Government senator's minority report

Introduction

1.1 Government senators have considered the majority report and disagree with its findings: the evidence taken during the inquiry does not support the position that the Government's decision to defer the listing of certain medicines under the Pharmaceutical Benefits Scheme (PBS) is a major change in Government policy. It has always been the role of the Pharmaceutical Benefits Advisory Committee (PBAC) to provide expert recommendations to the Government on listings. Similarly, it has always been the role of Government to make final decisions on listing of medicines under the PBS, based on the recommendations made by the PBAC and the Pharmaceutical Benefits Pricing Authority (PBPA).

1.2 The current Government remains committed to timely and affordable access to medicines for all Australians, and to delivering policy outcomes as outlined in the Memorandum of Understanding (MOU) with Medicines Australia. The Government continues to implement reforms to improve the operation, cost-effectiveness and timeliness of the PBS system in consultation with industry and other stakeholders.

1.3 The deferrals announced on 25 February 2011 are just that: deferrals based upon a financially responsible approach to funding the PBS. It is erroneous to suggest that the deferral of six medicines will in any way undermine the healthcare of Australians. Government senators note that the Government continues to be supportive of a viable medicines industry in this country for the current and future benefit of all Australians.[1]

Process of listing medicines on the PBS

1.4 The PBS has served Australians well since 1948. The PBAC was established under the *National Health Act 1953*; one of its principal roles is to recommend to the Minister for Health and Ageing which medicines should be subsidised by the Government under the PBS. In doing so, PBAC considers both the effectiveness and cost of the proposed medicines.

1.5 Many submitters praised the independent role that the PBAC has played, and continues to play, since its establishment. In fact Mr David Learmonth, Department of Health and Ageing (DoHA), noted that 'Every submission to the [committee's] inquiry and participant at the hearing praised the rigour of the PBAC process'.[2] Mr Robert Pask from the National Advocates Program, Multiple Sclerosis Australia, for example, told the committee:

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1 Department of Health and Ageing, *Submission 46*, p. 21.

2 Mr David Learmonth, Deputy Secretary, Department of Health and Ageing, *Committee Hansard*, 25 July 2011, p. 2.

> We have the utmost respect for the PBAC. We have been fortunate enough to meet with Professor Sansom and, from what we have seen of the process, we would like to see it stay.[3]

1.6 Government senators are similarly supportive of the invaluable role played by the PBAC in conducting intense and rigorous scrutiny of individual drugs, and note submitters' evidence that the PBAC process is world class.[4] However, the role of the PBAC is directed at the evaluation of medicines; it is the role of the Government to take into account wider considerations including fiscal matters. As Minister Roxon stated:

> ...by limiting its own investigations to the drug in question, it can concentrate on the merits or otherwise of that particular drug, not wider competing priorities.
>
> But just because PBAC doesn't consider these other priorities does not mean that nobody else should. In fact I would argue governments would be remiss if they don't.[5]

1.7 This is an important point: it always has been the obligation and responsibility of Government to consider recommendations from the PBAC on the suitability of listing particular drugs. The process is not now, and never has been, a 'rubber stamping' process. Decisions on listing remain the responsibility of Government. Mr Learmonth, DoHA, explained in detail this point:

> The PBAC is not a statutory authority such as the Reserve Bank or Civil Aviation Authority and does not make the decision regarding the listing of the medicine as a pharmaceutical benefit. This fact seems to be misunderstood in a number of the submissions to the inquiry, which infer that a positive recommendation to the PBAC is or should be binding on government. While the minister cannot list a medicine as a pharmaceutical benefit unless a positive recommendation is received from the PBAC, a positive recommendation allows the minister to consider a medicine for listing as a pharmaceutical benefit. It does not compel a government to give effect to that recommendation.[6]

1.8 Many submitters demonstrated an appreciation of the decision-making role of Government. Ms Carol Bennet of Consumers Health Forum of Australia stated, 'In fact we fully accept that the Government has the right and should make the final

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3 Mr Robert Pask, National Advocates Program, Multiple Sclerosis Australia, *Committee Hansard*, 21 July 2011, p. 41.

