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.
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> …
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> 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.
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> 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.
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> 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.
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> 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.