6

Annex on Pharmaceuticals

6.1 Considerable evidence was received on the potential impacts to the PBS as a result of the Pharmaceutical Annex (Annex 2-C) and it will therefore be the focus of this Chapter. The Annex reflects some joint obligations and common principles, and the exchange of letters (side letters) on pharmaceuticals sets out some specific commitments that Australia has made in relation to the processes by which new products are added to the list of medicines subsidised under the PBS.[1] These include issues of transparency and timeliness. According to the DFAT Factsheet, the Annex will 'provide more opportunities for companies seeking listing of new medicines on the PBS to have input into the process.'[2] It is this statement which has been the subject of much debate within the Australian community.

Agreed Principles of the PBS

> Australians' access to health services in general, and pharmaceuticals in particular, is enviable. Our system provides a clear pathway for all Australians to access medications they need for preventative care, disease treatment and modification, palliative care and maintenance of a lifestyle which would otherwise be curtailed or indeed ended in the absence of such medication.[3]
>
> - Dr Mukesh Haikerwal, Vice President, Australian Medical Association

---

1 DFAT, *Guide to the Agreement*, p. 10.

2 DFAT Factsheet, viewed on 9 February 2004, at www.dfat.gov.au/trade/negotiations/us_fta/outcomes/10_health.html.

3 Dr Mukesh Haikerwal, *Transcript of Evidence*, 3 May 2004, p. 13.

6.2 The Committee considers that it is of utmost importance to recognise that the existing structure of the PBS will be largely maintained. As Mr Deady stated

> the fundamentals of the PBS – the pricing and listing arrangements – were something that we were not prepared to negotiate on, but there were aspects of transparency and process that we were prepared to talk about.[4]

6.3 The Committee recognises the general agreement amongst many who presented evidence that the Agreement would not alter the PBS' operations, as demonstrated by Medicines Australia in their submission.

> There is nothing in the FTA which would lead to the dismantling of the PBS. The fundamental principles that underpin the PBS remain. The Agreement does not impair Australia's ability to deliver fundamental policy objectives in healthcare and does not change the fundamental architecture of the PBS.[5]

6.4 Views expressed by Medicines Australia were reiterated by the Australian Medical Association, who stated that they were satisfied at this stage with

> assurances we have been given by Australian Government negotiators that the draft Australia-US Free Trade Agreement (AUSFTA) of itself protects the essential framework of the Australian health system.[6]

6.5 The Committee is aware nonetheless of the extent of debate and concern that the Agreement has caused in the wider community. The Committee received evidence from many parties who are concerned that the implementation of a review mechanism will place additional pressures on the PBS and the PBAC. Dr Ken Harvey's view that 'the provisions under the free trade agreement will substantially weaken the Pharmaceutical Benefits Scheme' was echoed in similar terms by the Australia Institute, the Doctors Reform Society and Healthy Skepticism Inc in their submissions.[7]

6.6 In evidence to the Committee, Dr Ruth Lopert from the Department of Health and Ageing has said that the review mechanism will only formalise what already occurs in an informal context.

---

4 Mr Stephen Deady, *Committee Briefing*, 2 April 2004, p. 46.

5 Medicines Australia, *Submission 28*, p. 23.

6 Australian Medical Association, *Submission 146*, p. 1.

7 Dr Ken Harvey, *Transcript of Evidence*, 20 April 2004, p. 2., and the organisations' submissions 70, 87 and 179 respectively.

> When a drug is rejected for listing on the PBS, there is often intense lobbying that is applied to that situation. What this process does is formalise and institutionalise a channel for that. It is important to recognise that there is an opportunity for a review mechanism to enhance the transparency and accountability of the process.[8]

6.7 Dr Lopert's views were confirmed by Medicines Australia in their submission, which stated in part

> There is no new process whereby companies can ask for higher prices for medicines. The FTA text formalises an existing process whereby companies can ask the Government to consider the value of their medicines.[9]

6.8 Further to concerns that the structure of the PBS would be weakened were claims that the costs would increase under the Agreement, whether because of increased pressure by pharmaceutical companies under the review process, or because of the extra administrative costs to the scheme resulting from the proposed changes.[10]

6.9 Concerns about costs were also raised by State and Territory Governments.[11] Despite claims by the Australia Institute that the Agreement will result in higher costs for the Commonwealth Government for the provision of the existing quantity of medicines through the PBS, and that

> while prices will not raise by as much as the US drug companies would have liked, the changes are likely to result in both higher prices in the short term and a faster rate of growth for drug prices in the medium to long term.[12]

the Committee heard no compelling evidence that would convince it of the linkage between the Agreement and any price rise.