4 Mr John Latham, Chairman and Managing Director, Pfizer Australia, *Committee Hansard*, 21 July 2011, p. 27.

5 The Hon. Nicola Roxon, MP, Minister for Health and Ageing, 'Opening Address to Consumers Health Forum PBS Summit', *Speech*, 29 April 2011, [p. 2].

6 Mr David Learmonth, Deputy Secretary, Department of Health and Ageing, *Committee Hansard*, 25 July 2011, p. 7.

decision about which drugs are listed'.[7] This was echoed by Mr Mark Glover of Allergan Australia who noted 'There is always the prerogative of government to manage expenditure'.[8]

1.9 Professor Lloyd Sansom, Chair of the PBAC also emphasised these separate roles of advisory committees and the Government:

> [Advisory committees] advise governments, and we have a democracy where governments make decisions.[9]

1.10 During the inquiry it was suggested that by exercising its role, the Government would undermine the position of the PBAC. Government senators remain unconvinced by this speculation. The PBAC is an independent statutory authority which has an enviable history of rigorous and exacting assessment. There is no risk to the standing of the PBAC through the Government continuing to exercise its separate, and legitimate, decision-making role in relation to listing of medicines.

1.11 Government senators note that eight medicines were considered and deferred by Cabinet in February 2011; two of these were subsequently reconsidered and listed. The Minister explained the deferrals:

> In most cases this is where there are existing, or alternative treatments that are already available, or there's no added clinical benefit although there may be some other convenient method for taking the medication.[10]

1.12 Government senators are of the view that the deferral of six medicines has been blown out of proportion for political gain. We note that these medicines will be listed when circumstances permit.[11] Arguments that suggest that the deferral will have a significant impact on the quality of healthcare provided in Australia fails to recognise that there are existing or alternative treatments or no added clinical benefit for most of the medicines. In addition, only six medicines were deferred. This is a very small number compared with the number of medicines listed already this year.

1.13 The committee heard evidence that in 2011 alone 152 medicines have been approved and/or listed at a cost of nearly $850 million.[12] Over the last four years the

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7 Ms Carol Bennett, Chief Executive Officer, Consumers Health Forum of Australia, *Committee Hansard*, 25 July 2011, p. 36.

8 Mr Mark Glover, Vice President and Managing Director, Allergan Australia, *Committee Hansard*, 21 July 2011, p. 22.

9 Emeritus Professor Lloyd Sansom, AO, Chair, Pharmaceutical Benefits Advisory Committee, *Committee Hansard*, 25 July 2011, p. 23.

10 The Hon. Nicola Roxon, MP, Minister for Health and Ageing, *Transcript of Doorstop*, 25 February 2011, [p. 1].

11 The Hon. Nicola Roxon, MP, Minister for Health and Ageing, 'Patients Benefit from New Medicines Listed on the PBS and NIP', *Media Release*, 25 February 2011, [p. 2].

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

Government has added almost 500 new medicines or brands of medicines to the PBS, at a cost of around $4 billion.[13] In 2011 eight medicines were deferred by the Government, and of these only six remain deferred. These six medicines represent less than 3.9 per cent of 2011 listings.[14]

1.14 Government senators observe that deferral of listing of a small number of medicines in February 2011 is not without precedent. In the past, the Government of the day has not listed other drugs that had been positively recommended by the PBAC. By way of example in 1994, a Federal Labor Government decided not to list nicotine patches; and in 2002 a Federal Coalition Government decided not to list sildenafil citrate (Viagra®).[15] Mr Learmonth, DoHA, outlined the similarities in these situations:

> ...in each case the pressure that we have spoken about on the PBS is significant and in those circumstances the government of the day has made judgements about what it believes ought to be a priority for funding not just of the PBS but, as a consequence, of course, across the remainder of government activity in health and beyond.[16]

1.15 Similarly, Government senators note that in relation to other matters sometimes the government of the day accepts the recommendations of the PBAC and sometimes it does not. This is explained in answers to questions on notice by Professor Lloyd Sansom, Chair, PBAC:

> Governments have also accepted other PBAC recommendations, such as price reductions for biological disease-modifying antirheumatic drugs listed on the PBS for the treatment of rheumatoid arthritis and recommendations that certain medicines should comprise therapeutic groups...Previous governments have decided not to accept other recommendations of the PBAC. For example, the recommendation of the PBAC in 2001 to maintain the price relativity between the ACE-inhibitor class of drugs and the ATRA class of drugs.[17]

1.16 The majority committee report makes much of assertions that the Government's decision to defer listings and refer all recommendations to Cabinet will make the decision-making process susceptible to influence through lobbying by pharmaceutical companies and consumer groups. Government senators reject these

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13 The Hon. Nicola Roxon, MP, Minister for Health and Ageing, 'Patients Benefit from New Medicines Listed on the PBS and NIP', *Media Release*, 25 February 2011, [p. 2].

