Government administration of the PBS needs more transparency

In the past weeks, the Government's administration of the Pharmaceutical Benefits Scheme has come under significant public scrutiny, highlighting the lack of transparency in the overall process. Dr Teresa Schafer discusses some of the key issues that this raises for the pharmaceutical sector in Australia.

Introduction

The Government's administration of the Pharmaceutical Benefits Scheme (PBS) is under considerable public scrutiny following Cabinet's decision on 25 February 2011 to indefinitely defer the PBS listing of seven new drugs which had been recommended for listing by the Pharmaceutical Benefits Advisory Committee (PBAC).

In the Senate Estimates Community Affairs Legislation Committee hearing on 31 May 2011 (Senate Estimates Hearing), the Department of Health and Ageing (DoHA) cited "fiscal" reasons and the availability of alternative drugs as the reasons for deferral of the PBS listings. These reasons, however, are questionable when they are considered against the reasons and criteria upon which the PBAC recommended the drugs for PBS listing in the first place.

In this submission, we address some of the Terms of Reference of the Senate Inquiry and thereby raise a number of issues regarding the Government's administration of the PBS.

Background

The Government's administration of the PBS is governed by the *National Health Act 1953* (Act) which, *inter alia*, sets out the legislative framework for the listing of drugs on the PBS. In essence, the Act provides that for the purposes of deciding whether or not to recommend to the Minister that a drug should be PBS listed, the PBAC shall consider the effectiveness and cost of therapy of the drug, including a comparison of the effectiveness and cost when compared with alternative therapies.[1] Drugs which are more costly than alternative therapies will not be recommended for PBS listing unless the drug provides a significant improvement in efficacy or reduction of toxicity than alternative therapies.[2]

In practice, new drugs are most commonly recommended by the PBAC on the basis of either cost-minimisation (where the health outcomes are no worse than alternative therapies) or acceptable cost-effectiveness (where the cost of treatment is outweighed by improvements in health outcomes). If the PBAC recommends a drug for PBS listing on cost-minimisation grounds, the price for the new drug will be the same as for alternative therapies. If the PBAC recommends a drug for PBS listing on cost effectiveness grounds, it will be on the basis that the PBAC is satisfied that any increase in the cost of the therapy (when compared with alternative therapies) will be offset by superior health outcomes.

The criteria and advice used to determine medicines to be deferred

In view of the above criteria which govern how the PBAC recommends drugs for PBS listing, the Government's decision to defer PBS listing of seven drugs on 25 February 2011 is questionable. Significantly, there has been minimal transparency and accountability in relation to the criteria that Cabinet used to determine which drugs would be deferred and which would be PBS listed. At the Senate Estimates Hearing, Ms Jane Halton (the Secretary of the DoHA) stated that she could not give details of the criteria Cabinet used to select which drugs would be PBS listed and, in fact, indicated that such criteria do not exist.[3] She added, however, that there were "explanations" for each of the drugs that were PBS listed.[4]

In the exercise of executive power, formal criteria are crucial to ensure proper and consistent government decision making. Given that a company's interests are affected by Government decisions as to whether or not a drug will be PBS-listed, such criteria ought to be in place in order to the demonstrate the legitimacy of a decision and to prevent the arbitrary and subjective exercise of Government power. In this regard, applicant pharmaceutical companies are entitled to know the case they have to meet when their applications are considered by Cabinet and the Minister, and to greater transparency in the Government's administration of the PBS.

The financial impact on the Commonwealth Budget of deferring the listing of medicines

The Government has claimed that the decision on 25 February 2011 to defer PBS listing of seven drugs was substantially based on "fiscal" grounds. On 21 June 2011, Federal Health Minister Nicola Roxon stated in a television appearance on the 7pm Project (Network Ten) that:

> *"No government… has ever wanted to reject or defer an application lightly and when fiscal circumstances are tight, we do need to weigh it up against all the other health expenditure people want like enough doctors, enough hospital beds, enough screening programs…"*

The Health Minister went on to state that the decision to defer some drugs *"where there were other alternative options available"* would facilitate the listing of more costly, new and innovative drugs for which no alternative treatment exists.

The same reasons were also mirrored in the responses from the DoHA in the Senate Estimates Hearing. However, these reasons, *ceteris paribus*, do not make sense when the criteria upon which the PBAC makes its recommendations are considered. As stated earlier, in order for the PBAC to recommend a drug or therapy for listing on the PBS, pharmaceutical companies are required to satisfy one of two criteria: either the drug is no worse than other PSB-listed alternative drugs (cost-minimisation) and is therefore priced at parity with the alternative drugs, or the drug is more cost-effective than other PBS-listed alternative drugs (that is, the cost of treatment is outweighed by improvements in health outcomes).

