The Senate

Finance and Public Administration References Committee

The Government's administration of the Pharmaceutical Benefits Scheme

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Participating Members for this inquiry

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Senator Sue Boyce	LP, Queensland

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ABBREVIATIONS

AMA	Australian Medical Association
APMA	Australian Pain Management Association
ARV	antiretroviral
BCNA	Breast Cancer Network Australia
BTAA	Brain Tumour Alliance Australia
CHF	Consumers Health Forum of Australia
COPD	Chronic Obstructive Pulmonary Disease
COSS Network	Council of Social Service Network
CPI	Consumer Price Index
CVA	Cancer Voices Australia
DoHA	Department of Health and Ageing
DVT	Deep Vein Thrombosis
GDP	Gross Domestic Product
GIFT	Gamete Intrafallopian Transfer
GMiA	Generic Medicines Industry Association
GSK	GlaxoSmithKline Australia
HIV/AIDS	Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome
IVF	In vitro fertilisation
LAI	Long-acting injections
MOU	Memorandum of Understanding
MS	Multiple Sclerosis
NAPWA	National Association of People Living with HIV/AIDS
NFP	Not-for-profit
OECD	Organisation for Economic Co-operation and Development
PBAC	Pharmaceutical Benefits Advisory Committee
PBPA	Pharmaceutical Benefits Pricing Authority
PBS	Pharmaceutical Benefits Scheme
PCEHR	Personally Controlled Electronic Health Record
PHARMAC	Pharmaceutical Management Agency of New Zealand
R&D	Research and development
Schedule	The Schedule of Pharmaceutical Benefits
TGA	Therapeutic Goods Administration

RECOMMENDATIONS

Recommendation 1

7.20 The committee recommends that the Government withdraw the statement made on 25 February 2011 regarding the deferral of the listing of new medicines and the new rules applying to listings from that point forward.

Recommendation 2

7.21 The committee recommends that the Government retract the statement that PBAC listing recommendations will not be proceeded with until savings are found to offset the costs of listing those medicines under the PBS.

Recommendation 3

7.22 The committee recommends that the Government should explicitly state that it rejects any implication that the listing of new medicines requires savings to be made elsewhere in the health portfolio.

Recommendation 4

7.23 The Government should restate its commitment to making an explicit decision regarding the listing of new medicines on the PBS within the terms and intent of the Memorandum of Understanding signed with Medicines Australia on 6 May 2010 and re-signed on 28 September 2010.

Recommendation 5

7.24 That the Government reinstate the '$10 million rule' so that medicines that have a financial impact of less than $10 million in each year over the forward estimates can be listed on the PBS Schedule by the minister without waiting for Cabinet approval.

Chapter 1

Introduction

Terms of reference

1.1 On 23 June 2011, the Senate referred the following matters to the Senate Finance and Public Administration References Committee for inquiry and report by 18 August 2011:

> The Government's administration of the Pharmaceutical Benefits Scheme (PBS), with particular reference to:
>
> (a) the deferral of listing medicines on the PBS that have been recommended by the Pharmaceutical Benefits Advisory Committee;
>
> (b) any consequences for patients of such deferrals;
>
> (c) any consequences for the pharmaceutical sector of such deferrals;
>
> (d) any impacts on the future availability of medicines in the Australian market due to such deferrals;
>
> (e) the criteria and advice used to determine medicines to be deferred;
>
> (f) the financial impact on the Commonwealth Budget of deferring the listing of medicines;
>
> (g) the consultation process prior to a deferral;
>
> (h) compliance with the intent of the Memorandum of Understanding signed with Medicines Australia in May 2010; and
>
> (i) any other related matter.[1]

Conduct of the inquiry

1.2 The inquiry was advertised in the newspaper *The Australian*, and through the internet. The committee invited submissions from the Commonwealth and State and Territory Governments and interested organisations.

1.3 The committee received 64 public submissions and one confidential submission. The list of individuals and organisations which made public submissions to the inquiry, together with other information authorised for publication by the committee, is at appendix 1. The committee held two days of public hearings, one in Melbourne on 21 July 2011 and one in Canberra on 25 July 2011. The list of witnesses who gave evidence at the public hearings is available at appendix 2. Submissions, additional information and the Hansard transcript of evidence may be accessed through the committee's website at http://www.aph.gov.au/Senate/committee/fapa_ctte/index.htm

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1 *Journals of the Senate*, 23 June 2011, p. 1102.

Acknowledgement

1.4 The committee thanks those organisations and individuals who made submissions and gave evidence at the public hearings.

Note on references

1.5 References in this report are to individual submissions as received by the committee, not to a bound volume. References to the committee Hansard are to the proof Hansard. Page numbers may vary between the proof and the official Hansard transcript.

Structure of the report

1.6 The report is structured as follows:

- Chapter 2 of the report provides a background to the Pharmaceutical Benefits Scheme (PBS) including the role of the Pharmaceutical Benefits Advisory Committee (PBAC), the process of listing medicines under the PBS, the costs of the PBS, and the recent Government decision to defer listings of a number medicines under the PBS.

  The chapter also provides background on the Memorandum of Understanding (MOU) between the Commonwealth Government and Medicines Australia signed with effect until 30 June 2014;
- Chapter 3 discusses the Government's decision to defer the listing of medicines under the PBS;
- Chapter 4 canvasses the financial impact of the PBS on the Commonwealth Budget;
- Chapter 5 covers the impacts on patients of the Government's decision to defer the listing of medicines;
- Chapter 6 discusses the consequences for the pharmaceutical sector and the availability of medicines in Australia; and
- Chapter 7 presents a summary of the committee's conclusions.

Personal comment from the Chair - Declaration of interest

1.7 As Chair I would like to restate for the public record that, prior to being elected to the Senate in November 2007, I was an employee of GlaxoSmithKline (GSK) from November 2002-December 2006 and that I undertook some consulting work with Medicines Australia in February 2008. I am also a shareholder in GSK Plc, as declared in the Register of Senator's Interests.

Chapter 2

Background

The Pharmaceutical Benefits Scheme

2.1 The Pharmaceutical Benefits Scheme (PBS) was established in 1948, and continues today as part of the Commonwealth Government's National Medicines Policy. The PBS is governed by the *National Health Act 1953*.[1]

2.2 The Government, through the PBS, subsidises the cost of medicines which are listed on the PBS Schedule (the Schedule) for all Australian residents who hold a current Medicare card.[2] Most of these medicines are dispensed by pharmacists for use by patients at home, however other higher risk medicines are only accessible from specialised medical services under supervision, such as chemotherapy medicines used in hospitals.[3]

2.3 Patients make a co-payment towards the cost of PBS medicines, which is adjusted on 1 January each year in line with the Consumer Price Index (CPI). From 1 January 2011, the co-payment for most PBS medicines is $34.20, or $5.60 for patients with a concession card, with the remaining cost of the medicines paid by the Commonwealth Government.[4]

The Pharmaceutical Benefits Advisory Committee

2.4 The Pharmaceutical Benefits Advisory Committee (PBAC) is an independent expert body comprised of doctors, health professionals and consumer representatives. The PBAC meets three times a year and is appointed by the Commonwealth Government.[5]

2.5 The main role of the PBAC is to assess applications for the listing of medicines on the PBS Schedule, and to make recommendations to the Minister for

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1 Department of Health and Ageing, *About the PBS*, 2011, http://www.pbs.gov.au/info/about-the-pbs (accessed 6 July 2011).

2 Visitors from countries which have Reciprocal Health Care Agreement with Australia (RHCA) can also access the scheme.

3 Department of Health and Ageing, *About the PBS*, 2011, http://www.pbs.gov.au/info/about-the-pbs (accessed 6 July 2011).

4 Department of Health and Ageing, *About the PBS*, 2011, http://www.pbs.gov.au/info/about-the-pbs (accessed 6 July 2011).

5 Department of Health and Ageing, *Pharmaceutical Benefits Advisory Committee*, 2011, http://www.pbs.gov.au/info/industry/listing/participants/pbac (accessed 6 July 2011); Department of Health and Ageing, *The Listing Steps*, http://www.pbs.gov.au/info/industry/listing/listing-steps (accessed 14 July 2011).

Health and Ageing as to whether particular medicines should be listed. New medicines cannot be listed unless a positive recommendation is made by the PBAC. In deciding whether a medicine should be listed under the PBS, the PBAC takes into consideration the medical conditions the medicine is registered for in Australia, its clinical-effectiveness, cost-effectiveness and safety in comparison with other treatments.[6]

The listing process

2.6 Only medicines registered on the Australian Register of Therapeutic Goods, which is maintained by the Therapeutic Goods Administration (TGA), or which have a positive recommendation that they be included on the register, can be considered for listing under the PBS. The TGA assesses and monitors medicines in Australia to ensure they are safe and effective.[7]

2.7 In order to have a medicine listed under the PBS, an application for the listing of the medicine must be made to the PBAC. There are five categories of submission to the PBAC as outlined below:

- Major Submissions
    - Tier 1: Applications for the listing of new medicines where cost-minimisation (or at least 'no worse than') is claimed, where pricing is based on a nominated dosage relativity, and where the prices to pharmacist proposed are in accord with the Pharmaceutical Benefits Pricing Authority (PBPA) methods of price calculations.
    - Tier 2: Submissions for new medicine listings where acceptable incremental cost-effectiveness is claimed (or new medicine listings where cost-minimisation is claimed but where pricing is not in accord with the PBPA criteria) and applications for changes to listings, both cost-minimisation and cost-effectiveness, and where the estimated net cost to the PBS is less than $10 million per annum in any of the first four years of listing.
    - Tier 3: Any submission where the estimated net cost to the PBS is estimated to be $10 million or more in any of the first four years of listing.

6 Department of Health and Ageing, *Pharmaceutical Benefits Advisory Committee*, 2011, http://www.pbs.gov.au/info/industry/listing/participants/pbac (accessed 6 July 2011).

7 Department of Health and Ageing, *Frequently Asked Questions*, 7 January 2010, http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pbs-general-faq.htm-copy2 (accessed 13 July 2011); Department of Health and Ageing, *The Listing Steps – Step 1: Seek advice from the PEB (Optional but recommended)*, http://www.pbs.gov.au/info/industry/listing/listing-steps/a-seek-advice-from-peb (accessed 14 July 2011).

- Minor Submissions
    - Secretariat: Submissions for minor changes to existing items. In these cases, there is no need for the PBAC to consider efficacy, price is not affected and there is no substantive financial impact on the PBS.
    - Other: Applications for minor changes to existing items that do not have significant financial implications but do require consideration by the PBAC because of their potential impact on the PBS.[8]

2.8 The PBAC assesses the applications for listing under the PBS, and either recommends that the medicine should be listed; or defers consideration pending the receipt of further information; or does not recommend that the medicine be listed. If the PBAC does not recommend the listing of a medicine on the PBS or an extension of a current PBS medicine listing for an additional indication, an independent review is available.[9]

2.9 The PBAC may also make recommendations regarding the use of a medicine, and any conditions or restrictions on those uses. The Minister of Health and Ageing can only approve government subsidisation of a medicine under the PBS in line with the independent recommendation received from the PBAC.[10]

2.10 Following each PBAC meeting, the PBPA meets. This non-statutory committee may recommend either a price range or a price ceiling for a medicine which has been approved by the PBAC, following negotiation with the sponsor.[11]

2.11 From 2001 until recently, Cabinet considered the subsidisation of medicines which were expected to cost over $10 million per year in any of the first four financial years of being listed. However, in early 2011 the Government stated that all changes to the PBS which have financial implications will now be considered by Cabinet, as

8 Department of Health and Ageing, *The Listing Steps*, http://www.pbs.gov.au/info/industry/listing/listing-steps (accessed 14 July 2011).

9 Department of Health and Ageing, *About the PBS*, 2011, http://www.pbs.gov.au/info/about-the-pbs (accessed 6 July 2011); Department of Health and Ageing, *The Listing Steps – Step 4: Send response*, http://www.pbs.gov.au/info/industry/listing/listing-steps/d-send-response (accessed 14 July 2011).