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

15 Emeritus Professor Lloyd Sansom, AO, Chair, Pharmaceutical Benefits Advisory Committee, answers to questions on notice, 25 July 2011, [p. 1].

16 Mr David Learmonth, Deputy Secretary, Department of Health and Ageing, *Committee Hansard*, 25 July 2011, p. 12.

17 Emeritus Professor Lloyd Sansom, AO, Chair, Pharmaceutical Benefits Advisory Committee, answers to questions on notice, 25 July 2011, [p. 1].

assertions. We are at a loss to understand why it would be asserted that lobbying could increase when Cabinet is considering all listings with a financial impact. As Mr Learmonth explained:

> Ultimately, it remains the case that the PBAC process goes on. Any drug or medicine that the government lists on the PBS must be recommended by the PBAC. That remains the hurdle. That has not stopped companies in the past lobbying. I am sure that they will continue to do so in the future.[18]

1.17 Government senators note that Cabinet has access to expert advice to assist them in their decision-making processes about listing of medicines on the PBS. The exhaustive process of PBAC considerations, including considerations of 'safety, clinical effectiveness and cost effectiveness (value-for-money) for the intended use, in comparison with other available treatments'[19] provides an excellent basis on which Cabinet is able to make assessments and decisions.

1.18 In addition, Cabinet is able to rely on 'the expert advice from the Department of Health and Ageing and the Chief Medical Officer'.[20] With these various forms of advice available to it, Cabinet is able to make considered decisions regarding impact of listing on the Budget, and subject listing applications 'to the same rigorous scrutiny that we put all new proposals in the Health portfolio through'.[21]

1.19 While Cabinet relies on its considered judgement, rather than formal criteria, in its decision-making process, it was noted by Government senators that the Government has stated a commitment to prioritising 'listing medicines on the PBS that treat serious and life threatening conditions where there are no alternative treatments on the PBS'.[22] Government senators remain assured that access to affordable medicines will remain a central feature of the PBS.

Financial impact on the Commonwealth budget

1.20 Government senators note that the Government is responsible for the overall budget, which includes the health budget. Every dollar spent on the health budget adds value but there are many calls on the budget. This means that sometimes difficult decisions need to be made. This point was noted by Ms Liliana Bulfone from Deakin University:

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18 Mr David Learmonth, Deputy Secretary, Department of Health and Ageing, *Committee Hansard*, 25 July 2011, p. 11.

19 Department of Health and Ageing, *Submission 46*, p. 15.

20 Department of Health and Ageing, *Submission 46*, p. 15.

21 The Hon. Nicola Roxon, MP, Minister for Health and Ageing, *Transcript of Doorstop*, 21 June 2011, [p. 1].

22 The Hon. Nicola Roxon, MP, Minister for Health and Ageing, *House of Representatives Hansard*, 25 May 2011, p. 4753.

> In a perfect world there would be no need for a cabinet review of PBAC decisions, but we do acknowledge that affordability of medications in the short term is definitely an issue that the government may need to consider, particularly in circumstances where the drug has an effect over a very long time horizon.[23]

1.21 Government senators recognise that the Government has had to make difficult decisions in the interests of prudent financial management, and are supportive of the Government's decisions to prioritise medications that are life-saving and where there is no alternative that's available to patients. This rationale was explained by Minister Roxon on 25 February 2011:

> ...the Government has to make a decision, especially on every decision that has financial implications, taking account of all the circumstances, and having done that we've made a decision that a number of medicines won't be listed this time. We're being public about that. We're making sure that everyone, who is an applicant in the pharmaceutical industry and the consumers, have that information available to them.[24]

1.22 However, the Minister noted that the Government remains committed to listing new medications as evidenced by the number of new medicines listed in 2011:

