Chapter 3

The Government's decision to defer the listing of medicines under the Pharmaceutical Benefits Scheme

> For almost 60 years our world-renowned PBS has subsidised and delivered to all Australians safe, efficacious and cost-effective medicines. It makes no sense for the Government to now introduce extraneous barriers which make it more difficult for those in most need to obtain necessary and life-changing (even at times life-saving) medicines...The PBS has been the lynchpin for enabling millions of Australians to live pain-free, active lives, therefore giving them opportunities to remain in the workforce and/or live independently. It is one of the fundamental components of Australia's universal health care system, Medicare.[1]

Introduction

3.1 Many witnesses clearly stated that the Government's decision to defer the listing of medicines under the Pharmaceutical Benefits Scheme (PBS) represents a major change in Government policy.[2]

3.2 It was noted that the decision was made without consultation with key stakeholders and that future listings of medicines on the PBS will be dependent on cost-savings in other areas.[3]

3.3 Of great concern were the long-term effects of the Government's policy of indefinite deferrals of medicines recommended by the Pharmaceutical Benefits Advisory Committee (PBAC) including the undermining of the role and standing of the PBAC;[4] the erosion of the quality of Australia's health system through reduced access to affordable and appropriate medicines; and, the erosion of the tenets of the National Medicines Policy.[5] More importantly, submitters pointed to the introduction

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1 Arthritis Australia, *Submission 25*, pp 1–2.

2 Ms Carol Bennett, Chief Executive Officer, Consumers Health Forum of Australia, *Committee Hansard*, 25 July 2011, p. 35. See also Ms Helen Tyrrell, Chief Executive Officer, Hepatitis Australia, *Committee Hansard*, 25 July 2011, pp 52–53.

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

4 Australian Pain Management Association, *Submission 14*, p. 5; Mr Paul Murdoch, Vice-President, Australian Pain Management Association, *Committee Hansard*, 21 July 2011, p. 46.

5 Chronic Illness Alliance, *Submission 4*, pp 2–3; National Association of People Living With HIV/AIDS, *Submission 6*, pp 2–3.

of a political element to the listing of medicines and the complete lack of a transparent process once the listing process has moved into Cabinet for final decision-making.[6]

The change to the administration of the PBS

3.4 The Government has put the view that the deferrals announced in February 2011 are not a major change to the way that the PBS is administered.

3.5 The Government's position was explained to the committee by Mr David Learmonth of the Department of Health and Ageing (DoHA), who noted that 'the roles of PBAC and government have not changed. The PBAC advises and the government decides, as has always been the case'.[7]

3.6 However, submitters were overwhelmingly of the view that the Government's decision to refer all medicines recommended by the PBAC for listing with financial implications to Cabinet for consideration, together with the decision to defer the listing of medicines, constitutes a significant change to the administration of the PBS. For example, Ms Carol Bennett, Consumers Health Forum of Australia (CHF), told the committee:

> We believe this is a substantial change from a previous arrangement where only drugs with a financial impact of over $10 million per year, in any of the first four years of PBS listing, had to be considered by cabinet.
>
> This is a major change...
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> We completely reject the arguments that the decision to indefinitely defer medicines listing by cabinet does not represent a change in policy. While we accept that the government has the final say on recommendations of the PBAC and we know that that has been the case all the way along, we note that the rejection of listings has only occurred in two previous instances.[8]

3.7 While acknowledging that there had been deferrals previously, Ms Bennett commented that the outcomes between previous deferrals and what is taking place now are vastly different:

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6 Chronic Illness Alliance, *Submission 4*, p. 5; National Association of People Living With HIV/AIDS, *Submission 6*, pp 3–4; Council of Social Service Network, *Submission 7*, p. 5; Consumers Health Forum of Australia, *Submission 9*, p. 4. See also Dr Christine Walker, Executive Officer, Chronic Illness Alliance, *Committee Hansard*, 21 July 2011, p. 39; Dr Brendan Shaw, Chief Executive, Medicines Australia, *Committee Hansard*, 25 July 2011, p. 25; Diabetes Australia, *Submission 5*, [p. 1]; The Australian Lung Foundation, *Submission 20*, [p. 1].

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

8 Ms Carol Bennett, Chief Executive Officer, Consumers Health Forum of Australia, *Committee Hansard*, 25 July 2011, p. 35. See also Ms Helen Tyrrell, Chief Executive Officer, Hepatitis Australia, *Committee Hansard*, 25 July 2011, pp 52–53.

> There have been two instances in the past in which drugs have been deferred when they have been given a positive recommendation by the PBAC. At the point that you suddenly say, after one PBAC meeting, that seven medicines and one vaccine are being deferred, that is a change in policy, I would argue. That is my definition of a change in policy. Certainly, for consumers, it is the actions that matter. It is not what we say is policy; it is what actually happens.[9]

3.8 The Government has indicated that the decision to defer listings was expected to be temporary.[10] However, concerns were raised that there are no indications of when a return to the previous process can be expected. Ms Helen Tyrrell, Hepatitis Australia, told the committee:

> We note that the reason for the February 2011 cabinet decision to defer PBS listings has been linked to the government's budget deficit and stated intention to return the federal budget to surplus by 2013. The clear expectation was that further deferrals could be expected until a budget surplus was achieved.[11]

3.9 While it was noted that two medicines that were initially deferred have been reconsidered by Cabinet and subsequently listed, Ms Tyrrell of Hepatitis Australia noted that the process for reconsideration has not been delineated.[12] The explanation of the reconsiderations by Mr Learmonth, DoHA, cast little light on the process:

> It was reconsidered in the budget context and the government made a decision to fund it consistent, again, with the minister saying that if these things were deferred they would be considered in future as circumstances permit.[13]

3.10 The Australian Medical Association noted that the medicine Duodart® for enlarged prostate had been reconsidered and subsequently listed only four months after being deferred. They explained that this raised a number of concerns:

> It is not clear what circumstances have changed in that short time to permit the listing of 'Duodart'. Further, the Government has not explained why it has decided to now list this one medicine ahead of the other six that were similarly deferred in February 2011.

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9 Ms Carol Bennett, Chief Executive Officer, Consumers Health Forum of Australia, *Committee Hansard*, 25 July 2011, p. 40.

