

CHAPTER 4

CABINET CONSIDERATION THRESHOLD

4.1 As discussed in Chapter 1, where a medicine being considered for inclusion on the Pharmaceutical Benefits Scheme (PBS) is estimated to cost government more than \$10 million in any of its first four full years of PBS listing, a submission on that drug must be considered by Cabinet.¹

4.2 Some submitters were concerned that the \$10 million threshold, which was originally set during the early 2000s, had not been increased since that time:

...our argument has always been that the threshold should be increased. The \$10 million threshold was set back in 2000 or 2001, and even just by indexing it to inflation it would be up to \$20 million. We think it needs to be increased.²

4.3 Medicines Australia claimed that consideration by Cabinet of high cost medicines delayed the approval process and meant that patients were waiting longer than necessary to gain access to high cost medicines through the PBS:

Our view is that the cabinet process generally adds six to 12 months to listing time. Given that Australians are already waiting three years for a medicine to appear on the PBS, that process needs to be looked at.³

4.4 To address this delay, Medicines Australia suggested that the threshold triggering consideration by Cabinet be increased:

...we certainly believe that the \$10 million threshold introduced at the turn of the century should be increased as recommended by the government's own Productivity Commission. It makes no sense that patients are being made to wait for sometimes life-saving treatments for a bureaucratic process whose rationale is unclear at best when those medicines have already been rigorously evaluated. At the very least, there are some medicines that simply should not get trapped in the cabinet process, and we are asking for the threshold to be updated to take account of that.⁴

4.5 The Consumers Health Forum of Australia (CHF) supported this proposal:

CHF notes the proposal in a number of other stakeholders' submissions that the threshold for cabinet approvals be increased from \$10 million to \$20

1 Department of Health and Ageing (DoHA), *Submission 27*, p. 20.

2 Dr Brendan Shaw, Chief Executive, Medicines Australia, *Committee Hansard*, 7 May 2010, p. 11.

3 Dr Brendan Shaw, Chief Executive, Medicines Australia, *Committee Hansard*, 7 May 2010, p. 11.

4 Mr Will Delaat, Chairman, Medicines Australia, *Committee Hansard*, 7 May 2010, p. 3.

million. CHF would not be opposed to this increase, particularly where it would expedite access to necessary medicines.⁵

4.6 In its 2008 *Annual Review of Regulatory Burdens: Manufacturing and Distributive Trades* report, the Productivity Commission noted:

The \$10 million threshold has not been indexed and will be triggered more often as the cost of medicines increases. The Government should consider the merits of increasing the threshold to account for price changes over the past six months and implementing an automatic annual indexation adjustment.⁶

4.7 In the interest of Australian patients having timely access to necessary medicines, the committee is of the view that the threshold for Cabinet consideration of high cost medicines be increased. Initially, the threshold should be adjusted to the value it would have had, had it been indexed annually since 2001 (when the threshold was introduced). From then on, the threshold should be indexed annually.

Recommendation 4

4.8 The committee recommends that:

- **the threshold for Cabinet consideration of high cost medicines be adjusted, initially to the value the threshold would have had, had it been indexed annually since 2001;**
- **subsequently, the threshold should be indexed annually; and**
- **the Department of Health and Ageing examine the most appropriate indicator for indexing the threshold.**

5 Ms Carol Bennett, Executive Director, Consumers Health Forum of Australia (CHF), *Committee Hansard*, 7 May 2010, p. 61.

6 Productivity Commission, *Annual Review of Regulatory Burdens: Manufacturing and Distributive Trades*, September 2008, p. 80.