The Senate

Community Affairs References Committee

Consumer Access to Pharmaceutical Benefits

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42nd Parliament

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Participating Members for this inquiry

Senator Concetta Fierravanti-Wells	LP, New South Wales
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ACRONYMS AND ABBREVIATIONS

A2RA	angiotensin II receptor antagonist
ACE inhibitor	angiotensin I converting enzyme inhibitor
ANZBMS	Australia and New Zealand Bone and Mineral Society
CCB	calcium channel blocker
CHF	Consumers Health Forum of Australia
DoHA	Department of Health and Ageing
GMiA	Generic Medicines Industry Association
H2RA	H2 receptor antagonist
MHCA	Mental Health Council of Australia
MOU	memorandum of understanding
MYEFO	Mid-Year Economic and Fiscal Outlook
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefits Scheme
PGA	The Pharmacy Guild of Australia
PPI	proton pump inhibitor
PSA	Pharmaceutical Society of Australia
statin-HP	high potency statin
the Act	*National Health Act 1953*

RECOMMENDATIONS

Recommendation 1

2.21 The committee recommends that the government examine ways in which there can be greater engagement with consumers in decisions to create new therapeutic groups, particularly when considering the potential impacts new therapeutic groups may have on consumers.

Recommendation 2

2.42 The committee recommends that the Pharmaceutical Benefits Advisory Committee:

- **develop agreed principles of what constitutes "interchangeable on an individual patient basis";**
- **develop criteria by which the "interchangeability" of a medicine will be determined; and**
- **publish both the agreed principles and criteria.**

Recommendation 3

3.10 The committee recommends that the Department of Health and Ageing provide regular and ongoing education and information to prescribers to ensure they are aware of the exemptions from payment of a brand premium and the process for seeking those exemptions on behalf of a patient.

Recommendation 4

4.8 The committee recommends that:

- **the threshold for Cabinet consideration of high cost medicines be adjusted, initially to the value the threshold would have had, had it been indexed annually since 2001;**
- **subsequently, the threshold should be indexed annually; and**
- **the Department of Health and Ageing examine the most appropriate indicator for indexing the threshold.**

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.

CHAPTER 2

CONSULTATION AND TRANSPARENCY

2.1 During the course of the inquiry, numerous submitters expressed concern about the process by which the government sought to create and inform stakeholders of its intention to create the new therapeutic groups announced in the 2009 Federal Budget and the 2009-10 Mid-Year Economic and Fiscal Outlook (MYEFO). These submitters were particularly unhappy about the lack of consultation and lack of transparency around the decision to create these new groups.

Consultation

2.2 The announcements by government of its intention to create a new therapeutic group for the statins-HP and the three therapeutic groups for drugs used to treat depression, osteoporosis and Paget disease were first made publicly in the 2009 Federal Budget on 13 May and the 2009-10 MYEFO released on 2 November 2009, respectively.

2.3 The Department of Health and Ageing (DoHA) provided the following timeline for consultation associated with the announcement of the three new therapeutic groups in the 2009-10 MYEFO:

2 November 2009	Intention to make the groups published in the MYEFO.
2 & 9 November 2009	Letters to affected companies and to peak industry bodies announcing the intention to form the new groups, and to affected companies advising pricing implications. Comments sought from affected companies.
16 November- 3 December 2009	Letters received from affected companies, a peak industry body and some medical professionals including comments about clinical issues surrounding interchangeability of the relevant drugs and about the decision-making process.
3 December 2009	Letter from the department to the Pharmaceutical Benefits Advisory Committee (PBAC) asking it to consider the clinical issues raised in the comments received.
3 December 2009	Letter to affected companies stating advice is likely to be sought from the PBAC on comments on clinical issues and asking that any further comments be provided to the PBAC by 16 December 2009 so that advice on the clinical issues raised could be provided to the decision-maker in early January 2010.

3-16 December 2009	Further comments received from affected companies and some medical professionals.
22 December 2009	Indicative pricing letters sent to companies that may be offered lower prices if the new therapeutic groups are formed in January 2010.
8-12 January 2010	The PBAC considered the material submitted in accordance with the consultation process before giving advice confirming its view that the groups should be formed and that the relevant medicines are interchangeable on an individual patient basis.
19 January 2010	The delegate considered the advice from the PBAC and the other comments and submissions provided in accordance with the consultation process and made the instrument forming the therapeutic groups (which commenced 21 January 2010).
20 January 2010	PBAC advice sent to affected companies.
20 January- 18 February 2010	Price offer letters sent to companies affected by lower pricing as a result of formation of the therapeutic groups. Negotiations with companies about pricing.
18 February 2010	All new prices agreed, with no therapeutic group premiums.[1]

2.4 The department further advised the committee that consultation on the formation of these therapeutic groups had occurred:

> Lastly, the suggestion that there was no consultation in forming the groups is simply wrong. We did outline the consultation process in the submission. All affected companies and other interested people had an opportunity to comment on the proposed formation of each of these groups before a decision was made, and the formation of the groups was based on advice from the independent expert, the PBAC.[2]

2.5 The department emphasised that when seeking comment from relevant pharmaceutical companies, the department had explained 'that this was not a conveying of a decision, this was a conveying of an intention, and we were asking them for comment'.[3]

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1 Department of Health and Ageing (DoHA), *Submission 27*, pp 17-18.

2 Mr David Learmonth, Deputy Secretary, DoHA, *Committee Hansard*, 7 May 2010, p. 93.

3 Mr Andrew Stuart, First Assistant Secretary, Pharmaceutical Benefits Division, DoHA, *Committee Hansard*, 7 May 2010, p. 94.