> ...even in difficult fiscal circumstances this Government is willing to consider proposed listings within required timeframes, and to list new drugs that come with a substantial cost.[25]

1.23 Government senators note that maintaining affordable access to medicines through the PBS, while preserving its long-term financial sustainability has been a matter of concern for successive governments over the years. The PBS, however, has continued to grow over the last 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.[26]

1.24 The committee heard that not only is the PBS one of the fastest growing programs in the health portfolio, it is also a high growth rate from a very large base.[27]

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

24 The Hon. Nicola Roxon, MP, Minister for Health and Ageing, *Transcript of Doorsto*p, 25 February 2011, [p. 4].

25 The Hon. Nicola Roxon, MP, Minister for Health and Ageing, 'Opening Address to Consumers Health Forum PBS Summit', *Speech*, 29 April 2011, [p. 3].

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

27 Mr David Carvalho, First Assistant Secretary, Social Policy Division, Budget Group, Department of Finance and Deregulation, *Committee Hansard*, 25 July 2011, p. 11.

Consequently it has a very significant fiscal impact.[28] The Government has worked towards ensuring that costs are contained while ensuring that Australians continue to have access to the best available medicines.

1.25 Government senators further note that the Government is addressing these issues in a variety of ways. By way of example, we note that with the enactment of the *Therapeutic Goods Administration (TGA) Amendment Act 2011* it is no longer possible for initial-brand sponsors to use copyright of the product information to block and/or delay follow-on generic medicines from entering the market.[29] This is a significant initiative on the part of the Government and will assist in consumers accessing generic medicines.

1.26 Government senators note that the small number of medicines that have had listing deferred have not disappeared from the Australian market. The committee heard that while medicines may not be available under the PBS for a subsidised price, if they are approved by the Therapeutic Goods Administration (TGA), consumers in Australia still have access to those medicines.[30]

The Memorandum of Understanding with Medicines Australia

1.27 The MOU between Medicines Australia and the Government was concluded in May 2011, and was subsequently announced in the 2010–11 Budget. The purpose of the MOU is spelled out in Clause 3:

> ...both parties intend that the MoU will promote the efficiency and sustainability of the PBS and support, by provision of a stable pricing policy environment, a viable and responsible medicines industry in Australia, consistent with the objectives of the National Medicines Policy.[31]

1.28 As noted by Dr Brendan Shaw, Medicines Australia, 'The MOU is an example of how policy can be developed and improved through constructive collaboration between government and business'.[32]

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28 Mr David Learmonth, Deputy Secretary, Department of Health and Ageing, *Committee Hansard*, 25 July 2011, p. 11.

29 Ms Kate Lynch, Chief Executive Officer, Generic Medicines Industry Association, *Committee Hansard*, 21 July 2011, p. 7.

30 Ms Liliana Bulfone, Senior Research Fellow, Deakin University, *Committee Hansard*, 21 July 2011, p. 4.

31 Department of Health and Ageing, *Submission 46*, p. 18, citing The Hon. Nicola Roxon, MP, Minister for Health and Ageing, second reading speech, National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010, *House of Representatives Hansard*, 29 September 2010, p. 80.

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

1.29 The committee heard that there are suggestions that the intent of the MOU has been breached. It is the view of Government senators that this is not correct. There has not been any departure from the provision of a stable pricing policy environment as outlined in Clause 3 above.

1.30 Furthermore, the specific commitment to maintaining current pricing policy, outlined in Clause 4 of the MOU has been maintained. As Mr Learmonth, DoHA, noted 'the intent of the MOU was to provide pricing stability—nothing else'.[33] Clause 4 states:

> The Commonwealth undertakes not to implement new policy to generate a price-related savings from the PBS during the period of the agreement, that is, measures that would change the ex-manufacturer price of particular medicines, other than reflected by this MOU.

1.31 Similarly Government senators refute the suggestion that the Commonwealth has departed from Clause 29 of the MOU:

> 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.