6.10 The Committee does however have some concerns about the balance of principles in the Agreement. These views were expressed by, among others, Dr Faunce and Professor Drahos.

> Article 1 of the FTA's Pharmaceutical Annex outlines 'agreed principles' utilized by the dispute panel in interpreting the text.

8 Dr Ruth Lopert, *Transcript of Evidence,* 14 May 2004, p. 60.

9 Medicines Australia, *Submission 28*, p. 21.

10 These views were expressed by some submissions, including from The Grail Centre, *Submission 97*, p. 6, and Uniting Care (NSW / ACT), *Submission 169*, p. 8.

11 Concerns about costs were specifically raised by the ACT Legislative Assembly, *Submission 180,* p. 1, the NSW Government, *Submission 66,* p. 2., and the Queensland Government, *Submission 206*, p. 8.

12 Australia Institute, *Submission 70,* p. 2.

> These emphasize 'innovation', the importance of R&D and 'competitive markets.' Missing, however, is an unambiguous and unqualified statement of Australia's right to make a priority of 'protecting public health' and, in particular, facilitating 'access to medicines for all.' These are the words that public health groups fought for and won in the WTO's *Doha Declaration* under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), but which the US is now circumventing through more restrictive bilateral FTAs.[13]

6.11 The views of Dr Faunce, Professor Drahos and Dr Harvey on these issues are echoed by the Australian Nursing Federation, who state

> the ANF considers that the proposed FTA in regard to the PBS is unbalanced and almost exclusively focuses on the rights of manufacturers at a potential cost to consumers.[14]

6.12 Dr Schrader referred at a public hearing to the principles' lack of reference to public health policy or equity.

> If you read the principles in annex 2-C, Pharmaceuticals, you can see that they are basically to reward innovation and research and development by pharmaceutical companies. It is not under public health principles or equity. Universal access is not even mentioned.[15]

6.13 The Committee believes that innovation and R&D are important matters for the pharmaceutical industry but should continue to be recognised as part of industry policy not health policy.

Patents and marketing of generic drugs

6.14 Issues of patents and marketing of generic drugs are discussed in Chapter 20 of this report, which considers the Intellectual Property Rights Chapter of the Agreement (Chapter 17).

---

13 Dr Tom Faunce and Professor Peter Drahos, *Submission 72*, p. 2. This reference to the TRIPS agreement in public health was also stated by Dr Ken Harvey, *Transcript of Evidence*, 20 April 2004, p. 3 and the Australasian Society for HIV Medicine, *Submission 75*, p. 3.

14 Australian Nursing Federation, *Submission 120*, p. 2.

15 Dr Tracy Schrader, *Transcript of Evidence*, 5 May 2004, p. 24.

Medicines Working Group

6.15 According to the *Guide to the Agreement*, the establishment of a Medicines Working Group will enable further discussion of the issues covered by the Annex. It will be similar to other Working Groups that are proposed, and will discuss aspects of the Agreement.

6.16 Dr Harvey's statement that

> all we know [about the medicines working group] at the moment is that it is meant to be made up of officials from the US health department and the Australian health department and it is meant to review future dealings of the free trade agreement in light of the principles[16]

reflects the negative effects foreshadowed by several groups, including the Doctors Reform Society, and the Australian Fair Trade and Investment Network (AFTINET).

6.17 The AMA states that it would be very concerned if the Medicines Working Group

> were to assume any role in setting rules or making decisions related to the PBS as this would undermine Australian sovereignty. We note and endorse assurances that this group of federal health officials from the US and Australia will be strictly a consultative forum.[17]

6.18 The Committee is notes concerns raised by the Association of People Living with HIV / AIDS in its submission as to the authority held by the Medicines Working Group. The Committee is not in a position to make a judgement as to the eventual operation of the Working Group but would support the continued involvement of health professionals in Australia and America in debates on the ongoing roles and operations of the Group.