The innovative pharmaceutical industry and affected sponsors

2.6 Medicines Australia took issue with the absence of consultation prior to the announcement of the new therapeutic groups and suggested the announcements had come as a surprise to the pharmaceutical industry. Dr Brendan Shaw, Chief Executive of Medicines Australia, stated 'The first we find out about those particular groups is when they are announced either in the budget or in the MYEFO. There is no consultation prior to that'.[4]

2.7 Individual manufacturers agreed:

> On 13 May 2009, the Government announced it would create a new TG for 'higher potency' HMG Co-A reductase inhibitors, i.e. Lipitor® – atorvastatin (manufactured by Pfizer) and Crestor® – rosuvastatin (manufactured by AstraZeneca). The Government announced the savings from this new TG would be $114 million over four years. Pfizer had not received any correspondence on this matter prior to the Budget announcement.[5]

And:

> In the case of the oral bisphosphonate osteoporosis and Paget disease therapeutic groups; while the PBAC provided advice to the Minister in June 2009 that these groups should be formed, there was no consultation with our company about the clinical implications for patients or the commercial impact of the decision. Sanofi-aventis received no communication about the proposal until it was announced in the Mid-Year Economic and Fiscal Outlook on 2 November 2009 – five months after the recommendation was made.[6]

2.8 sanofi-aventis suggested that the formation of therapeutic groups should include 'the same rigorous consultation with medicines manufacturers that is required for any medicines registration or reimbursement', for example by way of a major clinical submission by the affected sponsor to the PBAC.[7] Pfizer agreed that 'There must be a consistent approach to transparency and consultation for all PBS medicines'.[8]

2.9 Medicines Australia recommended removal of the therapeutic group policy entirely but suggested, if the policy continued, that:

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4 Dr Brendan Shaw, Chief Executive, Medicines Australia, *Committee Hansard*, 7 May 2010, p. 6.

5 Pfizer Australia, *Submission 33*, p. 19.

6 sanofi-aventis Australia Pty Ltd, *Submission 23*, p. 8.

7 sanofi-aventis Australia Pty Ltd, *Submission 23*, pp 8 & 9.

8 Pfizer Australia, *Submission 33*, p. 23.

> …the process of forming therapeutic groups should be transparent and give proper regard to principles of due process and natural justice for those sponsors that will be affected by any decision.[9]

And:

> When considering whether two or more drugs should be treated as "interchangeable on an individual patient basis" for the purposes of the formation of a Therapeutic Group, the PBAC must seek and consider comments from the sponsor, and notify the sponsor not less than a full PBS Listing cycle before the relevant PBAC meeting.[10]

2.10 The committee notes that the memorandum of understanding (MOU) agreed by the Commonwealth Government and Medicines Australia states that 'The Commonwealth will provide sponsors with reasonable notice of its intention to form any new Group, and seek sponsor comment prior to determination of any new Group'.[11]

2.11 The committee is of the view that the MOU will address the concerns regarding consultation raised by the innovative pharmaceutical industry. Further, the 'Resolution of issues in good faith' provisions of the MOU provide an avenue to resolve disputes between the government and industry should consultation on the creation of new therapeutic groups continue to be an issue.

2.12 The committee notes that the MOU was not agreed by generic pharmaceutical manufacturers, represented by the Generic Medicines Industry Association (GMiA). The committee understands, however, that the Department of Health and Ageing would consult with all sponsors – both innovative and generic manufacturers – in the event that the government sought to create further new therapeutic groups.

Consumers and physicians

2.13 The potential impact of the new therapeutic groups on patients was raised as a particular concern by consumer groups[12] and physicians[13] alike, and flagged as a reason why consultation prior to the formation of the therapeutic groups was necessary. These concerns included potential adverse side-effects which consumers

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9 Medicines Australia, *Answers to questions on notice*, 7 May 2010 (received 31 May 2010).

10 Medicines Australia, *Answers to questions on notice*, 7 May 2010 (received 31 May 2010).

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

12 See for example Epilepsy Council of Australia & Epilepsy Australia, *Submission 15*, p. 1 & Mr David Crosbie, Chief Executive Officer, Mental Health Council of Australia (MHCA), *Committee Hansard*, 7 May 2010, p. 29.

13 See Associate Professor Stephen Oakley, *Committee Hansard*, 7 May 2010, p. 67 & Dr Charles Inderjeeth, Member, Australian and New Zealand Society for Geriatric Medicine, *Committee Hansard*, 7 May 2010, pp 68 & 69.

might experience as a result of switching medicines,[14] additional costs and restricted access to medicines:

> …unless there is engagement with the people who are engaged in that relationship—particularly consumers, their carers and the people who are involved in trying to find the right kind of treatment for people—we worry about the trade-off against cost and accessibility. Cost and accessibility are really critical, but if we are going to trade off access to medicines or interchangeability of medicines then it needs to be done in a way that engages with people who are the direct experiencers—the consumers and the people who are trying to deal with a mental illness—and the people who are working with them.[15]

2.14 The Australian and New Zealand Bone and Mineral Society (ANZBMS), a specialist physicians group, raised the lack of consultation with doctors: 'As specialists in the treatment of Osteoporosis with first hand experience of the therapies available, we are concerned at the lack of consultation in the development of this economically driven proposal'.[16]

2.15 Organisations such as the Consumers Health Forum Australia (CHF)[17] and the Mental Health Council of Australia (MHCA)[18] were critical of the lack of consultation by government with consumers in deciding to create new therapeutic groups. Mr David Crosbie, Chief Executive Officer of the MHCA, stated:

> …there is a case for arguing a much greater level of engagement with consumers…At the moment, we are concerned that the level at which decisions are made, including decisions that we are now discussing about the groups, is inadequate in terms of properly consulting…[19]

2.16 Carers Australia felt that carers must also be properly consulted:

> The unique perspective of carers has to be taken into account when we are looking at any changes to the PBS. They are probably as aware as most health professionals of the impact of drugs on the person they are caring for. We know that, if there is a change in medication, particularly around mental illness, and the carer is not aware of it, it can have really serious consequences. So we would just ask that, when you are looking at changes in this area, you take the whole family into account and ensure family carers are part of the consultation process.[20]

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14 Epilepsy Council of Australia & Epilepsy Australia, *Submission 15*, p. 1.