1.32 It is of note that not only has the Government abided by this timetable, it has in fact done better than promised 'with two of the last high-cost listings being considered by Cabinet within one month of pricing being agreed'.[34]

A healthy pharmaceutical sector

1.33 Government senators note that only a very small proportion of medicines have been deferred compared with the significant number which have been listed since 2007:

> Since 2007, over 500 medicines or brands of medicines have been listed on the PBS, the Life Saving Drugs Program and the National Immunisation Program, at a cost of over $4 billion over five years. In 2011 alone, the government has approved and/or listed over 152 medicines, at a cost of nearly $850 million. In all this, only eight medicines were deferred by the government on 25 February this year, of which only six remain deferred. These six medicines represent less than 3.9 per cent of all listings in 2011 and less than one per cent of listings over the past four years.[35]

1.34 Further, Government senators note that deferrals are not permanent, and the Government has undertaken to reconsider the listing of deferred medicines as

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33 Mr David Learmonth, Deputy Secretary, Department of Health and Ageing, *Committee Hansard*, 25 July 2011, p. 2.

34 Department of Health and Ageing, *Submission 46*, p. 19.

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

circumstances permit. This is evidenced by the recent listing of some of the deferred medicines. In addition, no medicines recommended by the PBAC at its March 2011 meeting have been deferred. Mr Learmonth, DoHA, stated:

> Finally, whilst eight deferrals were announced in February this year, two of these have subsequently been listed. No medicines recommended by the PBAC, at its March 2011 meeting, were deferred by the government and, by September this year, 152 new drugs or amendments to listings of existing drugs will have been listed on the PBS, reflecting the government's continued commitment to list medicines.[36]

1.35 The committee heard that the process of making submissions, applying for listings and running clinical trials is a lengthy process. Industry in Australia is looking at working through issues with the Government to address concerns, rather than packing up and leaving the market:

> The fact that we are here talking to you means, hopefully, we are not going to be pulling investments out of Australia or stopping clinical trials or research and development. We are here to work with you...[37]

1.36 There is evidence of continuing support for the Australian market by pharmaceutical companies with no decrease in the number of submissions being received by the PBAC:

> Companies are still actively seeking listing on the PBS, as evidenced by the fact that there has been no change in the total number of submissions received for consideration by the PBAC over the last three months. On the contrary, the July meeting of the PBAC received a record number of submissions.[38]

Business as usual – a stable investment environment

1.37 The committee was at pains to ascertain whether any particular investment decision by a pharmaceutical company had been changed as a result of the deferral. Witnesses informed the committee that decisions pertaining to the launch of certain products will be postponed and delayed as a result, but Government senators note that witnesses were unable to identify a specific investment decision which had been changed as a result of the deferral.[39]

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36 Mr David Learmonth, Deputy Secretary, Department of Health and Ageing, *Committee Hansard*, 25 July 2011, p. 2.

37 Mr John Latham, Chairman and Managing Director, Pfizer Australia, *Committee Hansard*, 21 July 2011, p. 28.

38 Mr David Learmonth, Deputy Secretary, Department of Health and Ageing, *Committee Hansard*, 25 July 2011, p. 2.

39 Mr Jose Vieira, Managing Director, AstraZeneca Australia, *Committee Hansard*, 21 July 2011, pp 3–4; Mr Bruce Goodwin, Managing Director, Janssen-Cilag Australia Pty Ltd, *Committee Hansard*, 21 July 2011, p. 32.

1.38 Government senators note evidence provided by DoHA which explained that the deferred listings represent less than one per cent of all listings since 2007, and 3.9 per cent of all listings in 2011. Mr Learmonth put the view that in comparison with the level of risk associated with applying for PBAC approval, Cabinet consideration of listings presents a low level of risk to companies when they are making investment decisions:

> I would argue that the biggest hurdle for a company as to whether a drug ends up being subsidised on the PBS remains the PBAC, the Pharmaceutical Benefits Advisory Committee.
>
> In 2010, 63 per cent of all first-time, cost-effective submissions were rejected by the PBAC. This is not a one-off statistic but a consistent marker of the rigour of the assessment process undertaken. It is this assessment process which I would suggest is the main decision point for companies in determining whether to bring a drug to the subsidised market in Australia.[40]

1.39 Government senators note that Cabinet consideration of listings is not an additional risk or extra hurdle, as 'It has always been the case that cabinet makes decisions on which medicines should be listed and which should not'.[41] Mr Learmonth further explained:

> I do not think there has ever been any advisory committee for any government whose recommendations have always been automatically accepted by government. Certainly in the case of the PBAC it has always been the case that government has considered the recommendations, and certainly in the past there have been occasions when government has chosen not to accept those recommendations.[42]

