Chapter 6

Consequences for the pharmaceutical sector and the availability of medicines in Australia

> ...the key concern is the uncertainty that this creates for our future pipeline. The impact of this type of uncertainty on our business is immeasurable.
>
> It makes it impossible for us to plan adequately in terms of our workforce needs, our likely revenue base, our contribution to global performance, our clinical trials program, and results in the diminution of business confidence.[1]

Introduction

6.1 The possible implications of listing deferrals on the pharmaceutical sector, investment in research and development and the availability of medicines in the Australian market were raised by a number of submitters and clearly constitute significant grounds for concern.

Consequences for companies

6.2 Concerns regarding the implications of the Government's deferral decision have also united the pharmaceutical industry, with the generic and originator sectors agreeing that deferring the listing of medicines until savings are made to fund those listings is not the way to manage the Pharmaceutical Benefits Scheme (PBS).[2]

6.3 Submitters argued that the deferral decision undermines the pharmaceutical industry's confidence in Australia as a stable regulatory and policy environment for business and development, and this uncertainty may impact the strategic interest of pharmaceutical companies in bringing products to the Australian market.[3] Submitters also alluded that another possible consequence of this may be that clinical trial investment and special access programs may be reduced or abandoned.[4]

The impact of uncertainty on investment decisions

6.4 Putting together a submission to have a medicine listed on the PBS is an expensive and lengthy exercise, which involves evaluation of the medicine and

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1 Amgen Australia, *Submission 42*, [p. 1].

2 Ms Kate Lynch, Chief Executive Officer, and Mr Robert Ellis, Board Member, Generic Medicines Industry Association, *Committee Hansard*, 21 July 2011, p. 15.

3 National Association of People Living with HIV/AIDS, *Submission 6*, pp 3–4; Consumers Health Forum of Australia, *Submission 9*, p. 4; Ms Liliana Bulfone, Senior Research Fellow, Deakin University, *Committee Hansard*, 21 July 2011, pp 1–3.

4 National Association of People Living with HIV/AIDS, *Submission 6*, p. 4.

gathering all of the information required by the rigorous assessment process.[5] Further, the committee heard that on average it takes 2.2 submissions to receive a positive Pharmaceutical Benefits Advisory Committee (PBAC) recommendation. Medicines Australia explained that in comparison to other Organisation for Economic Co-operation and Development (OECD) countries, 'Australia is already regarded as a very difficult market to enter with a high regulatory burden (i.e. market entry costs)', and provided the committee with a breakdown of the costs involved:[6]

> ...to lodge a submission with the TGA, it is $200,000; to lodge a major submission to the PBAC is around $120,000; and if you get a rejection by the PBAC and you resubmit, it is another $120,000.[7]

6.5 The committee was told that the current state of affairs is causing a significant amount of uncertainty, as 'Companies have multiple products in their pipelines and they have to consider how to bring them to market and how to bring them onto the PBS'.[8] Allergan Australia submitted:

> The uncertainty created by the deferrals decision places Australian affiliates of multinational pharmaceutical companies at a considerable disadvantage when competing for funds to invest in PBS related activities and justify the considerable expenditure devoted to PBAC submissions.[9]

6.6 Similarly, Janssen-Cilag argued that without a stable and predictable environment, a small market like Australia may miss out on future investment:

> Like any business, predictability is essential to continue to develop and introduce innovative medicines in Australia. Comparatively speaking, Australia is a small market for global pharmaceutical companies and domestic subsidiaries often have to negotiate for inclusion in global market access plans. Key to this is the ability to demonstrate predictability within the political, policy and regulatory environment, without which, major industry players will simply switch their investment focus to other economies. This has significant flow-on effects for investment, jobs and importantly, access to medicines for Australians.[10]

6.7 Ms Liliana Bulfone of Deakin University explained to the committee that pharmaceutical companies will weigh up the costs and benefits of pursuing product listings before they proceed:

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5 Ms Liliana Bulfone, Senior Research Fellow, Deakin University, *Committee Hansard*, 21 July 2011, p. 3; Roche Products, *Submission 39*, p. 4.

6 Medicines Australia, *Submission 36*, pp 8 and 16.

7 Mr Andrew Bruce, Executive Director, Health Policy and Research, Medicines Australia, *Committee Hansard*, 25 July 2011, p. 28.