15 Mr David Crosbie, Chief Executive Officer, MHCA, *Committee Hansard*, 7 May 2010, p. 29.

16 Australian and New Zealand Bone and Mineral Society (ANZBMS), *Submission 9*, pp 2-3.

17 Consumers Health Forum (CHF), *Submission 20*, p. 3.

18 MHCA, *Submission 25*, p. 3.

19 Mr David Crosbie, Chief Executive Officer, MHCA, *Committee Hansard*, 7 May 2010, p. 29.

20 Ms Sue Aiesi, Policy, Communications and Research Manager, Carers Australia, *Committee Hansard*, 7 May 2010, p. 30.

2.17 The committee heard support from consumer and patient groups for greater inclusion of and consultation with consumers in the development of therapeutic groups. The CHF summarised this view:

> CHF argues that stakeholder consultation, including consumer consultation, is required in the formation of therapeutic groups to ensure that the relevant benefits and potential disadvantages are considered. Consumers are the people who are living with their medications on a daily basis…Their experiences must be taken into account…[21]

2.18 A number of consumer groups recommended ways in which consumers might be better included in decision-making about therapeutic groups through greater involvement in PBAC processes generally. These recommendations included:

- consumer impact statements – which have been used previously – to enable consumers to inform PBAC assessments of medicines for specific conditions;
- consumer consultation forums to inform consumers about PBAC processes and how they may contribute to those processes, as well as canvass consumer views on specific issues, conditions and / or medications;
- direct involvement by the PBAC with condition-specific consumer organisations to enable relevant consumers to provide medicine or condition-specific input ("targeted engagement");
- mandatory appointment of a consumer representative to each of the PBAC's subcommittees and working groups, and any other advisory / policy mechanism associated with the PBAC; and
- changes to the current confidentiality restrictions on the PBAC consumer representative to enable that representative greater scope to discuss and consult with consumers.[22]

2.19 The CHF specifically noted that consultation by the PBAC with consumers 'on the listing of particular drugs on the PBS through the development of consumer impact statements' had 'been really valuable'.[23]

2.20 With respect to the involvement of consumers in determining the creation of new therapeutic groups, and particularly when considering the potential impacts these may have on consumers, it is the committee's view that greater inclusion of consumers in the decision-making process would be appropriate.

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21 Ms Carol Bennett, Executive Director, CHF, *Committee Hansard*, 7 May 2010, p. 60.

22 See CHF, *Answers to questions on notice*, 7 May 2010 (received 19 May 2010); Arthritis Australia, *Answers to questions on notice*, 7 May 2010 (received 20 May 2010) & MHCA, *Answers to questions on notice*, 7 May 2010 (received 25 May 2010).

23 Ms Carol Bennett, Executive Director, CHF, *Committee Hansard*, 7 May 2010, p. 60.

Recommendation 1

2.21 The committee recommends that the government examine ways in which there can be greater engagement with consumers in decisions to create new therapeutic groups, particularly when considering the potential impacts new therapeutic groups may have on consumers.

Transparency

2.22 In addition to concerns regarding a lack of consultation, numerous submitters raised issues about the lack of transparency with respect to the government's decision to create the new therapeutic groups and the basis on which the new groups were created.

2.23 The committee heard conjecture as to the government's reason for creating the new therapeutic groups with some submitters suggesting the four therapeutic groups announced in 2009 'were implemented purely as a PBS savings measure without transparency or due process'[24] and were not about patient outcomes:

> The apparent rationale of the Therapeutic Groups policy is to produce savings to the Pharmaceutical Benefits Scheme (PBS)…While the creation of therapeutic groups may engineer savings to the PBS, there is no evidence available to PSA that indicates the measure necessarily works to improve patient outcomes.[25]

2.24 The Department of Health and Ageing advised the committee that the proposal to create the statins-HP therapeutic group:

> …was initiated by the Department as part of the 2009-10 Budget process. A range of savings proposals were put forward to the Minister by the Department, including a proposal for a Statins HP group. The Minister then submitted this proposal, among others, for Government consideration. The Government agreed that the therapeutic group be formed, subject to the advice of the PBAC.[26]

2.25 Similarly, the proposals to create therapeutic groups for the venlafaxine and desvenlafaxine derivatives and oral bisphosphonates were initiated by the department as one of a number of savings proposals for consideration by the government.[27]

2.26 The Pharmacy Guild of Australia (PGA), whilst supportive of the PBAC's role in determining therapeutic groups, felt that greater transparency was required:

> The Pharmacy Guild believes that the PBAC is the most appropriate body to determine therapeutic groups but would welcome more information

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24 Mr Will Delaat, Chairman, Medicines Australia, *Committee Hansard*, 7 May 2010, p. 2.

25 Pharmaceutical Society of Australia, *Submission 17*, p. 2.

26 DoHA, *Answers to questions on notice*, 7 May 2010 (received 15 June 2010).

27 DoHA, *Answers to questions on notice*, 7 May 2010 (received 15 June 2010).

> being made regarding the process and the basis on which it makes its decision. This would improve stakeholder confidence and, obviously, transparency in this policy.[28]

2.27 Further, when asked whether appropriate clinical data had been taken into account when the new therapeutic groups were being formed, Ms Toni Riley of the PGA stated:

> In my view—and this is very much my view—we have no idea of how they were reached. We have no idea what data was considered. We know there was no consultation with us. I have to say that I am very concerned about how they arrived at the decisions, but I do not know how they got there, and nobody is prepared to say. The lack of knowledge and the lack of transparency are of great concern.
>
> …
>
> It is of great concern. The lack of consultation and the lack of any indication as to how these decisions were arrived at are of concern to us.[29]

2.28 Other organisations, such as Medicines Australia and the CHF, also raised the issue of lack of transparency around the creation of new therapeutic groups.[30]

2.29 Medicines Australia queried 'how such decisions are made or the evidence used to make such a case' and argued that the criteria and the type of evidence used by the PBAC to determine whether medicines in a therapeutic group are interchangeable should be made available to affected sponsors.[31]

2.30 Indeed, the definition of 'interchangeable on an individual patient basis'[32] and the evidence used to determine interchangeability by the PBAC was of specific concern to some witnesses. This issue is further discussed below.

Definition of and evidence for interchangeability

2.31 As discussed in Chapter 1, the formation of therapeutic groups and the inclusion of particular medicines in those groups is based on the "interchangeability" of medicines. That is, that the medicines in a therapeutic group achieve the same

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28 Ms Toni Riley, National Councillor, The Pharmacy Guild of Australia, *Committee Hansard*, 7 May 2010, p. 38.