10 Department of Health and Ageing, *The Listing Steps*, http://www.pbs.gov.au/info/industry/listing/listing-steps (accessed 14 July 2011).

11 Department of Health and Ageing, *The Listing Steps*, http://www.pbs.gov.au/info/industry/listing/listing-steps (accessed 14 July 2011).

discussed further below. A listing may be accepted or rejected by Cabinet, and the final determination is confirmed by the Minister for Health and Ageing.[12]

2.12 The listing of medicines on the Schedule is authorised by the tabling of legislative instruments by the Minister for Health and Ageing.[13] When listed, the medicine will appear on the Schedule.[14]

Cost of the PBS

2.13 The total cost of the PBS is uncapped – it is driven by patient utilisation of the medicines available. While the Government manages the price of each medicine on the Schedule, as new medicines are added, and the utilisation of medicines already on the Schedule grows, the cost of the scheme increases.[15]

2.14 Over the 10 years to 2004–05, the cost of the PBS increased by about 13 per cent annually. The increasing costs of the PBS can be attributed to various factors including the listing of new medicines, increasing prescribing and utilisation of existing medicines and an ageing population.

2.15 Successive governments have attempted to contain the increasing costs of the PBS through various measures such as increases in patient co-payments, one-off price cuts, statutory price reductions and the extension of price disclosure arrangements.[16] The 2007 reforms of the PBS implemented many of these measures including:

- *Formularies* – medicines under the PBS were divided into two separate formularies, F1 comprising single brand medicines (except those

12 Department of Health and Ageing, *The Listing Steps*, http://www.pbs.gov.au/info/industry/listing/listing-steps (accessed 14 July 2011); Department of Health and Ageing, *The Listing Steps – Step 9: Agreement on usage estimates*, http://www.pbs.gov.au/info/industry/listing/listing-steps/i-agreement-on-estimates (accessed 14 July 2011); Commonwealth Government, *Portfolio Budget Statements 2011–12: Budget Related Paper No. 1.10: Health and Ageing Portfolio*, Commonwealth of Australia, Canberra, 2011, p. 121; Parliamentary Library, 'Making savings from the PBS – is deferring the listing of medicines the answer?', *Flagpost*, 4 April 2011, http://parliamentflagpost.blogspot.com/2011/04/making-savings-from-pbs-is-deferring.html (accessed 6 July 2011).

13 Department of Health and Ageing, *The Listing Steps – Step 10: Formal advice of listing*, http://www.pbs.gov.au/info/industry/listing/listing-steps/j-formal-advice-of-listing (accessed 14 July 2011).

14 Department of Health and Ageing, *PBAC Outcomes*, http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/pbac-outcomes (accessed 14 July 2011).

15 Department of Health and Ageing, *About the PBS*, 2011, http://www.pbs.gov.au/info/about-the-pbs (accessed 6 July 2011).

16 Parliamentary Library, 'Making savings from the PBS – is deferring the listing of medicines the answer?', *Flagpost*, 4 April 2011, http://parliamentflagpost.blogspot.com/2011/04/making-savings-from-pbs-is-deferring.html (accessed 6 July 2011).

interchangeable at a patient level with multiple brand medicines) and F2 comprising multiple brand medicines and single brand medicines interchangeable at the patient level. The division was intended to address the difficulty the Government experienced in paying competitive (lower) prices for multiple brand medicines by separating single brand medicines from multiple brand medicines for the purposes of reference pricing.[17]

At the time, the F2 formulary was further separated into two parts, F2A (medicines where price competition between brands was low) and F2T (medicines where price competition between brands was high) until 1 January 2011 when the two sub-formularies were intended to be merged to form a single F2 formulary.[18]

- *Pricing* – pricing rules for the medicines on each formulary were specified; in particular the circumstances in which price reductions would occur. In summary, the following pricing rules were applied:
  - a minimum 12.5 per cent reduction in the price of any bioequivalent or biosimilar brand of a medicine upon PBS listing (so long as the medicine had not previously been subject to a 12.5 per cent reduction);
  - from 1 August 2008, a staged 2 per cent price reduction every year for three years for medicines in F2A; and
  - on 1 August 2008, a one-off price reduction of 25 per cent for medicines in F2T.[19]
- *Price disclosure* – price disclosure provisions for medicines listed on the F2 formulary were introduced to ensure that the price the Government paid for multiple brand medicines more closely reflected the actual price at which those medicines were being supplied to pharmacies. The price disclosure requirements were applied to all new brands of a medicine listed on F2A from 1 August 2007. Upon merging the F2A and F2T sub-formularies (originally scheduled for 1 January 2011), the price disclosure requirements are to apply to all medicines listed on the F2 formulary.[20]

2.16 Prior to the Government's announcement of Cabinet deferral of consideration of particular medicines on 25 February 2011, the most recent attempt to manage the increasing cost of the PBS was through the Memorandum of Understanding (MOU)

17 Department of Health and Ageing, *The Impact of PBS Reform: Report to Parliament on the National Health Amendment (Pharmaceutical Benefits Scheme) Act 2007*, 2010, p. 28.

18 Department of Health and Ageing, *The Impact of PBS Reform: Report to Parliament on the National Health Amendment (Pharmaceutical Benefits Scheme) Act 2007*, 2010, pp 31–35.

19 Department of Health and Ageing, *The Impact of PBS Reform: Report to Parliament on the National Health Amendment (Pharmaceutical Benefits Scheme) Act 2007*, 2010, pp 31–35.

20 Department of Health and Ageing, *The Impact of PBS Reform: Report to Parliament on the National Health Amendment (Pharmaceutical Benefits Scheme) Act 2007*, 2010, pp 35–36.

signed between the Commonwealth Government and Medicines Australia, as discussed below.[21]

Memorandum of Understanding between the Commonwealth Government and Medicines Australia

2.17 On 6 May 2010, the Commonwealth Government and Medicines Australia signed an MOU with effect until 30 June 2014. The intent of the MOU is to:

> ...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, consistent with the objectives of the National Medicines Policy.[22]

2.18 The details of the MOU were announced as part of the 2010–11 Budget, with the expectation that the measures would deliver $1.9 billion in savings over the following five years, largely through price reductions for certain PBS medicines, and the extension of price disclosure arrangements.[23]

2.19 The MOU covered the following issues:

- strengthened price disclosure arrangements;
- price reductions for certain medicines listed on the PBS;
- the creation of new therapeutic groups;
- the consistent treatment of brands of medicines sold at the same price;
- comparators;
- parallel TGA and PBAC evaluation and assessment processes;
- a managed entry scheme from 1 January 2011;
- timing and maximum timeframes for PBS pricing negotiations and consideration by Cabinet; and
- resolution of issues in good faith.[24]

2.20 Following the 2010 Federal Election, and the subsequent extended caretaker period, the commencement date for one of the key pricing measures in the MOU,

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21 Parliamentary Library, 'Making savings from the PBS – is deferring the listing of medicines the answer?', *Flagpost*, 4 April 2011, http://parliamentflagpost.blogspot.com/2011/04/making-savings-from-pbs-is-deferring.html (accessed 6 July 2011).

22 Commonwealth Government and Medicines Australia, *Memorandum of Understanding*, 6 May 2010, p. 1.

23 Parliamentary Library, Bills Digest No. 13, 2010–11, *National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010*, 15 October 2010, p. 3.

24 Medicines Australia, *PBS MOU*, May 2010, http://medicinesaustralia.com.au/issues-information/pbs-mou/ (accessed 13 July 2011).

price disclosure, was delayed from 1 October 2010 to 1 December 2010. Consequently the MOU was re-signed on 28 September 2010 to reflect the change in the commencement date.[25]

Announcement of listing deferrals

2.21 On 25 February 2011, the Minister for Health and Ageing, the Hon. Nicola Roxon MP, announced the deferral of the listing of seven medicines under the PBS. The deferred listings were for the following medicines:

- dutasteride with tamsulosin hydrochloride (Duodart®), supplied in Australia by GlaxoSmithKline Australia to treat enlargement of the prostate gland;
- paliperadone palmitate (Invega Sustenna®), manufactured by Ortho-McNeil-Janssen Pharmaceuticals for the treatment of schizophrenia;
- oxycodone/naloxone (Targin®), supplied in Australia by Mundipharma for the treatment of chronic pain and to provide relief from constipation which is a typical side effect of opioid analgesics;
- budesonide with eformoterol (Symbicort®), supplied by AstraZeneca Australia for the treatment of severe asthma and chronic obstructive pulmonary disease;
- botulinum toxin type A (Botox®) extension, distributed in Australia by Allergan Australia for the treatment of hyperhidrosis (a severe sweating condition);
- dalteparin sodium (Fragmin®), supplied in Australia by Pfizer Australia to prevent the formation of blood clots and to treat Deep Vein Thrombosis (DVT);
- nafarelin (Synarel®), distributed in Australia by Pfizer Australia for the treatment of endometriosis and in vitro fertilisation (IVF) treatment.[26]

2.22 The minister explained that in most cases, for those medicines for which listing had been deferred 'there are existing, or alternative treatments that are already available, or there's no additional clinical benefit', and that priority has been given to life-saving medications.

2.23 The committee considers that as well as representing a profound misunderstanding of the role that different medicines within a given class can have on

25 Department of Health and Ageing, *Memorandum of Understanding with Medicines Australia*, September 2010, http://www.pbs.gov.au/info/industry/useful-resources/memorandum (accessed 13 July 2011).

26 The Hon. Nicola Roxon, MP, Minister for Health and Ageing, 'Patients benefit from new medicines listed on the PBS and NIP', *Media Release*, 25 February 2011, [p.2]; Research Australia, *Submission 12*, [pp 1–2].

patient wellbeing, this justification had never before been used as an excuse to defer consideration of PBAC recommendations.

2.24 It is also important to note that, for one of the medicines, Botox® used to treat hyperhidrosis, no alternative treatment is available.[27]

2.25 It was stated that deferred listings would be automatically reconsidered for listing by the Government 'when circumstances permit', but the minister was unable to advise of a timeframe within which the medicines would be reassessed.[28]

2.26 Only after the deferral announcement, did the minister seek the input of the industry, through Medicines Australia on the structure of the deferral and reconsideration process.[29]

2.27 As a consequence of the minister's 25 February 2011 announcement, the *Portfolio Budget Statements 2011–12* explained that 'the listing of some medicines would be deferred until fiscal circumstances permit' and outlined the Government's new position that all listings with a financial impact will now be considered by Cabinet:

> Given the need for fiscal discipline to achieve the Government's intention to return the Budget to surplus in 2012–13, all changes to the PBS with financial implications will be considered by the Cabinet.[30]

2.28 The deferral of the listing of these medications was characterised as a cost-saving measure 'in difficult financial and fiscal circumstances' to ensure the continued sustainability of the PBS into the future.[31] The minister focused solely on the cost of new medicines: 'Ultimately, just because a drug is proven to be clinically and cost-effective, doesn't mean it's the most urgent or pressing way to spend finite taxpayer money'.[32]

2.29 The minister maintained that the deferral was in keeping with the MOU with Medicines Australia, as the timeframe for considering applications had been met:

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27 The Hon. Nicola Roxon, MP, Minister for Health and Ageing, *Transcript of Doorstop*, Melbourne, 25 February 2011, [pp 1 and 5–6].

28 The Hon. Nicola Roxon, MP, Minister for Health and Ageing, *Transcript of Doorstop*, Melbourne, 25 February 2011, [p. 5].

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

30 Commonwealth Government, *Portfolio Budget Statements 2011–12: Budget Related Paper No. 1.10: Health and Ageing Portfolio*, Commonwealth of Australia, Canberra, 2011, p. 121.

31 The Hon. Nicola Roxon, MP, Minister for Health and Ageing, *Transcript of Doorstop*, Adelaide, 7 March 2011, [pp 4–5].

32 The Hon. Nicola Roxon, MP, Minister for Health and Ageing, 'Opening Address to Consumers Health Forum PBS Summit', *Speech*, 29 April 2011, [pp 2–3].