8 Dr Brendan Shaw, Chief Executive, Medicines Australia, *Committee Hansard*, 25 July 2011, p. 31.

9 Allergan Australia, *Submission 45*, p. 7.

10 Janssen-Cilag, *Submission 37*, p. 9.

> ...these reforms will introduce some uncertainties for manufacturers. In some circumstances, manufacturers may consider that the extra risks and costs that are involved in trying to have a drug listed on the PBAC, beyond just having it recommended by the PBS, outweigh the potential benefits of having the drug available on the PBS, particularly where the drug will be high cost and used for a small number of patients. That may mean that some manufacturers—I do not imagine there will be a massive number of drugs that fall into that category, but it may be bigger than we think—may choose not to bother to engage with the process of trying to get a PBS listing at all.[11]

6.8 While Mr David Learmonth of the Department of Health and Ageing (DoHA) acknowledged that Cabinet deferral of medicines is a new level of uncertainty, he also suggested that companies will learn to calibrate the level of risk involved in Cabinet consideration of listings:

> I think, like anything else, they will have developed their understanding of PBAC, for example, over time by getting experience with the process and seeing what is rejected or accepted at various levels of price and uncertainty, and the incremental cost-effectiveness ratio. They will build a sense of what they think they can get away with to maximise their chances and maximise their profit, having regard to both unit price and time of entry to the market. They make those judgments all the time. In this case, I think they would look at the decisions of government over the last year, which listed an overwhelming majority—96 per cent—of what has come forward. They will look at the statements of the minister in relation to what has been listed and what has not been listed, and they will equally start to calibrate and understand that risk.[12]

6.9 However, submitters explained that pharmaceutical companies had certainty and predictability under the previous listing process, and companies are keen to reinstate that certainty. It was argued that Cabinet consideration of listings has introduced a new level of uncertainty, as companies do not know by which criteria the listing of medicines will be assessed, and they can no longer anticipate which products will or will not be approved.[13] iNova Pharmaceuticals (Australia) commented:

> ...arrangements to bring these therapies to Australian patients require certainty of the PBS listing timeframes which is currently proving difficult in light of the recent PBS deferrals.
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> Specifically, we can no longer assume the PBS process as outlined in the National Health Act given that Cabinet involvement and the issue of

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11 Ms Liliana Bulfone, Senior Research Fellow, Deakin University, *Committee Hansard*, 21 July 2011, p. 1.

12 Mr David Learmonth, Deputy Secretary, Department of Health and Ageing, *Committee Hansard*, 25 July 2011, pp 7–8.

13 Mr John Latham, Chairman and Managing Director, Pfizer Australia, *Committee Hansard*, 21 July 2011, p. 29. See also Sanofi, *Submission 29*, [p. 2]; Mr Jose Vieira, Managing Director, AstraZeneca Australia, *Committee Hansard*, 21 July 2011, pp 19-20.

> managing the Federal Budget back to surplus have now usurped PBS relevant matters advised by the PBAC including clinical need, effectiveness, safety and value for money in spending tax payer dollars.[14]

6.10 Mr John Latham, Chairman and Managing Director of Pfizer Australia also added his concern and stated:

> The unpredictable nature of listings will become a key consideration for Pfizer in making future investment decisions for the Australian market, particularly in view of the business changes we are facing.[15]

6.11 This was echoed by Mr Bruce Goodwin of Janssen-Cilag Australia who commented:

> There is a higher risk associated with some of our new products coming through that was not there before. If the delay occurs it significantly impacts on the commercial viability. We have at least one product in that situation.[16]

6.12 The impact of deferrals on the generic medicines sector, which relies on the flow of medicines subsidised under the PBS was also considered. Ms Kate Lynch, of the Generic Medicines Industry Association (GMiA), agreed that deferrals would eventually affect the generic medicines industry.[17]

Financial impact and effects on stock and employment

6.13 Medicines Australia submitted that a number of the pharmaceutical companies affected by the deferral have suffered financial loss as a result of the Government's decision:

> Many of the affected companies incurred significant financial losses as a result of the sudden and unanticipated announcement of the deferrals in February. To meet the Government's own listing requirements, affected companies had purchased and warehoused stock (all of which carry expiry dates), employed people, established post-approval trials and monitoring programs for pharmacovigilence and invested heavily in education programs so that the medicines could be used safely and effectively. Much of this expense could not be recouped and became deadweight loss to the companies (and therefore to the Australian economy) as a result of the deferrals. Apart from the instant financial losses, companies are unsure

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14 iNova Pharmaceuticals (Australia), *Submission 11*, p. 2. See also Joint submission from Cancer Council Australia, the Clinical Oncological Society of Australia and the Medical Oncology Group of Australia, *Submission 32*, p. 2; Amgen Australia, *Submission 42*, [pp 1–2].