29 Ms Toni Riley, National Councillor, The Pharmacy Guild of Australia, *Committee Hansard*, 7 May 2010, p. 40.

30 See Dr Brendan Shaw, Chief Executive, Medicines Australia, *Committee Hansard*, 7 May 2010, p. 6 & Ms Carol Bennett, Executive Director, CHF, *Committee Hansard*, 7 May 2010, p. 60.

31 Medicines Australia, *Submission 29*, p. 14.

32 *National Health Act 1953*, s. 84AG(3).

health outcome and 'are very alike and work just as well as one another for the vast majority of people'.[33]

2.32 The *National Health Act 1953* (the Act) requires that when determining a therapeutic group, the Minister:

> …may have regard to advice (if any) given (whether before or after the commencement of this section) to the Minister by the Pharmaceutical Benefits Advisory Committee to the effect that a drug or medicinal preparation should, or should not, be treated as interchangeable on an individual patient basis with another drug or medicinal preparation.[34]

2.33 The Act does not define "interchangeable".

2.34 The committee heard concern regarding the definition, or lack thereof, of interchangeability. Professor Markus Siebel of the ANZBMS described his attempts to find a definition:

> …I would like to come back to the definition of 'interchangeability', which really is at the heart of the discussion here. I have been searching high and low for a definition of 'interchangeability', and the closest definition I came to was that by the Australian [Therapeutic Goods Administration], where they talk about 'essentially similar drugs' and they orient themselves by the European or EC guidelines. There are three criteria here—very clear, specific criteria. They say that (1) 'essentially similar drugs' have the same quantity and quality composition in terms of active principle and (2) that they have the same pharmaceutical form—for example, tablet form, which is the case. Thirdly, and this is important, I think, 'essentially similar drugs' are bioequivalent unless it is evident from scientific knowledge that the medicines differ significantly as regards safety or efficacy.[35]

2.35 Medicines Australia explained that they had sought a definition of interchangeability from the Department of Health and Ageing but had not been provided with one to the satisfaction of the pharmaceutical industry. Dr Brendan Shaw described the department's response to Medicines Australia's requests for a definition:

> The response is fairly circular, I think, because it is: 'What's interchangeability? Well, it's something that's interchangeable at a patient level.'…Then we ask them, 'What does that mean?'…Eventually the discussion becomes: 'Well, it's when the PBAC recommends that something is interchangeable at the patient level.' We say, 'Okay, what does that mean?' They say, 'When the PBAC says it is.' I think it is

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

34 *National Health Act 1953*, s. 84AG(3).

35 Professor Markus Siebel, Council Member and Member of Therapeutics Committee, ANZBMS, *Committee Hansard*, 7 May 2010, p. 25.

> probably fair to say that it has been a circular argument. There is no list of criteria, no definitions or anything like that.[36]

2.36 With respect to "interchangeability", the Department of Health and Ageing stated:

> The question of interchangeability of drugs in therapeutic groups differs from a finding by the Therapeutic Goods Administration that generic brands of a drug are sufficiently bioequivalent to be treated as identical.[37]

And:

> The requirement in the legislation is that the inclusion of a drug in a therapeutic group is based on the expert advice of the Pharmaceutical Benefits Advisory Committee (PBAC) that drugs are interchangeable at the individual patient level. This is the definition in the legislation.
>
> Interchangeable at the patient level means that the independent expert PBAC judges that some drugs are very alike and work just as well as one another for the vast majority of people.[38]

2.37 Professor Lloyd Sansom, Chair of the PBAC, went further by outlining the PBAC's interpretation of interchangeability:

> The PBAC has interpreted the statement of the term 'interchangeable on a patient basis' in the following way: drugs within the therapeutic group are very alike—that is, they belong to the same therapeutic class and, in the vast majority of patients, would work just as well as one another. That is, in commencing a patient on any one of the drugs in a therapeutic group it would make no difference in health outcomes for the vast majority of patients. This does not mean of course that each patient will respond exactly the same to every medicine in the group. Clearly, it is unrealistic to expect that. We are not clones of one another and individual differences will always exist in regard to both response and toxicity. Further, the history of the formation of therapeutic groups acknowledges that fact by allowing applications for exemptions from any therapeutic group premium. So to say that the interchange at the patient level has to be the same with each individual is not the way PBAC has interpreted this legislation at all. For the majority of patients, no specific characteristic is apparent which would predict that a patient may respond better to one medicine than another within a therapeutic group.[39]

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36 Dr Brendan Shaw, Chief Executive, Medicines Australia, *Committee Hansard*, 7 May 2010, pp 8-9.

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

38 DoHA, *Answers to questions on notice*, 7 May 2010 (received 15 June 2010).

39 Professor Lloyd Sansom, Chair, Pharmaceutical Benefits Advisory Committee (PBAC), *Committee Hansard*, 7 May 2010, pp 75-76.

2.38 In the absence of a specific definition or criteria used to determine the interchangeability of medicines on an individual basis, Medicines Australia questioned how the PBAC was determining interchangeability and on what data it was relying to do so.[40]

2.39 Medicines Australia was adamant that data used in a cost-minimisation submission to demonstrate that one medicine was 'non-inferior' to another was not appropriate to determine interchangeability at an individual level:

> It has been suggested to Medicines Australia that evidence presented in the cost-minimisation submissions are the principal source for determining whether a medicine is interchangeable on an individual patient basis with another medicine. There is good reason, however, to be cautious about using this type of evidence for such a purpose.
>
> Cost-minimisation submissions typically only present data from trials that are specifically designed to establish that a medicine is 'non-inferior.' That is to say, they are designed to test the hypothesis that statistically a drug is no worse clinically than the drug to which it is being compared. It is generally accepted as inappropriate to infer any other conclusion from such trials, including any conclusion that one drug might be superior or even that the drugs are equivalent. Such claims are normally satisfied through superiority or equivalence trials respectively.
>
> If, indeed, the PBAC is using non-inferiority trials as the principal source of evidence to advise that medicines are "interchangeable on an individual patient basis", Medicines Australia believes that the Committee is using evidence that is not suitable for answering the relevant question.[41]