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

11 Ms Helen Tyrrell, Chief Executive Officer, Hepatitis Australia, *Committee Hansard*, 25 July 2011, p. 52.

12 Ms Helen Tyrrell, Chief Executive Officer, Hepatitis Australia, *Committee Hansard*, 25 July 2011, p. 52.

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

> While the Government's basis for deferring listing medicines on the PBS is unclear, the listing process can only be political. The AMA considers these listing processes and decisions must be fair, equitable and transparent, and not subject to political interference.
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> The AMA contends that Cabinet Ministers are not qualified to make decisions about which PBAC recommended medicines should not be listed, or those that should be listed ahead of others.
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> In addition, the AMA is not aware that Cabinet is provided with a cost benefit analysis of the impact of deferring the listing of medicines that takes into account direct and indirect costs and benefits to patients, the health care system and to the Australian economy.[14]

3.11 Submitters found this lack of transparency a major concern, with Hepatitis Australia commenting that:

> As an organisation, Hepatitis Australia supports the government's push for transparency as part of the National Health Reforms and believes this principle should also be applied to the Cabinet decision-making processes around PBS listings.[15]

3.12 Ms Tyrrell went on to observe that once people have lost confidence in the PBS approval system, 'a level of cynicism is to be expected, particularly regarding the government's future intentions'.[16]

3.13 The lack of any indication on the part of the Government about how long the deferrals will continue other than that they will be reconsidered 'when circumstances permit' has created uncertainty about how Cabinet is making these decisions.[17] Dr Brendan Shaw, Medicines Australia, explained:

> I think we have one sentence that refers to life saving and no alternatives. But we really have no other guidance about how and when it is going to occur, how long a deferral will stay in place and, if it is based on financial circumstances, when those financial circumstances are sufficiently benign that we would be able to go back to the old process.[18]

3.14 Consumer groups similarly expressed great concern about the lack of information around the deferrals process with Mr David Menadue, National Association of People Living with HIV/AIDS (NAPWA), commenting that:

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14 Australian Medical Association, *Submission 16*, p. 3.

15 Hepatitis Australia, *Submission 21*, p. 3.

16 Ms Helen Tyrrell, Chief Executive Officer, Hepatitis Australia, *Committee Hansard*, 25 July 2011, p. 52.

17 The Hon. Nicola Roxon, MP, Minister for Health and Ageing, 'Opening Address to Consumers Health Forum PBS Summit', *Speech*, 29 April 2011, [p.4].

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

> ...drugs can potentially be backlogged ad infinitem. We have no way of knowing, as a community group vitally concerned with the progress of the latest listings of drugs and where they are on in the drug approval process, whether they are being held up in cabinet or under what time frame they will be considered.[19]

A flawed Cabinet process

3.15 Submitters noted that the listing of medicines under the PBS was considered a global benchmark for rigorous evaluation and assessment.[20] The committee heard that the previous system was considered fair, clear and transparent. Mr John Latham, Pfizer Australia, told the committee that:

> The Pharmaceutical Benefits Scheme is envied around the world as the best system for providing medicines to citizens. This world-class status is not just based upon the fact that the system provides universal coverage to the newest medicines; it is more so because the decision making for which medicines are provided is based upon recommendations made by an independent group of clinicians and specialists, with cost-effectiveness as the key determinant for the selection criteria. The prices of new medicines in Australia are amongst the lowest in the OECD.[21]

3.16 Stakeholders and consumers were of the view that the Government's actions had undermined the integrity of the process.[22] The Australian Medical Association (AMA), for example, stated:

> As far as the AMA can tell from Government announcements, there appears to be two criteria that Cabinet is now using to defer listing medicines on the PBS after PBAC has recommended the listing:
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> - the medicines are for conditions for which there are existing treatments already available on the PBS; and
> - the circumstances do not permit listing.

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19 Mr David Menadue, Special Representative, National Association of People Living with HIV/AIDS, *Committee Hansard*, 21 July 2011, p. 48.

20 National Association of People Living With HIV/AIDS, *Submission 6*, p. 3. See also Dr Brendan Shaw, Chief Executive, Medicines Australia, *Committee Hansard*, 25 July 2011, p. 25; Ms Carol Bennett, Chief Executive Officer, Consumers Health Forum of Australia, *Committee Hansard*, 25 July 2011, p. 35; Australian Pain Management Association, *Submission 14*, p. 3; Osteoporosis Australia, *Submission 22*, [p. 1].

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

22 Mr David Menadue, Special Representative, National Association of People Living with HIV/AIDS, *Committee Hansard*, 21 July 2011, p. 48; Ms Carol Bennett, Chief Executive Officer, Consumers Health Forum of Australia, *Committee Hansard*, 25 July 2011, p. 35; Mr John William Stubbs, Executive Officer, Cancer Voices Australia, *Committee Hansard*, 25 July 2011, p. 44; Ms Barbara Hocking, Executive Director, SANE Australia, *Committee Hansard*, 25 July 2011, p. 49.

> The AMA considers both criteria to be inappropriate. In respect of the first criterion, the AMA considers it is a false 'saving' as the market for that type of medicine does not grow but sales of the medicine in question are funded by reduced sales in its direct competitors.
>
> In respect of the second criterion, because there is no transparency about the exact circumstances that will permit listing, Cabinet decisions to list medicines on the PBS are now purely political.[23]

3.17 Mr Menadue, NAPWA, also argued that 'Australia is throwing out a robust, workable system of drug regulation that currently has the confidence of the community and industry stakeholders alike'.[24] He captured the sentiment of other submitters when he added that 'if it ain't broke do not fix it'.[25]

Lack of transparency

3.18 Many submitters argued that a completely non-transparent process was being substituted for the previously transparent process. Ms Bennett, CHF, explained that:

> ...consumers are concerned that there is no transparency in the new process. We do not know what criteria are being used to decide which new medicines are listed, whether cabinet is drawing on any additional evidence apart from that considered by the PBAC, or what expertise is available to cabinet to make its decisions.[26]

3.19 It was also apparent that the Government's actions have created an unprecedented level of public angst. Ms Bennett emphasised to the committee that consumer concern on this issue was unparalleled:

> CHF has an enormous level of consumer concern about these changes, unprecedented in our 24 years of advocating for Australian health consumers. In June, 60 health consumer organisations joined with us to condemn the policy change and call for its reversal. More have contacted us since then, supporting our campaign. More than half of the submissions to this inquiry have come from individual health consumers or consumer organisations. This level of concern cannot be disregarded.[27]

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

24 Mr David Menadue, Special Representative, National Association of People Living with HIV/AIDS, *Committee Hansard*, 21 July 2011, p. 48.

25 Mr David Menadue, Special Representative, National Association of People Living with HIV/AIDS, *Committee Hansard*, 21 July 2011, p. 48.

26 Ms Carol Bennett, Chief Executive Officer, Consumers Health Forum of Australia, *Committee Hansard*, 25 July 2011, p. 35.