Review mechanism for PBAC decisions

6.19 A particularly contentious issue in the Agreement is the review mechanism proposed under the Pharmaceuticals Annex and that it will act as a possible threat to the PBAC.[18] The *Guide to the Agreement* states that

16 Dr Ken Harvey, *Transcript of Evidence*, 20 April 2004, p. 9.

17 Dr Mukesh Haikerwal, *Transcript of Evidence*, 3 May 2004, pp. 14-15.

18 See for example Ms Nicola Ballenden, *Transcript of Evidence*, 6 May 2004, p. 77.

> in the interests of greater transparency and accountability, Australia has agreed to establish a review mechanism that will be made available to companies when an application to have a drug added to the PBS has been rejected by the PBAC.
>
> The details of how the review process will operate will be worked out in the context of Australia's legal and administrative framework.[19]

6.20 Evidence received by the Committee demonstrated widespread concerns in the Australian community about pressure on the PBAC, and the impact of these changes to

> open the door for major US pharmaceutical companies, possessing very extensive legal, financial and technical resources, to lobby the PBAC, pursue appeals against negative decisions, and generally secure much greater leverage in price negotiations.[20]

6.21 These views were generally reiterated by several groups including the Australian Consumers Association and Healthy Skepticism Inc.[21]

6.22 The Committee received information on several related issues: the establishment of the review mechanism: its rules and operation, and the possible ways in which it may be used by US drug companies to exert pressure on the PBAC and the PBS. Dr Ruth Lopert, from the Department of Health and Ageing advised that

> a number of stakeholders have already been consulted … We have held stakeholder briefings in which representatives of other organisations have put forward very strong and carefully thought through views on how they see the review mechanism should be implemented and we are continuing to canvass those opinions with a view to arriving at an implementation of the review mechanism which reflects the interest of the key stakeholders.[22]

6.23 Dr Lopert later confirmed that 'after some degree of consultation with key stakeholders a paper will be developed and circulated for further comment from a broader range of interests'.[23] The Committee accepts that, as the consultation process has recently commenced, procedural rules have not yet

---

19 DFAT, *Guide to the Agreement*, p. 12.

20 ACT Government, *Submission 180*, p. 2.

21 Australian Consumers Association, *Submission 195*, p. 5 and Healthy Skepticism Inc., *Submission 179*, p. 2.

22 Dr Ruth Lopert, *Committee Briefing*, 2 April 2004, p. 51.

23 Dr Ruth Lopert, *Transcript of Evidence*, 14 May 2004, p. 59.

been developed and that it is difficult to be precise about what procedural rules will apply.[24]

6.24 The Committee understands that essentially, it is expected that the review process will have the capacity for an application to be reviewed where the PBAC has rejected a listing.

> It is anticipated that the outcome of that review would be a referral back to the PBAC to review certain aspects of the application or to take into consideration some perspectives that the reviewers felt had not been adequately considered or given due weight in the original assessment of the application.[25]

6.25 The Committee heard from several groups about the ability of powerful pharmaceutical groups to lobby to have their products listed. As Dr Ken Harvey states

> it seems to me inevitable that they will use their public relations power, their marketing power, their money and their lawyers – all the opportunities they have – to create pressure on PBAC to modify and soften their decision. That is likely to lead, therefore, to less stringent concern about pharmacoeconomics or broader indications than the evidence might otherwise have portrayed.[26]

6.26 Similar concerns were raised by Dr Patricia Ranald of AFTINET, the Australian Nurses Federation and the Australian Society for HIV Medicine.

> … it is naïve to think that, because this review process is in a trade agreement, the US companies will not pursue it very vigorously.[27]
>
> The ANF is concerned that this new step will lead to greater opportunities for the pharmaceutical manufacturers to utilise an army of publicists, lawyers and lobbyists to change the outcomes of a robust and respected system that is the PBAC.[28]
>
> This allows more opportunity for US pharmaceutical companies to exert pressure to have their products listed – through lobbying and their massive legal and PR machines.[29]

6.27 The Committee acknowledges the concerns raised by Dr Harvey, AFTINET and the Australasian Society for HIV Medicine with regard to the situation

24 Dr Ruth Lopert, *Committee Briefing*, 2 April 2004, p. 52.
25 Dr Ruth Lopert, *Committee Briefing*, 2 April 2004, p. 51.
26 Ken Harvey, *Transcript of Evidence*, 20 April 2004, p. 6.
27 Dr Patricia Ranald, *Transcript of Evidence*, 19 April 2004, p. 42.
28 Australian Nursing Federation, *Submission 120*, p. 2.
29 Australasian Society for HIV Medicine, *Submission 75*, p. 1.

that might arise where a pharmaceutical company might use a positive review result to launch a political campaign designed to influence a subsequent PBAC outcome, even where the PBAC might not wish to support it. The Committee also acknowledges the concerns of the AMA that the review process may not be transparent and may actually be able to circumvent the decisions of the PBAC and the PBAC process.[30]

6.28 The Committee also received evidence on how the structure of the mechanism might be acceptable to stakeholders as well as the Australian public. The AMA suggests that the review process

> needs to be undertaken by a specialised subcommittee comprising experts relevant to the subject under review. It should consider only information originally provided to the PBAC and relevant to the requested review, and reporting back must be to the PBAC and not directly to the government.[31]

