CHAPTER 1

INTRODUCTION

Terms of Reference

1.1 On 25 November 2009, the Senate referred the following matter to the Community Affairs References Committee for inquiry and report by 30 June 2010:

> Consumer access to pharmaceutical benefits and the creation of new therapeutic groups through the Pharmaceutical Benefits Scheme (PBS), including:
>
> (a) The impact of new therapeutic groups on consumer access to existing PBS drugs, vaccines and future drugs, particularly high cost drugs;
>
> (b) The criteria and clinical evidence used to qualify drugs as interchangeable at a patient level;
>
> (c) The effect of new therapeutic groups on the number and size of patient contributions;
>
> (d) Consultation undertaken in the development of new therapeutic groups;
>
> (e) The impact of new therapeutic groups on the classification of medicines in F1 and F2 formularies;
>
> (f) The delay to price reductions associated with the price disclosure provisions due to take effect on 1 August 2009 and the reasons for the delay;
>
> (g) The process and timing of consideration by Cabinet of high cost drugs and vaccines; and
>
> (h) Any other related matters.

1.2 On 22 June 2010, the reporting date for the inquiry was extended to 26 August 2010.

1.3 On 26 August 2010, the committee tabled a brief report concluding:

> On 19 July 2010, the Governor-General prorogued the 42nd Parliament and dissolve the House of Representatives. After due consideration, the committee has determined that it is unable to provide a comprehensive report at this time. The committee will reconsider the issues of this inquiry in the event that it is re-referred to the committee in the new parliament.[1]

1.4 The evidence received by the committee during the 42nd Parliament was tabled in the Senate at that time.

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1 Community Affairs References Committee, *Consumer Access to Pharmaceutical Benefits Report*, 26 August 2010, p. 2.

1.5 On 30 September 2010, the Senate re-referred the inquiry, with the same terms of reference, to the committee for inquiry and report by 25 November 2010. The Senate agreed to allow the committee to consider and use the submissions and oral evidence received by the committee during its inquiry in the 42nd Parliament.[2]

Conduct of the inquiry

1.6 In accordance with usual practice, the inquiry was advertised in *The Australian* and on the internet, inviting submissions by 31 March 2010. The committee also invited submissions from numerous organisations and individuals.

1.7 Upon re-referral, the inquiry was re-advertised in *The Australian* and on the internet, inviting submissions by 20 October 2010. The committee also invited those organisations and individuals who had made submissions to the previous inquiry to provide additional information to update or amend their earlier submissions.

1.8 The committee received 35 submissions, listed at Appendix 1.

1.9 The committee held a public hearing in Canberra on 7 May 2010. The witnesses are listed at Appendix 2.

Background

The Pharmaceutical Benefits Scheme

1.10 The PBS was created in 1948 and is now enacted by the *National Health Act 1953*.[3]

1.11 The scheme enables Australians to access government-subsidised prescriptions currently at a cost of $33.30 for general patients and $5.40 for concessional patients.[4]

1.12 There are currently over 740 medicines in more than 1850 forms available on the PBS.[5] In 2008-09, approximately 182 million PBS prescriptions were dispensed at a cost to government of $7.7 billion.[6]

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2 Community Affairs References Committee, *Report on matters referred to the Community Affairs References Committee in the 42nd Parliament*, 30 September 2010, p. 1.

3 Department of Health and Ageing (DoHA), *What is the PBS?*, available: http://www.pbs.gov.au/html/consumer/pbs/about (accessed 2 May 2010).

4 DoHA, *New PBS Safety Net thresholds*, available: http://www.health.gov.au/internet/main/publishing.nsf/Content/pbs-safetynet-changes (accessed 6 May 2010).

5 DoHA, *Submission 27*, p. 5.

6 DoHA, *Submission 27*, p. 5.

1.13 Before being listed on the PBS, medicines must be considered by the Pharmaceutical Benefits Advisory Committee (PBAC).[7] The PBAC is an independent, statutory body comprising health professionals (doctors, academics, a pharmacist and a health economist) and a consumer representative.[8] The PBAC considers the clinical and cost-effectiveness of a medicine in comparison to other available treatments and provides advice to the Minister for Health and Ageing as to whether a medicine should be listed on the PBS.[9]

Therapeutic group policy

1.14 The therapeutic group policy, to be applied to some PBS-listed medicines, was first announced by the Commonwealth Government in the 1997-98 Federal Budget.[10] The first four therapeutic groups were created in February 1998 and comprised the:

- angiotensin I converting enzyme (ACE) inhibitors;
- calcium channel blockers (CCBs);
- H2 receptor antagonists (H2RAs), and
- HMG-CoA reductase inhibitors (statins).[11]

1.15 The inclusion of these drugs in therapeutic groups was based on advice from the PBAC 'that the drugs in each group are very alike and work just as well as one another for the vast majority of people'.[12]

1.16 The therapeutic group policy does not mean that patients must switch to a medicine, or switch between medicines, in a therapeutic group because it is less expensive than a medicine they are already taking.[13]

1.17 Following formation of the therapeutic groups, the government applied the therapeutic group pricing policy. The pricing policy meant that the government 'paid one level of PBS subsidy for all medicines containing the drugs within each of the

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7 DoHA, *Submission 27*, p. 5.

