

Chapter 7

Conclusions and recommendations

7.1 The Government's decision to defer the listing of certain medicines under the Pharmaceutical Benefits Scheme (PBS), despite positive recommendations by the Pharmaceutical Benefits Advisory Committee (PBAC), and the decision to subject all future listings with financial implications for the budget to Cabinet review, constitutes a major, unnecessary and unwelcome change in government policy. This profound and ill-considered change in policy puts at risk affordable access to medicines for Australians, and will have significant consequences for the pharmaceutical sector, including research and development.

7.2 The committee notes the PBS has operated effectively to provide Australian patients with affordable access to necessary medicines since its establishment in 1948, and is a central feature of Australia's health system. A series of reforms have been progressively implemented, in consultation with industry and stakeholders, to improve the operation, cost-effectiveness and timeliness of the PBS system. The benefits of recent reforms have yet to be fully realised.

7.3 The committee acknowledges that the cost of the PBS has continued to grow due to a number of factors including an ageing population, growth in population and the development of new treatments. However, evidence received by the committee has demonstrated that reforms implemented throughout the PBS's history have worked to ensure that the PBS remains sustainable. Submitters strongly argued that the PBS remains affordable for a wealthy country like Australia. Committee members agree with this sentiment.

7.4 The committee also acknowledges that it is the Government's responsibility to be mindful of budgetary constraints, however it considers that responsible fiscal management should be applied at a whole of government level as opposed to trying to create savings through piecemeal and ill-advised policy changes.

7.5 The February 2011 announcement of the deferral of the listing of seven medicines which had been recommended for listing on the PBS by PBAC was claimed by the Government to be a legitimate decision in light of Australia's fiscal position and Budget deficit. In addition to these deferrals, the Government advised that Cabinet would consider all PBAC recommendations for listing of medicines on the PBS that represented a cost to the Government, not just those with cost implications over \$10 million per annum. Again, this was claimed to be based on responsible fiscal management:

Given the need for fiscal discipline to achieve the Government's intention to return the Budget to surplus in 2012–13, all changes to the PBS with financial implications will be considered by the Cabinet.¹

7.6 This announcement came as a complete surprise to industry, consumer and patient groups alike and constituted a significant departure from previous policy. Many organisations felt that they had been negotiating in good faith with the Government regarding ways to ensure the sustainability of the PBS, and were disappointed that they had not been consulted with, or informed prior to, the public announcement on the decision. The committee is concerned that the failure of government to consult with industry and stakeholders prior to taking this decision to change the listing process and the possible contravention at least of the spirit of the Memorandum of Understanding (MOU) entered into by the Government and Medicines Australia will have repercussions when it comes to future negotiations with industry.

7.7 The committee heard universal praise regarding the way that the PBAC carries out its statutory role of comprehensively assessing and recommending the suitability of medicines using health economic models. Submitters argued that the PBAC decision-making process is world-class, as its decisions are based upon recommendations made by an independent group of clinicians and specialists, with cost-effectiveness as a key determinant.

7.8 However, with Cabinet now making decisions about the listing of all medicines with a cost to government without clear criteria or timelines, the integrity of the PBS is at risk. Unlike PBAC processes, it appears that no criteria of any form have been used by Cabinet in coming to its decisions in relation to deferrals and listings. Clearly, the lack of transparency of Cabinet's decision-making process, and the absence of a clear timeframe for the reconsideration and listing of deferred medicines, undermines the integrity of PBS: the Government has abandoned a well-respected, time-honoured, criteria-bound, evidence-based and transparent system for a system which reflects none of these qualities.

7.9 In light of the evidence received, the committee is concerned that the change in policy will lead to a politicisation of the listing process in a number of respects. First, there is a risk Cabinet decision-making will become vulnerable to lobbying. Further, the better resourced stand to exert greater influence, to the exclusion of those smaller and less well-represented groups. Finally, it was noted that the Government has sought to make future listings dependent upon gaining opposition support for other savings measures. The committee is of the view that any such politicisation will only serve to undermine the integrity and quality of Australia's listing process.

7.10 Further, the committee is concerned that the independence and reputation of the PBAC will be irreversibly damaged by the referral of all listings for Cabinet

1 Commonwealth Government, *Portfolio Budget Statements 2011–12: Budget Related Paper No. 1.10: Health and Ageing Portfolio*, Commonwealth of Australia, Canberra, 2011, p. 121.

consideration. Should the recommendations of the PBAC be regularly rejected it will become increasingly difficult to attract and retain experts of the calibre that presently comprise the PBAC. As a result, the Government of the day may be tempted to appoint less independent PBAC members in order to avoid controversy over deferral decisions.

7.11 This Cabinet's lack of understanding of the PBS and medicines policy is evidenced by the Cabinet's failure to appreciate the difference between an assessment of a medicine's effectiveness at a population level as opposed to effectiveness at an individual level.