27 Ms Carol Bennett, Chief Executive Officer, Consumers Health Forum of Australia, *Committee Hansard*, 25 July 2011, p. 35.

3.20 It was noted that the decision shows disregard for the independent statutory role of the PBAC which operates at arm's length from the Government.[28] An independent and expert panel of the PBAC already evaluates the cost-effectiveness and clinical benefit of all medicines submitted for consideration.[29] The Council of Social Service Network stated:

> The PBAC is an independent statutory body established to provide expert advice to the Minister. Its advice is based on independent assessment made in the best interests of the community in terms of health, safety and cost...The Commonwealth Government is now politicising a process that used to have expertise, integrity and independence.[30]

Lack of expertise

3.21 In contrast to the expertise of the PBAC, submitters pointed out that 'Cabinet members do not have the necessary expertise to assess whether drugs are clinically necessary and provide value for money, while the members of the PBAC do have this expertise'.[31] Similarly, submitters questioned whether this kind of micro-management was a good use of Cabinet's valuable time.[32]

3.22 Cystic Fibrosis Australia explained this concern:

> So now we are looking at the possibility of 20 or so politicians deciding whether consumers will have access to the best affordable medicines, this is not being decided by experts. A decision like this may actually end up costing tax payers more money because sick people may have to seek other more expensive treatments, go into hospital for care and stop taking part in the workforce.[33]

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28 iNova Pharmaceuticals (Australia), *Submission 11*, p. 3. See also Dr Brendan Shaw, Chief Executive, Medicines Australia, *Committee Hansard*, 25 July 2011, p. 25; Ms Helen Tyrrell, Chief Executive Officer, Hepatitis Australia, *Committee Hansard*, 25 July 2011, p. 53; Council of Social Service Network, *Submission 7*, p. 5.

29 National Association of People Living With HIV/AIDS, *Submission 6*, p. 3; Council of Social Service Network, *Submission 7*, p. 5; Consumers Health Forum of Australia, *Submission 9*, p. 4.

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

31 Consumers Health Forum of Australia, *Submission 9*, p. 4. See also Dr Christine Walker, Executive Officer, Chronic Illness Alliance, *Committee Hansard*, 21 July 2011, p. 39; Ms Geraldine Robertson, *Submission 2*, [p. 1]; Cancer Voices Australia, *Submission 8*, p. 2; Cystic Fibrosis Australia, *Submission 18*, [p. 1].

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

33 Cystic Fibrosis Australia, *Submission 18*, p. 1. See also Ms Carol Bennett, Chief Executive Officer, Consumers Health Forum of Australia, *Committee Hansard*, 25 July 2011, p. 35.

3.23 Concern was also expressed that Cabinet decisions are being made without any scientific or medical advice on the appropriate order or time period of deferrals.[34] Ms Tyrrell of Hepatitis Australia explained:

> As the cabinet process is non-transparent, it is impossible to know if the politicians who are now making these decisions have critical information available to them. For example, deferring the hepatitis C treatment drugs would work against the goals of the Third National Hepatitis C Strategy, which was approved by all of Australia's health ministers only last year.[35]

A critical misunderstanding – population v patient level assessment of medicines

3.24 The lack of Cabinet scientific and medical expertise appropriate for making decisions on whether or not to list a medicine is evidenced by a failure to appreciate the difference between an assessment at a population level and an assessment at an individual level. It is also apparent in a range of evidence provided to the committee that for certain deferred medicines the nominated 'alternatives' are not, in fact, necessarily alternatives at the patient level.

3.25 DoHA has submitted that 'alternative medicines exist for all the deferred medicines, except for one'.[36] However, the committee heard that although alternative medicines might exist for the majority of deferred medicines, this was an assessment that had been made at the level of the general population. At the level of individuals the circumstances may be different: there may be a range of people where the listed medicine may not be able to be used as patients may not respond to it or they may experience adverse effects. In such cases those people may have no access to an alternative at an affordable price. As discussed in chapter 5, listing of only one medicine for a particular condition means that some consumers have access to an appropriate medicine, whereas others do not.

3.26 Ms Liliana Bulfone of Deakin University challenged the Government regarding the availability of alternative medicines. She stated that 'we are not sure that this claim holds any weight or is valid for a few reasons'.[37] Ms Bulfone went on to state that whereas a medicine may be 'equivalent' at a population level it may not be equivalent at an individual level:

> There is the group of drugs that have been recommended for listing on the basis of the fact that they are no worse than what is already there. They are essentially cost minimised, which means their cost is limited by the cost of the currently available therapies. I think it needs to be appreciated that when a drug is equivalent at a population level it does not mean the drug is

34 National Association of People Living With HIV/AIDS, *Submission 6*, p. 3.

35 Ms Helen Tyrrell, Chief Executive Officer, Hepatitis Australia, *Committee Hansard*, 25 July 2011, p. 52.

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

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

> interchangeable patient by patient. If you have got 50 per cent responders and 10 per cent having adverse events with one drug and you also have 50 per cent responders and 10 per cent having side effects with another drug, it does not mean that they are the same patients that are going to respond and have adverse events.[38]

3.27 Dr Bill Ketelbey of Pfizer Australia also contested the DoHA submission regarding the availability of alternative medicines listed on the PBS. He told the committee that 'the therapies proposed in the Department of Health's submission as alternatives to Pfizer's deferred medicines are not appropriate for all patients'.[39] Dr Ketelbey went on to provide an example of where a medicine described as not clinically interchangeable in the Therapeutic Goods Administration (TGA) approved product information had been nominated as an 'alternative' medicine in the DoHA submission.[40]

3.28 AstraZeneca Australia also contested the DoHA submission regarding the availability of alternative medicines listed on the PBS. They argued that given 'the lack of consultation with relevant Stakeholders (in particular patients and their treating healthcare professionals) prior to making the decision to defer listing...it is unclear as to the source of advice used to ascertain if indeed currently listed medicines provide true alternatives to the deferred medicines'.[41]

3.29 Similarly, Janssen-Cilag Australia, in answer to a question on notice, contradicted the evidence presented by Mr Learmonth, DoHA, regarding the interchangeability of paliperidone and risperidone. Mr Learmonth had stated that:

> Most of these drugs (deferred in February) 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. For example, paliperidone long acting, known as Invega Sustenna, which is a treatment for schizophrenia, was recommended by the PBAC on the grounds that it is of similar efficacy and toxicity to the existing long-acting therapy, Risperdal Consta, but it has a net cost to government. Both of these long acting injections are made by the same company, Janssen-Cilag. In fact paliperidone, or Invega Sustenna, is a metabolite of risperidone. This

38 Ms Liliana Bulfone, Senior Research Fellow, Deakin University, *Committee Hansard*, 21 July 2011, p. 1. See also Ms Carol Bennett, Chief Executive Officer, Consumers Health Forum of Australia, *Committee Hansard*, 25 July 2011, p. 36; Ms Helen Tyrrell, Chief Executive Officer, Hepatitis Australia, *Committee Hansard*, 25 July 2011, p. 52; Hepatitis Australia, *Submission 21*, p. 3.

