Chapter 4

Financial impact of the Pharmaceutical Benefits Scheme on the Commonwealth Budget

Introduction

4.1 The decision of Cabinet to defer listings of Pharmaceutical Benefits Advisory Committee (PBAC) approved medicines in February 2011 was predicated on budget savings and 'the need for fiscal discipline'.[1] The committee heard that not only is the Pharmaceutical Benefits Scheme (PBS) an affordable investment, but that the anticipated savings from the decision are small. It appears that the decision represents a major false economy, with a failure to consider the broader health economic gains that could be achieved with more appropriate medicines. The committee received evidence of more effective ways that savings could be made.

Overall costs and growth of the PBS

4.2 The committee heard that the cost of the PBS continues to grow, and is probably growing faster than other similar size or magnitude health programs.[2] The Department of Health and Ageing (DoHA) explained that:

> The cost of the PBS has continued to grow over the past ten years, averaging growth of about nine percent a year and it is estimated it will cost about $9 billion this financial year (2010–11). This growth rate is higher than the six percent annual increase for general hospital and medical services, and much higher than the Consumer Price Index.
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> Given current fiscal circumstances, the Government is concentrating on listing medicines that treat serious or life threatening conditions where there are no alternative treatments.[3]

4.3 Mr David Learmonth, DoHA, provided further detail to the committee:

> In 2009–10, around 184 million PBS subsidised prescriptions were dispensed, at a cost of $8.3 billion expenditure and, in 2010–11, it is estimated to be around $9 billion. As reported in the portfolio budget statements 2011–12, in 2008–09 PBS growth was 9.2 per cent. In 2009–10,

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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.

2 Mr David Learmonth, Deputy Secretary, Department of Health and Ageing, *Committee Hansard*, 25 July 2011, p. 11; Mr David De Carvalho, First Assistant Secretary, Social Policy Division, Budget Group, Department of Finance and Deregulation, *Committee Hansard*, 25 July 2011, p. 11.

3 Department of Health and Ageing, *Submission 46*, p. 7.

> PBS growth was nine per cent. In 2010–11 and 2011–12, PBS growth is estimated to be 7.7 per cent and 6.5 per cent respectively.[4]

4.4 The committee heard that it is to be expected that expenditure on the PBS will increase as many medicines didn't even exist 25 years ago. A higher level of spending is appropriate because there is more to spend it on and people are being treated when they otherwise would not have been.[5]

4.5 However, Medicines Australia questioned whether PBS growth is inappropriately high and therefore a threat to the long-term sustainability of the PBS. They submitted that:

> Such assertions are rarely accompanied by any serious analysis or questioning of what an appropriate rate of growth is for pharmaceutical (or health care) expenditure in a highly developed and ageing country such as Australia.[6]

4.6 Medicines Australia also argued that the growth of the PBS is at historic lows:

> For 2009–2010 expenditure on the PBS grew at 9%. Whilst final data from 2010–2011 are not yet available, Medicines Australia anticipates that the figure is likely to fall from the 2009–10 figure to between 6% and 8%, a view that accords with the Treasury's own projections. Further, although sometimes volatile and uncertain due to data lags, publically available Medicare data show that growth has slowed during 2010–2011 relative to that experienced during 2009–2010.[7]

4.7 In addition, Medicines Australia contended that the most appropriate metric for judging the appropriateness of the level of government health expenditure is in fact Gross Domestic Product (GDP) and stated that:

> By this measure, pharmaceutical expenditure in Australia has hovered between 0.6% and 0.65% of GDP for over a decade. The Government's own Intergenerational Report 2010 adopted this approach and projected that the PBS as a proportion of GDP will rise only to 0.7% in the time period to 2020.[8]

4.8 Submitters and witnesses put the view to the committee that the PBS is affordable.[9] The Generic Medicines Industry Association (GMiA) submitted that 'of

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4 Mr David Learmonth, Deputy Secretary, Department of Health and Ageing, *Committee Hansard*, 25 July 2011, p. 1.