2.40 Professor Sansom informed the committee that medicines in a therapeutic group are listed on the Pharmaceutical Benefits Scheme (PBS) on a cost-minimisation basis but did not specifically clarify whether this information was used to determine whether medicines in a therapeutic group were interchangeable:

> If the sponsor is unable to show superiority but provides satisfactory evidence that the medicine is no worse than its comparator, in either efficacy and/or toxicity, it is recommended at the same price as its comparator to ensure that the system pays no more for the same health outcome. That is a statement that I commonly use in public: the same bang, the same buck. Mr Delaat, this morning, called it cost minimisation. It is the same thing.
>
> The cost-minimisation approach is taken, irrespective of whether the medicines are a member of the same pharmacological class. They may in fact be medicines within completely different mechanisms of action but whose patient relevant outcomes are no worse than one another. The same outcome warrants the same price in the context of a funding or pricing program.

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40 Mr Will Delaat, Chairman, Medicines Australia, *Committee Hansard*, 7 May 2010, p. 2.

41 Medicines Australia, *Submission 29*, pp 12-13.

> All the drugs within a therapeutic group are in the same therapeutic class and have been funded on the basis of being no worse than one another with respect to the dominant indication.[42]

2.41 The committee notes the apparently intractable positions in which the pharmaceutical industry and the department / PBAC find themselves with respect to the issue of defining and determining "interchangeability", and the ongoing confusion and frustration that has resulted. The committee believes that the PBAC is the most appropriate body to define and determine "interchangeability" given its expertise and advisory role. However, it is the view of the committee that agreed principles of what constitutes "interchangeable on an individual patient basis" and the requirements for meeting or otherwise those principles would improve the transparency and rigour of the process for determining therapeutic groups.

Recommendation 2

2.42 The committee recommends that the Pharmaceutical Benefits Advisory Committee:

- **develop agreed principles of what constitutes "interchangeable on an individual patient basis";**
- **develop criteria by which the "interchangeability" of a medicine will be determined; and**
- **publish both the agreed principles and criteria.**

42 Professor Lloyd Sansom, Chair, PBAC, *Committee Hansard*, 7 May 2010, p. 75.

CHAPTER 3

EXEMPTION FROM PAYMENT OF THERAPEUTIC GROUP PREMIUMS

3.1 As outlined in Chapter 1, drugs in a therapeutic group may be subject to a charge in addition to the co-payment amount, known as a 'therapeutic group premium'.[1] This additional fee is paid by the consumer and only applies to a medicine where the manufacturer does not accept the Pharmaceutical Benefits Scheme (PBS) price under the therapeutic group pricing policy.[2]

3.2 At present, there are 523 brands of medicines in therapeutic groups. Of those, six have a therapeutic group premium applied ranging in value from $2 to $4.35.[3]

3.3 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'.[4] In this circumstance, the Commonwealth Government pays the patient premium where the prescriber has obtained an authority from Medicare Australia, based on one of the following specified criteria:

- the patient suffers from adverse effects when taking all of the drugs in the group that have no therapeutic group patient premium;
- the patient experiences drug interaction issues when taking all of the drugs in the group that have no therapeutic group patient premium;
- it is expected that the patient would experience drug interaction issues if they took any of the drugs in the group that have no therapeutic group patient premium; or
- transferring the patient to a drug in the therapeutic group that has no therapeutic group premium would cause patient confusion resulting in problems with compliance.[5]

3.4 During the course of the inquiry, a number of doctors suggested to the committee that oral bisphosphonates were not interchangeable at a patient level on the basis of:

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1 Department of Health and Ageing (DoHA), *Submission 27*, p. 15.

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

3 Mr David Learmonth, Deputy Secretary, DoHA, *Committee Hansard*, 7 May 2010, p. 93.

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

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

> …clinically significant differences in these agents in terms of their speed of onset and persistence of effect at offset. There are areas where there are distinctly different levels of evidence on efficacy, e.g. corticosteroid osteoporosis treatment, between the different agents. Moreover there are differences that may relate to compliance as to whether they can be administered weekly, monthly or annually.[6]

3.5 As a result of these clinical differences between the oral bisphosphonates, doctors in the field were concerned that the creation of a therapeutic group for the bisphosphonates might result in 'patients suffering financial or therapeutic penalty'.[7]

3.6 It became apparent to the committee that some of these doctors were unaware that they were able to request on exemption on behalf of their patients, so as to avoid any financial or therapeutic disadvantage. Dr Gabor Major stated he 'certainly was not aware…that we can ring up and request a special dispensation for the patient'.[8] Professor Stephen Oakley and Dr Charles Inderjeeth were equally unaware of the exemptions.[9]

3.7 The department advised that a two-year education campaign was carried out, commencing in 1997-98, to inform prescribers of the introduction and implications of the therapeutic group policy:

> The education campaign included:
>
> - Direct mailings to prescribers of PBS medicines;
> - A telephone help line service;
> - A health professionals and consumer groups information kit;
> - Consumer leaflets for distribution by medical practices and pharmacies;
> - Articles in the Health Insurance Commission (now Medicare Australia) Forum and other professional and consumer group newsletters; and
> - An insert in the Schedule of Pharmaceutical Benefits, which at the time, was distributed free-of charge to doctors at each update.[10]

3.8 The committee is concerned that doctors responsible for prescribing medicines in therapeutic groups may be unaware that they are able to seek an exemption from a therapeutic group premium on behalf of their patients. The

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6 Professor John Eisman AO, *Submission 6*, p. 1. See also Associate Professor Stephen Oakley, *Committee Hansard*, 7 May 2010, p. 67 & Dr Gabor Major, *Committee Hansard*, 7 May 2010, p. 70.

7 Professor John Eisman AO, *Submission 6*, p. 1. See also Associate Professor Geoff Littlejohn, *Submission 7*, p. 1 & Dr David Kandiah, *Submission 5*, p. 1.

8 Dr Gabor Major AC, *Committee Hansard*, 7 May 2010, p. 71.

9 Associate Professor Stephen Oakley & Dr Charles Inderjeeth, Member, Australian and New Zealand Society for Geriatric Medicine, *Committee Hansard*, 7 May 2010, pp 71 & 72.