Further

> To ensure that the independent review process delivers true accountability to the public, the industry will support a process that:
>
> a. Is conducted at arms length from the process which provides the original recommendation to Government
>
> b. Involves an independent objective appraisal of the matters dealt with in the initial process of arriving at a determination — the facts, all aspects of the recommendation. For PBAC submissions, this includes the scientific analysis / findings and economic analysis / findings
>
> c. Enables determinations to undergo review, where the original advice to Government is confirmed or can vary from the original determination
>
> d. Is conducted in such a way as to make public outcomes from the review process at the first opportunity, and
>
> e. Is consistent with the currently agreed processes for the publication of negative decisions of the PBAC.[32]

6.29 The Committee considers that it is of utmost important that the review mechanism 'does not in any way undermine the PBAC's role as the only

30 Dr Mukesh Haikerwal, *Transcript of Evidence*, 3 May 2004, p. 17.

31 Dr Mukesh Haikerwal, *Transcript of Evidence*, 3 May 2004, p. 14.

32 Medicines Australia, *Submission 28*, p. 16.

body that can recommend to the Minister for Health and Ageing whether a drug can be listed on the PBS'.[33]

> The independent review system will not be able to force PBS listing. The final say and decision making on whether a medicine achieves PBS listing remains in the hands of the Executive Government and Health Minister. Whatever the PBAC or an independent review system may conclude the ultimate authority remains with the Government. The Minister retains the power to list or not list a medicine and to decide on the conditions that are placed for such listing.[34]

6.30 The Committee trusts that the concerns of the Australian Consumers' Association, among others, about the basis of the criteria under which decisions are taken according to the independent review mechanism will be allayed by evidence received from Dr Lopert of the Department of Health and Ageing.

> While not wishing to pre-empt the outcome, my understanding is that it would not be appropriate for a review to consider any facts other than those which had also been put before the PBAC in its original consideration of the matter. The PBAC is not empowered, for want of a better word, to consider the cost of R&D as one of the facts that it considers.[35]

6.31 The Committee notes the views of Medicines Australia and the Department of Health and Ageing that a system of independent review for decisions made by the PBAC is 'a safeguard for Australians to make sure that the right decision has been made for the community's needs'[36] and that

> The purpose of the review mechanism is, if you like, to create a second look – to take another view where PBAC has made a decision not to recommend the listing of a drug on the PBS. It will not look specifically at prices, so it will not have the capacity to recommend an increase in price.[37]

6.32 The Committee also acknowledges the point made by Medicines Australia, rarely made elsewhere within the recent debate about the review process, that the ability to demonstrate procedural fairness is important, 'considering the high level of investment industry makes in developing a

33 Dr Ruth Lopert, *Transcript of Evidence*, 14 May 2004, p. 60.
34 Medicines Australia, *Submission 28*, p. 8.
35 Dr Ruth Lopert, *Transcript of Evidence*, 14 May 2004, p. 61.
36 Medicines Australia, *Submission 28*, p. 6.
37 Dr Ruth Lopert, *Committee Briefing*, 2 April 2004, pp. 50-51.

new medicine and the need for timely access to critical medicines by the community'.[38]

6.33 The Committee understands that Australia will shape the review process subject to the commitments outlined in this Annex. Many of the concerns raised should be incorporated in the Department's consultations. There were several specific questions raised during the course of the inquiry about the shape of the review mechanism which should be the subject of departmental consultation.

Recommendation 5

In establishing the independent review of PBAC processes (for PBS listing under Annex 2-C of the Agreement), the Committee recommends that, in order to ensure that the fundamental integrity of the PBS is retained, the following principles be taken into account:

- **the review should focus on the issues of concern rather than re-opening the whole application**
- **the review should be undertaken by a specialised subcommittee comprising experts relevant to the subject of the requested review**
- **the subcommittee should consider only that information provided to the PBAC, and relevant to the requested review**
- **the subcommittee should report back to PBAC, and not directly to government**
- **the review process should be pragmatic, and facilitate, not delay, the PBAC approval processes for PBS listing of pharmaceuticals**
- **the review process be transparent and the findings and reasons for decisions made publicly available.**

38 Medicines Australia, *Submission 28*, p. 6.

Transparency

6.34 The Committee was pleased to receive many differing opinions with regard to issues of transparency in the Agreement. With regard to the PBS, the Committee believes that the increasingly apparent insistence on transparency in international relations and trade dealings is to be supported.