5 Mr Mark Glover, Vice President and Managing Director, Allergan Australia, *Committee Hansard*, 21 July 2011, p. 24.

6 Medicines Australia, *Submission 36*, p. 24.

7 Medicines Australia, *Submission 36*, p. 25.

8 Medicines Australia, *Submission 36*, p. 27.

9 Generic Medicines Industry Association, *Submission 31,* p. 4.

24 reporting OECD nations, Australia has the third lowest spend on pharmaceuticals as a percentage of GDP'.[10] Mr Robert Ellis of GMiA also told the committee that:

> We are providing one of the lowest cost health systems of any OECD country. We are providing a brilliant quality of life here and a key part of that is the PBS, with the PBS being a very affordable instrument of government and an aspect of providing the healthcare system.[11]

4.9 It was also argued that 'the PBS is an important investment to maintain the current and future health of Australians that may reduce the need for more costly acute services long term'.[12] Dr Brendan Shaw of Medicines Australia told the committee that that the PBS is a sustainable, well-run program that delivers major benefits to the health of the nation.[13]

4.10 While the general view was that the PBS is affordable, other submitters were supportive of the need for the Government to exercise fiscal responsibility in relation to pharmaceutical expenditure. Yet they expressed concerns with the process to cut costs through the deferral of listings. Deakin Health Economics elaborated:

> We understand and agree that there is a limit to how much money a government can spend on pharmaceutical products and that funds directed to pharmaceuticals have an opportunity cost (i.e., there are always competing priorities that need to be balanced and managed). We also appreciate that the decision about how public funds should be allocated rests with Government. We therefore wish to make it clear that we don't have any issues with the principles expressed that government may need to prioritise spending within and across various government programs. However, we have a number of concerns around the process that the Government is using to prioritise the PBAC's recommendations into a list of medications that should be listed on the PBS without delay and a list of medications where listing on the PBS can be delayed.[14]

Financial impact of the Government decision to defer listings

4.11 The Government has stated in the *Portfolio Budget Statements 2011–12* that the listing of some medicines would be deferred till fiscal circumstances permit. The minister has stated that 'our government makes commitments to ensure that every bit

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10 Generic Medicines Industry Association, *Submission 31,* p. 4.

11 Mr Robert Ellis, Board Member, Generic Medicines Industry Association, *Committee Hansard*, 21 July 2011, p. 12.

12 SANE Australia, *Submission 10*, [p. 2]. See also iNova Pharmaceuticals (Australia), *Submission 11*, p. 2; Council of Social Service Network, *Submission 7*, p. 5.

13 Dr Brendan Shaw, Chief Executive, Medicines Australia, *Committee Hansard*, 25 July 2011, p. 25.

14 Deakin Health Economics, Deakin University, *Submission 19*, pp 2–3.

of expenditure is balanced by savings'.[15] In relation to the financial impact on the Commonwealth Budget of deferring the listing of medicines, DoHA submitted that:

> The cost of individual measures considered by the Cabinet, including potential PBS listings are Cabinet in Confidence.
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> As has been previously publicly advised, the total cost of the PBS medicines deferred is over $100 million.[16]

4.12 However, submitters provided other estimates of the savings from the deferrals and argued that it was a relatively small amount. Dr Shaw of Medicines Australia told the committee that it is difficult to estimate savings as a result of the decision to defer listing:

> ...but our back-of-the-envelope calculation is about $20 million to $25 million a year per year for the four-year period, which in a scheme of $8 billion or $9 billion a year seems to me to be a relatively small percentage of that scheme for the impact that it is going to have on the future listing of new medicines.[17]

4.13 The Australian Medical Association (AMA), Consumers Health Forum of Australia (CHF) and Deakin Health Economics also commented that the cost of a new medicine must also take into account any decrease in the use of an alternative medicine already listed.[18] Ms Liliana Bulfone of Deakin University explained:

> If they use the new drug, they are not using the old drug. The cost of one is just transferred to the other, so that is a false saving. For that reason the government is trying to say that it is having it both ways and that is just not possible.[19]

4.14 In addition, it was argued that Australia's financial position is not so dire that the listing of the deferred medicines would have a catastrophic impact. The Council of Social Service Network for example, stated that:

> We do not believe that the current economic outlook is so exceptional[ly] dire that funding the medicines would jeopardise Australia's financial

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15 The Hon. Nicola Roxon, MP, Minister for Health and Ageing, Press Conference – Canberra, *Transcript*, 21 June 2011, [p. 3].