1.40 In response to suggestions that companies are able to more easily calibrate the risk involved in the PBAC assessment process, as it is a known quantity, with clear requirements and criteria, Mr Learmonth stated that despite any familiarity with the PBAC process, listing applications will often not be accepted on initial submission:

> Does that always pan out in terms of the behaviour of the companies in so far as they all bring beautifully evidenced, competitively priced product? No. Sometimes they do and they are accepted and other times not. Despite all that transparency and familiarity, we will see products that take seven cycles through the PBAC and take a 70 per cent price drop to actually get through...Equally, there are no strict guidelines around PBAC approvals. There are guidelines around what a submission needs to look like but there are no, for example, guidelines that specify the incremental cost-

40 Mr David Learmonth, Deputy Secretary, Department of Health and Ageing, *Committee Hansard*, 25 July 2011, p. 2.

41 Mr David Learmonth, Deputy Secretary, Department of Health and Ageing, *Committee Hansard*, 25 July 2011, p. 5.

42 Mr David Learmonth, Deputy Secretary, Department of Health and Ageing, *Committee Hansard*, 25 July 2011, pp 9–10.

> effectiveness ratio at which the PBAC will find a medicine cost-effective. There has never been and it allows some judgment by the PBAC.[43]

1.41 The suggestion was put to the committee that the Government's decision to defer listings has resulted in the waste of stock. However, the committee heard that this will not be the case where a product can be used for other indications:

> In relation to us, Botox fortunately has PBS funding for eight different indications so far, ranging from kids with cerebral palsy to adult spasticity post-stroke to movement disorders. It has been around a long time and it is well funded...It is less of an issue for us because Botox is used for a lot of other very valuable medical indications.[44]

1.42 The Department of Health and Ageing substantiated this point:

> Decisions about whether to obtain stock, ahead of formal advice from the Department one month prior to the actual date that the listing will proceed, are commercial decisions made by individual companies. Companies are not required to pre-stock, in anticipation of a positive listing outcome. They are only required to assure the Department, that, when listing does proceed, they will be able to make stock available on the PBS. Once approval to list on the PBS is known, companies are able to proceed with their projected listing date or defer listing if they are unable to supply by that date.
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> It is not for the Department to speculate on each individual company's capacity to supply prior to advising of the approval to list.
>
> In relation to the six PBS listings that remain deferred, companies can still sell stock privately and to hospitals. Further, it should be noted that of the six PBAC recommendations that remain deferred, three of the medicines are already subsidised through the PBS for other indications. These are:
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> - Botox® ($11.8 million in PBS expenditure in 2009-10);
> - budesonide with eformoterol (Symbicort® - $66.3 million in PBS expenditure in 2009-10 for asthma); and
> - dalteparin sodium (Fragmin® - 0.9 million in PBS expenditure in 2009-10)[45]

1.43 Government senators also note the comments of Professor Sansom. Professor Sansom has been chair of the PBAC since 2001 and has an in depth knowledge of the pharmaceutical industry in Australia. Professor Sansom was of the view that the Australian market is stable and the supply of medicines will not be affected:

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43 Mr David Learmonth, Deputy Secretary, Department of Health and Ageing, *Committee Hansard*, 25 July 2011, pp 6–7.

44 Mr Mark Glover, Vice President and Managing Director, Allergan Australia, *Committee Hansard*, 21 July 2011, p. 20. See also Mr Jose Vieira, Managing Director, AstraZeneca Australia, *Committee Hansard*, 21 July 2011, p. 20.

45 Department of Health and Ageing, *Submission 46*, p. 11.

> We have a high reputation. We are highly skilled in clinical science. I think companies will make the judgement. This is quite a stable market. Once you get listing, this is a very stable market. I think it is a commercial decision and I do not believe it will have a major impact at all.[46]

Research and Development

1.44 Government senators note that the Government is working through the Pharmaceuticals Industry Council and related programs and initiatives to attract clinical research to Australia and build on the country's intellectual capital.[47] An example of the Government's commitment to advance and encourage more research and development and investment is the implementation of the R&D tax credit, which will 'reduce the cost of R&D by 10 per cent and make Australia more internationally competitive as a destination for medical research investment'.[48] In addition the Government has been working to implement the recommendations of the Clinical Trials Action Group to streamline the clinical trial approval process.[49]