8 DoHA, *PBAC Membership*, available: http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pbs-general-listing-pbacmembership.htm (accessed 6 May 2010).

9 DoHA, *Pharmaceutical Benefits Advisory Committee*, available: http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pbs-general-listing-committee3.htm#pbac (accessed 29 July 2010).

10 DoHA, *Submission 27*, p. 10.

11 DoHA, *Submission 27*, p. 10.

12 DoHA, *Submission 27*, p. 10.

13 Mr David Learmonth, Deputy Secretary, DoHA, *Committee Hansard*, 7 May 2010, pp 92-93.

four groups. This applied regardless of whether or not the drugs had the same PBS listings'.[14]

1.18 The therapeutic group pricing policy has been applied and continues to apply to all therapeutic groups created since the first groups in 1997-98. In general terms, the pricing policy ensures that medicines in a therapeutic group 'have the same monthly treatment cost despite variations in prescribed doses'.[15]

1.19 In 2007, during the introduction of a range of reforms to the PBS, the government formed another two therapeutic groups comprising the angiotensin II receptor antagonists (A2RAs) and proton pump inhibitors (PPIs).[16] It was also at this time that the therapeutic group policy was legislated in the *National Health Act 1953* 'by providing in the Act, for the first time, that therapeutic groups are formed by determination in a legislative instrument made by the Minister'.[17]

1.20 The Department of Health and Ageing (DoHA) advised that:

> Under the Act the Minister can form a therapeutic group only after obtaining advice from the PBAC in relation to the proposed determination. Further, when deciding on the drugs that comprise a group the Minister may have regard to any PBAC advice to the effect that a drug should, or should not, be treated as interchangeable on an individual patient basis with another listed drug. The PBAC has corresponding functions for providing the advice about formation of groups and interchangeability of drugs.[18]

1.21 In the 2009-10 Federal Budget, the government announced the creation of a seventh therapeutic group for the high potency statins (statins-HP).[19] This group was formed in September 2009.[20]

1.22 On 2 November 2009, the government released the 2009-10 Mid-Year Economic and Fiscal Outlook (MYEFO) which estimated an increase in expenditure on health and ageing of $4.8 billion over four years, due in part to projected expenditure on pharmaceutical benefits.[21] The MYEFO also announced the establishment of three new therapeutic groups under the PBS covering venlafaxine and desvenlafaxine derivatives (anti-depressants) and oral bisphosphonates (for the

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14 DoHA, *Submission 27*, p. 10.

15 DoHA, *Submission 27*, p. 9.

16 DoHA, *Submission 27*, p. 11.

17 Prior to 2007, the therapeutic group pricing policy had been an administrative measure; DoHA, *Submission 27*, p. 11

18 DoHA, *Submission 27*, p. 11.

19 DoHA, *Submission 27*, p. 12.

20 DoHA, *Submission 27*, p. 12.

21 The Hon Nicola Roxon MP, Minister for Health and Ageing, 'MYEFO points to rising health costs', media release, 2 November 2009.

treatment of osteoporosis and Paget disease).[22] The creation of these additional therapeutic groups was anticipated to deliver savings of $48.2 million over four years, commencing 1 April 2010.[23]

1.23 The three therapeutic groups announced in the 2009-10 MYEFO were formed with effect from 21 January 2010, with the associated price changes due to come into effect on 1 April 2010.[24]

1.24 However, on 11 March 2010, before the associated price changes occurred, the Senate disallowed Parts 8, 9 and 10 of the *National Health (Pharmaceutical Benefits – Therapeutic Groups) Determination 2010* which provided for the creation of the three therapeutic groups announced in the MYEFO.[25] As a result, these three therapeutic groups have not yet come into effect.

Therapeutic group premium

1.25 Drugs in a therapeutic group may be subject to a charge in addition to the co-payment amount, known as a 'therapeutic group premium'.[26] This additional fee is paid by the consumer and only applies to a medicine where the manufacturer does not accept the PBS price under the therapeutic group pricing policy.[27]

1.26 However, when prescribing a medicine subject to a therapeutic group premium, a doctor may apply for a patient to be exempt from paying the premium on the basis that it would be 'clinically inappropriate for a patient to be prescribed a different medicine in the therapeutic group in order to avoid a therapeutic group premium'.[28] In this circumstance, the Commonwealth Government pays the patient premium where the prescriber has obtained an authority from Medicare Australia, based on one of a number of specified criteria (please refer to Chapter 3).[29]

Cabinet consideration of high cost drugs

1.27 Where a medicine being considered for inclusion on the PBS is estimated to cost government more than $10 million in any of its first four full years of PBS listing,

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22 DoHA, *Submission 27*, p. 12.

