

## Deferring PBAC decisions: rationing as a reality

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At first glance, a decision not to implement a recommendation by the Pharmaceutical Benefits Advisory Committee (PBAC) to list a drug on the Pharmaceutical Benefits Scheme (PBS) seems ridiculous. The Australian PBS has a worldwide reputation for its rigorous cost-effectiveness analyses. What could be the logic for not listing a drug that has been judged to be cost effective? There are several issues to consider.

First, we should recognise that a new drug is judged to be cost effective based on calculations from appropriate clinical trials. These calculations must show that the overall price to be paid (that is, the cost) for one person to live a year longer (adjusted for quality of life) compares favourably with that calculated for other drugs that are already listed on the PBS.

However, such an analysis tells us nothing about how spending money on the drug compares with other possible uses of the money. More lives might be saved, for instance, by spending the money on other areas of the health budget, such as employing more nurses, or even outside the health budget, such as building bicycle paths. In an ideal world, other possible uses of the money would be subjected to cost-effectiveness analyses equal in rigour to those for new drugs. However, the data needed for such analyses are never likely to be available, so judgements must be based on other criteria. This immediately raises the difficult question of what those other criteria should be. However, the difficulty of the question should not mean that we automatically put it in the 'too hard basket'.

Second, we should recognise that the listing of a new drug on the PBS can lead to an increased overall cost to government – in some cases a major increase – despite the drug being assessed as cost effective. For example, the marketing skills of the pharmaceutical industry will often lead to a rapid increase in the overall use of a drug class when there is a new addition to the class, even though the new drug is of equal cost effectiveness to existing drugs within that class. 'Leakage' of indications, where the drug is prescribed for indications other than those on which the cost-effectiveness analysis was based, can also lead to much greater costs without necessarily achieving additional benefits.

Third, even if the drug is cost effective, the cost commences immediately, but the benefits often only accrue in later years. Apart from the practical issue of finding the extra money upfront, this raises the equity issue of today's taxpayers paying for future taxpayers' benefits.

The PBS, for all its virtues, is not perfect. I would argue, for example, that costs will inevitably continue to rise while the PBS is driven by submissions from pharmaceutical companies wanting their products to be subsidised by the public purse. The industry is extremely good at 'playing the game' and tightly controls the design and publication of the trials that generate the data used in cost-effectiveness calculations. It is also expert at marketing its products and creating increased demand (and thus costs), whether or not a true need exists for new products.

## From the Editor



Welcome to the new look *Australian Prescriber*. The first issue of the new design is filled with interesting information.

We begin with Rob Moulds and Brendan Shaw giving their opinions on the decision to defer the inclusion of some new drugs on the Pharmaceutical Benefits Scheme.

The Pharmaceutical Benefits Scheme also provides doctors with a range of drugs for use in an emergency. A table of suggested doses appears in this issue, but are some of the drugs still appropriate for practice in the 21st century? John Holmes assesses the emergency drugs and proposes some changes to the contents of the doctor's bag.

Opioids are not only used in emergencies, but are also prescribed for chronic pain. As there has been an increased use of opioids for non-cancer pain, Michael McDonough advises on how to reduce the dangers of this treatment.

Dangerous drugs need not be prescription medicines. Medicines Safety Update warns us about the hazards of some of the products available from the internet. Patients may not mention that they are using a product such as a complementary medicine. Margaret Duguid reminds us to ask patients about all the medicines they are taking. This is an important part of the process of medication reconciliation which aims to reduce medication errors.

Benjamin Davies is also concerned about drugs and other substances available online. Some substances can be difficult to detect in the laboratory.

Laboratory testing has a role in identifying the cause of fever in travellers. However, Anthony Gherardin and Jennifer Sisson emphasise the continuing importance of a thorough history and examination.

We have become accustomed to a healthcare system where only the best will do, regardless of the cost. My experience of working for many years in a country with far fewer resources than Australia has taught me that good use of older and cheaper drugs can achieve excellent clinical results. Is it really so unreasonable to be asked to use drugs that are 'almost as good' for a bit longer, rather than expect immediate access to every new drug that is assessed to be cost effective?

A positive aspect of the current debate is that it has resulted in a window, albeit brief and probably inadvertently created, during which we can reconsider the whole function of the PBS – which was created to ensure the public had access to new and expensive drugs to treat life-threatening conditions. The PBS continues to be a pillar of the National Medicines Policy, which states 'cost should not constitute a substantial barrier to people's access to medicines they need'.<sup>1</sup>

Is it time to return to basics and start with the conditions that need to be treated, rather than the

drugs for which the pharmaceutical industry is seeking subsidy? Shouldn't we learn from developing countries where guidelines for therapy drive essential drug lists rather than the other way around? Rigorous cost-effectiveness analysis will always be an essential tool in guiding the allocation of public money to the PBS. However, it makes more sense for those analyses to aid the development of guidelines for treating the conditions affecting Australians rather than using them as the sole determinant for adding a new drug to the PBS, which is in practice Australia's essential drugs list. ◀

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## Good use of older and cheaper drugs can achieve excellent clinical results

### REFERENCE

1. Department of Health and Ageing. National Medicines Policy 2000. Canberra: Commonwealth of Australia; 1999. [www.health.gov.au/internet/main/publishing.nsf/Content/National+Medicines+Policy-1](http://www.health.gov.au/internet/main/publishing.nsf/Content/National+Medicines+Policy-1) [cited 2012 Jan 6]

## Deferring PBAC decisions: industry view

The Australian Government's decision in February 2011 to defer the listing of seven medicines and one vaccine on the Pharmaceutical Benefits Scheme (PBS) has been one of the most widely deplored health policies in recent memory. The decision appeared to ignore the advice of the government's own independent, expert advisory committee, the Pharmaceutical Benefits Advisory Committee (PBAC). It was condemned by the innovative and generic medicines industries, and also by patient groups, the medical profession, the broader community and academia. There were also motions in both houses of Parliament and a Senate inquiry.<sup>1</sup> Out of 65 submissions to the Senate inquiry, the only one to support the government's position was that of the Department of Health and Ageing.

It was in the wake of that inquiry that the Prime Minister announced, on 30 September 2011, that the six remaining deferred medicines (paliperidone palmitate, oxycodone/naloxone, budesonide with eformoterol, botulinum toxin type A, dalteparin sodium and nafarelin) would be listed on the PBS on 1 December 2011. The other two products (dutasteride and

pneumococcal conjugate vaccine) had been listed on 1 September 2011. This was a welcome breakthrough to an impasse that had lasted more than seven months.

These listings were particularly good news for the patients who had been waiting for additional affordable treatments for conditions such as severe axillary hyperhidrosis, schizophrenia and chronic pain. In an agreement co-signed by Medicines Australia, the Consumers Health Forum, the Generic Medicines Industry Association and the Australian Government, the signatories committed to continue negotiations to seek a satisfactory solution. The government also agreed that for a period of 12 months no more medicines that cost under \$10 million a year would be deferred while the negotiations continued.

The announcement fell well short of resolving the issue. It was a case of two steps forward, one step back and raised more questions than it answered. The agreement to accept PBAC advice on medicines under \$10 million is a temporary measure which gives little long-term confidence that the government is committed to reversing its policy permanently.

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