15 Mr John Latham, Chairman and Managing Director, Pfizer Australia, *Committee Hansard*, 21 July 2011, p. 27. See also Pfizer Australia, *Submission 35*, p. 17.

16 Mr Bruce Goodwin, Managing Director, Janssen-Cilag Australia, *Committee Hansard*, 21 July 2011, p. 32.

17 Ms Kate Lynch, Chief Executive Officer, Generic Medicines Industry Association, *Committee Hansard*, 21 July 2011, p. 15.

> whether to make further investment, place launch plans on hold or cease investment altogether.[18]

6.14 Concerns were raised that due to the deferral of listings, medical stocks would expire and would have to be destroyed. Mr Learmonth, DoHA explained that the importation of stock is a business decision taken by the company:

> Firstly, there is no requirement to have stock in country when a decision is made; there is only a requirement for companies to say they will have stock available at the time of listing. It is entirely up to the company how they manage that risk. Secondly, these are multinational companies operating multinational supply chains to multiple markets around the world. Access to those markets happens in different ways and at different times, and they juggle their supply chains accordingly. Finally, there are other markets, even within Australia, where medicines can be sold—whether it is on the private market or the state hospital system. I am certainly aware of drugs that are sold on those markets when they are not on the PBS. It is up to the company to manage the risk in the context of managing a global supply chain and global market access.[19]

6.15 However, Pfizer Australia submitted that under the National Health Act, as part of the post PBAC process, a company is required to submit to the PBS listings section a notification of the guarantee to supply the medicine from the date of PBS listing:

> In the case of the deferred Pfizer medicines, we were required to provide this information prior to 15 February 2011 for a 1 April 2011 PBS listing. Pfizer was not informed of the deferral until 25 February 2011. Once the company has committed to supply from a certain date, it must commence the necessary procedures to meet this government-required commitment. This includes manufacturing and/or importing stock, which generally requires 2-3 months.[20]

6.16 Mundipharma submitted that at the time that its stock was imported, the $10 million threshold was in place, and its product, Targin®, did not exceed that threshold, therefore, in order to meet its obligations under the guarantee of supply upon the listing of the product, Mundipharma imported a quantity of stock:

> Mundipharma notes that only those new PBS listings with an anticipated incremental cost to the PBS greater than $10 million in any of the first four years of listing were, at that time, required to be considered by Cabinet. As Targin® tablets do not fall into this definition; we respectfully suggest that the company was entitled to anticipate a PBS listing date, as planned, of 1st April 2011. In the event, Mundipharma was confounded by the non-

18 Medicines Australia, *Submission 36*, p. 15.

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

20 Pfizer Australia, answers to questions on notice and additional information, [pp 1–2].

> communicated change to the process whereby all recommended PBS listings with a potential cost to the PBS are now referred to Cabinet for a decision. We repeat that if we had received advanced notice of this critical change to the PBS listing process Mundipharma would not have imported stock into Australia at that time.[21]

6.17 The committee heard that where a product is listed for the treatment of other indications, the stock will not go to waste. However, witnesses explained the decision by Cabinet to defer the listing of certain medicines would impact the stock that pharmaceutical companies have on hand in cases where the medicine can only be used for a single indication, stating, 'where this is a single product for a single indication there is nothing to be done other than to write it off'.[22] Dr John Whitlam, Medical Affairs Director of Mundipharma explained to the committee that Targin® falls into the latter category, as it is not listed on the PBS for other indications:

> Quite reasonably, we imported that stock on the assumption that we were going to get PBS listed. In fact we cannot move that stock, because we do not have the product listed on the PBS or another indication whereby we can transfer that significant amount of stock.[23]

6.18 As a result, Mundipharma estimates that over 14 000 units of Targin 5/2.5mg tablets will need to be destroyed at the beginning of the second quarter of 2011.[24]

6.19 The financial impact for companies will also be felt in terms of the preparations made to launch a product, as the investment in people and training is not recoverable.[25] GlaxoSmithKline Australia (GSK) explained how this new uncertainty affects business practice:

> The uncertainty and unpredictability of when our medicines might be listed makes it very difficult for GSK to plan manufacturing production to meet stock requirements, recruitment and training of new staff and investments in other local activities such as post marketing clinical research or medical education.[26]

6.20 Mr Jose Vieira, Managing Director, AstraZeneca Australia further added:

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21 Mundipharma, answers to questions on notice and additional information, 21 July 2011, p. 7.

