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].