16 Department of Health and Ageing, *Submission 46*, p. 16.

17 Dr Brendan Shaw, Chief Executive, Medicines Australia, *Committee Hansard*, 25 July 2011, p. 26.

18 Australian Medical Association, *Submission 16*, p. 2; Ms Liliana Bulfone, Senior Research Fellow, Deakin University, *Committee Hansard*, 21 July 2011, p. 2. See also Ms Carol Bennett, Chief Executive Officer, Consumers Health Forum of Australia, *Committee Hansard*, 25 July 2011, p. 41.

19 Ms Liliana Bulfone, Senior Research Fellow, Deakin University, *Committee Hansard*, 21 July 2011, p. 2.

> position or that funds could not be made available from other areas of the budget.[20]

4.15 While there may be savings to the Government in this Budget cycle, many submitters argued that deferring listing on the PBS was a false economy in the longer-term. It was noted that the medicines considered by Cabinet have already been rigorously assessed by the PBAC and recommended on the basis of their cost-effectiveness so that the additional costs to the PBS are justified by improvements in health. The Council of Social Service Network commented that the Government has not challenged the PBAC's assessment of cost-effectiveness of the deferred medicines.[21] The Western Australian Government also commented:

> ...in its decision making process, PBAC does take into account, the net costs and benefits of a new medicine and adopts a principle of cost-effectiveness or value for money. For these reasons, it would be reasonable to expect that the cost impact of introducing these drugs onto the PBS would be marginal.[22]

4.16 Submitters commented that the PBS is an important investment in maintaining the current and future health of Australians which may reduce the need for more costly acute care in the future. It was argued that it appears that the Government has not considered the broader health economic gains that could be achieved with timely access to appropriate medicines.[23] The AMA, for example, stated:

> Access to a range of proven medicines funded under the PBS allows medical practitioners to make decisions about the optimal medical treatment of the patient, based on the patient's particular clinical circumstances, without patients having to make decisions about what they can afford.[24]

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20 Council of Social Service Network, *Submission 7*, p. 5.

21 Council of Social Service Network, *Submission 7*, p. 5.

22 Government of Western Australia, Department of Health, *Submission 63*, p. 2.

23 Research Australia, *Submission 12*, [p. 3]; Chronic Illness Alliance, *Submission 4*, pp 4–5; Dr Christine Walker, Executive Officer, Chronic Illness Alliance, *Committee Hansard*, 21 July 2011, p. 39; Mental Illness Fellowship of Australia, *Submission 13*, pp 2–3; Diabetes Australia, *Submission 6*, p. 2; Private Mental Health Consumer Carer Network (Australia), *Submission 1*, p. 2; Mr Bruce Goodwin, Managing Director, Janssen-Cilag Australia, *Committee Hansard*, 21 July 2011, p. 28; Ms Helen Tyrrell, Chief Executive Officer, Hepatitis Australia, *Committee Hansard*, 25 July 2011, p. 53; Council of Social Service Network, *Submission 7,* p. 5; Brain Tumour Alliance Australia, *Submission 17*, p. 5; Breast Cancer Network Australia, *Submission 24*, p. 3; Arthritis Australia, *Submission 25*, p. 2; National Seniors Australia, *Submission 50*, p. 2; The Royal Australasian College of Physicians, *Submission 61,* p. 1.

24 Australian Medical Association, *Submission 16*, p. 2.

4.17 As a result, short-term savings of deferring the listings may therefore be mitigated by the longer-term negative financial impact on the Budget.[25] Ms Carol Bennett of CHF articulated these concerns to the committee:

> ...consumers have rejected the argument that deferring listing of medicines on the PBS will bring the budget back into surplus. Quite aside from the fact that the PBAC already considers whether these medicines are cost-effective, there are considerable savings to be made across the budget if people have access to the right medicines that meet their treatment needs. Consumers receiving the right treatment will require fewer hospitalisations, fewer appointments with health professionals and fewer treatments to address side-effects. And, beyond the health budget, consumers receiving effective treatments are more likely to be able to participate more fully in society, contributing to the workforce and as taxpayers. [26]