> ...unlike in the old days if there were financial pressures or if there were reasons that a Government didn't want to list a medicine, they just deferred considering it in Cabinet, or let it get lost for six or 12 months, to a lot of frustration from the pharmaceutical industry.
>
> We are complying with the terms of the agreement and have brought forward all of those applications...we've made a decision that a number of medicines won't be listed at this time. We're being public about that. We're making sure that everyone, who is an applicant in the pharmaceutical industry and the consumers, have that information available to them.[33]

2.30 The committee considers this is nothing less than a mischievous attempt to avoid admitting that this constitutes a breach of the MOU. It is nonsensical to assert that 'consideration' is met by a deferral, itself a refusal to make a decision.

2.31 Stakeholders have voiced a significant degree of concern regarding the Government's decision to indefinitely defer the listing of medicines which have received a positive recommendation from the PBAC. Many organisations have raised concerns regarding the impact of the decision on patients, their families and carers, the impact on the integrity of the PBAC assessment system, and the lack of transparency surrounding the Cabinet's decisions regarding which medicines to defer.[34]

2.32 In the past it has been very rare for a medicine which has received a positive recommendation from the PBAC not to be listed. In 2002, an exception to this process occurred when the then Minister for Health, Senator the Hon. Kay Patterson, decided not to list Viagra® under the PBS, despite the medicine receiving a positive recommendation from the PBAC. The advice received from the PBAC had noted that the listing of that particular medicine might have a significant budgetary impact on the PBS. This decision also caused significant concern throughout the industry at the time.[35]

2.33 A further exception took place in 1994 in relation to nicotine patches, which were assessed as cost-effective in the long-term but were not considered to be affordable in the short-term due to expected demand for the product.[36]

2.34 In light of significant stakeholder concern regarding the 25 February 2011 announcement, the minister attended a roundtable conference with peak health

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

34 Consumers Health Forum of Australia, *Summary of Outcomes: PBS Deferral Decision Forum*, 29 April 2011, [pp 1–3].

35 Parliamentary Library, 'Making savings from the PBS – is deferring the listing of medicines the answer?', *Flagpost*, 4 April 2011, http://parliamentflagpost.blogspot.com/2011/04/making-savings-from-pbs-is-deferring.html (accessed 6 July 2011).

36 Deakin Health Economics, Deakin University, *Submission 19*, p. 2; Mr David Learmonth, Deputy Secretary, Department of Health and Ageing, *Committee Hansard*, 25 July 2011, p. 10.

consumer organisations, the Consumers Health Forum, the Australian Medical Association, Medicines Australia and the Generic Medicines Industry Association on 29 April 2011 in Melbourne. Following the roundtable, the Consumers Health Forum stated:

> The stakeholder groups at the meeting appreciated the Minister's willingness to attend and to hear their views. However, the discussion at the meeting has not reduced our high level of concern about this decision.[37]

37 Consumers Health Forum of Australia, *Summary of Outcomes: PBS Deferral Decision Forum*, 29 April 2011, [p. 3].

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...
>
> 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.
>
> 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.
>
> 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:
>
> - 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).
>
> 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.
>
> 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.
>
> 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.
>
> 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.
>
> 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.
>
> 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.

Chapter 4

Financial impact of the Pharmaceutical Benefits Scheme on the Commonwealth Budget

Introduction

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

Overall costs and growth of the PBS

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

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

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

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

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1 Commonwealth Government, *Portfolio Budget Statements 2011–12: Budget Related Paper No. 1.10: Health and Ageing Portfolio*, Commonwealth of Australia, Canberra, 2011, p. 121.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Financial impact of the Government decision to defer listings

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Committee comment

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

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

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

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

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

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

Other possible savings measures

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

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

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

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

- maximise use of the Personally Controlled Electronic Health Record (PCEHR) by prescribers in order to reduce PBS outlays for duplicate scripts, and reduce adverse events;

- cease implementation of the 'continued dispensing' measure in the 5th Community Pharmacy Agreement that allows pharmacists to dispense PBS medicines without prescription or reference to a medical practitioner. This will address the continued dispensing of medicines that are no longer required, providing for significant savings;

- withdraw prescribing rights under the PBS from non-medical practitioners; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Committee comment

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

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

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

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

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

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

Chapter 5

Consequences for patients

> Listing new therapies on the PBS is a key investment in the health of Australians and not a mere cost. These are therapies that have been shown to meet a clinical need and improve health outcomes, for example, increase survival or greater quality of life, often saving costs elsewhere in the healthcare system. Another benefit is that these medicines increase the offering of therapies to meet individual patient needs, which otherwise would not occur if there was a 'one size fits all approach' to managing illnesses in Australia based on few PBS listings...people in need of new medicines recommended for listing by the PBAC on the basis they are effective and a worthwhile investment of taxpayer money should not have access denied due to (indefinite) PBS listing deferral. Such delay may potentially create a two tiered system whereby only those able to pay fully for new non-PBS listed medicines can access them, while many Australians with serious illnesses are denied access. Is this what Australians want?
>
> The PBS is a fundamental investment in Australians' health, and is not a cost containment tool to help manage the Federal Budget back to surplus.[1]

Introduction

5.1 The effects of the Government's decision to defer the listing of medications on the Schedule of Pharmaceutical Benefits (the Schedule) on patients, particularly in relation to the affordability and accessibility of medications, and the associated repercussions for individual and public health were made abundantly evident throughout the committee's inquiry.

5.2 Evidence received by the committee indicates that the Government's deferral decision is likely to result in an increased financial impost on patients who may already be struggling to pay for existing medicines, and as a result, unsubsidised medications may be inaccessible to a proportion of patients, resulting in inequitable access to the most appropriate treatment. Further, inability to access appropriate treatment entails risks not only to the health of individuals, but also to public health, and will result in further strain on the health system.

5.3 The Consumers Health Forum of Australia (CHF) informed the committee that it has seen an unprecedented level of concern from consumers about the changes to the Pharmaceutical Benefits Scheme (PBS) listing process. Following the deferral announcement, the CHF undertook a survey of the views of consumers, and 95.1 per

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

cent of respondents indicated that they are concerned about the Government's decision.[2]

5.4 Ms Liliana Bulfone of Deakin University commented that the long-term effect on patients who are unable to access deferred medicines may not be known, but stated 'to say that they are not disadvantaged I think is wrong'.[3]

Financial impost

5.5 Submitters noted that the PBS plays a central part in ensuring the affordability of medicines. Without medicines being listed on the PBS, many appropriate medications would be out of the financial reach of patients.[4] The Council of Social Service (COSS) Network noted that many low-income and disadvantaged Australians already struggle financially to access medicines which are subsidised under the PBS.[5] National Seniors Australia provided similar comments and noted that there are some older Australians, including concession card holders, who defer buying subsidised medicines because of the co-contribution they have to make.[6]

5.6 It was noted that medicines are only one of the financial burdens carried by patients. Submitters commented that patients also face out-of-pocket expenses for tests, surgery and other medical procedures, loss of income, and travel expenses, especially for patients from rural and regional areas.[7]

5.7 The Chronic Illness Alliance noted that those with chronic illness already spend a large proportion of their household income on medicines which are PBS listed, and often go without other essential items in order to afford their medicines, as health expenditure is rarely discretionary.[8] This was demonstrated by a survey undertaken by the Chronic Illness Alliance in 2003 of people in regional Victoria with chronic illness. The survey found that households with chronic illness in rural and

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2 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', April 2011, p. 4. See also Ms Carol Bennett, Chief Executive Officer, Consumers Health Forum of Australia, *Committee Hansard*, 25 July 2011, pp 39–40.

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

4 Council of Social Service Network, *Submission 7*, p. 4; Cancer Voices Australia, *Submission 8*, p. 2; Private Mental Health Consumer Carer Network (Australia), *Submission 1*, p. 2; Research Australia, *Submission 12*, [p. 3]; Roche Products, *Submission 39*, p. 4; Brain Tumour Alliance Australia, *Submission 17*, p. 2.

5 Council of Social Service Network, *Submission 7*, pp 4–5.

6 National Seniors Australia, *Submission 50*, p. 1.

7 Cancer Voices Australia, *Submission 8*, p. 2; Brain Tumour Alliance Australia, *Submission 17*, p. 2.

8 Chronic Illness Alliance, *Submission 4*, pp 3–4; Council of Social Service Network, *Submission 7*, pp 4–5; Australian Pain Management Association, *Submission 14*, p. 5.

regional Victoria will pay for their health needs regardless of income, and spend more on PBS and over-the-counter medications than any other health-related item. However, as a result, these families experience considerable poverty and financial distress, and will go 'without other essentials such as food, heating, family holidays and recreation and clothing in order to pay for essential medicines'.[9]

5.8 It was also noted that those with mental illness also find it difficult to find and retain employment and are often on disability support or are homeless and therefore under financial distress.[10]

5.9 Multiple Sclerosis (MS) Australia also commented on the vulnerability of those with chronic conditions to shifts in government policy:

> People with chronic illnesses that are reliant on the health and welfare system are far more vulnerable to shifts in public policy than other Australians and have fewer options in being able to adapt to new arrangements – particularly if they have negative consequences (such as reduced access to supports, higher levels of compliance or higher costs).
>
> Their lives are already compromised in terms of employment, community participation and overall quality of life, and decisions such as the deferrals are a visible reminder of their vulnerability.[11]

5.10 The Government's decision to defer the listing of medicines was characterised as 'a form of cost-shifting' to consumers. Concern was voiced that consumers, some already burdened with high health-related costs, may now have no option but to purchase medicines which are not listed on the PBS in order to obtain the treatment most suitable for them or to go without the medicines altogether. GlaxoSmithKline Australia (GSK) stated:

> Continuing deferral of PBS listing for medicines transfers an increased proportion of the costs of important medicines from the Government to the patient. This will force some patients to make difficult choices about their medical care according to their capacity to pay.[12]

5.11 This was illustrated by evidence provided by Mr Robert Pask, who informed the committee that as a person with multiple sclerosis, he spends over $250–$300 per month on medications. Mr Pask also suffers from narcolepsy but is not in a position to afford the approved anti-fatigue medication for this condition which would cost an extra $300 per month:

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9 Chronic Illness Alliance, *Submission 4*, p. 4.

10 Private Mental Health Consumer Carer Network (Australia), *Submission 1*, p. 2.

11 MS Australia, *Submission 43*, p. 6.

12 GlaxoSmithKline Australia, *Submission 44*, p. 9. See also Chronic Illness Alliance, *Submission 4*, p. 3; AstraZeneca Australia, *Submission 47*, p. 1; Medicines Australia, *Submission 36*, p. 13.

> I am not in a position to afford it and I am lucky enough that I can get through most days without falling asleep. When you add that on you can be looking at $600 a month.[13]

5.12 It was strongly argued that any decision which results in cost shifting to patients is unacceptable, as Ms Carol Bennett of CHF explained:

> The issue is that it certainly does create huge barriers to access to treatment for the most disadvantaged people—the people who have chronic conditions who cannot work full-time because they are ill and simply do not have the income to purchase these medicines when they are not subsidised. We hear stories all the time about people having to make really difficult choices about whether they buy a medicine or whether they put food on the table, pay their electricity bill or whatever—and this is for when drugs are subsidised. When drugs are not subsidised, it puts them out of the reach of many consumers.[14]

5.13 Further, if approved medicines are not subsidised under the PBS, submitters argued that patients, as taxpayers, are in effect paying twice for medicines:

> Patients denied PBS access to such cost effective medicines because they have been deferred, who choose to pay the full cost themselves, will in effect be paying twice for their medicine.[15]

5.14 The committee received direct evidence of the impact of the cost of medicines not listed on the PBS on consumers. Ms Elizabeth Graham submitted:

> The deferral of the listing of these medications means the burden of cost remains with patients who need them. In my own case, the monthly cost of treatment by medication is considerable; the need to continue with an efficacious medication which is unlisted adds to my burden. While I can afford it, I will continue with its use, but fear the time will come when my financial situation will make it necessary to change to a PBS listed medication. Should this scenario become reality, I will be forced to use other medications to counteract the side effects of the PBS listed medication; this is a situation of false economy as additional medications will be those listed on the PBS. I am certain I am not alone in facing this situation.[16]

5.15 The COSS Network argued that as a result of the decision to defer listings, inequitable access to medicines for low-income and disadvantaged Australians will be

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13 Mr Robert Pask, National Advocates Program, Multiple Sclerosis Australia, *Committee Hansard*, 21 July 2011, p. 42. For another example, see Mr John Stubbs, Executive Officer, Cancer Voices Australia, *Committee Hansard*, 25 July 2011, p. 46.