Arguably, the PBS listing of drugs on cost-minimisation grounds will introduce new alternative therapies which will compete for market share with other drugs which are PBS listed for the same indications. This may actually result in downward pressure on price, which will be reflected in reduced costs and consequent savings for the Government and patients. Even if it could be argued that there is no downward pressure on price, drugs which are recommended for PBS listing on cost-minimisation grounds are priced at parity with respect to their PBS-listed alternatives. An additional market participant will therefore simply adjust the market share of existing alternative treatments, but should not place any additional strain on Government resources.

In relation to drugs which satisfy the cost-effectiveness criteria, the PBS listing of such drugs would theoretically result in superior health outcomes and concomitant savings to Government in expenditure in the overall health portfolio. Accordingly, whilst there may be a perceived increase in the cost to the PBS, this will be offset by savings in other areas of the health portfolio.

The consultation process prior to a deferral

The Senate Estimates Hearing revealed that the deferred PBS listings dated back to prior to July 2010.[5] At that time, only drugs with financial cost implications to the Government of $10 million or more in any one year were referred to Cabinet for PBS listing approval. Conveniently, however, on the same day that the deferral of PBS listing of seven drugs was announced, the Government also announced that all drugs which had a financial implication had to be considered by Cabinet, regardless of cost.

The discourse in the Senate Estimates Hearing regarding one particular drug, Synarel, is particularly noteworthy. The Senate Estimates Hearing disclosed that in response to a previous consideration by the PBAC of ganirelix, a drug used in patients undergoing IVF treatment, the PBAC Secretariat wrote to two companies, Pfizer and Merck Serono, regarding similar medicines marketed by these companies, which the PBAC considered might be suitable for the section 100 IVF/GIFT Program (Program). The PBAC Secretariat advised both companies that the PBAC would be willing to consider applications for the Program. The PBAC Secretariat allegedly wrote to Pfizer, the sponsor of the drug Synarel (nafarelin), on 23 December 2009, and the evidence indicates that Merck Serono, the sponsor of the drug cetrorelix, was also contacted.

The PBAC allegedly stated in its letter that it considered that there was a clinical need for these products on the Program. According to evidence in the Senate Estimates Hearing from Ms Adriana Platona, the Assistant Secretary of the Pharmaceutical Evaluation Branch, *"[i]f one [drug] was listed there [was] always the intention to write to other suppliers to also get some benefit from competition from other suppliers"*. In this regard, Ms Platona confirmed that the Government's motivation, apart from clinical need, was to decrease the cost to the PBS by setting up competition through the PBS listing of alternative drugs.

This raises some very interesting issues. Presumably, the applications which were submitted by Pfizer and Merck Serono to the PBAC in respect of Synarel and cetrorelix, respectively, were based on cost-minimisation. This being the case, the rationale that the PBAC used to "invite" Pfizer and Merck Serono to apply for PBS listing of their drugs is the same rationale that ought to be used to argue that any drugs which the PBAC recommends for PBS listing on cost-minimisation grounds should not be deferred. That being the case, the Government's statement that the reasons that the PBS listing deferrals are substantially fiscal, when four of the seven drugs which were deferred were recommended for listing on cost-minimisation grounds, is clearly flawed.

Interestingly, it appears that Merck Serono's drug, cetrorelix, was PBS listed on 1 December 2010. Given that both Pfizer and Merck Serono were "invited" to apply for PBS listing of their alternative therapies to ganirelix, there may be a legitimate expectation that both drugs would be PBS listed in the event that the PBAC gave a positive recommendation. The fact that there is also evidence that both companies were required to pay the fees of their applications, would arguably strengthen the legitimate expectation. The fact that cetrorelix was PBS listed but Synarel was not raises even more questions about the consistency of decision-making, apprehensions of bias and issues of fair play. Whilst there has been limited judicial testing of decisions of the PBAC and Minister for Health as they relate to PBS listing, flawed decision-making clearly increases the Government's exposure to judicial review actions.

Compliance with the intent of the Memorandum of Understanding signed with Medicines Australia in May 2010 (and re-signed on 28 September 2010)

The intent of the Memorandum of Understanding (MoU) is to promote the *"efficiency and sustainability of the PBS and support, by the provision of a stable pricing policy environment, a viable and responsible medicines industry in Australia"*.[6] It generally provides undertakings in relation to PBS pricing policies and is concerned with promoting stability in the pricing reforms on the PBS that relate to issues such as price disclosure, therapeutic group formations and statutory price reductions after medicines are listed on the PBS.