4.18 These concerns were echoed in a joint submission from Cancer Council Australia, the Clinical Oncological Society of Australia and the Medical Oncology Group of Australia:

> Drugs that the PBAC recommends for PBS listing have been assessed as both effective and cost-effective against existing treatments so they represent equivalent or better efficacy and value than existing drugs. If the new drugs are not listed on the PBS then medical practitioners will need to continue prescribing existing medications. This means that costs will still accrue to the PBS. In addition, if the existing drugs are less effective or more toxic than the new drugs, then cost savings from the new drugs will not be realised, such as reduced medical or hospital costs through better management of side-effects.[27]

4.19 The committee was provided with an example of how the timely access to medicines can have a broader positive economic effect. Although the effective treatment of HIV/AIDS is dependent on new and emergent medicines, there are significant public health benefits from treatment, which in turn accrues savings. This was stressed by the National Association of People Living with HIV/AIDS:

> As the health of a person with HIV is improved the amount of virus they carry is reduced to very low levels, thus making onward transmission of the virus very difficult.[28]

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25 Diabetes Australia, *Submission 5*, p. 1; Council of Social Service Network, *Submission 7*, p. 5; Ms Barbara Hocking, Executive Director, SANE Australia, *Committee Hansard*, 25 July 2011, p. 49.

26 Ms Carol Bennett, Chief Executive Officer, Consumers Health Forum of Australia, *Committee Hansard*, 25 July 2011, p. 36. See also Mr Brian Stafford, *Submission 3*, [pp 1–2].

27 Cancer Council Australia, the Clinical Oncological Society of Australia and the Medical Oncology Group of Australia, *Submission 32*, p. 2.

28 National Association of People Living with HIV/AIDS, *Submission 6*, p. 1.

4.20 The committee was also provided with an example of how the listing of a specific medicine, Targin®, could actually save the Government money, contrary to claims made by DoHA. Dr John Whitlam explained that 'in answer to a question, the deputy secretary of Department of Health and Ageing had said that there will be no savings from the reduction of opioid induced constipation'. Dr Whitlam went on to explain that this is actually not correct, 'In fact, we agreed with the department itself that there will be a saving of $6.5 million over five years'.[29]

4.21 Dr Whitlam went on to argue that by listing Targin® there would also be cost-savings to the Government through the reduction in abuse and diversion of OxyContin. He noted that in answer to a question regarding such savings 'the deputy secretary responded that he was not aware that the Government would have those figures'. Once again, Dr Whitlam stated this was a 'misrepresentation':

> ... we agreed with his department that there would be a cost saving of $8.4 million over five years. Therefore, inherently, Targin is not just oxycodone containing a laxative if we are getting cost savings of that nature.[30]

4.22 The view was also put to the committee by the Chronic Illness Alliance that the deferral decision represents a change in priority from timely access to affordable medicines to budgetary considerations, and represents a cost shift to patients. Similarly, Multiple Sclerosis (MS) Australia submitted:

> Where people with MS are concerned the most important aspect of this deferral relates to budgetary considerations seeming to outweigh the established operations of the PBS evaluation system.[31]

4.23 It was also submitted that the deferral decision shifted costs from the Commonwealth Government to the Northern Territory Government Department of Health:

> As cost could represent a significant barrier to access of some medicines, where clients are unable to meet the cost, these medicines are funded by the Department until they are PBS listed. For this interim period, until the Australian Government effectively subsidises the medicine, the cost is typically borne by the Department.[32]

Committee comment

4.24 The committee notes that the Government's decision does indeed represent a false economy, failing as it does to take into consideration that patients receiving

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29 Dr John Whitlam, Medical Affairs Director, Mundipharma, *Committee Hansard*, 21 July 2011, p. 32.

30 Dr John Whitlam, Medical Affairs Director, Mundipharma, *Committee Hansard*, 21 July 2011, p. 32.

31 Multiple Sclerosis (MS) Australia, *Submission 43*, pp 5–6.

32 Northern Territory Government, Department of Health, *Submission 62*, p. 2.

appropriate treatment will require fewer hospitalisations, fewer appointments with health professionals and fewer treatments to address side-effects. While comparatively small short-term savings may be found, the longer-term costs of this policy will outweigh any savings.