10 DoHA, *Answers to questions on notice*, 7 May 2010 (received 15 June 2010).

exemptions are intended to protect patients from additional costs, in cases where medicines in a therapeutic group are not interchangeable at the individual patient level. However, the exemptions cannot achieve this if those responsible for prescribing medicines that attract a therapeutic group premium are unaware of the exemptions.

3.9 The committee acknowledges the work undertaken by the department to educate prescribers at the time the therapeutic group policy was first introduced during 1997-98. The committee believes, however, that regular and ongoing education and information is required to ensure prescribers are aware of the exemptions from payment of a brand premium and the process for seeking those exemptions on behalf of a patient via a Medicare authority.

Recommendation 3

3.10 The committee recommends that the Department of Health and Ageing provide regular and ongoing education and information to prescribers to ensure they are aware of the exemptions from payment of a brand premium and the process for seeking those exemptions on behalf of a patient.

CHAPTER 4

CABINET CONSIDERATION THRESHOLD

4.1 As discussed in Chapter 1, where a medicine being considered for inclusion on the Pharmaceutical Benefits Scheme (PBS) is estimated to cost government more than $10 million in any of its first four full years of PBS listing, a submission on that drug must be considered by Cabinet.[1]

4.2 Some submitters were concerned that the $10 million threshold, which was originally set during the early 2000s, had not been increased since that time:

> …our argument has always been that the threshold should be increased. The $10 million threshold was set back in 2000 or 2001, and even just by indexing it to inflation it would be up to $20 million. We think it needs to be increased.[2]

4.3 Medicines Australia claimed that consideration by Cabinet of high cost medicines delayed the approval process and meant that patients were waiting longer than necessary to gain access to high cost medicines through the PBS:

> Our view is that the cabinet process generally adds six to 12 months to listing time. Given that Australians are already waiting three years for a medicine to appear on the PBS, that process needs to be looked at.[3]

4.4 To address this delay, Medicines Australia suggested that the threshold triggering consideration by Cabinet be increased:

> …we certainly believe that the $10 million threshold introduced at the turn of the century should be increased as recommended by the government's own Productivity Commission. It makes no sense that patients are being made to wait for sometimes life-saving treatments for a bureaucratic process whose rationale is unclear at best when those medicines have already been rigorously evaluated. At the very least, there are some medicines that simply should not get trapped in the cabinet process, and we are asking for the threshold to be updated to take account of that.[4]

4.5 The Consumers Health Forum of Australia (CHF) supported this proposal:

> CHF notes the proposal in a number of other stakeholders' submissions that the threshold for cabinet approvals be increased from $10 million to $20

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1 Department of Health and Ageing (DoHA), *Submission 27*, p. 20.

2 Dr Brendan Shaw, Chief Executive, Medicines Australia, *Committee Hansard*, 7 May 2010, p. 11.

3 Dr Brendan Shaw, Chief Executive, Medicines Australia, *Committee Hansard*, 7 May 2010, p. 11.

4 Mr Will Delaat, Chairman, Medicines Australia, *Committee Hansard*, 7 May 2010, p. 3.

> million. CHF would not be opposed to this increase, particularly where it would expedite access to necessary medicines.[5]

4.6 In its 2008 *Annual Review of Regulatory Burdens: Manufacturing and Distributive Trades* report, the Productivity Commission noted:

> The $10 million threshold has not been indexed and will be triggered more often as the cost of medicines increases. The Government should consider the merits of increasing the threshold to account for price changes over the past six months and implementing an automatic annual indexation adjustment.[6]

4.7 In the interest of Australian patients having timely access to necessary medicines, the committee is of the view that the threshold for Cabinet consideration of high cost medicines be increased. Initially, the threshold should be adjusted to the value it would have had, had it been indexed annually since 2001 (when the threshold was introduced). From then on, the threshold should be indexed annually.

Recommendation 4

4.8 The committee recommends that:

- **the threshold for Cabinet consideration of high cost medicines be adjusted, initially to the value the threshold would have had, had it been indexed annually since 2001;**
- **subsequently, the threshold should be indexed annually; and**
- **the Department of Health and Ageing examine the most appropriate indicator for indexing the threshold.**

5 Ms Carol Bennett, Executive Director, Consumers Health Forum of Australia (CHF), *Committee Hansard*, 7 May 2010, p. 61.

6 Productivity Commission, *Annual Review of Regulatory Burdens: Manufacturing and Distributive Trades*, September 2008, p. 80.

CHAPTER 5

OTHER ISSUES RAISED DURING THE INQUIRY

5.1 A number of organisations raised other concerns regarding pharmaceuticals and pharmaceutical policy. These included concerns regarding reforms to the Pharmaceutical Benefits Scheme (PBS) and the pricing of generic medicines on the PBS, as well as programs and services provided by pharmacists, which are discussed in this chapter.

PBS reform and generic medicines

5.2 The Generic Medicines Industry Association (GMiA) was supportive of 'the concept of therapeutic groups'[1] and the use of therapeutic groups as 'a policy tool to ensure that medicines on the PBS delivering the same health outcomes receive the same level of government subsidy'.[2] The GMiA was, however, concerned about the reforms to the PBS in 2007 and the impact of these:

> The recent PBS reforms that separate the PBS formularies results in the Government paying higher prices for F1 medicines that deliver the same health outcomes as F2 medicines, in some instances.[3]

5.3 The association was particularly concerned about the impact of PBS reform on the generic medicines sector:

> GMiA notes that one of the key consequences of PBS reform is the reduction of prices of generic medicines. The generic medicines sector plays a crucial role in delivering affordable medicines to the Australian public after the market exclusivity period of originator medicines has expired. The commercial viability of the generic medicines sector is driven by volume. A Government policy that reduces the PBS list price of generic medicines in the absence of volume drivers significantly risks undermining the viability of the generic medicines sector.[4]

5.4 The GMiA felt that the separation of the PBS into two formularies, F1 and F2, and the absence of reference pricing between the two formularies meant there was a need for 'other policy mechanisms to ensure that more expensive medicines are used appropriately and that the most cost effective use of PBS expenditure is achieved'.[5] On that basis, and to address their concerns regarding the ongoing viability of the generic medicines sector, the GMiA made the following recommendations:

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1 Generic Medicines Industry Association (GMiA), *Submission 16*, p. 14.

