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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'.[1]

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.

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

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Deferring PBAC decisions: industry view

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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.[1] 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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On the very same day as the Prime Minister's announcement, another drug, dabigatran, was sent for further review. This was despite a recommendation by the PBAC that the drug be listed on the PBS. Again this has caused significant uncertainty for the companies that supply medicines to the PBS.

For companies submitting medicines for PBS listing, the decision generated enormous uncertainty

Cabinet taking an increasingly interventionist approach to the listing of medicines on the PBS raises a number of questions and concerns for patients as well as the companies that supply the PBS. It is unclear what criteria were used by Cabinet to select which medicines would be listed and which would not.

For the pharmaceutical companies submitting medicines for listing on the PBS, the decision generated enormous uncertainty. After the announcement in February 2011, a number of companies indicated that they would suspend their applications for listing new medicines on the PBS due to the ongoing uncertainty. Eleven out of 26 companies, or around 42%, responding to a Medicines Australia member survey conducted in 2011 indicated that they were considering delaying submissions of new medicines for the PBS because of the government's decision to defer the listing of some medicines.[2] Politicians making decisions about which medicines to list on the PBS effectively adds a new, higher hurdle in the listing process that companies cannot plan for.

For patients, the decisions to defer medicines denied them subsidised access to additional treatment options. While the government argued at the time that there were alternatives available, it became increasingly clear that the deferred medicines provided additional treatment options that were valued by patients and doctors.

The government openly acknowledged that the reason it deferred these medicines and vaccines was not through any lack of efficacy in the medicines themselves, but because of its concerns about its own financial situation. However, the Department of Health and Ageing's own 2011 annual report[3] shows that for 2010–11, expenditure on the PBS grew at 5.7% in nominal terms. Taking into account that inflation grew over the same period at 3.6% suggests that the PBS is growing at around 2% in real terms. This is more or less equal to the government's target for all expenditure growth.

The government's own Intergenerational Report projects that the PBS as a proportion of gross domestic product will be flat until 2020.[4] This means that the government's own projections show that the PBS will not be growing faster than the economy out to 2020. So whatever concerns the government has about broader health expenditure, the PBS is one area that is being well contained. For a major healthcare program to have such minimal growth, while still providing access to the latest medicines to a growing and ageing population, is an extraordinary achievement.

By denying Australians subsidised access to new medicines that have been assessed by experts to be clinically and cost effective, we run the real risk that we will end up with a two-tier health system. High-income patients can afford the most effective and convenient treatment options, while the rest will have to make do with less convenient treatments already on the PBS.

Australia should not be a country where we cannot afford to provide medicines for sick people. Providing industry with some level of predictability improves their ability to provide medicines to Australians through the PBS.

Dr Shaw is Chief executive of Medicines Australia, the industry association representing Australia's innovative medicines industry.

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