Other possible savings measures

4.25 A number of industry organisations explained to the committee that they had been responsive to government concerns about ensuring the financial sustainability of the PBS. As an example, Mr Andrew Bruce of Medicines Australia told the committee that:

> One of the things is that when the government came and expressed anxieties around the fiscal elements of the PBS we sat down with them. We tried to put in long-term policy settings which would get ongoing efficiencies to the market.[33]

4.26 The committee heard that savings flowing from the Memorandum of Understanding (MOU) between Medicines Australia and the Commonwealth Government in November 2010 were estimated to be at least $1.9 billion. Dr Shaw of Medicines Australia noted that 'these savings are yet to flow through the system, and we expect still more savings in addition to these, going forward'.[34] These large savings could be contrasted with estimated savings of $20 to 25 million per year, over four years, as a result of the decision to defer listings.[35]

4.27 The AMA provided a number of suggestions that they argue could reduce unnecessary PBS outlays with the potential to provide significant savings. They submitted that the Government should:

- maximise use of the Personally Controlled Electronic Health Record (PCEHR) by prescribers in order to reduce PBS outlays for duplicate scripts, and reduce adverse events;
- cease implementation of the 'continued dispensing' measure in the 5th Community Pharmacy Agreement that allows pharmacists to dispense PBS medicines without prescription or reference to a medical practitioner. This will address the continued dispensing of medicines that are no longer required, providing for significant savings;
- withdraw prescribing rights under the PBS from non-medical practitioners; and

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33 Mr Andrew Bruce, Executive Director, Health Policy and Research, Medicines Australia, *Committee Hansard*, 25 July 2011, p. 34.

34 Dr Brendan Shaw, Chief Executive, Medicines Australia, *Committee Hansard*, 25 July 2011, p. 25.

35 Dr Brendan Shaw, Chief Executive, Medicines Australia, *Committee Hansard*, 25 July 2011, p. 26.

- ensure the mandatory price disclosure rules are fully implemented including in cases of one-off discounting, and by prohibiting bulk purchasing in the first month of the price disclosure year.[36]

4.28 The GMiA noted that the recent reforms to the PBS were designed to achieve greater value for money paid by the Commonwealth for medicines subject to competition.[37] However, they submitted that 'the Government is not fully leveraging the savings opportunity stemming from the reforms'.[38]

4.29 The GMiA submitted three key recommendations that they argued would 'ensure that Australians continue to have access to essential medicines through the PBS':

- counter market strategies deployed by holders of intellectual property for PBS listed medicines that inappropriately impede the market entry of follow-on generic medicines;
- ensure sponsors have the opportunity to successfully obtain price increases for specific medicines granted under the rigorous PBPA review mechanism; and
- direct new policies at doctors, pharmacists and consumers to ensure that further savings accrue to the Government from increased usage of follow-on generic medicines.[39]

4.30 The GMiA also noted that restrictive medicines pricing policy can lead to increased prices over time and stated:

> The Federal Government's decision to defer indefinitely price increases recommended by the PBPA on the basis of demonstrated commercial grounds, for PBS listed medicines with a demonstrated cost-effective, medical need and no alternative substitute medicine, significantly jeopardises the ongoing supply of these essential medicines to patients.
>
> Price increases are generally only recommended by the PBPA where the sponsor can demonstrate a clear commercial need AND where there is no alternative medicine available at a more competitive price.
>
> ...Restrictive prescription medicine pricing policy can result in the exit of major generic players, reduced competition in the market place and eventual increased prices of generic medicines over time.[40]

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36 Australian Medical Association, *Submission 16*, pp 3–4.