39 Dr Bill Ketelbey, Country Medical Director, Pfizer Australia, *Committee Hansard*, 21 July 2011, p. 27.

40 Dr Bill Ketelbey, Country Medical Director, Pfizer Australia, *Committee Hansard*, 21 July 2011, p. 27.

41 AstraZeneca Australia, *Submission 47*, p. 12.

> simply means that paliperidone is the substance that the body converts risperidone into when that drug is taken.[42]

3.30 Janssen-Cilag Australia explained that there are in fact significant pharmacokinetic differences between paliperidone and risperidone:

> Contrary to Mr Learmonth's statement, there are clear pharmacokinetic differences between paliperidone and risperidone long-acting injections (LAIs).
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> Paliperidone palmitate is formulated as a water soluble suspension with a particle size distribution that has sustained release properties designed for once-monthly (4 weekly) intramuscular injections, with a rapid uptake to therapeutic plasma levels. In contrast, due to its extremely low water solubility, risperidone long-acting dissolves slowly, taking 21 days from the first injection to release risperidone.
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> After absorption, paliperidone palmitate is hydrolysed to paliperidone (9-hydroxyrisperidone). Although 9-hyroxyrisperidone is an active metabolite of risperidone, paliperidone palmitate and risperidone long-acting injections are not interchangeable due to substantial differences in their pharmacokinetic profiles.
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> Firstly, the differing pharmacokinetic profile of risperidone LAI results in a two-weekly injection interval, with an eight week delay to attaining therapeutic drug levels. To accommodate this delay to efficacy, six weeks (or more) of daily administration of oral antipsychotics (risperidone) is required. In contrast, the rapid and sustained pharmacokinetic release profile of paliperidone palmitate ensures early symptom improvement (by day 4 after initiation) and attainment of therapeutic plasma levels within 1 week of initiation, with efficacy maintained during a longer, 4-weekly injection interval.
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> In clinical practice, this means paliperidone palmitate can be used in the acute patient setting, where clinicians are required to release patients back into the community within 8-10 days where possible.
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> Secondly, paliperidone palmitate is primarily excreted by the kidneys whereas risperidone long-acting injection relies mostly on liver metabolism for elimination. A lack of reliance on liver metabolism is an important pharmacokinetic difference, minimising the risk of inter-patient variability in the ability to metabolise and/or eliminate paliperidone palmitate as follows: enables use of paliperidone palmitate in patients with mild to moderate liver impairment without dose adjustment or concern for drug accumulation due to abnormal hepatic function; ensures no impact on the metabolism of paliperidone palmitate due to smoking, which can induce liver metabolism of some long-acting antipsychotics, resulting in the requirement for higher doses; and, ensures no impact that genetic polymorphisms may have on an individual variation in the ability to

42 Mr David Learmonth, Deputy Secretary, Department of Health and Ageing, *Committee Hansard*, 25 July 2011, pp 3–4.

> metabolise antipsychotics; for example, there can be ‘fast’ or ‘slow’ hepatic metabolisers of risperidone.
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> Therefore, unlike risperidone LAI, the pharmacokinetic features of paliperidone palmitate LAI result in rapid attainment of therapeutic plasma levels and efficacy, maintenance of therapeutic concentrations allowing for 4-weekly dosing, with minimal inter-patient variability due to a lack of liver metabolism.[43]

3.31 Positive Life NSW also submitted that in the case of a major health condition such as HIV/AIDS there is often a range of co-morbid health conditions requiring treatment, in addition to antiretroviral (ARV) therapies. They noted that 'potential interactions between ARV medications and the medications prescribed for other health conditions can become complex and further restrict prescribing options'. This is exacerbated when PBS listings of new and innovative medicines have been held up.[44]

3.32 In a critical admission, Mr Learmonth of the Department of Health and Ageing acknowledged that 'It is potentially true' that a medicine which does not provide clinical superiority on a population assessment to other already listed 'alternative' medicines, may provide therapeutic superiority on an individual level for patients for whom the currently available medicines are ineffective.[45]

Competing agenda

3.33 Ms Bennett also raised concerns that Cabinet, which already has substantial and pressing responsibilities, does not have enough time to consider every medicine that has already been approved by the PBAC and commented:

> We are now looking at a situation where you have got the federal cabinet involved in the micromanagement of decisions about every single drug that goes up in the context of all the other considerations that federal cabinet must have and that creates a problem of access. It creates a problem of transparency because we do not know on what basis every single one of those drugs is being considered by the cabinet. It will ultimately create a backlog of drugs that are going up to cabinet and being deferred. The PBAC is meeting three times a year. If the cabinet is considering every one of those drugs, that becomes a real issue in terms of resources and how much the cabinet can actually do to consider every one of those drugs that goes up. Consumer access is the concern because quite clearly it may well become compromised if the number of applications that are going through

43 Janssen-Cilag Australia, answers to questions on notice and additional information, 21 July 2011, pp 1–2.

44 Positive Life NSW, *Submission* 26, pp 3–4. See also ACON, *Submission* 26, [p. 1].

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

> to the cabinet become backlogged because there are simply not the resources to consider them all.[46]

Lack of criteria for decisions

3.34 Along with concerns about delays in the listing of vital medicines, submitters pointed to the lack of formal criteria used by Cabinet in reaching its decisions. AstraZeneca Australia submitted that:

> The deferrals policy is characterised by a lack of clarity regarding the criteria used to select medicines for deferral, a lack of consistency between the stated 'criteria' and the medicines which have subsequently been selected for deferral and a lack of transparency regarding the source of advice used to facilitate the decision-making process.[47]

3.35 The committee heard evidence that the Government applies no formal criteria or definitions when making decisions on which medicines to list subsequent to the PBAC process. Mr Learmonth, DoHA, stated that Cabinet:

> ...has based its judgment on certain key facts about or attributes of the medicine—the nature of the disease that is being treated, its severity, whether there are alternative therapies available and so on.[48]

3.36 The committee notes that the Government has concentrated on 'listing medicines that treat serious or life-threatening conditions where there are no alternative treatments on the PBS'.[49] When asked for a definition of this phrase Mr Learmonth did not provide one, stating instead that:

> It is a statement of principle the government has made. These are questions of judgment for the government under the circumstances and based on the facts.[50]

3.37 Many submitters expressed grave concern that the lack of defined criteria for Cabinet decision-making has led to significant uncertainty for patients, practitioners and industry.[51] This was articulated in a joint submission from Cancer Council Australia, the Clinical Oncological Society of Australia and the Medical Oncology Group of Australia:

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46 Ms Carol Bennett, Chief Executive Officer, Consumers Health Forum of Australia, *Committee Hansard*, 25 July 2011, p. 36. See also Ms Helen Tyrrell, Chief Executive Officer, Hepatitis Australia, *Committee Hansard*, 25 July 2011, p. 52; Hepatitis Australia, *Submission 21*, p. 3.