6.35 The Committee agrees with the view of the AMA that commercial-in-confidence secrecy surrounding research data is a major restraint on the quality use of medicines and that information given to the PBAC should be available to clinicians to ensure best practice management. The Committee was advised that 'such transparency across the whole PBS approval process is fundamental to AMA support for the FTA'.[39] This would involve the application of transparency principles to include pharmaceutical companies as well as the PBAC and the Pharmaceutical Benefits Pricing Authority (PBPA).[40]

Direct-to-consumer advertising

6.36 A further area where concerns were raised with regard to Annex 2-C was with the dissemination of pharmaceutical information via the internet. The concern is that this may allow direct-to-consumer advertising in Australia.[41] The Committee would be extremely concerned if this were the case, as it notes Dr Harvey's concerns that the practice of direct-to-consumer advertising has been clearly associated with the increased use of products often not in accordance with best practice principles.[42]

6.37 The Committee accepts however that there is no provision in the Agreement which suggests that the practice of advertising direct to consumers will take place.

> The FTA text articulates that any marketing and advertising to consumers must comply with existing laws. Current Australian law states that advertising direct to consumers by industry is prohibited.[43]

---

39 Dr Mukesh Haikerwal, *Transcript of Evidence*, 3 May 2004, p. 14.

40 Australian Medical Association, *Submission 146*, p. 2.

41 Dr Ken Harvey, *Transcript of Evidence*, 20 April 2004, p. 4.

42 Dr Ken Harvey, *Transcript of Evidence*, 20 April 2004, p. 4.

43 Medicines Australia, *Submission 28*, p. 17.

Plasma Fractionation Arrangements

6.38 According to the Side Letter on Blood Plasma, Australia is obliged to review Australian blood plasma fractionation arrangements by 1 January 2007. The Committee understands that the review will be undertaken by Commonwealth, State and Territory Governments and will include examining whether, in the future, suppliers of fractionation services should be selected through competitive tender processes.[44]

6.39 According to the DFAT Factsheet on Health Outcomes, Australia's policy on self-sufficiency in blood products will not be affected and blood plasma products for use in Australia will continue to be derived from plasma collected from Australian blood donors.

6.40 The Committee received evidence on this issue from the Australian Red Cross Blood Service, and Baxter Healthcare Corporation.[45] Both are in support of the Agreement.

Recommendation 6

The Committee recommends that Australia's policy of self-sufficiency in blood products continue to be maintained.

Concluding observations

6.41 The Committee notes that, while much of the evidence it received in relation to Annex 2-C was based on strong concerns and admirable motivations of the community groups, organisations and individuals who have been involved in this inquiry, the Committee assessed whether the AUSFTA *as a whole* is in the national interest.

6.42 The Committee recognises and appreciates evidence from several sources in defence of the Australian health care system, and notes the lobbying currently taking place in several countries, including the US, for the establishment of a similar system where citizens have access to a PBS-style

44 DFAT Factsheet, viewed on 14 June 2004, at http://www.dfat.gov.au/trade/negotiations/us_fta/outcomes/10_health.html

45 Baxter Corporation, *Submission 114* and Australian Red Cross Blood Service, *Submission 187* Representatives from each organisation also appeared at public hearings to present evidence on this issue (19 April 2004 and 6 May 2004 respectively).

system for the provision of medicines. The Committee would be extremely concerned should the PBS be undermined or threatened with regard to this, or any, international trade agreement.

6.43 With regard to some of the measures under the Pharmaceuticals Annex in the Agreement, such as the Medicines Working Group and the independent review mechanism, the Committee hopes that these bodies may serve to set an example of transparency and consultation, rather than threaten or undermine the PBS and the PBAC in Australia. The Committee concurs with Dr Lopert's views that, while there has been some criticism of the text of the Agreement in relation to the nature of the review mechanism is ambiguous

> I would characterise it as indicating a degree of flexibility in that, in developing the way in which we will implement this obligation, it would not be appropriate to define within a treaty level obligation in the document the precise nature of the implementation of that obligation. It is a matter for Australia to develop in consultation with key stakeholders as a domestic issue, as long as we meet the letter of the obligation contained in the text.[46]

6.44 The Committee thanks the health professionals, organisations and individuals who provided evidence to the Committee on the Pharmaceuticals Annex. The Committee is certain that their ongoing involvement and vigilance will ensure that any mooted changes, either domestically or internationally, which may be seen to threaten or undermine the Australian health system, will be the subject of spirited debate and public involvement in the future. The Committee considers this the most healthy sign of a functioning democracy.

46 Dr Ruth Lopert, *Transcript of Evidence*, 14 May 2004, pp. 58-59.