14 Ms Carol Bennett, Chief Executive Officer, Consumers Health Forum of Australia, *Committee Hansard*, 25 July 2011, pp 39–40.

15 GlaxoSmithKline Australia, *Submission 44*, p. 9.

16 Ms Elizabeth Graham, *Submission 54*, [pp 1–2].

exacerbated.[17] This point was illustrated by one of the respondents to the CHF survey who commented 'I am one of the people who need some of these new drugs, and being on a pension I cannot afford them unless they are on the PBS'.[18]

5.16 Submitters and witnesses also argued that the deferral decision may result in a two-tiered system in which the most appropriate medicine for some patients will be beyond their financial reach, and will only be accessible to those with the financial capacity to purchase unsubsidised medicines:[19]

> My concern is that, with that sort of a decision, we are heading more down the path of a two-tiered health system, where if you are wealthy you can afford the more convenient treatments. I know there are arguments about compliance, injections and once a month or twice a month—there are arguments about those sorts of things—but if you are wealthy you can afford to get them. If you are not, you have to rely on what is on the PBS. My concern is that, by going down this path, you are increasingly heading to a stage where all the older and less effective or less convenient and cheaper stuff is on the government scheme, but there is a range of treatments that are newer, better and can be more convenient for patients, and it will be the wealthy who will be able to access those, not the less wealthy.[20]

5.17 Although many consumers do not choose to purchase unlisted medicines, for those that do, the financial impact is large. Mr Brian Stafford commented that paying for the most appropriate medicine to treat a condition when that medicine is not listed on the Schedule can have significant financial ramifications for patients and their families:

> At the outset of the illness we owned 3 houses. By the time of the patient's death all the properties had been sold in order to pay our bills over the period of the illness. Not only is it the cost of expensive medications it is the years of lost earnings from work for the person who has to give up paid employment in order to become a full time carer. I now live in a rented house without sufficient capital left to buy any home for myself. However, my family member who was ill for some 10 years received the best medical care and medications because they were needed and they worked.[21]

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17 Council of Social Service Network, *Submission 7*, pp 4–5. See also Health Consumer's Council (WA), *Submission 33*, [p. 2].

18 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', April 2011, p. 4.

19 National Association of People Living with HIV/AIDS, *Submission 6*, p. 4; iNova Pharmaceuticals (Australia), *Submission 11*, p. 2; Dr Brendan Shaw, Chief Executive, Medicines Australia, *Committee Hansard*, 25 July 2011, p. 25.

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

21 Mr Brian Stafford, *Submission 3*, p. 1.

5.18 Pfizer Australia further submitted that even if a patient is financially able to purchase unlisted medicines, these medicines may not always be available if they are not listed:

> Even if the patient is able to self fund there is no guarantee a medicine will be available privately as the manufacturer may not be able to support the medicine without PBS subsidisation. Furthermore, if a medicine is not listed on the PBS, this may affect availability in hospitals.[22]

5.19 Diabetes Australia also pointed to other costs to consumers of the deferral of medicines: if the best medication for a condition is not available, the consumer may face escalating healthcare costs as effective treatment is delayed.[23]

5.20 Mr Jose Vieira of AstraZeneca Australia also addressed the costs of the deferral to consumers and argued that sometimes the alternative medicines can also offer patients cost-savings in terms of their treatment.[24] This point was illustrated with reference to Symbicort®, provided by AstraZeneca Australia for the treatment of chronic obstructive pulmonary disease (COPD), and the alternative medicine, Seretide®, currently available under the PBS:

> Each pack of Seretide® contains sufficient doses to provide for one month's worth of therapy for COPD. In contrast, each pack of Symbicort® contains sufficient doses to provide for two month's worth of therapy for COPD. Thus, over the period of a year, a patient receiving Symbicort® for COPD will pay for 6 prescriptions (with each pack of Symbicort® lasting 2 months). By comparison, a patients receiving Seretide® for COPD will pay for 12 prescriptions (with each pack of Seretide® lasting one month). As can be seen from Table 1 below, the net result is that patients pay twice as much for treatment with Seretide® for COPD as compared to Symbicort®.

Table 1 Annual cost to patients with COPD treated with Symbicort® and Seretide® respectively

Product	Cost per prescription		Scripts/year	Annual cost to patient	
	Concessional	General		Concessional	General
Symbicort®	$5.60	$34.20	6	$33.30	$205.20
Seretide®			12	$67.20	$410.40

> It should be noted that an increase in patient co-payments means that patients contribute more to the cost of their medicines. Subsequently, because a COPD patient pays less for Symbicort® (compared to Seretide®), Government pays more. This aspect was the key motivation for the decision to defer the PBS listing of Symbicort® for COPD, which suggests a preference to shift costs from the Government to patients.[25]

22 Pfizer Australia, *Submission 35*, p. 14.

23 Diabetes Australia, *Submission 5*, [p. 1].

24 Mr Jose Vieira, Managing Director, and Dr Simon Fisher, Medical Director, AstraZeneca Australia, *Committee Hansard*, 21 July 2011, pp 19 and 22.

25 AstraZeneca Australia, *Submission 47*, p. 5.

5.21 The Northern Territory Government Department of Health submitted that it has a mechanism in place to provide affordable access to essential medicines which have not yet been listed under the PBS:

> The Department currently has a policy to facilitate access to essential medicines where the cost of medicines would otherwise serve as a barrier. Under this arrangement, medicines that are deemed to be essential by medical specialists but are not covered by the Australian Government subsidy arrangements will have the costs met by the Department.
>
> Where a medicine is initiated while it is still under consideration for PBS listing, the Department meets the full cost until such time as it is listed...This effectively provides a safety net for limiting the consequences to patients of such deferrals.[26]

Access to medicines

5.22 Many submitters were of the view that the Government's deferral decision jeopardises access to alternative medicines for Australian health consumers, and also increases the delay patients experience in accessing affordable treatments which have been already assessed as cost-effective by the Pharmaceutical Benefits Advisory Committee (PBAC).

Access to alternative medicines

5.23 Submitters argued strongly that patients should have access to the latest and most effective treatments and the medicines which best suit their individual needs. A medicine which is an alternative to existing medication, which does not have unacceptable side-effects, should be available on the PBS.[27] Dr Simon Fisher from AstraZeneca Australia provided the committee with an example to illustrate why having access to alternative medications is important for patients:

> I wanted to talk to you about one elderly gentleman by the name of George who has chronic obstructive airways disease. I treated him with the currently listed PBS medicine. He unfortunately had an adverse experience on that medicine and he came back to see me because he had stopped taking the medicine and become much more short of breath to the point where his activities of daily living—washing, cleaning, walking down the street—were now impossible. So I looked for an alternative medicine, in a hypothetical today situation, on the PBS and I realised there is no alternative medicine for him, despite one medicine being TGA registered for the treatment of chronic obstructive pulmonary disease and in fact recommended by the PBAC. That is the medicine that AstraZeneca sponsors, Symbicort. I would be unable to use Symbicort for George because it is not listed on the PBS as a consequence of this policy.

26 Northern Territory Government, Department of Health, *Submission 62*, p. 1.

27 Cancer Voices Australia, *Submission 8*, p. 2; Private Mental Health Consumer Carer Network (Australia), *Submission 1*, p. 2.

> Therefore, I would have to put George in an ambulance to take him to hospital where he would be admitted, investigated, treated and stabilised for his chronic obstructive pulmonary disease. That is the doctor-patient interface consequence of the deferral policy. It is a direct negative effect on patients.[28]

5.24 Submitters argued that deferral of listings also serve to restrict 'clinical options to prescribed medications' which in turn reduces health outcomes.[29] Ms Anna Wise, CHF, explained, in relation to Invega Sustenna®, that:

> ...with psychiatric medications it can be so tremendously difficult to find one which actually works for a person. They can have to try so many that to have an option which is clinically effective and cost effective not made available to treating clinicians could make a real difference to so many mental health patients.[30]

5.25 This argument was supported by GSK Australia, which submitted:

> The first medicine in any therapeutic class to successfully enter the market and achieve listing on the PBS is not necessarily the best and it is essential that clinicians have access to a range of treatment choices where these exist and are proven to meet the cost effectiveness criteria for listing on the PBS...the deferral of PBS listing for medicines is a barrier to healthcare and reduces the capacity of treating clinicians to make the best treatment choice for their patients. Instead of making a decision based on the clinical requirements of the patient, a doctor must also make a prescribing decision that takes into consideration the affordability of a medicine for that patient.[31]

5.26 One of the respondents to the CHF survey who was concerned about the Government's deferral decision commented, 'It seems the Government is limiting access to medicines that a lot of people will need and may not be able to afford, and changing the goal posts to do it'.[32]

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28 Dr Simon Fisher, Medical Director, AstraZeneca Australia, *Committee Hansard*, 21 July 2011, p. 18.

29 Mr Paul Murdoch, Vice-President, Australian Pain Management Association, *Committee Hansard*, 21 July 2011, p. 45. See also Australian Medical Association, *Submission 16*, p. 2; Medicines Australia, *Submission 36*, p. 14.

30 Ms Anna Wise, Senior Policy Manager, Consumers Health Forum of Australia, *Committee Hansard*, 25 July 2011, p. 41.

31 GlaxoSmithKline Australia, *Submission 44*, p. 9. See also Breast Cancer Network of Australia, *Submission 24*, p. 2; Pfizer Australia, *Submission 35*, p. 14; Ms Elizabeth Graham, *Submission 54*, [p. 2]; Fabry Support Group Australia, *Submission 60*, [p. 2].

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', April 2011, p. 5.

Inequitable access to medicines

5.27 A further matter raised by witnesses was the potential for increased inequity in access to medicines. It was argued that small patient groups, for example, those with brain tumours, risk becoming more disenfranchised. If the listing process becomes politicised and more open to the influence of groups with more political presence and influence, medicines for small patient groups may not receive equal consideration:

> ...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.[33]

5.28 It was also argued that inequity can arise within patient groups because of delays in listing. Ms Liliana Bulfone of Deakin University used Invega Sustenna® as an example of how the Government's deferral decision 'introduces inequities' in access:

> ...if you are a patient who responds to Consta, which is the drug that was the comparator in this particular case, you have access to a subsidised drug, but if you are a patient who does not happen to respond to that drug or who has adverse events, you do not have the same equity of access to an equivalent drug, a drug that is as cost effective and as effective.[34]

5.29 While it is generally agreed that not all medicines can be listed and there will always be patients who won't have access to various medications under the PBS, Dr Brendan Shaw of Medicines Australia stated that in the past listings have been based on clinical effectiveness and health economics. The concern with the current situation is that patients will have their access to better medicines delayed for fiscal reasons as opposed to health economic reasons.[35]

5.30 Dr Fisher of AstraZeneca Australia further explained that pharmaceutical companies are trying to facilitate patient access to medicines, but that the deferral decision impedes patient access to treatment:

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33 Ms Carol Bennett, Chief Executive Officer, Consumers Health Forum of Australia, *Committee Hansard*, 25 July 2011, p. 38. See also Mr Matthew Pitt, Chair, Brain Tumour Alliance Australia, *Committee Hansard*, 25 July 2011, p. 46.