47 AstraZeneca Australia, *Submission 47*, p. 9.

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

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

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

51 Deakin Health Economics, Deakin University, *Submission 19*, p. 3; Breast Cancer Network Australia, *Submission 24*, p. 3.

> One of the key problems created by subjecting decisions regarding PBS listings to the Cabinet process is that there is no transparency around the criteria, advice or processes used to arrive at these decisions.
>
> This is a backward step when so much has been done in recent years to improve the transparency of the PBAC listing process.[52]

3.38 Submitters pointed out that unlike decisions made by Cabinet, the PBAC process is well-understood and well-respected, and a formal set of criteria are outlined in the relevant legislation.[53] Deakin Health Economics, Deakin University, stated that:

> Our greatest concern is that a set of non-disclosed and potentially arbitrary set of criteria (if any exist!) are being used to divide a list of positive recommendations made by PBAC into two groups: (a) recommendations that should be implemented without delay; and (b) recommendations whose implementation be deferred.
>
> The criteria that have been used to divide the list of PBAC's recommendations into those should be implemented without delay and those that can be delayed have not been articulated by the Government.[54]

3.39 In addition, evidence was heard that the new system of Cabinet deferral of listings is not evidence-based. Mr Paul Murdoch, Australian Pain Management Association (APMA), commented that the Government:

> ...has claimed to be committed to evidence based decision making. It has also sought, quite rightly, to introduce a greater transparency to a range of health technology assessment processes, including of course the listing of pharmaceuticals and covering a wide range of other areas. This new policy in our view is directly contrary to these principles, being neither evidence based nor transparent. It is important to note that integrity, particularly of a system, is hard to establish but very easy to lose.[55]

3.40 The committee notes that two medicines that had been deferred have subsequently been listed. Committee members were keen to ascertain whether there had been a change in criteria used by the Government when reviewing that decision. In response, Mr Learmonth, DoHA, stated that 'there are no criteria in any form by which Cabinet makes these decisions – in any form'.[56]

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

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

54 Deakin Health Economics, Deakin University, *Submission 19*, p. 3.

55 Mr Paul Murdoch, Vice-President, Australian Pain Management Association, *Committee Hansard*, 21 July 2011, p. 45.

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

Committee comment

3.41 The committee notes that the decision to defer listings of PBAC recommended medicines under the PBS constitutes a major, unnecessary and unwelcome change in government policy. The Government has exchanged a well-respected, criteria-bound, evidence-based and transparent system for a system that is none of these things. Cabinet is duplicating an already existing process, albeit without the appropriate qualifications or information available to the PBAC. This is wasteful. Micromanaging the process in this way also represents a poor use of Cabinet's time and is likely to result in significant and unacceptable delays.

3.42 The committee notes that a decision not to list a medicine under the PBS because it is deemed that alternatives are available represents a profound lack of understanding of how medicines work. Medicines may work at a population level, however, they may not be interchangeable at the individual level. Or if they are, they may not lead to the same benefits to patients or individual health outcomes. For any condition this potentially creates two classes of people; those who have access to a suitable medicine that is subsidised and those who do not. The committee finds this unacceptable.

3.43 The committee also considers it unacceptable that Cabinet attempts to make these decisions without criteria of any description being published and against which such decisions are measured. Not only will this lead to poor decision-making but it will introduce great uncertainty for industry, consumer groups and patients.

Impact of the change to the administration of the PBS

3.44 Submitters pointed to a number of issues arising from the change to the administration of the PBS. These included the undermining of Australia's broader health policy including the long-term viability of the PBS and quality of the health system, the possible politicisation of the approval process, and the reintroduction of uncertainty in the approval process.

Long-term implications for the quality of Australia's health system

3.45 Evidence received by the committee raised concerns that the Government's decision to defer the listing of medicines on the PBS was occurring in isolation, divorced from the broader health policy context and outside of other PBS reform processes. Mr Menadue, NAPWA, explained to the committee that:

> There has been an ongoing PBS reform process that has been implemented across many aspects of the regulatory process and which has been delivered with consultation and buy-in from industry and patients alike. This was also done in a spirit of collaboration and transparency. The PBS deferrals currently upon us are not part of this, and they are most unwelcome.[57]

57 Mr David Menadue, Special Representative, National Association of People Living with HIV/AIDS, *Committee Hansard*, 21 July 2011, p. 48.

3.46 The committee heard from Mr Mark Glover of Allergan Australia that discussions about how to deliver savings and reform to the PBS should take place in a broad policy context, rather than at the level of individual medicines and their deferral.[58] It was argued that the deferral was not only a short-term policy but also was outside the normal Budget processes. Mr Latham, Pfizer Australia, commented that:

> We believe it is an example of a short-term policy with significant unintended consequences to both patients and manufacturers. It provides very limited financial gain to the government but significant disadvantage for consumers, reflected in the number of submissions that have been received from consumer organisations.[59]

3.47 NAPWA added:

> The decision is also confusing in terms of the rationale and placement of these changes prior to delivery of a formal Commonwealth Budget, and outside of the scope and processes agreed for other proposed PBS reform matters being delivered.[60]

3.48 Concerns were expressed that over the longer-term, through the deferral decision, and the consequent lack of alternative medicines, Australia stood to downgrade its medical system to be more akin to the New Zealand model.[61]

3.49 The committee heard that the New Zealand model is one in which only one molecule is listed per class, limiting access to suitable medicines. Further, in this system, medicines are tendered for, rather than being listed on a cost-effectiveness basis. Dr Simon Fisher concluded that this would not be called a modern healthcare system, and is not a system that Australian healthcare consumers would aspire to.[62]

3.50 Dr Brendan Shaw of Medicines Australia elaborated:

> ...you have a government for budgetary reasons saying that we cannot list these medicines. I am not saying that Australia has reached the New Zealand model yet—I would happily debate that. But my concern is that government is starting to say things like 'Yes, these medicines are cost effective and we can see that a modern industrialised country should be able

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

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

60 National Association of People Living With HIV/AIDS, *Submission 6*, p. 2.

61 Dr Brendan Shaw, Chief Executive, Medicines Australia, *Committee Hansard*, 25 July 2011, p. 33. See also Dr Simon Fisher, Medical Director, AstraZeneca Australia, *Committee Hansard*, 21 July 2011, pp 18–19.