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

23 Dr John Whitlam, Medical Affairs Director, Mundipharma, *Committee Hansard*, 21 July 2011, p. 31.

24 Mundipharma, answers to questions on notice and additional information, 21 July 2011, p. 7.

25 Mr Jose Vieira, Managing Director, AstraZeneca Australia, *Committee Hansard*, 21 July 2011, p. 20.

26 GlaxoSmithKline Australia, *Submission 44*, p. 2.

> All the launches that we are planning for new products in Australia—all the decisions to start the launch—will be postponed by the date in which the cabinet will take the final decision. We look at what happened in other countries, the probability of success, understanding their rules, the likelihood of approval. We need to hold back because we cannot allocate resources to prepare my company to launch new products if we can end up with decisions such as the one that I am describing...And it is clear: products that could have been launched a few months after the cabinet decision will take much longer because we will start to prepare our organisations just after that decision and not before that.[27]

6.21 Mr Rob Baveystock of Mundipharma also explained that they have delayed a significant amount of employment which was to take place on the basis of the PBS listing of Targin®.[28]

6.22 These arguments were supported by evidence submitted by AstraZeneca regarding the timelines by which commercial decisions were made prior to the deferral announcement:

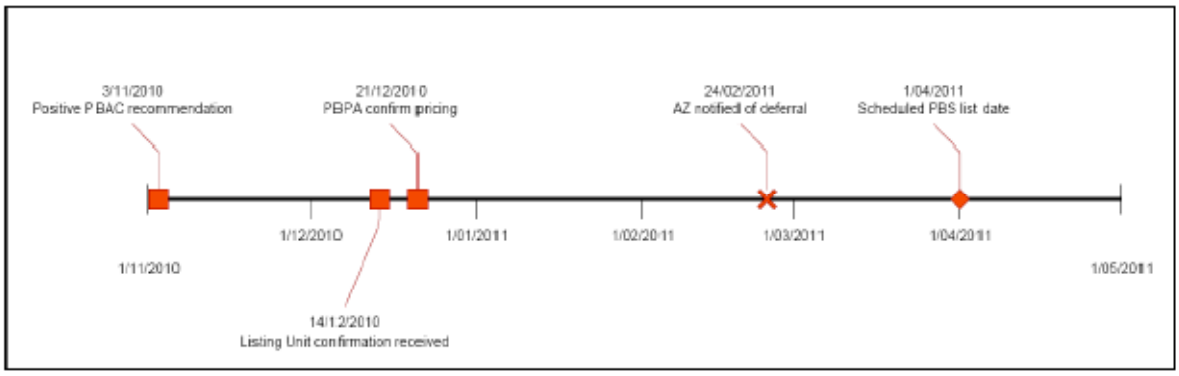
> The PBAC issued a positive recommendation to list Symbicort® for the treatment of COPD [chronic obstructive pulmonary disease] following consideration at its November, 2010 meeting. AstraZeneca subsequently received notification of the Pharmaceutical Benefits Pricing Authority's (PBPA) acceptance of our pricing proposal for Symbicort® for the COPD indication on the 21st of December, 2010. The Listing Unit had previously confirmed (14 December, 2010) that all required documentation was in place to proceed with a 1st April 2011 listing, subject to pricing being agreed with the PBPA. On this basis, launch activities were fully underway when we received notification via telephone on the 24th February 2011 that the listing for COPD had been deferred. Figure 1 below presents a timeline of the chain of events leading up to the notification of deferral.[29]

27 Mr Jose Vieira, Managing Director, AstraZeneca Australia, *Committee Hansard*, 21 July 2011, pp 23–24. See also Mr Bruce Goodwin, Managing Director, Janssen-Cilag Australia, *Committee Hansard*, 21 July 2011, p. 32; Roche Products, *Submission 39*, p. 5.

28 Mr Rob Baveystock, Managing Director, Mundipharma, *Committee Hansard*, 21 July 2011, pp 31–32.

29 AstraZeneca Australia, *Submission 47*, pp 6–7.

Figure 1 Timeline of events leading to notification of deferral of PBS listing of Symbicort® for COPD



Source: AstraZeneca Australia, Submission 47, pp 6–7.