34 Ms Liliana Bulfone, Senior Research Fellow, Deakin University, *Committee Hansard*, 21 July 2011, pp 1–2. See also Deakin Health Economics, Deakin University, *Submission 19*, p. 5; Joint submission from Cancer Council Australia, the Clinical Oncological Society of Australia and the Medical Oncology Group of Australia, *Submission 32*, p. 2.

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

> We as an industry are dedicated to maintaining that access and in no shape or form would we or I ever wish to consider withholding that access or slowing it down. But that is what this policy does.[36]

Delay in access to medicines

5.31 A key concern raised by submitters is that due to the deferral of the listing of these medicines, patients are experiencing a delay in accessing valuable and cost-effective treatments, which have been assessed and approved by the PBAC.[37]

5.32 Cancer Voices Australia (CVA) cited the example of Erbitux, a medicine which can extend the lives of those with late stage bowel cancer. Erbitux was deferred by Federal Cabinet in July 2010. In June 2011 the Minister for Health and Ageing announced that it would be listed from 1 September 2011, however, in the interim, this decision has left many patients unable to access Erbitux for over 15 months.[38]

5.33 A number of submitters also raised concerns with the delay in affordable access to essential medicines caused by deferrals, which in some cases remains indefinite, as there has not yet been any indication as to when, or if, those medicines which remain deferred will be reconsidered.[39]

5.34 CHF explained that these concerns do not only relate to the medicines which have already been deferred, but to the uncertainty about which medicines may be deferred into the future:

> Consumers now face even greater uncertainty about when they will have access to the latest, most effective medications, as even after a positive PBAC recommendation there is a risk that Cabinet will again decide to defer listing of some drugs.[40]

5.35 Mr Matthew Pitt of the Brain Tumour Alliance of Australia (BTAA) noted that while no specific brain tumour medicines have as yet been deferred, the possibility that they could be, and that access to new treatments might be restricted, is very concerning:

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36 Dr Simon Fisher, Medical Director, AstraZeneca Australia, *Committee Hansard*, 21 July 2011, p. 19.

37 Mr Mark Glover, Vice President and Managing Director, Allergan Australia, and Dr Bill Ketelbey, Country Medical Director, Pfizer Australia, *Committee Hansard*, 21 July 2011, pp 19 and 27–28; Dr Brendan Shaw, Chief Executive, Medicines Australia, *Committee Hansard*, 25 July 2011, p. 25. See also Ms Helen Tyrrell, Chief Executive Officer, Hepatitis Australia, *Committee Hansard*, 25 July 2011, p. 52; Sanofi, *Submission 29*, [p. 2].

38 Cancer Voices Australia, *Submission 8*, p. 2.

39 Consumers Health Forum of Australia, *Submission 9*, p. 3. See also Ms Helen Tyrrell, Chief Executive Officer, Hepatitis Australia, *Committee Hansard*, 25 July 2011, p. 52.

40 Consumers Health Forum of Australia, *Submission 9*, p. 3.

> ...given that we are so starved for advances in treatment, the prospect that one day an effective treatment could be deferred absolutely scares us to the core. It is very worrying.[41]

5.36 Ms Helen Tyrrell noted that constituents of Hepatitis Australia are now concerned about whether they will be able to access new treatments which are due to be considered by the PBAC in the near future:

> There are two new hepatitis C treatment medicines that are due to be considered by PBAC in the immediate future. In clinical trials, the addition of either one of these drugs has resulted in significantly improved cure rates compared to the current standard treatment.
>
> The February 2011 decision to defer PBS listings has created nervousness amongst our constituents. Those who were delaying treatment until the new hepatitis C therapies became available are now wondering if they should start treatment with therapies that have much lower cure rates or keep waiting and hope that the new therapies are approved before their liver disease progresses any further, which in itself would make a cure harder to achieve.[42]

5.37 The implications of delayed access to the most effective and appropriate treatment for a condition can be significant, as explained by GSK:

> Delays in access to the best, most cost effective medicines will mean longer periods of debilitating illness for patients, time off work, increased use of other health services and, in some cases, could be life threatening. If they continue, the impacts will flow through to the wider economy through decreased workforce participation, increasing welfare payments, increasing health and hospital costs.[43]

5.38 Mr Denis Strangman noted that both New Zealand and the United Kingdom (UK) had responded actively to address the issue of timely access to treatment for particular groups of cancers. In the UK a special fund, the Cancer Drugs Fund, has been created to provide access to promising new therapies. In relation to New Zealand he quoted from the *Pharma Times* of 7 July:

> PHARMAC [the Pharmaceutical Management Agency of New Zealand] is also creating a pathway to assess treatments more quickly for patients whose condition would significantly deteriorate or who would miss the opportunity for significant improvement during the usual time taken to assess a Pharmaceutical Schedule application.[44]

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41 Mr Matthew Pitt, Chair, Brain Tumour Alliance Australia, *Committee Hansard*, 25 July 2011, p. 48.

42 Ms Helen Tyrrell, Chief Executive Officer, Hepatitis Australia, *Committee Hansard*, 25 July 2011, pp 52, 55 and 56.

43 GlaxoSmithKline Australia, *Submission 44*, p. 10.

44 Mr Denis Strangman, Secretary, Brain Tumour Alliance Australia, *Committee Hansard*, 25 July 2011, p. 45.

5.39 Submitters also argued that delays are likely to arise from Cabinet consideration, as Federal Cabinet will now consider the listing of every new medicine, and not just those with a financial impact of over $10 million each year.[45] Ms Bennett explained to the committee that when the $10 million threshold was in place the listing approval process for high-cost items tended to be more lengthy due to the requirement for Cabinet consideration, and on this basis calls had been made to lift the threshold to ensure patients faster access to medicines.[46] CHF concluded:

> People with chronic illnesses should not have to suffer continued delays in access to medicines because of the Government's very short term budgetary goals.[47]

Impact on health outcomes

5.40 Many submitters expressed concern that there will be adverse health outcomes for patients who are unable to meet the cost of medicines not listed on the PBS. As a result of high costs, patients may instead elect to use an alternative medicine which is listed on the PBS, but which may not be as effective, or may have undesirable side-effects.[48] The Australian Pain Management Association (APMA) submitted:

> ...if patients cannot afford the non-listed medications, they may cease medications, take the medications on a basis or frequency less than medically recommended, or utilize inferior (but cheaper) medications. Each of these consequences will have implications for the individual, especially over time. Conditions, and or symptoms, can and will worsen. Consequential medical costs, health outcomes and quality of life/functionality impacts will result.[49]

5.41 The COSS Network noted that inability to access the most appropriate treatment will impact both individual and public health:

> The Government's decision to defer the listing of pharmaceuticals recommended by the Pharmaceutical Benefits Advisory Committee (PBAC) will mean that the most vulnerable sick consumers will be unable to afford some critical medicines and vaccines. This will have negative

45 Consumers Health Forum of Australia, *Submission 9*, p. 3; Ms Carol Bennett, Chief Executive Officer, Consumers Health Forum of Australia, *Committee Hansard*, 25 July 2011, p. 36.

46 Ms Carol Bennett, Chief Executive Officer, Consumers Health Forum of Australia, *Committee Hansard*, 25 July 2011, p. 38.

47 Consumers Health Forum of Australia, *Submission 9*, pp 5–6. See also Cystic Fibrosis Australia, *Submission 18*, p. 2.

48 Private Mental Health Consumer Carer Network (Australia), *Submission 1*, pp 1–2; Council of Social Service Network, *Submission 7*, pp 4–5; Novo Nordisk, *Submission 23*, [p. 2]; Joint submission from Cancer Council Australia, the Clinical Oncological Society of Australia and the Medical Oncology Group of Australia, *Submission 32*, p. 2.

49 Australian Pain Management Association, *Submission 14*, pp 5–6.

> impacts on their individual health, and also the broader health and well-being of our society.[50]

5.42 CVA also voiced its concern that patients will not be receiving the best treatment for their condition due to the deferral decision:

> We are deeply concerned that medications that can provide patients with proven substantial health benefits are not being listed on the PBS and that, as a result, some Australians will not be receiving the best possible proven treatment for their medical condition.[51]

5.43 These concerns were echoed by Dr Fisher from AstraZeneca Australia, who explained that patients will continue to be treated, but the issue is that around 30 per cent of patients will have an adverse event from the medication they are prescribed, and if medicines which provide an alternative treatment continue to be deferred, these patients will be at risk of complications.[52]

5.44 Mr Stafford described the possible impact on a patient's quality of life if the appropriate medicine is not subsidised under the PBS:

> I found that the proven best treatments in our case were through pharmaceutical medications that were not subsidised on the PBS. I did not pay for the necessary medication for over 5 years because I was rich. I bought the medications because they worked. They worked in that they gave the patient a quality of life that she would otherwise have been denied.
>
> The alternative was to accept the GP's recommendations of only PBS subsidised drugs, none of which would have helped the patient, and have the patient committed to a locked institution until her death.[53]

5.45 Submitters also pointed to other benefits which may accrue from the use of alternative medicine regimes, for example, certain medicines may make 'compliance' with the treatment regimes required for various conditions easier, and therefore directly improve health outcomes.[54] A case in point is the deferred antipsychotic medication Invega Sustenna®. Mr Bruce Goodwin, Janssen-Cilag Australia, referred to the compliance benefits associated with Invega Sustenna®:

> There is a well-established body of evidence supporting the use of antipsychotic medications to reduce relapse. In particular, long-lasting injectables are shown to improve adherence to medication. In fact, around 80 per cent of patients remain adherent on long-lasting injectables whereas

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50 Council of Social Service Network, *Submission 7*, pp 4–5.

51 Cancer Voices Australia, *Submission 8*, p. 4.

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

53 Mr Brian Stafford, *Submission 3*, p. 1.

54 Diabetes Australia, *Submission 5*, [p. 1]; Mr Bruce Goodwin, Managing Director, Janssen-Cilag Australia, *Committee Hansard*, 21 July 2011, p. 25.

> only 50 per cent remain adherent on oral medications as an alternative. Of course, if you do not take your medication you are more likely to get sick again.[55]

5.46 NAPWA also raised concerns that health outcomes would be compromised if new and improved medicines and therapies are delayed, or are withdrawn from or not made available in the Australian system.[56] Ms Tyrrell of Hepatitis Australia noted that any deferral in the treatment of Hepatitis C can have significant implications, including 'increasing liver fibrosis, cirrhosis, liver cancer, the need for a transplant, liver failure and death'.[57] In addition, submitters also argued that delay in access to medicines can impact on the longevity of patients. One respondent to the CHF survey provided an example to demonstrate that a delay in access to medicine can lead to loss of life:

> Delay in listing Azacitidine last year (recommended by PBAC September 2009, listed February 2011) meant some of Leukaemia Foundation's patients died waiting for this new drug while awaiting Cabinet approval for PBS listing[58]

Benefits of effective treatment of medical conditions

5.47 Chronic Illness Australia and other submitters explained that access to affordable medicines is important for those suffering from chronic illness, not only in terms of staying alive but also in affording them quality of life, thereby enabling them to participate more actively in the community and the economy.[59] iNova Pharmaceuticals (Australia) commented:

> Listing new therapies on the PBS is a key investment in the health of Australians and not a mere cost. These are therapies that have been shown to meet a clinical need and improve health outcomes, for example, increase survival or greater quality of life, often saving costs elsewhere in the healthcare system.[60]

5.48 Further, NAPWA noted that there is a public health benefit in the effective treatment of medical conditions such as HIV, because as the 'health of a person with

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55 Mr Bruce Goodwin, Managing Director, Janssen-Cilag Australia, *Committee Hansard*, 21 July 2011, p. 25.

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

57 Ms Helen Tyrrell, Chief Executive Officer, Hepatitis Australia, *Committee Hansard*, 25 July 2011, p. 56.

58 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', April 2011, p. 5. 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; Roche Products, *Submission 39*, pp 3–4.