1.45 Mr Learmonth, DoHA, further stated that he could not see the link between the deferral of certain listings, and implications for research and development and clinical trials in Australia:

> They are quite different decisions, though—having a clinical trial in Australia versus accessing the funded market. Clinical trials are conducted as propositions internationally. As I say, these are large multinational pharmaceutical companies. On the innovative side, they will locate their clinical trials—and they are often multisite clinical trials—in circumstances that most suit them in terms of generating the evidence that they will use to claim reimbursement all around the world in various markets and from various payers. Those will go to a range of things, such as availability of populations, price and clinical infrastructure. They will make a lot of judgments about where they locate trials, having regard to how best and most cost-effectively to generate evidence. That is an entirely separate matter from, having obtained that evidence, how and where they choose to take that evidence and seek reimbursement in particular markets. So I cannot see the link.[50]

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46 Emeritus Professor Lloyd Sansom, Chair, Pharmaceutical Benefits Advisory Committee, *Committee Hansard*, 25 July 2011, p. 22.

47 Mr David Learmonth, Deputy Secretary, Department of Health and Ageing, *Committee Hansard*, 25 July 2011, p. 9.

48 Medicines Australia, answers to questions on notice 25 July 2011, [p. 4]

49 Medicines Australia, answers to questions on notice 25 July 2011, [p. 5].

50 Mr David Learmonth, Deputy Secretary, Department of Health and Ageing, *Committee Hansard*, 25 July 2011, p. 9.

The Australian medicines market - available and accessible medicines

1.46 The committee heard that while medicines may not be available under the PBS for a subsidised price, if they are approved by the Therapeutic Goods Administration (TGA), consumers in Australia still have access to those medicines.[51] Witnesses further confirmed that there is a small private or hospital market for some of the deferred medicines.[52]

1.47 Government senators note that, with the exception of Botox®, there are alternative medicines available to those which have been deferred, and therefore patients will still be treated. While the effectiveness and appropriateness of those alternatives for an individual may be debated, alternative treatments are available for those medicines, with the exception of Botox®.[53] DoHA submitted:

> Based on the evidence provided to the PBAC which is reflected in the PBAC recommendations, four of the six medicines that remain deferred to date, paliperidone (Invega Sustenna®), budesonide with eformoterol (Symbicort®), dalteparin sodium (Fragmin®) and nafarelin (Synarel®) produce similar health outcomes to existing PBS-listed therapies. They did not demonstrate superior clinical benefits to those items already on the PBS, but had an additional cost to the Commonwealth budget.
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> With respect to oxycodone with naloxone (Targin®), the PBAC considered that it could provide an alternative pain management therapy to opioids alone or in conjunction with prophylactic laxatives. This was reflected in the cost of this medicine which was similar to oxycodone plus an over-the-counter laxative. The potential for reduction in illicit drug use claimed in the submission to the PBAC was not based on evidence.[54]

1.48 Furthermore, Government senators note that the PBAC did not find any evidence of clinical superiority in relation to the deferred medicines, and the medicines in question were deferred on a sound basis:

> Most of these drugs were cost-minimised or 'me too' drugs, with no added efficacy or health outcome and no less toxicity than existing treatments but with a net cost to the government.[55]

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51 Ms Liliana Bulfone, Senior Research Fellow, Deakin University, *Committee Hansard*, 21 July 2011, p. 4.

52 Mr Rob Baveystock, Managing Director, Mundipharma Pty Ltd, *Committee Hansard*, 21 July 2011, p. 31.

53 Dr Simon Fisher, Medical Director, AstraZeneca Australia Pty Ltd, *Committee Hansard*, 21 July 2011, p. 21.

54 Department of Health and Ageing, *Submission 46*, p. 10.

55 Mr David Learmonth, Deputy Secretary, Department of Health and Ageing, *Committee Hansard*, 25 July 2011, p. 2.

1.49 While the alternatives may not be the most preferable treatment for all individuals, Government senators note evidence provided by Professor Sansom that there will always be some patients who will not have access to a particular medicine under the PBS, as it is not sustainable to list every single medicine:

> Even when PBAC says, 'No, the drug is not cost effective,' we know that there will be patients who may have benefitted from that drug. That pertains to every decision that PBAC makes. Let me put it another way: for any country to go to a purely individualised patient system—that would mean you would make every drug available without any restrictions so you can try as many as you like—the system would be broke in a very short space of time.[56]

1.50 Mr Learmonth, DoHA, explained that the concerns about increased uncertainty impacting on commercial decisions to make medicines available in Australia needs to be put in context:

> ...the risk to the extent that you can characterise it as risk in making this decision to enter the market is at the PBAC end where over 60 per cent of first-time cost-effective applications are rejected. That is where the significant uncertainty is. The uncertainty, if you want to characterise it as that, represented by deferrals is extremely small in comparison.
>
> Finally, I would say that these are large, sophisticated, multinational companies. They make their investment decisions in a range of markets. They will look at what is going on and they will take a very hard-headed business approach to understanding what the risk is. The principal risk remains the PBAC's consideration and the rigorousness of that process. They will have looked at the pattern of what the government has approved—and it has approved over 150 new medicines and listings this year and it has continued to defer only six—and they will make their judgments accordingly, and I believe they will continue to bring things to market in Australia where they believe they are good products.[57]

1.51 Indeed Mr Mark Glover of Allergan Australia emphasised that the major concern for industry is the accessibility of medicines for patients, rather than the availability of the medicines in Australia:

> I do not think anybody is saying from the industry point of view—and certainly I have not said it—that medicines are going to stop coming to Australia as a result of this deferral policy.[58]

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56 Emeritus Professor Lloyd Sansom, Chair, Pharmaceutical Benefits Advisory Committee, *Committee Hansard*, 25 July 2011, p. 22. See also Ms Liliana Bulfone, Senior Research Fellow, Deakin University, *Committee Hansard*, 21 July 2011, p. 4.

57 Mr David Learmonth, Deputy Secretary, Department of Health and Ageing, *Committee Hansard*, 25 July 2011, p. 6.

58 Mr Mark Glover, Vice President and Managing Director, Allergan Australia, *Committee Hansard*, 21 July 2011, p. 19.

1.52 Mr John Latham of Pfizer Australia echoed these sentiments:

> When you look at the role of the pharmaceutical industry and what we do, our role is really to innovate and work in a system that discovers and brings new medicines to market. Those medicines are there to treat diseases. For critics to say that the industry are threatening to not bring new products to Australia because we do not like the system is rubbish. We are here and our job is to discover medicines and bring them to citizens around the world.[59]

Government senator's view

1.53 Government senators, having considered the evidence provided to the committee, are of the view that the Government's decision to defer the listing of certain medicines under the PBS is not major change in Government policy. The final decision on listing of medicines on the PBS has always be the responsibility of Government.

1.54 In this instance, the Government has taken a difficult decision on the ground of financial responsibility. It has also ensured that most of the medicines deferred have an alternative already listed on the PBS. In addition, the PBAC found that for most of the medicines there was no added efficacy or health outcome and no less toxicity than existing treatments. Government senators also note that no medicines approved for listing by the PBAC at its March 2011 meeting have been deferred and that the Government continues to approve listing of high-cost drugs.

1.55 There were suggestions during the inquiry, that the Government, by its actions had jeopardised the access of Australians to medicines. This is not true. The Government continues to support the role of the PBAC while undertaking a responsible approach to the financial sustainability of the PBS. Government senators do not consider that the pharmaceutical companies present in the Australian market will withdraw. The Australian market is stable and provides a good investment environment for those companies. In addition, there has been no evidence of a decrease in the number of submissions to the PBAC for consideration.

1.56 The Government will continue to work towards ensuring that affordable and effective medicines are available in a timely manner for Australian consumers. Government senators note that the MOU with Medicines Australia will continue to deliver improvements and point to the Government's commitment to a viable medicines industry in this country. Suggestions that Australians are facing a system similar to that in place in New Zealand are far from reality.

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59 Mr John Latham, Chairman and Managing Director, Pfizer Australia, *Committee Hansard*, 21 July 2011, p. 28.

1.57 Finally, Government senators reiterate that the PBS has served Australians well since 1948 and we see no reason to change it.

Senator Helen Polley
Deputy Chair

Senator Anne McEwen