62 Dr Simon Fisher, Medical Director, AstraZeneca Australia, *Committee Hansard*, 21 July 2011, pp 18–19.

> to access these but we cannot afford them.' My concern is that if we continue down that path will we head towards that model.[63]

3.51 Dr Shaw explained that access to medicines in New Zealand is now very constrained:

> When you look at what has happened in New Zealand over the last 20 years, the industry has basically abandoned New Zealand. There are medicines available there. Some of the medicines available in New Zealand are forty years old and have become lesser used in Australia. Basically, a lot of the New Zealand market is now run out of Australia because of the commercial environment in New Zealand. Patients in New Zealand have to wait much longer for medicines than patients in Australia. There is various data that we are happy to provide you with that shows that New Zealand, in terms of access to medicines, is one of the worst countries in the OECD.[64]

3.52 Dr Shaw also explained to the committee that the New Zealand model has had a serious impact on health outcomes:

> We are starting to see worse health outcomes in cardiovascular disease from the delay in listing medicines there. Patients in New Zealand have to wait many more years than in Australia. There are adverse events in hospitals when the government switches suppliers. New Zealand is characterised by having much older medicines than Australia. We have patients sometimes approaching the companies here in Australia trying to get access to medicines because they are not available in New Zealand.[65]

Committee comment

3.53 The committee notes that the process of deferring listings of medicines without clear criteria and on a false assessment of 'savings' will, over time, substantially erode both the quality and equity of access to medicines that has long been at the core of the Australian health system. The capping of the pharmaceutical scheme in New Zealand has produced just these effects. This is not acceptable.

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63 Dr Brendan Shaw, Chief Executive, Medicines Australia, *Committee Hansard*, 25 July 2011, p. 33.

64 Dr Brendan Shaw, Chief Executive, Medicines Australia, *Committee Hansard*, 25 July 2011, p. 33. See also Dr Simon Fisher, Medical Director, AstraZeneca Australia, *Committee Hansard*, 21 July 2011, pp 18–19.

65 Dr Brendan Shaw, Chief Executive, Medicines Australia, *Committee Hansard*, 25 July 2011, pp 30–31.

Politicisation of the approval process

3.54 Many submitters raised concerns that the approval process has become, or will become politicised.[66] It was feared that the new process would be more vulnerable to lobbying, with larger interest groups and those able to launch expensive campaigns potentially gaining greater influence. The spectre of listings being conditional on opposition support for other areas of government policy was also raised.[67] For example, Ms Bennett, CHF, commented:

> ...the lack of any transparency has created real consumer concern that a new political element has now been added to the process. In the absence of any credible explanation of why some medicines have been deferred while others have been listed, there is really no other conclusion that consumers can reach. Consumers are concerned that the listing process will become open to political whims and external interference. Consumers do not want a situation in which drugs are listed on the PBS to win votes or boost opinion polls; nor do they want a process which allows those consumer organisations with the loudest voices or the most media and political nous to see their drugs listed while other groups must wait indefinitely. And they absolutely do not want to see a process in which pharmaceutical companies can directly lobby cabinet members to achieve a positive outcome.[68]

3.55 Medicines Australia echoed these concerns and stated that:

> Recent statements suggest the Government is prepared to link access to future medicines to Opposition support for its policies in other areas, most notably its proposed changes to the private health insurance rebate scheme.[69]

3.56 Medicines Australia argued 'there is widespread disappointment in the community at these statements because they represent the over-politicisation of the long-standing, evidence-based process that previously characterised the listing of medicines'.[70] They illustrated this link further, quoting from Minister Roxon's press conference on 21 June:

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66 Chronic Illness Alliance, *Submission 4*, p. 5; National Association of People Living With HIV/AIDS, *Submission 6*, pp 3–4; Council of Social Service Network, *Submission 7*, p. 5; Consumers Health Forum of Australia, *Submission 9*, p. 4. See also Dr Christine Walker, Executive Officer, Chronic Illness Alliance, *Committee Hansard*, 21 July 2011, p. 39; Dr Brendan Shaw, Chief Executive, Medicines Australia, *Committee Hansard*, 25 July 2011, p. 25; Diabetes Australia, *Submission 5*, [p. 1]; The Australian Lung Foundation, *Submission 20*, [p. 1]; Australian Medical Association, *Submission 16*, p. 2.

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

68 Ms Carol Bennett, Chief Executive Officer, Consumers Health Forum of Australia, *Committee Hansard*, 25 July 2011, pp 35–36.

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

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

> ...in the future, listing innovative new drugs like Erbitux and Gilenya will become harder and harder if the Opposition continues to block sensible savings measures. It's time for the Opposition to stand up and act responsibly to recognise that savings that are captured in measures like the private health insurance proposals and the Chronic Disease Dental Scheme are essential if we are to keep Australia's health system and Pharmaceutical Benefits Scheme sustainable.

and

> We need to be able to do that and this is a very important long term question, I think, for the Opposition to have to start behaving responsibly if they want these sorts of innovative drugs to be able to be funded in the future.[71]

3.57 Committee members strongly reject the false association the Government attempts to make between opposition to the Government's attacks on one part of the health system and continuing access to new medicines that have been recommended as cost-effective by the PBAC.

3.58 A number of submitters were worried that the decision could lead to increased lobbying by pharmaceutical companies. Ms Sandra Younie of Deakin University explained:

> It certainly leaves the government open to being seen to be making decisions not on a transparent basis and that they may be subjected to pressure. It is sort of like management by squeaky wheel. Whoever yells the most, whoever has the most money to throw at a marketing campaign after a drug has been deferred—it leaves you open to that.[72]

3.59 The committee also heard that government may be subject to lobbying by health consumers. Dr Christine Walker, Chronic Illness Alliance, commented:

> This is sometimes both created and manipulated by the industry itself, but it is also based on emotions of the consumers rather than on the evidence that they may not be able to understand fully. It would be much harder for elected officials to withstand that kind of emotiveness than for an independent body.[73]

3.60 The Mental Health Council of Australia also pointed to problems arising from lobbying by consumer groups:

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

72 Ms Sandra Younie, Senior Research Fellow, Deakin University, *Committee Hansard*, 21 July 2011, p. 2.

73 Dr Christine Walker, Executive Officer, Chronic Illness Alliance, *Committee Hansard*, 21 July 2011, p. 39. See also Mr David Menadue, Special Representative, National Association of People Living with HIV/AIDS, *Committee Hansard*, 21 July 2011, pp 48–49.

