

Australian Greens Additional Comments

Introduction

1.1 The Government's decision to defer the listing of seven drugs and one vaccine on the PBS has been universally condemned by the pharmaceutical industry, health practitioners and consumers. The Australian Greens agree with the evidence received to this effect and support the recommendations of the majority report. The Government should resile from its current strategy of reviewing all listing decisions in cabinet and looking for short-term savings by deferring individual medicines.

1.2 However, we acknowledge the necessity of the executive Government's role in the listing process. All decisions of the PBAC are based on a solid cost-benefit analysis, so all recommendations are therefore a sound long-term investment in the nation's health. There may be cases where a genuine conflict arises between long-term benefits - which may accrue over decades - and the exigencies of short-term budget management. For this reason, it's appropriate that the Government should have the final say on the timing of additions to the Schedule. It is important that any such decisions are made via a process that is open, transparent and accountable.

1.3 As the Government noted in relation to funding bowel cancer screening versus funding a late stage bowel cancer drug, there are competing and urgent priorities for every health dollar,¹ and it is important that the PBS operate as efficiently as possible. Evidence to the inquiry suggests several other avenues that may be more profitably explored as ways to achieve better PBS efficiency.²

Achieving lower priced generic medicines

1.4 Several witnesses and other analysts have suggested that the price paid for generic medicines is high by world standards and there are large savings still to be realised in this area.³ Statutory price reductions combined with mandatory price disclosure have led to some savings, but creates little incentive for generics companies to discount heavily in order to gain market share. Further gains may be made if the incentives could be realigned.

1 The Hon. Nicola Roxon, MP, Minister for Health and Ageing, Commonwealth of Australia, Transcript, Press Conference-Canberra, 21 June 2011, [p.4].

2 Dr Brendan Shaw, Chief Executive, Medicines Australia, *Committee Hansard*, 25 July 2011, p. 25; Australian Medical Association, *Submission 16*, pp 3–4; Generic Medicines Industry Association, *Submission 31*, pp 4 and 6–7; Mr John Latham, Chairman and Managing Director, Pfizer Australia, *Committee Hansard*, 21 July 2011, p. 31; Chronic Illness Alliance, *Submission 4*, pp 5–6.

3 Chronic Illness Alliance, *Submission 4*, pp 5–6; Generic Medicines Industry Association, *Submission 31*, pp 5–7; Mr John Latham, Chairman and Managing Director, Pfizer Australia, *Committee Hansard*, 21 July 2011, p. 31.

1.5 Tendering, along the lines employed in New Zealand, has usually been discounted in Australia as being incompatible with a thriving generics industry. However, other mechanisms have been suggested. Dr Liliana Bulfone has outlined a scheme⁴ in which generics manufacturers make private bids, and are listed on the Schedule at the lowest price for that drug. Other brands then attract a corresponding brand premium at the pharmacy, which may encourage generics manufacturers to make further discounts in order to be able to secure and hold market share.

1.6 Reform in this area is particularly important as 'blockbuster' drugs such as Lipitor® (atorvastatin) go off-patent. With billions potentially to be saved⁵ this seems a more worthwhile area of potential reform than ad hoc deferrals of PBAC approved medicines. A strengthening of price reporting and price reduction mechanisms, within and across therapeutic groups, should be considered.

Evergreening of patents by originator companies

1.7 Delays in the introduction of generic versions of widely-used drugs can have a significant effect on PBS expenditure. The committee heard testimony about the 'evergreening' of patents, where originator companies use the copyright system or minor and even spurious innovations to litigate and extend the patent protection of their drugs.⁶ This can have the effect of deferring, for a period of years, the availability of cheaper generic medicines on the PBS with a subsequent cost to the public purse.

1.8 Reform in this area is difficult as the integrity of the patent system and intellectual property rights must be maintained. In the case of a dispute over the expiration of a pharmaceutical patent, it is clearly up the originator company and the generic medicines industry to litigate the intellectual property issues. If the generic manufacturer is successful, they are able to recoup lost profits from the originator company for the period by which the introduction of a generic drug was delayed. Under these circumstances, the Commonwealth has not sought to recover the costs to the PBS which can be substantial. Attempts to do so would have to be reconciled with the rights of patent holders to defend genuine claims, but if the Commonwealth was able to recover some of these costs, the incentives to use the courts to delay generics

4 Bulfone, Liliana. High prices for generics in Australia: More competition might help [ZPaper in special issue: The Pharmaceutical Benefits Scheme and the Dilemmas of Medicines Policy. Lofgren, Hans (ed).] [online]. Australian Health Review, v.33, no. 2, May 2009: 200–214. <<http://search.informit.com.au/fullText;dn=200909889;res=APAFT>>

5 Clarke PM, Fitzgerald EM. Expiry of patent protection on statins: effects on Pharmaceutical expenditure in Australia. *Med J Aust* 2010; 192: 633-636.

6 Ms Kate Lynch, Chief Executive Officer, and Mr Robert Ellis, Board Member, Generic Medicines Industry Association, *Committee Hansard*, 21 July 2011, pp 10–11; Generic Medicines Industry Association, *Submission 31*, p. 5.

manufacturers without a solid basis would be lessened. In some instances, savings to the PBS could amount to tens of millions of dollars.⁷

Savings from change of prescriber habits

1.9 The cost impact of listing a medicine on the PBS is often difficult to predict as it can be heavily dependent on the take-up by prescribers. The issue of 'leakage', where drugs are prescribed outside of their anticipated therapeutic group, is well known. This real-world variation in prescriber behaviour could have an impact on the cost-effectiveness of the drug, for instance, if a drug becomes widely prescribed under sub-optimal therapeutic settings. Although it makes clear sense for the price of drugs to be reviewed, a review of the cost-effectiveness may suggest areas where doctor education or a change in the listing settings could make significant savings. For example, one of the most prescribed PBS medicines is Lipitor® 40mg (atorvastatin). In many cases, a lower dose may provide the same clinical outcome, but there is currently little reason for doctors to start at a smaller (and cheaper) dosage or reduce the dosage at a later date. There is potential for significant savings to be realised through a combination of education of practitioners and changes to the therapeutic conditions attached to a drug's listing.

Recommendation 1

That the Government investigate alternative methods of pricing generic medicines as an alternative cost-saving measure to the deferral of listings by Cabinet.

Senator Richard Di Natale

7 The Generic Medicines Industry Association suggests, for instance, that the delay (by Sanofi-Aventis) in the introduction of generic clopidogrel in Australia cost the PBS over \$60 million.