Clause 4 of the MoU states that the *"Commonwealth undertakes not to implement new policy to generate price-related savings from the PBS for the term of the agreement."*[7] It could be argued that the Government's policy decision to have *all* PBS drug applications reviewed by Cabinet for fiscal reasons is a "new policy" that seeks to "generate price-related savings". Similarly, the policy to indefinitely defer the PBS listings for "fiscal" reasons could also be seen as a new policy to generate price-related savings and could constitute a departure from the undertakings of the MoU.

Furthermore, Clause 29 states that "*for those submissions required to be approved by Cabinet, the Commonwealth will use its best endeavours to implement a maximum time frame of six months for consideration and decision by Cabinet.*" Clearly, a decision by the Government to defer PBS listings indefinitely could be in breach of this undertaking.

Interesting legal questions arise where new Government policies are implemented which are inconsistent with its undertakings under the MoU. If an MoU is not intended to be a legally binding document, it should provide explicitly that the parties do not intend to enter into a legally binding arrangement, but nevertheless intend to comply the MoU's framework. Use of phrases such as *"the parties must"* or *"the parties will"* tend to convey a binding intention, but the law is not clear cut. However, even if the Government's deferral of PBS listings and referral of all recommendations for PBS listing to Cabinet would be unlikely to give rise to an action in contract (for breach of the terms of the MoU), the terms of the MoU do at least raise the question as to whether there is a legitimate expectation on the part of a pharmaceutical company that the Government will comply with the undertakings in the MoU. On this basis, if the Minister has failed to take into account the terms of the MoU and has thereby failed to meet a legitimate expectation which stems from the MoU, it may open the door to a judicial review action.

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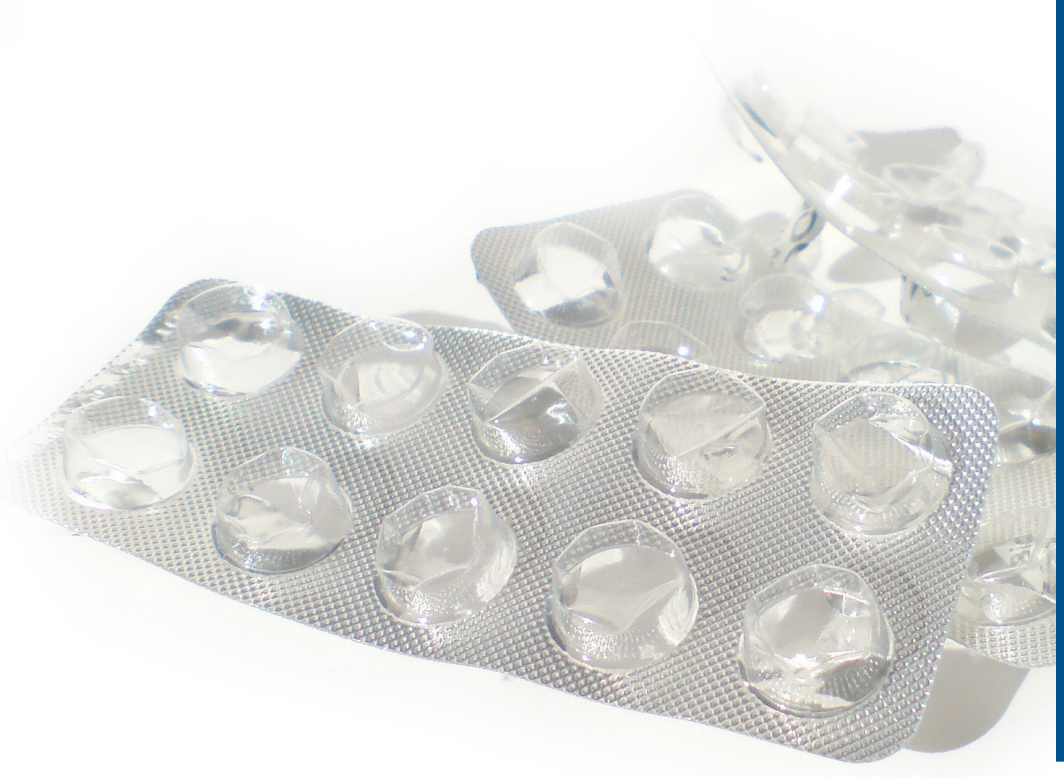
Endnotes

1. Section 101(3A) of the Act.
2. Section 101(3B)(a) of the Act.
3. Senate Estimates Hearing Transcript, at Page 93.
4. Ibid.
5. Senate Estimates Hearing Transcript, at Page 91.
6. Clause 3 of MoU
7. That is from 28 September 2010 to 30 June 2014



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