6.23 Mr Learmonth, DoHA, noted that companies are still applying to have products listed under the PBS, with no change in the total number of submissions received by the PBAC in the last three months.[30] However, witnesses argued that any impact of the Government's decision to subject all PBAC recommendations to Cabinet review will not be immediately clear, therefore it is not necessarily correct to surmise that business has continued as usual without any repercussions. In light of this, industry is hoping to work with government to prevent any adverse outcomes:

> The process for making submissions and listings, starting with the TGA and finishing with the PBAC, is an 18-month to two-year period. It is not as if I am going to bring in a product tomorrow and make a submission the next day. You cannot turn these things on and off. So the fact that he is saying that everything is going okay is fine. It is like the clinical trials. Clinical trials can stop. It takes time for clinical trials to turn around. 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...[31]

6.24 In response to the Consumer Health Forum of Australia's (CHF) survey, some consumers raised concerns about possible flow-on effects if the products of pharmaceutical companies are not listed on the PBS, as this may result in not-for-profit (NFP) health organisations receiving less funding from pharmaceutical companies. One respondent to the survey commented:

> Because a particular drug has not been accepted, funding that was to come to a NFP Health organisation from a pharmaceutical company to deliver a national disease program will not be received, thereby adversely impacting

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

31 Mr John Latham, Chairman and Managing Director, Pfizer Australia, *Committee Hansard*, 21 July 2011, p. 28. See also Dr Brendan Shaw, Chief Executive, and Mr Andrew Bruce, Executive Director, Health Policy and Research, Medicines Australia, *Committee Hansard*, 25 July 2011, p. 31.

> the Australian consumer who would have benefited from the delivery of the national program.[32]

Committee comment

6.25 The committee holds significant concerns regarding the uncertainty which has resulted from the Government's decision to defer the listing of medicines. The committee notes that companies will always manage risk in making business decisions, and prior to the Government's deferral decision, companies had a long-standing understanding of the PBAC evaluation process and the criteria employed in the assessment of a listing application, on which they based their risk assessments. Now, however, companies are not aware of the criteria which Cabinet is using to make decisions on deferrals, and the committee acknowledges the evidence provided which indicates that this added layer of uncertainty will undoubtedly impact on investment decisions, to the detriment of health consumers in Australia.

Consequences for research and development

6.26 Pfizer Australia submitted that the cost of bringing a medicine from development to the consumer can amount to $1.2 billion.[33] As part of the development process, pharmaceutical companies conduct clinical trials. Clinical trials are not only important for the development process, but also provide access to new medicines for selected patients. This is a significant benefit.

6.27 However, as noted by Medicines Australia, there has been a decline in industry investment in Australian clinical trials and manufacturing. This decline will continue as a consequence of 'the injection of further uncertainty into the business environment'.[34] Dr Brendan Shaw cited New Zealand as an example of where industry has reduced the number of clinical trials due to cost-saving measures by government:

> If you go to New Zealand, you will find that the industry has basically given up on New Zealand. The number of clinical trials done in New Zealand is very small. The industry has abandoned New Zealand. There is no R&D. The industry has given up.[35]

6.28 Pharmaceutical companies also provided evidence of the potential impact of the deferral decision on the investment in research and development (R&D) and clinical trials in Australia. Mr Simon Fisher, AstraZeneca Australia, stated:

> ...in Australia we are in a global competition for research and development. Research and development can be placed in any country and it is up to us to

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32 Consumers Health Forum of Australia, *Submission 9*, Attachment A, 'Keep your Cabinet out of our medicines: Results of a consumer survey on changes to the PBS listing process', p. 9.

33 Pfizer Australia, *Submission 35*, p. 5.

34 Medicines Australia, *Submission 36*, p. 9.

35 Dr Brendan Shaw, Chief Executive, Medicines Australia, *Committee Hansard*, 25 July 2011, p. 30.

> demonstrate why research and development at clinical trials should come to Australia. With these types of deferral processes and ad hoc policies it becomes more and more difficult to justify the bringing of R&D into Australia.[36]

6.29 GSK Australia added:

> GSK Australia must compete with other GSK local operating companies for a share of the global investments in early phase clinical trials. Many emerging markets are increasing their capability for high quality clinical research and offering financial or market access incentives to attract investment. Increased uncertainty about the eventual use of a medicine in Australia will make it increasingly difficult for us to secure local sites as part of global phase II and phase III clinical trials.[37]

6.30 Janssen-Cilag informed the committee that it is already reconsidering clinical trial investments:

> These significant impacts cannot be ignored. The deferral decision has prompted Janssen to review its commitment to clinical programs and other activities planned to support the introduction of new medicines in our pipeline.[38]

6.31 Pfizer Australia further submitted that an indefinitely prolonged listing consideration process will serve as a disincentive to invest in the research and development of new medicines, as patent life continues to diminish throughout the length of the approval process:

> Companies whose multi-billion dollar research and development investments result in the discovery of a medical application for new molecules generally apply for patent protection. The rigorous and crucially important testing regime usually consumes half of that patent life.
>
> It is important to recognise that the patent clock continues to tick while regulatory processes drag on. When Cabinet defers medicines which have demonstrated their safety, efficacy and cost effectiveness, the patent life of these medicines is effectively shortened. This further reduces the appeal of investing in research and development for new medicines.[39]

6.32 Research Australia submitted that if pharmaceutical companies experience difficulty in listing their medicines under the PBS, this could result in a disincentive invest in research and development in the long-term, thereby impacting on the development of new medicines:

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36 Dr Simon Fisher, Medical Director, AstraZeneca Australia, *Committee Hansard*, 21 July 2011, p. 24.

37 GlaxoSmithKline Australia, *Submission 44*, p. 11.

38 Janssen-Cilag, *Submission 37*, p. 13.

39 Pfizer Australia, answers to questions on notice and additional information, [p. 2].

> The potential long term impact of PBS deferrals on the health and medical R&D sector could be exponential. Australian research discoveries leading to new medicines, cannot progress from 'bench to bedside' without the support of the pharmaceutical industry. The industry directly employees over 14,000 people in Australia; invests over $1 billion in research and development every year; has exports totaling $4 billion in 2009 – 2010; and supports clinical trial activity of more than $262 million in 2008 – 2009.[40]

6.33 Submitters representing health consumers voiced concern that reluctance by pharmaceutical companies to invest in bringing new medicines and run clinical trials in Australia will affect the access of Australian patients to the latest treatments, and will put health outcomes at risk. Mr David Menadue, National Association of People Living with HIV/AIDS (NAPWA), commented:

> What I am saying is that it is a rapidly evolving process. There is a conference being held in Rome at the moment where new therapies are being discussed, so I would imagine the pressure will be on drug companies in Australia—the Australian arms, anyway—to look to whether they should be, say, trialled in Australia. Australia has a very good record, and that is partly because of our stable regulatory processes. But also we have a Medicare system, so people are able to come to the table and it is an even playing field for people in the clinical trial area. It is regarded as a good place to do clinical trials, so we often get some of the world's first treatments at the moment, and that is partly to do with the fact that we have a good Medicare system that allows doctors to do these trials and to run them fairly well. But it is also a matter of the drug companies being able to see something for their investment in the long term, and of course we are concerned about that being put in jeopardy.[41]

6.34 In a similar vein, Cancer Voices Australia (CVA) noted concerns about the possible downstream effects of the deferral decision particularly on small patient groups, access to clinical trials and the availability of medicines in Australia:

> I have real concerns about the downstream effects of something like this. I was a member of the clinical trials action group, which looked at ways and means of getting people onto clinical trials, and one thing is the availability or lack of availability of patient groups here...With a low number of patients, we need to get clinical trials and we need to have the drugs available in Australia. If the approval process is going to be seen to be not transparent, and if it is stalled in any way, it could have real downstream effects, especially for cancer patients in this country.[42]

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40 Research Australia, *Submission 12*, [p. 3]. See also Novo Nordisk, *Submission 23*, [p. 2].

41 Mr David Menadue, Special Representative, National Association of People Living with HIV/AIDS, *Committee Hansard*, 21 July 2011, pp 48–49.

42 Mr John Stubbs, Executive Officer, Cancer Voices Australia, *Committee Hansard*, 25 July 2011, p. 45.

6.35 However, Mr Learmonth, DoHA, did not support the view that the deferral of listing would adversely affect clinical trials. Mr Learmonth noted that running a clinical trial is a different decision to that of applying to access the funded pharmaceutical market in a country:

> 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.[43]

Committee comment

6.36 The committee notes the department's evidence, however considers that it does not adequately address the concerns raised by the organisations which actually invest in clinical trials. The department acknowledged that decisions on where to run clinical trials will be based on how to 'best and most cost-effectively' generate evidence. As demonstrated by the concerns raised by the pharmaceutical companies who made submissions to this committee, this is the precise reason that clinical trials in Australia are threatened by the Government's deferral decision. Global companies have a range of options regarding the location of clinical trials, and if the regulatory environment in Australia is viewed as unstable it will act as a great disincentive to run any such trials in Australia. The committee agrees that these repercussions will be felt most by Australian health consumers who will be unable to access these innovative, and sometimes life-saving trials — a most unsatisfactory outcome.