> Introducing a Cabinet review process may undermine the independence of these decisions. For example, different sections of the health and health consumer sector are funded to provide the best possible voice for their constituents at the coalface of policy and program development, and on occasion the success of one part of the health sector can come at the cost of others within the health and health consumer sector. While it is important to have each part of the sector advocating for the best outcomes for their constituency, decisions about PBS listings need to remain independent from the influence of the health and health consumer sector and other interested parties. Ensuring that Cabinet decisions consider the independent advice offered by the PBAC may go some way to alleviating concerns about independence.[74]

3.61 Finally, the committee heard concerns that consumers who are reliant on medicines that are less commonly used, or who do not have access to such good advocates or lobbyists may become disadvantaged in a more politicised approval environment. Ms Bennett explained:

> For consumers, that is a real concern—particularly when there is no clear criteria on which cabinet is making decisions—if it means that the loudest groups, the most resourced groups or companies that are the most able to get the ear of government may well end up getting their drug listed on the PBS versus a small, niche-market drug for a group of consumers who may not have the same public profile or benefits to government that may be delivered from the listing of that drug. It creates a real concern.[75]

3.62 This disadvantage was explained further by Mr Matthew Pitt of the Brain Tumour Alliance Australia:

> Unfortunately the people who do have brain tumours tend not to stay around in advocacy for various reasons, not least is the morbidity and mortality and also the trauma caused by it. Even given our numbers we actually have a reduced political power and a reduced presence because of the impact of the disease on families. We are doubly afflicted.[76]

Implications for the PBAC

3.63 Submitters expressed concern that over time the professionalism and pre-eminence of the PBAC would be eroded, as a direct consequence of the decision for cabinet to consider all listings. AstraZeneca Australia argued that:

> By overriding the recommendations made by its own Expert Committee, the Government risks undermining the very system which is recognised

74 Mental Health Council of Australia, *Submission 53*, p. 4.

75 Ms Carol Bennett, Chief Executive Officer, Consumers Health Forum of Australia, *Committee Hansard*, 25 July 2011, p. 37. See also Arthritis Australia, *Submission 25*, p. 2.

76 Mr Matthew Pitt, Chair, Brain Tumour Alliance Australia, *Committee Hansard*, 25 July 2011, p. 46.

> throughout the world as a model for delivering optimal health outcomes in a cost-effective and equitable manner.[77]

3.64 APMA submitted that the decision will:

> ...compromise the ability of the Government to attract and retain the services of the highly qualified and eminent experts who currently undertake the assessment and analysis, and must over time influence the considerations undertaken by this expert body. Repeated rejections of recommendations by experts, well aware of the sound basis of their recommendations and the degree to which they reflect the intentions of Parliament through adherence to the legislatively mandated assessment criteria, must inevitably lead consciously or unconsciously to changes in how the assessment is undertaken and their conclusions and recommendations are derived. [78]

3.65 Mr Murdoch of APMA, explained to the committee:

> The membership of the PBAC is of eminent people who are also very, very busy. I think that, from their integrity, they would be reluctant to continue to contribute their valuable time to a process that is not treated seriously by the government.[79]

3.66 APMA also expressed concern that 'it could also tempt future Governments to appoint less independent experts to avoid having to regularly reject recommendations to list large numbers of medicines'.[80] Mr Murdoch explained further to the committee that the availability of sufficiently eminent people:

> ...is likely to be threatened where the eminent experts are not able to do their job. Were it not or even if it is, each time a government overturns or refuses to agree with an expert recommendation, such as one from the PBAC, it will invariably lead to at least some controversy. It presents political difficulties for a government so the temptation will inevitably be, irrespective of the composition of the government, to avoid that by having PBAC members who are not likely to cause controversies.[81]

Committee comment

3.67 The committee is concerned that the deferral decision stands to damage the independence and reputation of the PBAC. If the recommendations of the PBAC are

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77 AstraZeneca Australia, *Submission 47*, p. 1.

78 Australian Pain Management Association, *Submission 14*, p. 5.

79 Mr Paul Murdoch, Vice-President, Australian Pain Management Association, *Committee Hansard*, 21 July 2011, p. 46.

80 Australian Pain Management Association, *Submission 14*, p. 5.

81 Mr Paul Murdoch, Vice-President, Australian Pain Management Association, *Committee Hansard*, 21 July 2011, p. 46. See also Professor Michael Cousins, Director, Pain Australia, *Committee Hansard*, 21 July 2011, p. 46.

not even considered by Cabinet it will become increasingly difficult to attract and retain the calibre of people that presently comprise the PBAC.

Compliance with the intent of the Memorandum of Understanding

3.68 The Memorandum of Understanding (MOU) between Medicines Australia and the Commonwealth Government was signed in May 2011, and was subsequently announced in the 2010–11 Budget.

3.69 The committee heard that pharmaceutical companies have engaged in significant cooperative work with the Government aimed at streamlining both the TGA approval process and the PBAC approval process. Yet, the final Cabinet approval process had sometimes taken a long time. This problem had been resolved when the MOU was concluded; ensuring that in future Cabinet would take no longer than six months to make a decision on approval. As Mr Latham, Pfizer Australia, explained 'there are other things in there as well, but that predictability was one of the main things that we asked for'.[82]

3.70 A decision to defer listings now introduces great uncertainty into a system that had become more streamlined and more predictable. As Mr Latham explained:

> They did not say no. If they had said no, then fine, but they did not. They did not say yes and they did not say no. It is the decision that you have when you are not having a decision. If they had said no, that is fine, but they did not; they said it is deferred. That is the uncertainty that we are dealing with.[83]

3.71 Mr Murdoch of APMA told the committee that he considered that the decision to defer listing indefinitely can, in fact, be considered a rejection of a listing. He explained:

> During this session I intend to talk about the new government policy to reject rather than defer pharmaceutical listing. I think that is a semantic means of downplaying the seriousness and implications of this new approach. In almost any other legal jurisdiction, a decision such as the one taken by cabinet to date would be deemed to be refusal.[84]

3.72 Mr Latham went on to explain to the committee that this new level of uncertainty was occurring right at the very end of a long process:

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82 Mr John Latham, Chairman and Managing Director, Pfizer Australia, *Committee Hansard*, 21 July 2011, p. 30.