23 Mid-Year Economic Outlook 2009-10, available: http://www.budget.gov.au/2009-10/content/myefo/download/MYEFO_2009-10.pdf (accessed 7 April 2010), p. 197.

24 DoHA, *Submission 27*, p. 12.

25 *National Health (Pharmaceutical Benefits – Therapeutic Groups) Determination 2010*, Parts 8, 9 & 10.

26 DoHA, *Submission 27*, p. 15.

27 DoHA, *Submission 27*, p. 15.

28 DoHA, *Submission 27*, p. 16.

29 DoHA, *Submission 27*, p. 16.

a submission on that drug must be considered by Cabinet.[30] The threshold is intended to ensure that Cabinet ministers are aware of government expenditure.

1.28 The threshold of $10 million for Cabinet consideration was originally set in 2002 and has not changed since that time.[31]

1.29 Since November 2007, it has taken on average 7.1 months from PBAC recommendation to Cabinet consideration of a medicine.[32]

Memorandum of Understanding

1.30 During the course of the inquiry, on 6 May 2010, the Minister for Health and Ageing and Medicines Australia signed a memorandum of understanding (MOU) with effect until 30 June 2014. In the MOU, the government undertook not to create any new therapeutic groups during the period of the MOU (except in particular circumstances) and agreed to 'provide sponsors with reasonable notice of its intention to form any new Group, and seek sponsor comment prior to determination of any new Group'[33] but stated:

> The three Therapeutic Groups which the Commonwealth had announced an intention to form in the 2009 Mid-Year Economic and Fiscal Outlook, do not represent new Therapeutic Groups for the purposes of paragraphs 16 and 17 and, thus, are not covered by this MOU. These comprise drugs for the treatment of depression, osteoporosis, and Paget disease.[34]

1.31 Paragraphs 28 and 29 of the MOU detail the Commonwealth's undertakings with respect to reducing the period of time taken for Cabinet consideration of high cost drugs:

> The Commonwealth will work with industry to examine possible methods to reduce the time taken to finalise PBS pricing negotiations after a PBAC recommendation, including for those PBS submissions that require Cabinet approval…[35]

And:

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30 DoHA, *Submission 27*, p. 20.

31 Productivity Commission, *Annual Review of Regulatory Burdens on Business: Manufacturing and Distributive Trades*, 16 September 2008, p. 80.

32 DoHA, *Submission 27*, p. 20.

33 Commonwealth Government & Medicines Australia, *Memorandum of Understanding*, 6 May 2010, p. 4.

34 In paragraphs 16 and 17 of the MOU, the government has undertaken not to create any new therapeutic groups, except in certain prescribed circumstances, and to provide reasonable notice of its intention to create new therapeutic groups; Commonwealth Government & Medicines Australia, *Memorandum of Understanding*, 6 May 2010, p. 4.

35 Commonwealth Government & Medicines Australia, *Memorandum of Understanding*, 6 May 2010, p. 6.

> 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. The six months will commence from the date of notification by the Department of Health and Ageing to the sponsor that pricing is agreed.[36]

1.32 The MOU also includes 'Resolution of issues in good faith' provisions which state, in part:

> In the event that a dispute occurs between the Commonwealth and Medicines Australia in relation to the operation of this MOU, and that cannot be settled in discussion with the relevant Deputy Secretary, the Chief Executive of Medicines Australia and the Secretary of the Department of Health and Ageing will meet in the first instance to resolve the issue. In the event that the dispute is still not resolved, the matter will be referred to a meeting between the Minister for Health and Ageing and representatives of the Medicines Australia Board.[37]

Issues raised during the inquiry

1.33 A number of issues were raised during this inquiry including:

- the therapeutic group policy and creation of new therapeutic groups generally;
- the lack of consultation and transparency during the process of creating the four new therapeutic groups announced during 2009 in the Federal Budget and in the 2009-10 MYEFO specifically;
- related to the above, the definition of and evidence for "interchangeability" for the purpose of creating therapeutic groups;
- the lack of awareness amongst doctors of their ability to seek an exemption on behalf of a patient from payment of a therapeutic group premium;
- the $10 million cost threshold for consideration of high cost medicines by Cabinet; and
- the time taken by Cabinet to consider high cost medicines.

1.34 The issues regarding the creation of further therapeutic groups and the time taken by Cabinet to consider high cost medicines appear to have been addressed by the MOU. The other issues regarding the lack of consultation and transparency; the definition and evidence for interchangeability; the lack of awareness amongst doctors about exemptions; and the $10 million threshold for Cabinet consideration remain outstanding and will therefore be examined in the following chapters of this report.

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36 Commonwealth Government & Medicines Australia, *Memorandum of Understanding*, 6 May 2010, p. 6.

37 Commonwealth Government & Medicines Australia, *Memorandum of Understanding*, 6 May 2010, p. 6.

1.35 Other issues raised during the inquiry regarding reforms to the PBS in 2007 and the pricing of generic medicines, as well as professional services provided by pharmacists, are discussed in the final chapter of this report.