6.37 The Government's decision to defer the listing of medicines and subject all future listing decisions to Cabinet consideration, could clearly have significant implications for the discovery and development of new medicines, and the access of Australian patients to important clinical trials. The committee is very concerned that the Government's decision will subject Australian health consumers to a situation similar to that currently faced by patients in New Zealand who have limited access to clinical trials. In the committee's view any such outcome is completely unacceptable for Australia.

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

Consequences for the availability of medicines in the Australian market

6.38 Submitters noted the need to ensure that improved drugs are available to the patients who need them.[44] Concerns were raised that the deferral decision may undermine the confidence of the pharmaceutical industry in the stability of the Australian regulatory and policy environment, and may affect decisions regarding whether companies will bring medicines into Australia given the current arrangements.[45] Submitters further argued that if pharmaceutical companies decide that they do not want to risk their products being deferred, and therefore do not apply to have their products listed on the PBS Schedule, medicines may simply not be available to Australian consumers.[46]

6.39 AstraZeneca Australia outlined the processes by which it decides what medicines will be marketed in a particular country:

> Australian affiliates compete with other markets to secure permission and resources to launch new products and indications. Cabinet deferrals introduce significant commercial uncertainty which may drive companies to preferentially devote resources to launching first in markets with a greater degree of policy stability. 'Innovative' medicines in particular require significant investment in production infrastructure. The commercial uncertainty which accompanies the deferral policy makes it difficult for companies to prioritise investment in production capacity for the Australian market over other markets. Thus, the deferrals policy has the potential to delay access to the 'innovative' medicines it is purportedly designed to support.[47]

6.40 Submitters explained that the PBS process is part of an intricate framework which ensures that new and improved medicines reach the patients who need them, and listing on the PBS is the last stage in the process which takes research from the bench top to the consumer. NAPWA explained:

> ...a drug pipeline offering improvements in outcome and life enabling responses for any patient group is only as good as the system ensuring these drugs becoming available to the patients concerned. In Australia, the PBS processes have been the enabling architecture for these advances to reach the population, across all disease areas.[48]

6.41 Dr Shaw of Medicines Australia also noted that it takes a significant length of time to get a medicine to patients, whether that is through clinical development and

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44 National Association of People Living with HIV/AIDS, *Submission 6*, pp 2–3.

45 National Association of People Living with HIV/AIDS, *Submission 6*, p. 3; Consumers Health Forum of Australia, *Submission 9*, p. 4; Sanofi, *Submission 29*, [p. 1].

46 Consumers Health Forum of Australia, *Submission 9*, p. 4.

47 AstraZeneca Australia, *Submission 47*, p. 8. See also Allergan Australia, *Submission 45*, p. 8.

48 National Association of People Living with HIV/AIDS, *Submission 6*, p. 2. See also Research Australia, *Submission 12*, [p. 3].

research processes or the listing process. Dr Shaw added that companies make commercial decisions about when they bring medicines to the market and which ones they choose. These decisions are influenced by a range of factors, including the cost of the listing process, how the medicine is going to be used in the market and what is the likelihood of success. Dr Shaw concluded:

> A company is not going to spend hundreds of thousands of dollars of its own money to put a drug through the process if it does not think it is going to get listed, when it has got other alternatives there. So this is causing a lot of uncertainty for companies in terms of their ability to bring new medicines. I will not name the companies but I have spoken with a number of managing directors in industry and they are genuinely concerned because they want to bring new medicines to the Australian public.[49]

6.42 This evidence was substantiated by Deakin Health Economics:

> Furthermore, manufacturers are, in most cases, required to pay substantial sums of money to have their drug considered by the PBAC. To then have to negotiate a new hurdle (the approval of the drug by Cabinet according to some undisclosed set of criteria) may mean that the consideration of the benefit of having a drug available on the PBS is outweighed by the costs and risks of achieving a PBS listing such that, over time, manufacturers may choose to not engage with the process of trying to make drugs available on the PBS in Australia such that drugs may be available in the private system but not the public system. This will be detrimental to Australian patients as they will have to bear the full cost of drugs and, in many cases, it is likely that the costs associated with a drug will put the drug out of reach altogether. For drugs with small markets where costs to patients are likely to be prohibitive, manufacturers may not even make the drug available in the private market.[50]

6.43 Mr Mark Glover, Allergan Australia, explained 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.[51]

6.44 However, Mr Vieira, AstraZeneca Australia, commented that the deferral decision will affect the decisions that pharmaceutical companies make, and as a consequence, access to medicines for Australian patients will be delayed:

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49 Dr Brendan Shaw, Chief Executive, Medicines Australia, *Committee Hansard*, 25 July 2011, p. 27. See also Novo Nordisk, *Submission 23*, [p. 2].

