. http://www.health.gov.au/internet/wcms/publishing.nsf/Content/A2F23E7630B8F9F3CA257227007F1EC7/$File/strengthening-your-PBS161106.pdf [cited 2007 Nov 12]
2. Choice. Prescription prices: survey results summary. 2006 Nov. http://www.choice.com.au/viewArticle.aspx?id=105514&catId=100231&tid=100008&p=2&title=Prescription+prices [cited 2007 Nov 12]
3. Searles A, Jefferys S, Doran E, Henry DA. Reference pricing, generic drugs and proposed changes to the Pharmaceutical Benefits Scheme. Med J Aust 2007;187:236-9.
4. Pharmacy Guild of Australia. Submission to Inquiry into National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2007. http://www.aph.gov.au/Senate/committee/clac_ctte/nat_hth_pbs_07/submissions/sub07.pdf [cited 2007 Nov 12]
5. Parliament of Australia Senate Community Affairs Committee. Inquiry into National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2007. Submissions index. http://www.aph.gov.au/Senate/committee/clac_ctte/nat_hth_pbs_07/submissions/sublist.htm [cited 2007 Nov 12]
6. Pharmaceutical Benefits Scheme (PBS) reform. PBS fact sheet. http://www.health.gov.au/internet/wcms/publishing.nsf/Content/pbs_reform_02feb07.htm [cited 2007 Nov 12]
7. Faunce TA. Reference pricing for pharmaceuticals: is the Australia-United States Free Trade Agreement affecting Australia's Pharmaceutical Benefits Scheme?. Med J Aust 2007;187:240-2.

Conflict of interest: none declared

Letters

Letters, which may not necessarily be published in full, should be restricted to not more than 250 words. When relevant, comment on the letter is sought from the author. Due to production schedules, it is normally not possible to publish letters received in response to material appearing in a particular issue earlier than the second or third subsequent issue.

Managing chronic obstructive pulmonary disease

Editor, – I wonder why alpha-1 antitrypsin deficiency was not mentioned in the article on 'Managing chronic obstructive pulmonary disease' (Aust Prescr 2007;30:59–63). There is worldwide evidence that this genetic problem is much more common than it was thought in the past. In fact the World Health Organization advises that everybody with chronic obstructive pulmonary disease should be tested for alpha-1 antitrypsin deficiency, especially since there is treatment for it, though no cure.

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Professor Michael Abramson, Associate Professor Christine McDonald and Professor Nicholas Glasgow, authors of the article, comment:

We thank Dr Kennedy for drawing attention to the role of alpha-1 antitrypsin deficiency in chronic obstructive pulmonary disease (COPD). This genetic disorder is evidence for the elastase–antielastase hypothesis of emphysema. The prevalence of severe homozygous (ZZ) alpha-1 antitrypsin deficiency has been estimated at around 1/4,727 in European populations.[1] Although 75–85% of such individuals will develop emphysema, tobacco smoking is still the most important risk factor for COPD even in this group. Targeted screening suggests 1–4.5% of patients with COPD have underlying severe alpha-1 antitrypsin deficiency.[2] The index of suspicion should be high in younger patients with predominantly basal disease and a family history. The diagnosis can be made by measuring serum levels of alpha-1 trypsin. If they are reduced, genotyping should be performed. Whether people who are heterozygous (MZ, MS) are also at an increased risk of COPD remains controversial.

Although replacement therapy is available, trials conducted to date have been underpowered to confirm beneficial effects on the rate of decline in lung function or on survival. One placebo-controlled randomised trial suggested some reduction in the loss of lung tissue as assessed by CT scan.[3] Therapy involves intravenous administration of alpha-1 trypsin concentrate purified by fractionation of normal human plasma or recombinant alpha-1 trypsin. These products can restore alpha-1 trypsin levels above the protective threshold for some weeks. Replacement therapy is available through the Special Access Scheme. A national patient support group can be contacted at http://health.groups.yahoo.com/group/Alpha1-ANZ.

References

1. Blanco I, de Serres FJ, Fernandez-Bustillo E, Lara B, Miravitlles M. Estimated numbers and prevalence of PI*S and PI*Z alleles of alpha1-antitrypsin deficiency in European countries. Eur Respir J 2006;27:77-84.