59 Chronic Illness Alliance, *Submission 4*, p. 3; Diabetes Australia, *Submission 5*, [p. 1].

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

HIV is improved the amount of virus they carry is reduced to very low levels, thus making onward transmission of the virus very difficult'.[61]

5.49 The committee also heard that effectively treating a medical condition can prevent co-morbidity, or suffering from other conditions caused by or linked to the original condition, which not only impact on the quality of life of the patient, but also create further burden on the health system in terms of resources and cost.[62]

5.50 Mr Pask of MS Australia explained to the committee what it means to him to have access to the medicines he requires:

> I have multiple sclerosis and I have type 2 diabetes—even though I do not admit to it—arthritis and a few other things, so I am dependent on so many medications. In theory, I am able to work three days a week. But I do work a lot longer than that...But I am only able to do that because the medications are there.
>
> ...I do not believe we look enough at the value of medications, as far as keeping people in work and getting people back into work. Obviously, the cost benefit is what we get out of it. Because of my medications, I have been given an opportunity to keep going and keep working and doing stuff that I really love doing. But if I were not working I would not be able to afford a lot of that stuff...[63]

Consequences of not having access to the deferred medicines

5.51 As discussed in chapter 3, the committee heard that not all alternative medications are equal, and for some patients, alternative treatments are not a viable option. The committee sought to quantify the impact on patients of the Government's decision to defer particular medicines, and found that potentially the deferral of these products could affect:

- 100,000 people in Australia living with schizophrenia;[64]
- an estimated 50,000 to 100,000 Australian patients living with chronic pain;[65]
- potentially up to 40,000 patients who would be eligible for the Botox® treatment;[66]

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

62 Ms Elizabeth Trapani, and Ms Chey-Anne Ellsum, *Committee Hansard*, 21 July 2011, p. 35.

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

64 Mr Bruce Goodwin, Managing Director, Janssen-Cilag Australia, *Committee Hansard*, 21 July 2011, pp 25 and 28.

65 Mr Rob Baveystock, Managing Director, Mundipharma, *Committee Hansard*, 21 July 2011, pp 26 and 28.

66 Mr Mark Glover, Vice President and Managing Director, Allergan Australia, *Committee Hansard*, 21 July 2011, p. 20.

- almost one in five Australians over 40 years of age who are affected by chronic obstructive pulmonary disease;[67]
- about 24,000 patients over five years with venous thromboembolism;[68] and
- potentially 10,000 patients receiving in vitro fertilisation (IVF) and gamete intrafallopian transfer (GIFT) interventions.[69]

5.52 The following discussion focuses on three of the medicines deferred: Invega Sustenna®, Targin® and Botox® (for the treatment of hydohidrosis).

Case Study 1: Invega Sustenna® (paliperidone palmitate)

5.53 Invega Sustenna® is a treatment for schizophrenia which is administered monthly through an injection to the arm. While it acts in a similar way pharmacologically to another antipsychotic medication, risperidone, it differs to all other antipsychotics in the method in which it is administered.[70]

5.54 Ms Bennett noted that the CHF has received a particularly strong response from consumers about the deferral of Invega Sustenna®:

> ...largely because the concern there is that there are real issues around compliance of mental health consumers. When you have to attend a clinic and have two injections a month, versus attending a clinic and having one injection a month, that may seem fairly insignificant to the average person. But for somebody who is trying to manage their lives and has to involve a carer, has to get to a clinic and has to maintain a treatment regime and could well, if they do not take their medication, end up hospitalised and psychotic—and all the implications that go with that—that is a pretty significant quality of life impact. So, for those consumers, that stood out to me as being one of the drugs that it is pretty hard to argue that there is an alternative available for, when the alternative can mean the difference between somebody being hospitalised or not.[71]

5.55 Mr David Learmonth of the Department of Health and Ageing (DoHA) noted that the PBAC recommended Invega Sustenna® on the basis that its efficacy and toxicity is similar to the existing treatment, Risperdal Consta®, but concluded that the claim of clinical superiority was not justified on the evidence presented:

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67 Dr Simon Fisher, Medical Director, AstraZeneca Australia, *Committee Hansard*, 21 July 2011, p. 20.

68 Dr Bill Ketelbey, Country Medical Director, Pfizer Australia, *Committee Hansard*, 21 July 2011, p. 28

69 Dr Bill Ketelbey, Country Medical Director, Pfizer Australia, *Committee Hansard*, 21 July 2011, p. 28.

70 SANE Australia, *Submission 10*, [p. 1].

71 Ms Carol Bennett, Chief Executive Officer, Consumers Health Forum of Australia, *Committee Hansard*, 25 July 2011, p. 41.

> No benefit in reduction of relapses was demonstrated, nor was there any evidence to support the claim that this alternative drug reduces the number of days patients spend in hospital.[72]

5.56 However, a number of submitters argued quite strongly that Invega Sustenna® is an important alternative medicine. Ms Bulfone of Deakin University used Invega Sustenna® as an example to illustrate that alternative medications are not equivalent on a patient-by-patient basis:

> Invega Sustenna for schizophrenia is a really good example of where the drug on a population level results in the same average benefit to patients in a clinical trial, but for an individual patient, particularly as this drug has different pharmacological properties to its comparator, the profile of side-effects that goes with it is also different. A patient may not be able to tolerate Consta, which is currently available and was the comparator in that case, but they will be able to tolerate Invega Sustenna, or they may respond to one but not the other. Yes, there are alternatives, but they may not work.[73]

5.57 A respondent to the CHF survey also explained the value of an alternative treatment for patients who have not responded well to existing treatments:

> The Government has promised to increase funding for mental health, yet in this recent decision it has refused to allow a new drug to be listed for the treatment of schizophrenia. As with any drug that treats conditions of the brain, one drug does not suit everyone, and by refusing to allow the availability of a new drug, this Government is depriving those with schizophrenia who have not responded well to existing drugs of an opportunity to achieve good mental health. This action flies in the face of this Government's stated position on mental health.[74]

5.58 SANE Australia commented that, for people living with schizophrenia, the difference in administration of Invega Sustenna® has significant benefits, and should not be trivialised:

> A monthly injection makes adherence much more likely and reduces by half or more the number of visits to a doctor. For people whose symptoms include reduced cognitive ability and motivation, it increases the likelihood that they will attend the appointment; it also halves the attendant trouble and cost of a journey to the doctor's surgery or clinic. This in turn benefits the carer as well as freeing up the clinician's time and administration costs. A monthly injection to the arm is also more easily given, more dignified

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

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

74 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', April 2011, p. 11.

> and less traumatic than a fortnightly injection to the buttock (especially where the person is being treated involuntarily).[75]

Case Study 2: Targin® (oxycodone/naloxone)

5.59 Targin® is used for the treatment of pain and has been approved by the Therapeutic Goods Administration (TGA) for managing moderate to severe pain which is unresponsive to non-narcotic pain relief medication.[76] Respondents to the CHF survey commented that Targin® has benefits over other available 'alternatives' in that it provides a substitute for the more addictive Oxycontin, and 'as a combination of oxycodone and naloxone cleverly avoids the opioid bowel dysfunction seen with other opiod analgesics and reduces significantly the potential for abuse'.[77]

5.60 Submitters explained that Targin® has the potential to reduce the abuse and diversion of strong prescription opioids, and is 'the first opioid analgesic that incorporates abuse deterrence technology to help address this major community issue'.[78]

> Opioid diversion is something we cannot just push aside; it is becoming a much, much bigger problem throughout the world. This preparation would be extremely unattractive to opioid abusers because it is not designed for intravenous use. If it was injected intravenously, because of the blocking drug contained in the preparation it would cause an immediate and very severe withdrawal. It is the start of our abilities to provide pain management with a specifically designed preparation that will not have any appeal whatsoever to opioid abusers.[79]

5.61 The committee was told that it is difficult to quantify the potential for reduced drug diversion and abuse, and insufficient evidence on this characteristic was provided to the PBAC for a definite conclusion.[80] While the technology incorporated into this medicine will not stop abuse entirely, from a practitioners point of view:

> ...at least it would overcome the problem, when we are prescribing the current range of opioid drugs for a patient with medical indications, of us

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75 SANE Australia, *Submission 10*, [p. 1]. See also Ms Barbara Hocking, Executive Director, SANE Australia, *Committee Hansard*, 25 July 2011, pp 49–50; Research Australia, *Submission 12*, [p. 4].

76 Mundipharma, *Submission 38*, p. 5.

77 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', April 2011, p. 11. See also Mr Rob Baveystock, Managing Director, Mundipharma, *Committee Hansard*, 21 July 2011, p. 26.

78 Mr Rob Baveystock, Managing Director, Mundipharma, *Committee Hansard*, 21 July 2011, p. 26.

79 Professor Michael Cousins, Director, Painaustralia, *Committee Hansard*, 21 July 2011, p. 44.

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

> having to be concerned that this drug might, by various means, be diverted to other users.[81]

5.62 Mr Learmonth of DoHA noted that in its PBAC submission Mundipharma did not claim that Targin® was superior to the currently available oxycodone in combination with over the counter laxatives.[82] However, in its submission, Mundipharma explained that opioid-induced constipation has distinct causative factors, and laxatives do not address the cause of the condition, rendering them a 'less than adequate treatment'.[83]

5.63 Mr Rob Baveystock, Managing Director, Mundipharma, added that while there are opioid analgesics available to treat chronic pain, these treatments have shortcomings:

> Whilst these medicines are undoubtedly effective in relieving severe disabling pain, they are also potentially associated with serious side effects, including opioid-induced bowel dysfunction, often including severe opioid-induced constipation, and potential for addiction. What is apparently not understood by government is that this is not the type of constipation that otherwise healthy individuals might suffer from time to time. It is far worse; it is almost inevitable; it results in increased cost to the community and government; and, importantly, it cannot be treated with simple laxatives. Severe constipation can lead to impaction and hospitalisation and can aggravate cancer pain, resulting in a pattern of increasing opioid dosages in an attempt to relieve pain...there is no strong opioid analgesic available in Australia which treats chronic disabling pain while simultaneously addressing the cause of opioid-induced constipation and helping to prevent it.[84]

Case Study 3: Botox® (botulinum toxin type A)

5.64 Botox® has been TGA registered for the treatment of severe primary hyperhidrosis of the axillae (underarms). This condition manifests through severe, excessive sweating, and as a result, patients suffer constant wetness and staining of clothing, and dehydration and maceration of the skin, which can result in secondary skin infections. Patients can also experience difficulty in grasping objects and writing. Effective treatment can improve the social functioning and mental health of those

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81 Professor Michael Cousins, Director, Painaustralia, *Committee Hansard*, 21 July 2011, p. 47.

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

83 Mundipharma, *Submission 38*, p. 15.

84 Mr Rob Baveystock, Managing Director, Mundipharma, *Committee Hansard*, 21 July 2011, p. 26.

affected by hyperhidrosis who can become withdrawn and depressed as a result of the condition and its symptoms.[85]

5.65 As recognised in treatment guidelines, Botox® provides a unique second-line treatment for those affected by hyperhidrosis whose condition is not effectively managed through prescription topical aluminium chloride antiperspirants. It also provides a less invasive treatment option prior to the consideration of surgery, which is only undertaken in a minority of patients. In making a positive recommendation for the listing of Botox® for the treatment of severe hyperhidrosis, the PBAC noted that there were no other second-line treatments for severe hyperhidrosis of the axillae on the PBS, that the condition has significant impact on the quality of life of patients, and that there was a clinical need for botulinum toxin.[86]

5.66 Submitters explained that treatment of severe hyperhidrosis through the use of lotions or surgery is not necessarily successful, and the side-effects of these options are often less than desirable. Ms Elizabeth Trapani explained to the committee that she has pursued a number of local treatment options for her daughter, Ms Chey-Anne Ellsum, who suffers from severe hyperhidrosis:

> ...we used every lotion, potion, spray and roll-on we could get our paws on. We had no luck.[87]

5.67 Given the invasive nature of the surgical option, the comparatively low success rate, the fact that it is not a permanent solution, and the potential side-effects of the surgery which can include a collapsed lung, palsy of the face and increased sweating, Ms Trapani explained 'When we found out the dangers of this surgery, it was not an option I wanted to pursue for my daughter'.[88]

5.68 Mr Mark Glover of Allergan Australia noted that in explaining why the listing of Botox® under the PBS was deferred, the minister has acknowledged that there is no alternate treatment available under the PBS, and further, has stated that hyperhidrosis is a mild condition for many people. However, Allergan Australia took issue with this reasoning, as the TGA approved indication and PBAC recommended listing for Botox® are for severe disease.[89]

5.69 Further, Botox® treatment is expensive – in Ms Ellsum's case, the initial treatment cost just under $1900, a cost which for many people is prohibitive.