83 Mr John Latham, Chairman and Managing Director, Pfizer Australia, *Committee Hansard*, 21 July 2011, p. 30.

84 Mr Paul Murdoch, Vice-President, Australian Pain Management Association, *Committee Hansard*, 21 July 2011, p. 44. See also Mr David Menadue, Special Representative, National Association of People Living with HIV/AIDS, *Committee Hansard*, 21 July 2011, p. 48.

These things take 10 years to come through and then all of a sudden you are that close and then it falls down at the end and we are told we cannot afford it. We should be talking about whether we can or cannot afford it rather than putting this thing into limbo for the next 18 months because we are told this decision is going to apply until we come back into surplus. That is where we have a problem as an industry and as Australians.[85]

3.73 Mr Learmonth, DoHA, responded to these comments and stated:

It is true that the deferrals represent a change. It is also true that what the industry wanted and were looking for was stability, and that is why they proceeded with discussion and negotiation of an MOU with the government. This is different, however, to what the MOU does as a negotiated document. The MOU represents and reflects the scope of that agreement. In this case, the intent of the MOU itself is clear. Notwithstanding what anyone's motivation might have been for generating and negotiating one, the intent of the document is clear. Indeed, there is an intent clause which spells it out. Clause 3 of the MOU states:

> "Both parties intend that the MOU will promote the efficiency and sustainability of the PBS and support, by the provision of a stable pricing policy environment, a viable and responsible medicines industry in Australia …"

Clause 4 of the MOU 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."

This is the undertaking reflected in the MOU. This is the intent of the MOU—to provide certainty with respect to pricing and no more. Recommendations to the PBAC and the PBPA have always required government approval, and the referral of all listings with a financial impact for cabinet consideration is consistent with the commitments made under the MOU. This is not new pricing policy.

Finally, it has been suggested that the Commonwealth has departed from clause 29 of the MOU, specifically:

> "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."

Since this came into effect the government has consistently met or indeed bettered this timetable for consideration, with two of the last high-cost

85 Mr John Latham, Chairman and Managing Director, Pfizer Australia, *Committee Hansard*, 21 July 2011, p. 30.

> listings being considered by cabinet within one month of pricing being agreed. I think that is the record.[86]

3.74 Yet, both submitters and witnesses argued, in relation to clause 29 of the MOU, that the decision to defer listings on the PBS was in fact inconsistent with the spirit or intent of the MOU.[87] Others went further. Mr Latham, Pfizer Australia, told the committee that 'the unilateral decision on 25 February to indefinitely defer listings of new medicines on the PBS is a clear breach of the MOU'.[88]

3.75 The MOU between the Government and Medicines Australia was cited as a good example of a cooperative approach to addressing the question of sustainable health expenditure, unlike the unilateral decision to defer listing of medicines. Mr Latham submitted that:

> From the commercial side, the industry and the government signed a memorandum of understanding in September last year which demonstrated our joint commitment to sustainable health expenditure. The MOU was the result of the medicines industry and the government working hand in hand to solve PBS funding issues caused then by the GFC. By working collaboratively, we produced a sensible and well-thought-out agreement. Taxpayers maintained access to new medicines, the government banked nearly $2 billion in the forward estimates and the industry was assured that it would receive a predictable business environment in which it could make decisions about investment and employment.[89]

3.76 Deakin Health Economics submitted that the lack of adherence to the spirit of the MOU may have unforeseen consequences:

> It is our opinion that the lack of adherence to the spirit of the MOU is short-sighted as it is possible, if not likely, that the failure of the government to act in good faith in this instance will have repercussions for future negotiations between the pharmaceutical industry and government. Furthermore, it is possible that the failure of the government to uphold the spirit of the MOU will have flow-on effects for negotiations of agreements between government and other industries.[90]

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86 Mr David Learmonth, Deputy Secretary, Department of Health and Ageing, *Committee Hansard*, 25 July 2011, p. 3.

87 Research Australia, *Submission 12*, [p. 2]; Mr Mark Glover, Vice President and Managing Director, Allergan Australia, *Committee Hansard*, 21 July 2011, p. 16; Dr Brendan Shaw, Chief Executive, Medicines Australia, *Committee Hansard*, 25 July 2011, p. 29; Novo Nordisk, *Submission 23*, [pp 2–3];

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

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

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

Lack of consultation

3.77 Many submitters told the committee that the deferral announcement was completely unexpected and the changes were implemented without consultation with industry, consumer or patient groups.[91] Many submitters, in good faith, had worked closely and cooperatively with government on addressing changes to the PBS that would address financial sustainability, so the fact that this decision was announced suddenly and without warning caused great disappointment amongst stakeholders.[92]

3.78 Ms Tyrrell, Hepatitis Australia, stated:

> With regard to the consultation process, Hepatitis Australia was both surprised and shocked by the Gillard government's decision in February 2011 to depart from the established practice and defer PBS listings. This decision appears to demonstrate a disturbing lack of respect for health consumer consultation prior to instigating major changes in established practice which have a direct impact on the health and wellbeing of people in need of subsidised quality medicines.[93]

3.79 Mundipharma also noted that it had little consultation in relation to the deferral of its medicine and that 'apart from the initial phone call late on 24 February (the day prior to the Minister's announcement) neither the Government nor the Department had taken any initiative to proactively contact Mundipharma to discuss this important decision'. Mundipharma went on to note that apart from this call 'all interactions with both the Government and the Department of Health & Ageing have been initiated by Mundipharma'.[94]

3.80 Noting their disappointment about the lack of consultation, Mundipharma outlined the consequences for the company:

> Until that time, Mundipharma was given every reason to believe the process for the listing of Targin® tablets was proceeding on track according to normal Departmental processes. Had earlier advice been received, issues around the importation from the UK of stock of considerable value and consequent associated financial loss to Mundipharma could obviously have been avoided.[95]

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91 National Association of People Living With HIV/AIDS, *Submission 6*, p. 2; Dr Brendan Shaw, Chief Executive, Medicines Australia, *Committee Hansard*, 25 July 2011, pp 25 and 28; Ms Carol Bennett, Chief Executive Officer, Consumers Health Forum of Australia, *Committee Hansard*, 25 July 2011, p. 40; Cancer Voices Australia, *Submission 8*, p. 4; Painaustralia, *Submission 15*, p. 2.

92 Dr Brendan Shaw, Chief Executive, Medicines Australia, *Committee Hansard*, 25 July 2011, p. 29.

93 Ms Helen Tyrrell, Chief Executive Officer, Hepatitis Australia, *Committee Hansard*, 25 July 2011, p. 53.

94 Mundipharma, answers to questions on notice and additional information, 21 July 2011, p. 4.

95 Mundipharma, answers to questions on notice and additional information, 21 July 2011, p. 4.