37 Generic Medicines Industry Association, *Submission 31*, p. 4.

38 Generic Medicines Industry Association, *Submission 31*, p. 4.

39 Generic Medicines Industry Association, *Submission 31*, p. 4.

40 Generic Medicines Industry Association, *Submission 31*, pp 6–7.

4.31 Finally, the GMiA explained why new policies directed at doctors, pharmacists and consumers would ensure that further savings accrue to the Government from increased usage of follow on generic medicines:

> Every time a follow-on generic medicine is dispensed in Australia, in place of the initial brand, savings are delivered to the national economy. However, the Government is missing out on making significant savings because the opportunity to use a follow-on generic medicine occurs only about half as often as it does in, say, the US. Further, on more than one in every four of those occasions, a follow-on generic medicine - the only kind that drives savings to the national economy - is not dispensed. These savings are lost because of an absence of policies – commonly applied in comparable economies overseas – that promote the timely availability, dispensing and usage of follow-on generic medicines.[41]

4.32 Mr John Latham of Pfizer Australia commented on medicines coming off patent and noted that over the next five years $2.4 billion worth of products currently on the PBS will come off patent. He explained:

> That is going to be a major savings for the government. Once these drugs come off patent you have competition, you have prices coming down—you have a mechanism for that. Unfortunately, the government is not allowed to put into forward estimates the savings, unless they have a price agreement, which is the reason that they got a guarantee for us. When PBS reform came in originally, when we split generics away from these innovative new products, we thought there was going to be a $3 billion saving. The latest estimate is that there is going to be $6 to $8 billion worth of savings to the government. Those savings are coming through. The government is not allowed for accounting reasons to look at those, but they are there, they are tangible and they will start as early as 2012. We are already seeing now in price disclosure price reductions of 31 per cent and 71 per cent in some of the Pfizer drugs that we have in hospitals. So the system is in place and is working.[42]

4.33 The Chronic Illness Alliance noted that there are other means of saving PBS costs, and pointed to the systems in Canada, New Zealand and the Netherlands. Whereas in Australia regulation provides a price cut of 16 per cent when a generic competitor enters the market, in Canada the price cut when a medicine comes off patent is 75 per cent, while in New Zealand and the Netherlands a tender system is in place to deliver cheaper medicines.[43]

4.34 The committee heard that many areas of Government expenditure are not subject to a rigorous economic evaluation. In contrast, medicines which have received

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41 Generic Medicines Industry Association, *Submission 31*, pp 5–6.

42 Mr John Latham, Chairman and Managing Director, Pfizer Australia, *Committee Hansard*, 21 July 2011, p. 31.

43 Chronic Illness Alliance, *Submission 4*, pp 5–6.

a positive recommendation from the PBAC have already been subject to a rigorous process that includes effectiveness, safety and cost-effectiveness. Ms Bulfone explained:

> With a lot of other government expenditure programs there is not that level of rigour in determining whether they are cost effective, so you do not know how cost effective they are. I think the example we gave in the submission is of the bowel cancer screening program. That program may or may not be a cost-effective use of funds. We do not know, because it has not been evaluated in the way that a drug has been evaluated. So to say, 'We are going to direct our funds from something we know is cost effective to something we do not know is cost effective' is potentially putting less money into an area that gives you less return, less bang for your buck, effectively.[44]

4.35 Similarly, the committee heard from Mr Mark Glover of Allergan Australia that:

> Of the $50 billion that is spent on health each year, $9 billion of it is drugs. We get thoroughly reviewed. We know that. For the other $41 billion I would suggest there is room for improvement.[45]

4.36 These sentiments were echoed by GlaxoSmithKline Australia (GSK):

> Indeed, it is difficult to name any other program across Government that can lay claim to equivalent rigour in assessing the economic value of government expenditure or where an equivalent level of program overspending risk is borne by the private sector.
>
> For this reason GSK firmly believes that Government should find any necessary budget savings from other less cost effective, less evidence based areas of government spending.[46]

Committee comment

4.37 The committee noted that, unusually, both the Generic Medicines Industry Association and Medicines Australia were both of the same mind in opposing the Government's position that they were not going to list new medicines until someone finds the money, and that this is not the way to fund or manage the PBS.

4.38 A number of far more significant savings that the Government could leverage from existing reforms were provided by submitters.[47]

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44 Ms Liliana Bulfone, Senior Research Fellow, Deakin University, *Committee Hansard*, 21 July 2011, pp 2–3.

45 Mr Mark Glover, Vice President and Managing Director, Allergan Australia, *Committee Hansard*, 21 July 2011, p. 23.

46 GlaxoSmithKline Australia, *Submission 44*, p. 3.

47 Generic Medicines Industry Association, *Submission 31*, p. 4.