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85 Mr Mark Glover, Vice President and Managing Director, Allergan Australia, *Committee Hansard*, 21 July 2011, p. 16.

86 Mr Mark Glover, Vice President and Managing Director, Allergan Australia, *Committee Hansard*, 21 July 2011, p. 16.

87 Ms Elizabeth Trapani, *Committee Hansard*, 21 July 2011, pp 34 and 36–37.

88 Ms Elizabeth Trapani, *Committee Hansard*, 21 July 2011, pp 34 and 36–37.

89 Mr Mark Glover, Vice President and Managing Director, Allergan Australia, *Committee Hansard*, 21 July 2011, p. 17.

Ms Trapani explained that they were fortunate that Ms Ellsum's grandparents were able to assist with the payments.

5.70 Ms Ellsum provided the committee with an insight into how living with hyperhidrosis had affected her life, and the difference it has made to be able to access the Botox® treatment. She also noted that if the Botox® treatment for hyperhydrosis was listed under the PBS, it would be more accessible not only for her, but also for others suffering from the same condition:

> I have had it since I was three, but it got really bad in puberty. That was when I was in high school, so I was like the magnet for bullying; everyone went at me, because they did not understand, and no-one understands. It caused my depression. There were days when I did not want to get out of bed because it is so controlling. I blamed myself lots of the times when I had it; I thought it was just me who had it. It draws people back; it stops people from doing things. It deprived me of most of my youth; I did not do the things I wanted to do because it was so controlling and conflicting with my life. I could not do my deb this year because I was afraid of what people would think, and that really made me sad.
>
> With the Botox, it has been amazing. It is the biggest improvement that I have ever heard about, and it has worked. I am planning to do my deb next year, and now I am doing all the things that I have always wanted to do. I am here now. This is not something I would have done back then. I am here because there are people out there who cannot get this. I would be stuck if it were not for my grandparents, because they are the only people who are getting me through this. I would not have this if it were not for them.[90]

Committee comment

5.71 Evidence received by the committee highlights that many Australian health consumers are under significant financial burden, particularly those with chronic illness and those on low-incomes. The PBS process should ensure that the most effective medications are available at an affordable price for all Australians. However, the Government has now introduced a further consideration to the listing of medications: an unclear, undefined fiscal hurdle with no specific timeline.

5.72 This a short-term consideration which will have adverse affects on patients. For some consumers, the deferred medicines represent a more appropriate treatment regime, or in some cases, the only effective treatment. In the committee's view, it is unacceptable that the Government is denying access to these treatments.

5.73 The committee is concerned that the Government's decision to defer the listing of certain medications will exacerbate inequitable access to medicines for low-income and disadvantaged Australians. The committee is of the view that this will lead to a two-tiered system in which only those with adequate financial capacity will

90 Ms Chey-Anne Ellsum, *Committee Hansard*, 21 July 2011, pp 34–35.

be able to access newer, more effective treatments, which will remain out of financial reach for lower-income patients.

5.74 The committee considers that timely access to affordable appropriate alternative medications is a centrally important feature of the PBS. The committee notes the consequences in terms of quality of life and adverse events of not having access to an appropriate and effective medication as illustrated by the case studies discussed in this chapter. This not only has repercussions for the health of individuals, but also for broader public wellbeing and demands on the public health system. In light of this the committee is of the view that health outcomes of Australian patients should not be compromised by restricted access to a small or pre-determined number of medicines in a given class due to the Government's budgetary considerations.

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.
>
> 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:

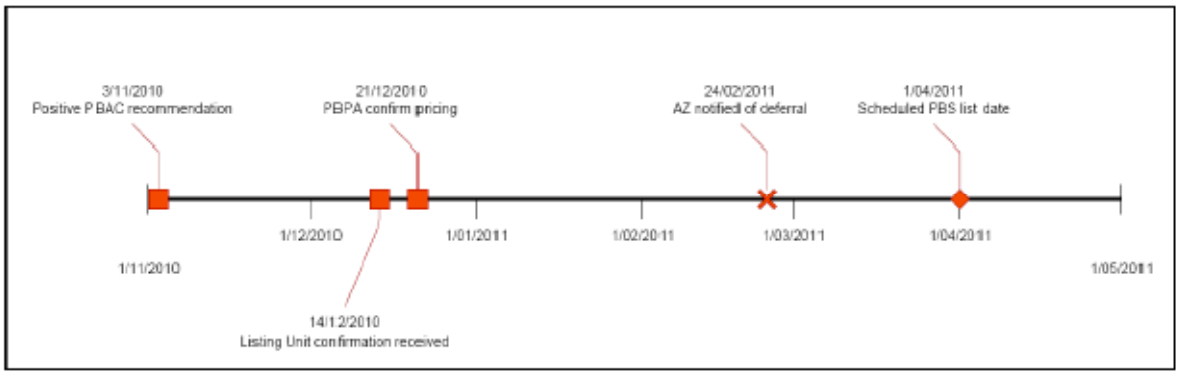
> The PBAC issued a positive recommendation to list Symbicort® for the treatment of COPD [chronic obstructive pulmonary disease] following consideration at its November, 2010 meeting. AstraZeneca subsequently received notification of the Pharmaceutical Benefits Pricing Authority's (PBPA) acceptance of 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.

Chapter 7

Conclusions and recommendations

7.1 The Government's decision to defer the listing of certain medicines under the Pharmaceutical Benefits Scheme (PBS), despite positive recommendations by the Pharmaceutical Benefits Advisory Committee (PBAC), and the decision to subject all future listings with financial implications for the budget to Cabinet review, constitutes a major, unnecessary and unwelcome change in government policy. This profound and ill-considered change in policy puts at risk affordable access to medicines for Australians, and will have significant consequences for the pharmaceutical sector, including research and development.

7.2 The committee notes the PBS has operated effectively to provide Australian patients with affordable access to necessary medicines since its establishment in 1948, and is a central feature of Australia's health system. A series of reforms have been progressively implemented, in consultation with industry and stakeholders, to improve the operation, cost-effectiveness and timeliness of the PBS system. The benefits of recent reforms have yet to be fully realised.

7.3 The committee acknowledges that the cost of the PBS has continued to grow due to a number of factors including an ageing population, growth in population and the development of new treatments. However, evidence received by the committee has demonstrated that reforms implemented throughout the PBS's history have worked to ensure that the PBS remains sustainable. Submitters strongly argued that the PBS remains affordable for a wealthy country like Australia. Committee members agree with this sentiment.

7.4 The committee also acknowledges that it is the Government's responsibility to be mindful of budgetary constraints, however it considers that responsible fiscal management should be applied at a whole of government level as opposed to trying to create savings through piecemeal and ill-advised policy changes.

7.5 The February 2011 announcement of the deferral of the listing of seven medicines which had been recommended for listing on the PBS by PBAC was claimed by the Government to be a legitimate decision in light of Australia's fiscal position and Budget deficit. In addition to these deferrals, the Government advised that Cabinet would consider all PBAC recommendations for listing of medicines on the PBS that represented a cost to the Government, not just those with cost implications over $10 million per annum. Again, this was claimed to be based on responsible fiscal management:

> Given the need for fiscal discipline to achieve the Government's intention to return the Budget to surplus in 2012–13, all changes to the PBS with financial implications will be considered by the Cabinet.[1]

7.6 This announcement came as a complete surprise to industry, consumer and patient groups alike and constituted a significant departure from previous policy. Many organisations felt that they had been negotiating in good faith with the Government regarding ways to ensure the sustainability of the PBS, and were disappointed that they had not been consulted with, or informed prior to, the public announcement on the decision. The committee is concerned that the failure of government to consult with industry and stakeholders prior to taking this decision to change the listing process and the possible contravention at least of the spirit of the Memorandum of Understanding (MOU) entered into by the Government and Medicines Australia will have repercussions when it comes to future negotiations with industry.

7.7 The committee heard universal praise regarding the way that the PBAC carries out its statutory role of comprehensively assessing and recommending the suitability of medicines using health economic models. Submitters argued that the PBAC decision-making process is world-class, as its decisions are based upon recommendations made by an independent group of clinicians and specialists, with cost-effectiveness as a key determinant.

7.8 However, with Cabinet now making decisions about the listing of all medicines with a cost to government without clear criteria or timelines, the integrity of the PBS is at risk. Unlike PBAC processes, it appears that no criteria of any form have been used by Cabinet in coming to its decisions in relation to deferrals and listings. Clearly, the lack of transparency of Cabinet's decision-making process, and the absence of a clear timeframe for the reconsideration and listing of deferred medicines, undermines the integrity of PBS: the Government has abandoned a well-respected, time-honoured, criteria-bound, evidence-based and transparent system for a system which reflects none of these qualities.

7.9 In light of the evidence received, the committee is concerned that the change in policy will lead to a politicisation of the listing process in a number of respects. First, there is a risk Cabinet decision-making will become vulnerable to lobbying. Further, the better resourced stand to exert greater influence, to the exclusion of those smaller and less well-represented groups. Finally, it was noted that the Government has sought to make future listings dependent upon gaining opposition support for other savings measures. The committee is of the view that any such politicisation will only serve to undermine the integrity and quality of Australia's listing process.

7.10 Further, the committee is concerned that the independence and reputation of the PBAC will be irreversibly damaged by the referral of all listings for Cabinet

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1 Commonwealth Government, *Portfolio Budget Statements 2011–12: Budget Related Paper No. 1.10: Health and Ageing Portfolio*, Commonwealth of Australia, Canberra, 2011, p. 121.

consideration. Should the recommendations of the PBAC be regularly rejected it will become increasingly difficult to attract and retain experts of the calibre that presently comprise the PBAC. As a result, the Government of the day may be tempted to appoint less independent PBAC members in order to avoid controversy over deferral decisions.

7.11 This Cabinet's lack of understanding of the PBS and medicines policy is evidenced by the Cabinet's failure to appreciate the difference between an assessment of a medicine's effectiveness at a population level as opposed to effectiveness at an individual level.

7.12 The Government has argued that for some deferred medicines there is an alternative already listed on the PBS. However, it is indisputable that medicines may not always be interchangeable for individuals: for some patients these deferred medicines represent a more appropriate treatment, or in some cases, the only effective treatment. The committee considers that the Government's view that medicines with 'alternatives' listed under the PBS can be deferred is based on a poor understanding of the complexities inherent in assessing the effectiveness of medicines for individuals. This essentially creates two classes of people: those who have access to a suitable medicine that is subsidised; and those who do not. In the committee's view, it is unacceptable that, by deferring the listing of these alternatives on the basis that others are available, the Government is undermining the PBS by hindering affordable access to these life-changing treatments.

7.13 The Government has made much of the need to be fiscally responsible in the current economic climate. However, the evidence received by the committee called into question the level of the savings that will actually flow to the Government as a result of the deferral. Witnesses stated that the savings calculations were flawed as they did not take into account patients switching from old medications to new medications. In addition, evidence suggested that patients receiving appropriate treatment will require fewer hospitalisations, fewer appointments with health professionals and fewer treatments to address side-effects and adverse events. Further, the quality of life of consumers will be improved as will their ability to participate in the economy. The committee is of the view that this policy may well only result in comparatively small savings in the short-term and in the long-term the cost of not listing medicines may significantly outstrip these small savings.

7.14 Submitters, including both Medicines Australia and the Generic Medicines Industry Association, opposed the Government's position that new medicines will not be listed until savings are found to offset listing costs and argued that this is not the way to fund or manage the PBS. The committee agrees with this position and is of the view that health outcomes of Australian patients should not be compromised due to the Government's budgetary considerations.