50 Deakin Health Economics, Deakin University, *Submission 19*, p. 6.

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

> We need to put on hold some important decisions in terms of investment to prepare our companies and therefore delay in launching new drugs will come not only because of the deferral but because it is naturally delaying access. But also it will take much longer for us as a company to prepare ourselves to launch new drugs. Sometimes we need to make some investment to expand production capacity and it takes time. The lead time to launch new drugs is long. An important business decision will be taken only after the final decision of cabinet.[52]

6.45 This view was also supported by Mr Andrew Bruce, Medicines Australia:

> We surveyed our membership and we did it deliberately anonymously. Companies are commercial entities. They have legal obligations. They will not come out and signal to the market what their future plans are; hence, we did it anonymously. Eleven of those companies came back and said they were considering delaying seeking a listing through the TGA or the PBAC. Will those companies come out and put their name to it? No. They would be highly unlikely to do that. It is very risky for them to do it so that is why we did it anonymously. I think it was instructive that, in two of the responses we got, the companies specifically identified small products. Companies do not want to go out there and say, 'We're going to not do this niche product, this niche population,' but they will say it anonymously. I think what surprised us was the number, so it is not rhetorical flourish.[53]

6.46 iNova Pharmaceuticals also noted that it is reconsidering whether to apply for PBS listing for a new product:

> ...iNova is planning for PBS access to an in-house developed therapy, which treats a certain type of skin cancer and represents an advance over current treatments. However, we now question the worth of continuing to invest in this new formulation for Australia since its potential PBS listing could be placed on hold indefinitely.[54]

6.47 Janssen-Cilag explained that they are facing similar decisions about introducing new medicines:

> Janssen has several new medicines in its pipeline for which there is a high clinical need. However, the current lack of predictability in Australia's reimbursement system is likely to affect the priority given to introducing new medicines in Australia compared with other nations.[55]

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52 Mr Jose Vieira, Managing Director, AstraZeneca Australia, *Committee Hansard*, 21 July 2011, pp 19-20.

53 Mr Andrew Bruce, Executive Director, Health Policy and Research, Medicines Australia, *Committee Hansard*, 25 July 2011, p. 27.

54 iNova Pharmaceuticals (Australia), *Submission 11*, p. 2.

55 Janssen-Cilag, *Submission 37*, p. 12.

6.48 The committee was provided with evidence that companies do make decision not to proceed with the listing of medicines due to cost considerations. Ms Bulfone provided the committee with the following example:

> I know of one drug that went through the PBS process, was recommended and went to cabinet. It is a very old drug; it has been around for many years. The manufacturer of the drug had discontinued the drug. Even though it was not going to make a large company much money, it was going to make a smaller company enough to survive. A very small company took this drug on and they got a positive PBAC recommendation. After it went to cabinet they referred it back to PBAC and they said that it needed to have cost effectiveness, but because the drug is so old—and this just happened in this last week—the evidence is not as strong as evidence that is generated in the current climate, where there is a much better process for clinical trials and everything. That company has decided not to make the drug available on the PBS or bothered to apply again because it is unlikely to get a positive PBAC recommendation, again because of the requirement...[56]

6.49 Dr Shaw cited New Zealand as an example of a health system in which access to medications has been adversely affected due to the Government's focus on cost-saving above health outcomes:

> We have a case study of a health system that has been screwed down in terms of costs savings so much so that industry has given up on it, and it is just across the Tasman. It is in New Zealand. We have patients sometimes approaching the companies here in Australia trying to get access to medicines because they are not available in New Zealand.
>
> As I say, the industry have given up. This is a case study of what can happen when a government puts expenditure and costs ahead of the broader health outcomes and the benefits that the health system brings. I do not want to see that happen here.[57]

Committee comment

6.50 The committee is of the view that the uncertainty introduced as a result of the Government's deferral decision will affect the investment decisions of the pharmaceutical industry, including investment in research and development and the running of clinical trials in Australia. The committee is concerned that as a result of the impact on the pharmaceutical sector, and the chain of processes which link to provide patients with medicines, ultimately, the access of consumers to appropriate and effective medications will be delayed and compromised.

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

57 Dr Brendan Shaw, Chief Executive, Medicines Australia, *Committee Hansard*, 25 July 2011, p. 30.