7.12 The Government has argued that for some deferred medicines there is an alternative already listed on the PBS. However, it is indisputable that medicines may not always be interchangeable for individuals: for some patients these deferred medicines represent a more appropriate treatment, or in some cases, the only effective treatment. The committee considers that the Government's view that medicines with 'alternatives' listed under the PBS can be deferred is based on a poor understanding of the complexities inherent in assessing the effectiveness of medicines for individuals. This essentially creates two classes of people: those who have access to a suitable medicine that is subsidised; and those who do not. In the committee's view, it is unacceptable that, by deferring the listing of these alternatives on the basis that others are available, the Government is undermining the PBS by hindering affordable access to these life-changing treatments.

7.13 The Government has made much of the need to be fiscally responsible in the current economic climate. However, the evidence received by the committee called into question the level of the savings that will actually flow to the Government as a result of the deferral. Witnesses stated that the savings calculations were flawed as they did not take into account patients switching from old medications to new medications. In addition, evidence suggested that patients receiving appropriate treatment will require fewer hospitalisations, fewer appointments with health professionals and fewer treatments to address side-effects and adverse events. Further, the quality of life of consumers will be improved as will their ability to participate in the economy. The committee is of the view that this policy may well only result in comparatively small savings in the short-term and in the long-term the cost of not listing medicines may significantly outstrip these small savings.

7.14 Submitters, including both Medicines Australia and the Generic Medicines Industry Association, opposed the Government's position that new medicines will not be listed until savings are found to offset listing costs and argued that this is not the way to fund or manage the PBS. The committee agrees with this position and is of the view that health outcomes of Australian patients should not be compromised due to the Government's budgetary considerations.

7.15 Many Australian health consumers, particularly those with chronic conditions, already experience significant financial burdens. The committee is concerned that the decision to defer listings will exacerbate the financial distress of some consumers as

the deferral may result in consumers either being unable to afford the medicines they need, or having to go without other essential items in order to purchase unlisted medications. This represents unacceptable cost-shifting to patients who can least afford to bear an increased financial burden. In addition, Australia may end up with a two-tiered system in which newer, more effective treatments will be out of reach for lower-income patients who cannot afford to pay the unlisted price for medicines.

7.16 The committee considers that a lack of timely access to affordable appropriate alternative medications will not only have dire consequences in terms of quality of life and adverse events for individual Australian patients. It will also have repercussions for broader public wellbeing and demands on the public health system.

7.17 The committee is very concerned about the uncertainty which has arisen from the Government's decision to defer the listing of medicines. While companies will always manage risk in making business decisions, prior to the Government's deferral decision risk assessments were based on a long-standing understanding of the PBAC evaluation process and the criteria employed in the assessment of a listing application. However, in the current circumstances, companies are not aware of the criteria which Cabinet is using to make decisions on deferrals—this creates additional risk for companies operating in Australia. The committee is of the view that this added layer of uncertainty will undoubtedly impact on investment decisions by the pharmaceutical sector, to the detriment of health consumers.

7.18 The committee considers that the Government's decision to defer the listing of medicines, and subject all future listing decisions to Cabinet consideration, may have significant implications for the discovery and development of new medicines, and the access of Australian patients to important clinical trials. The committee is concerned that this will disrupt a chain of processes that will ultimately compromise Australian health consumers' access to appropriate and effective medications.

7.19 The committee considers that the unprecedented changes introduced by the Government to the listing of medicines in Australia is unacceptable and is based on short-term and ill-conceived policy goals. The Government has taken a world-class and rigorous evaluation process and replaced it with non-transparent Cabinet deliberations. This will result in poor outcomes for consumers and the health system generally. The committee considers that the Government is exposing Australia's health system to significant risk and should immediately list all medicines deferred and return to the system of Cabinet consideration of medicines with a financial impact over \$10 million.

Recommendation 1

7.20 The committee recommends that the Government withdraw the statement made on 25 February 2011 regarding the deferral of the listing of new medicines and the new rules applying to listings from that point forward.

Recommendation 2

7.21 The committee recommends that the Government retract the statement that PBAC listing recommendations will not be proceeded with until savings are found to offset the costs of listing those medicines under the PBS.

Recommendation 3

7.22 The committee recommends that the Government should explicitly state that it rejects any implication that the listing of new medicines requires savings to be made elsewhere in the health portfolio.

Recommendation 4

7.23 The Government should restate its commitment to making an explicit decision regarding the listing of new medicines on the PBS within the terms and intent of the Memorandum of Understanding signed with Medicines Australia on 6 May 2010 and re-signed on 28 September 2010.

Recommendation 5

7.24 That the Government reinstate the '\$10 million rule' so that medicines that have a financial impact of less than \$10 million in each year over the forward estimates can be listed on the PBS Schedule by the minister without waiting for Cabinet approval.

Senator Scott Ryan
Chair