7.15 Many Australian health consumers, particularly those with chronic conditions, already experience significant financial burdens. The committee is concerned that the decision to defer listings will exacerbate the financial distress of some consumers as

the deferral may result in consumers either being unable to afford the medicines they need, or having to go without other essential items in order to purchase unlisted medications. This represents unacceptable cost-shifting to patients who can least afford to bear an increased financial burden. In addition, Australia may end up with a two-tiered system in which newer, more effective treatments will be out of reach for lower-income patients who cannot afford to pay the unlisted price for medicines.

7.16 The committee considers that a lack of timely access to affordable appropriate alternative medications will not only have dire consequences in terms of quality of life and adverse events for individual Australian patients. It will also have repercussions for broader public wellbeing and demands on the public health system.

7.17 The committee is very concerned about the uncertainty which has arisen from the Government's decision to defer the listing of medicines. While companies will always manage risk in making business decisions, prior to the Government's deferral decision risk assessments were based on a long-standing understanding of the PBAC evaluation process and the criteria employed in the assessment of a listing application. However, in the current circumstances, companies are not aware of the criteria which Cabinet is using to make decisions on deferrals–this creates additional risk for companies operating in Australia. The committee is of the view that this added layer of uncertainty will undoubtedly impact on investment decisions by the pharmaceutical sector, to the detriment of health consumers.

7.18 The committee considers that the Government's decision to defer the listing of medicines, and subject all future listing decisions to Cabinet consideration, may have significant implications for the discovery and development of new medicines, and the access of Australian patients to important clinical trials. The committee is concerned that this will disrupt a chain of processes that will ultimately compromise Australian health consumers' access to appropriate and effective medications.

7.19 The committee considers that the unprecedented changes introduced by the Government to the listing of medicines in Australia is unacceptable and is based on short-term and ill-conceived policy goals. The Government has taken a world-class and rigorous evaluation process and replaced it with non-transparent Cabinet deliberations. This will result in poor outcomes for consumers and the health system generally. The committee considers that the Government is exposing Australia's health system to significant risk and should immediately list all medicines deferred and return to the system of Cabinet consideration of medicines with a financial impact over $10 million.

Recommendation 1

7.20 The committee recommends that the Government withdraw the statement made on 25 February 2011 regarding the deferral of the listing of new medicines and the new rules applying to listings from that point forward.

Recommendation 2

7.21 The committee recommends that the Government retract the statement that PBAC listing recommendations will not be proceeded with until savings are found to offset the costs of listing those medicines under the PBS.

Recommendation 3

7.22 The committee recommends that the Government should explicitly state that it rejects any implication that the listing of new medicines requires savings to be made elsewhere in the health portfolio.

Recommendation 4

7.23 The Government should restate its commitment to making an explicit decision regarding the listing of new medicines on the PBS within the terms and intent of the Memorandum of Understanding signed with Medicines Australia on 6 May 2010 and re-signed on 28 September 2010.

Recommendation 5

7.24 That the Government reinstate the '$10 million rule' so that medicines that have a financial impact of less than $10 million in each year over the forward estimates can be listed on the PBS Schedule by the minister without waiting for Cabinet approval.

Senator Scott Ryan
Chair

Government senator's minority report

Introduction

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

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

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

Process of listing medicines on the PBS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Financial impact on the Commonwealth budget

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

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

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

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

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

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

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

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

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

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

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

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

> ...averaging growth of about nine percent a year and it is estimated it will cost about $9 billion this financial year (2010–11). This growth rate is higher than the six percent annual increase for general hospital and medical services, and much higher than the Consumer Price Index.[26]

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

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

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

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

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

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

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

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

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

The Memorandum of Understanding with Medicines Australia

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

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

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

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

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

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

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

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

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

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

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

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

> For those submissions required to be approved by Cabinet, the Commonwealth will use its best endeavours to implement a maximum time frame of six months for consideration and decision by Cabinet.

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

A healthy pharmaceutical sector

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

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

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

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

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

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

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

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

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

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

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

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

Business as usual – a stable investment environment

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1.42 The Department of Health and Ageing substantiated this point:

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

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

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

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

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

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

Research and Development

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

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

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

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

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

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

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

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

The Australian medicines market - available and accessible medicines

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1.52 Mr John Latham of Pfizer Australia echoed these sentiments:

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

Government senator's view

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

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

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

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

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

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

Senator Helen Polley
Deputy Chair

Senator Anne McEwen

Australian Greens Additional Comments

Introduction

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

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

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

Achieving lower priced generic medicines

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

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

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

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

1.5 Tendering, along the lines employed in New Zealand, has usually been discounted in Australia as being incompatible with a thriving generics industry. However, other mechanisms have been suggested. Dr Liliana Bulfone has outlined a scheme[4] in which generics manufacturers make private bids, and are listed on the Schedule at the lowest price for that drug. Other brands then attract a corresponding brand premium at the pharmacy, which may encourage generics manufacturers to make further discounts in order to be able to secure and hold market share.

1.6 Reform in this area is particularly important as 'blockbuster' drugs such as Lipitor® (atorvastatin) go off-patent. With billions potentially to be saved[5] this seems a more worthwhile area of potential reform than ad hoc deferrals of PBAC approved medicines. A strengthening of price reporting and price reduction mechanisms, within and across therapeutic groups, should be considered.

Evergreening of patents by originator companies

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

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

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

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

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

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

Savings from change of prescriber habits

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

Recommendation 1

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

Senator Richard Di Natale

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

APPENDIX 1

Submissions and additional information received by the committee

Submissions

1 Private Mental Health Consumer Carer Network (Australia)
2 Geraldine Robertson
3 Brian Stafford
4 Chronic Illness Alliance
5 Diabetes Australia
6 National Association of People Living with HIVAIDS
7 Council of Social Service Network
8 Cancer Voices Australia
9 Consumers Health Forum of Australia
10 SANE Australia
11 iNova Pharmaceuticals (Aust) Pty Ltd
12 Research Australia
13 Mental Illness Fellowship of Australia
14 Australian Pain Management Association Inc.
15 Painaustralia Limited
16 Australian Medical Association
17 Brain Tumour Alliance Australia Incorporated
18 Cystic Fibrosis Australia
19 Deakin Health Economics, Deakin University
20 The Australian Lung Foundation
21 Hepatitis Australia
22 Osteoporosis Australia
23 Novo Nordisk
24 Breast Cancer Network Australia
25 Arthritis Australia
26 Positive Life NSW
27 Australasian College of Dermatologists
28 ACON
29 Sanofi
30 Queensland Positive People

31 Generic Medicines Industry Association

32 Joint submission from Cancer Council Australia, the Clinical Oncological Society of Australia and the Medical Oncology Group of Australia

33 Health Consumers' Council (WA)

34 Medical Oncology Group of Australia

35 Pfizer Australia

36 Medicines Australia

37 Janssen-Cilag Pty Ltd

38 Mundipharma Pty Ltd

39 Roche

40 Arafmi Mental Health Carers and Friends Association (WA) Inc

41 Australian Federation of AIDS Organisations

42 Amgen Australia Pty Ltd

43 MS Australia

44 GlaxoSmithKline Australia

45 Allergan Australia Pty Ltd

46 The Department of Health and Ageing

47 AstraZeneca Australia Pty Ltd

48 Elizabeth Trapani

49 Cancer Voices NSW

50 National Seniors Australia

51 Janne Graham

52 Carol Hughes

53 Mental Health Council of Australia

54 Elizabeth Graham

55 Name withheld

56 Australian Pompe's Association

57 Matthew Peters

58 Valerie Hanrahan

59 Health Consumers NSW

60 Fabry Support Group Australia

61 The Royal Australasian College of Physicians

62 Northern Territory Government Department of Health

63 Department of Health Western Australia

64 Confidential

65 Dr Kathryn Antioch

Additional information received

1 Generic Medicines Industry Association (GMiA), *Case study – amiloride,* tabled at the Melbourne public hearing on 21 July 2011

2 Chronic Illness Alliance, 'Prescription drug subsidies in Australia and New Zealand', *Australian Prescriber,* Vol 33, No. 1, February 2010, tabled at the Melbourne public hearing on 21 July 2011

3 Allergan Australia, Answers to Questions on Notice taken at the Melbourne public hearing on 21 July 2011, provided on 29 July 2011

4 Mundipharma Australia, Answers to Questions on Notice taken at the Melbourne public hearing on 21 July 2011 and additional information, provided on 5 August 2011

5 Janssen-Cilag Australia, Answers to Questions on Notice taken at the Melbourne public hearing on 21 July 2011 and additional information, provided on 5 August 2011

6 Medicines Australia, Answers to Questions on Notice taken at the Canberra public hearing on 25 July 2011, provided on 8 August 2011

7 Pharmaceutical Benefits Advisory Committee, Answers to Questions on Notice taken at the Canberra public hearing on 25 July 2011, provided on 9 August 2011

8 Pfizer Australia, Answers to Questions on Notice taken at the Melbourne public hearing on 21 July 2011 and additional information, provided on 10 August 2011

9 Department of Health and Ageing, Answers to Questions on Notice taken at the Canberra public hearing on 25 July 2011, provided on 12 August 2011

APPENDIX 2

Public hearings and witnesses

Thursday, 21 July 2011
Committee Room G6, Victorian Parliament House, Melbourne

Witnesses

Deakin University
Ms Liliana Bulfone, Senior Research Fellow
Ms Sandra Younie, Senior Research Fellow

Generic Medicines Industry Association
Ms Kate Lynch, Chief Executive Officer
Mr Robert Ellis, Board Member

Allergan Australia
Mr Mark Glover, Vice-President and Managing Director
Mr Duncan O'Brien, Market Access Director

AstraZeneca Australia
Mr Jose Vieira, Managing Director
Dr Simon Fisher, Medical Director

Janssen-Cilag Australia
Mr Bruce Goodwin, Managing Director
Professor Jayashri Kulkarni, Professor of Psychiatry, Faculty of Medicine, Monash University

Mundipharma
Mr Rob Baveystock, Managing Director
Dr John Whitlam, Medical Affairs Director

Pfizer Australia
Mr John Latham, Managing Director
Dr Bill Ketelbey, Country Medical Director

Ms Elizabeth Trapani and Ms Chey-Anne Ellsum

MS Australia
Mr Robert Pask, Coordinator, National Advocacy Program

Chronic Illness Alliance
Dr Christine Walker, Chief Executive Officer

Australian Pain Management Association
Mr Paul Murdoch, Vice-President

Painaustralia
Professor Michael Cousins, Director

National Association of People Living with HIV/AIDS
Mr David Menadue, Special Representative

Monday, 25 July 2011
Committee Room 2S1, Parliament House, Canberra

Witnesses

Department of Health and Ageing
Mr David Learmonth, Deputy Secretary
Ms Felicity McNeill, A/g First Assistant Secretary, Pharmaceutical Benefits Division
Ms Adriana Platona, Assistant Secretary, Pharmaceutical Evaluation Branch

Department of Finance and Deregulation
Mr David Martine, Deputy Secretary, Budget Group
Mr David de Carvalho, First Assistant Secretary, Social Policy Division, Budget Group

Pharmaceutical Benefits Advisory Committee
Emeritus Professor Lloyd Sansom, Chair

Medicines Australia
Dr Brendan Shaw, Chief Executive
Mr Andrew Bruce, Director, Health Policy and Research

Consumers Health Forum of Australia
Ms Carol Bennett, Chief Executive Officer
Ms Anna Wise, Senior Policy Manager

Cancer Voices Australia
Mr John Stubbs, Executive Officer

Brain Tumour Alliance Australia
Mr Matthew Pitt, Chair
Mr Denis Strangman, Secretary
Ms Renee Hindson, Member

SANE Australia
Ms Barbara Hocking, Executive Director

Hepatitis Australia
Ms Helen Tyrrell, Chief Executive Officer