2 GMiA, *Submission 16*, p. 13.

3 GMiA, *Submission 16*, p. 3.

4 GMiA, *Submission 16*, p. 4.

5 GMiA, *Submission 16*, p. 14.

- *Price signal to encourage consumers to choose a generic medicine* – the GMiA suggested that the government introduce 'a clear price advantage that provides an incentive for the patient to choose a generic medicine', claiming that this was 'critical to ensure that Australians continue to receive the important savings that generic medicines offer the community'.[6] The GMiA recommended that this price signal take the form of an additional $5.00 added to the patient co-payment whenever a patient chooses an original brand of a medicine over a generic brand.[7]
- *Floor price for generic medicines* – it was recommended by the GMiA that the government introduce a floor price 'of $5.00 ex-manufacture below which, when a medicine reaches the floor price...no further price cuts will be applicable to the medicine'.[8] The GMiA believed the floor price was required because 'if there are further price reductions to the price of generic medicines, the ongoing supply of low cost essential medicines and patients' health may be jeopardised'.[9]
- *Monthly listing on the PBS* – the GMiA explained that currently there are three times per year (1 April, 1 August and 1 December) when a sponsor may list a medicine on the PBS and that sponsors must notify the Department of Health and Ageing on 1 December, 1 May or 1 September, respectively, to effect a PBS listing.[10] The GMiA argued that greater cost savings could be achieved (from price reductions such as the 12.5 per cent reduction associated with the listing of a generic on the PBS) if medicines could be listed on the PBS on a monthly basis rather than every four months because 'the cost savings on some products could be realised up to three months earlier than allowed under the current system'.[11]

5.5 The committee acknowledges the concerns raised by the GMiA. The committee did not examine these issues in depth and did not have sufficient evidence to enable it to make a decision with respect to the GMiA's recommendations. The committee notes, however, that the ongoing viability of the generic medicines sector continues to be an issue.

Professional pharmacy services

5.6 The Pharmaceutical Society of Australia (PSA) discussed professional services provided by pharmacists and noted that the Fourth Community Pharmacy

6 GMiA, *Submission 16*, p. 4.

7 GMiA, *Submission 16*, p. 4.

8 GMiA, *Submission 16*, p. 5.

9 GMiA, *Submission 16*, p. 4.

10 GMiA, *Submission 16*, p. 5.

11 GMiA, *Submission 16*, p. 5.

Agreement (2005-2010) included funding for 'a range of patient-focussed professional pharmacy programs and services'.[12] The PSA was disappointed that:

> ...the development and implementation of several important programs and services have been unduly delayed during the Fourth Agreement and PSA understands that a considerable proportion of allocated funding may remain unspent when the Agreement ceases on 30 June 2010.[13]

5.7 The PSA believed that the Fifth Community Pharmacy Agreement (negotiated by the government and the Pharmacy Guild of Australia, and commenced on 1 July 2010) should be based on a number of principles, including the delivery of quality professional pharmacy services and integrated professional pharmacy services within the health system to meet the changing health care needs of the Australian population.[14]

5.8 The PSA suggested that the existing arrangements for the negotiation of Community Pharmacy Agreements be reviewed:

> ...to ensure that:
>
> - proposals for professional programs and services that are considered for funding under these Agreements are formulated on behalf of the pharmacy profession and its patients;
> - these programs and services are developed in a timely fashion; and
> - all programs and services are implemented efficiently and effectively.[15]

5.9 The PSA went on to recommend a number of programs or services which could be provided by pharmacists, including:

- *Clinical interventions by pharmacists* – the PSA recommended clinical interventions by pharmacists as a way to reduce adverse drug reactions and the unnecessary use of medicines. The PSA calculated that '[e]ach intervention performed by a pharmacist was estimated to result in $220 of direct cost savings'.[16]
- *Pharmacovigilance* – the PSA suggested a role for pharmacists in post-marketing pharmacovigilance, and recommended capitalising 'on the knowledge and skills of frontline pharmacists' in the 'detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem'.[17]

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12 Pharmaceutical Society of Australia (PSA), *Submission 17*, p. 3.

13 PSA, *Submission 17*, p. 3.

14 PSA, *Submission 17*, p. 3.

15 PSA, *Submission 17*, p. 4.

16 PSA, *Submission 17*, pp 4-5.

17 PSA, *Submission 17*, p. 6.

- *Collaborative prescribing* – the PSA advocated for prescribing by non-medical professionals by way of "collaborative prescribing".[18] The PSA proposed a system whereby:

> ...once a diagnosis has been established by a medical practitioner or a treatment plan prepared for an individual patient, part of the responsibility for management and some activities associated with ongoing prescribing are undertaken by a non-medical health professional based on patient responses and outcomes.[19]

5.10 The PSA suggested that collaborative prescribing might be most appropriate where patients suffer from chronic diseases such as asthma, diabetes or hypertension.[20]

5.11 In addition to its recommendations with respect to professional services provided by pharmacists, the PSA voiced concern about increases to patient co-payments for PBS-subsidised prescriptions and stated 'PSA contends that patient co-payments have now reached such a high level that there is a danger of patients foregoing some of their necessary medications due to cost'.[21]

5.12 The committee is aware that negotiation of the Fifth Community Pharmacy Agreement has concluded. The committee suggests, however, that the government and Pharmacy Guild of Australia consider the issues raised by the PSA when developing programs under the Community Pharmacy Agreement.

