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

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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.

A Senate Committee inquiry into the Bill held a public hearing on Friday 15 June 2007, and was required to report the following Monday. The Committee recorded that this provided insufficient time to analyse specific concerns raised in evidence, especially in relation to possible long-term impact of these reforms. The Senate Committee recommended that the Minister report to the Senate 12 months after implementation of the reforms on their impact, particularly on the cost of medicines to consumers.[5] The Bill was amended accordingly.

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.

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