Senator Rachel Siewert

Chair

18 PSA, *Submission 17*, p. 7.

19 PSA, *Submission 17*, p. 7.

20 PSA, *Submission 17*, p. 7.

21 PSA, *Submission 17*, p. 7.

APPENDIX 1

Public submissions received by the committee

Submissions received:

1 Confidential Submission

2 Thornley, Dr Stephen

3 Confidential Submission

4 Confidential Submission

5 Kandiah, Dr David A

6 Eisman, Professor John

7 Littlejohn, Professor Geoff

8 Glendenning, Professor Paul

9 Australian and NZ Bone and Mineral Society

10 Oakley, Dr Stephen

11 Major, Dr Gabor

12 Australian Medical Association (AMA)

13 Inderjeeth, Dr Charles A

14 Chronic Illness Alliance

15 Joint Epilepsy Council of Australia and Epilepsy Australia

16 Generic Medicines Industry Association Pty Ltd

17 Pharmaceutical Society of Australia

18 The Pharmacy Guild of Australia

19 Janssen-Cilag Australia

20 Consumers Health Forum of Australia

21 Osteoporosis Australia

22 Paroxysmal Nocturnal Haemoglobinuria (PNH) Support Association of Australia

- Attachment

23 Sanofi-Aventis Australia Pty Limited

24 Arthritis Australia

25 Mental Health Council of Australia

26 Carers Australia

27 Department of Health and Ageing

28 MS Australia

29 Medicines Australia

30 Hill, Minister John

31 AstraZeneca Pty Ltd

32 Faunce, Dr Thomas

33 Pfizer Australia

34 Australian NPC Disease Foundation Inc (VIC)

35 Abbott Australasia Pty Ltd

Additional information:

Arthritis Australia

- Response to questions taken on notice at public hearing 07.05.10, received 20.05.10

AstraZeneca Pty Ltd

- Response to questions taken on notice at public hearing 07.05.10 and Supplementary submission, received 31.05.10

Australian and NZ Bone and Mineral Society

- Additional information referred to and provided at public hearing 07.05.10
- Response to questions taken on notice at hearing 07.05.10, received 22.05.10

Chronic Illness Alliance

- Response to questions taken on notice at public hearing 07.05.10

Consumers Health Forum of Australia

- Response to questions taken on notice at public hearing 07.05.10, received 19.05.10

Department of Health and Ageing

- Response to questions taken on notice at public hearing 07.05.10, received 15.06.10
- Response to Committee correspondence seeking views on the Memorandum of Understanding signed between the Australian Government and Medicines Australia, received 16.06.10

Generic Medicines Industry Association Pty Ltd

- Correction to the record from public hearing 07.05.10, dated 17.05.10
- Additional information arising from hearing, dated 18.05.10

Janssen-Cilag Australia

- Supplementary submission and response to questions taken on notice at public hearing 07.05.10, received 31.05.10

Medicines Australia

- Supplementary submission and response to questions taken on notice at public hearing 07.05.10, received 31.05.10
- Response to Committee correspondence seeking views on the Memorandum of Understanding signed between the Australian Government and Medicines Australia, received 10.06.10

Mental Health Council of Australia

- Response to questions taken on notice at public hearing 07.05.10, received 25.05.10

Pfizer Australia

- Supplementary submission and response to questions taken on notice at public hearing 07.05.10, received 01.06.10

Pharmaceutical Benefits Advisory Council

- Response to questions taken on notice at public hearing 07.05.10, received 16.06.10

The Pharmacy Guild of Australia

- Supplementary submission including response to questions taken on notice at public hearing 07.05.10, received 14.05.10
- Response to Committee correspondence seeking views on the Memorandum of Understanding signed between the Australian Government and Medicines Australia, received 09.06.10

Sanofi-Aventis Australia Pty Limited

- Response to questions taken on notice at public hearing 07.05.10, received 31.05.10

APPENDIX 2

Public hearing

Friday, 7 May 2010
Parliament House, Canberra

Committee Members in attendance

Senators Siewert (Chair)
Senator Claire Moore (Deputy Chair)
Senator Concetta Fierravanti-Wells
Senator Scott Ryan

Witnesses

Medicines Australia

Mr Will Delaat, Chairman
Dr Brendan Shaw, Chief Executive
Mr Andrew Bruce, Executive Director, Health Policy and Research

Janssen-Cilag Australia

Mr Tim James, Manager – Corporate and Government Affairs

Sanofi-aventis Australia

Mr Paul Lindsay, Public Affairs Director
Dr Alex Condoleon, Medical Director

AstraZeneca

Dr Simon Fisher, Senior Director, Medical and Regulatory Affairs
Mr Kieran Schneemann, Government Affairs Director

Pfizer Australia

Mr David Miles, Senior Manager, Government Affairs
Dr Peter Stewart, Primary Care Medical Head, Australia and New Zealand

Australian and New Zealand Bone and Mineral Society

Professor Markus Seibel, Council Member

Chronic Illness Alliance *via teleconference*

Ms Jan Donovan

Arthritis Australia

Dr Mona Marabini, President
Ms Ainslie Cahill, Chief Executive Officer

Mental Health Council of Australia

Mr David Crosbie, Chief Executive Officer
Ms Melanie Cantwell, Deputy Chief Executive Officer

Carers Australia

Ms Sue Aiesi, Policy, Communications and Research Manager
Ms Jessica Beswick, Policy and Research Officer

MS Australia

Dr Elizabeth McDonald, Medical Director

Pharmacy Guild of Australia

Ms Toni Riley, National Councillor (Victoria)
Dr Michael Tatchell, Director Health Economics
Mr Vincent O'Sullivan, Manager Health Economics

Generic Medicines Industry Association

Ms Kate Lynch, Chief Executive Officer

Consumers Health Forum of Australia

Ms Carol Bennett, Executive Director
Ms Anna Wise, Senior Policy Manager

Dr Stephen Oakley *via teleconference*

Dr Gabor Major

Dr Charles Inderjeeth *via teleconference*

Pharmaceutical Benefits Advisory Committee

Emeritus Professor Lloyd Sansom, Chair

Department of Health and Ageing

Mr David Learmonth, Deputy Secretary
Mr Andrew Stuart, First Assistant Secretary, Pharmaceutical Benefits Division
Ms Felicity McNeill, Assistant Secretary, Pharmaceutical Evaluation Branch, Pharmaceutical Benefits Division
Dr John Primrose, Medical Advisor, Pharmaceutical Benefits Division
Mr Kim Bessell, Principal Pharmacy Advisor