Chapter 4

Pharmaceuticals and Health

4.1 The possible impact of the FTA on pharmaceutical prices in Australia, and on the Pharmaceutical Benefits Scheme (PBS) in particular, has been a critical issue in this inquiry. The PBS's capacity to contain drug prices affects all Australians, and should not be traded off for potential economic gains in certain areas of the economy. The level of public interest is evidenced by the many submissions to this inquiry expressing concern that the FTA will ultimately undermine the PBS and result in higher drug prices in Australia. This issue has also attracted significant media coverage, which has both reflected and heightened public concern. In light of the significant interest, the committee held a roundtable discussion on 21 June 2004 that brought together academic experts, health professionals, consumer advocates and members of the government negotiating team.[1] This roundtable discussion helped clarify some of the issues facing this committee, and the input of those involved was greatly appreciated.

4.2 Any increase to the price of pharmaceuticals in Australia would impact on both Commonwealth and state governments as well as Australian consumers. The Commonwealth subsidises around 80% of all prescription drugs bought in Australia through the PBS at a cost of over $5.1 billion per year.[2] State governments are also major pharmaceutical purchasers, with around $1.1 billion worth of pharmaceuticals dispensed in public hospitals in 2001-02.[3] If pharmaceutical prices were to increase, Australian consumers would ultimately pay for this through their taxes as well as facing higher out-of-pocket prices for non-subsidised medicines.

4.3 There are two sets of commitments in the FTA that have potential consequences for the PBS and drug prices in Australia. First, the provisions of Annex 2-C and the side letter on pharmaceuticals relate to listing and pricing arrangements of the PBS. These arrangements are central to the Australian government's ability to get maximum value for money in buying pharmaceuticals for Australian consumers. Second, the sections of Chapter 17 relating to pharmaceutical patents and the marketing approval process for generic drugs threaten to impact on the ability of cheaper generic pharmaceuticals to enter the market promptly when a patent expires. This would have flow-on consequences for the PBS, as the availability of generic drugs is important to the PBS's pricing system of comparing the cost-effectiveness of drugs. In this chapter the committee examines these two sets of issues in some detail.

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1 See *Transcript of Evidence*, 21 June 2004

2 www.health.gov.au/pbs/general/aboutus.htm, accessed 26 July 2004

3 Australian Institute of Health and Welfare, *Australia's Health 2004*, p.237

The Pharmaceutical Benefits Scheme

4.4 The PBS is an integral part of Australia's health care system. It is widely recognised as a world leader in controlling government expenditure on pharmaceuticals while providing consumers with equitable access to affordable medicines. Through the PBS, the Australian government can use its power to determine which pharmaceuticals will be eligible for PBS listing to negotiate prices often significantly lower than prices in other countries.[4] The result is that taxpayers and consumers benefit from comparatively low drug prices.

4.5 Many witnesses to this inquiry said unequivocally that Australia's social policies, such as the PBS, should be off limits for trade negotiations. The committee agrees that, as a core social policy in Australia, the PBS should never have been on the negotiating table. It notes with interest that several members of the US Congress expressed similar views during their debate on the FTA, for example:

> …I question whether it is appropriate to use trade policy to interfere in other nations' health systems. We certainly wouldn't accept such a demand from other countries.[5]

> Domestic healthcare policy should not be decided in trade agreements…It is wrong for us to interfere with another country's domestic health policy, particularly when it comes to the affordability of medicine which is an equally sensitive issue here in the United States…This is special interest policy making at its worst. The Bush Administration is letting the pharmaceutical industry use trade agreements to manipulate the drug laws of the United States and other countries in ways that the industry could not otherwise achieve.[6]

> I am concerned about the potential precedent of the Administration meddling excessively in the internal affairs of a trading partner. With regard to this treaty, the USTR initially sought substantial changes in Australia's drug-pricing program. Though the USTR was not completely successful, the agreement does give U.S. drug companies more say in what drugs are included under Australia's universal drug coverage program. While market access for U.S. goods is important, we shouldn't be in the business of bullying the world and potentially undermining a country's ability to provide prescription drugs to its citizens.[7]

This committee concurs with these members of congress that using a trade negotiation to interfere with another country's health system is inappropriate. It creates resentment

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4 Productivity Commission, *International Pharmaceutical Price Differences*, Research Report, July 2001, p.6

5 *Congressional Record – House*, 14 July 2004, p. H5717 (Mr Tom Allen)

6 *Congressional Record – Extensions of Remarks*, 16 July 2004, pp.E1397-E1398 (Mr Henry A. Waxman)

7 *Congressional Record – Extensions of Remarks*, 16 July 2004, p.E1399 (Mr Mark Udall)

and undermines support for the trade agreement. Just why the Australian government has not objected to this unreasonable interference in our domestic health policy is a question that has yet to be adequately answered.

4.6 Equally disturbing to this committee is that commitments relating to the PBS and pharmaceuticals were discussed even while the government was assuring parliament and stakeholders that the PBS was not on the negotiating table. Trade Minister Mark Vaile told parliament on several occasions in 2003 that the US negotiators were 'in no way going after the PBS'.[8] As late as November 2003, the Prime Minister was saying:

> …the elements of the PBS system are not going to be traded away in those negotiations…I want to make it very clear that we are not going to trade that wonderful facility away in the Free Trade Agreement…the PBS in its essential character is just not on the list and is not up for grabs or not up negotiation [*sic*][9]

4.7 Representing the Minister for Health, Senator Ian Campbell told the Senate in December 2003 that:

> The Prime Minister and the Minister for Trade have both made it very clear that the PBS is not on the table…the government is committed to maintaining a viable generic medicines industry and the negotiation of a free trade agreement will not – I repeat, not – compromise this commitment. I should also add that the United States has made no proposals to Australia regarding the PBS.[10]

4.8 But this committee now knows that, contrary to these misleading assertions, the PBS was in fact 'on the table' from the very first round of negotiations.[11] While the government may choose to characterise the initial phase of talks on the PBS as 'discussions' rather than 'negotiations', the fact remains that the PBS was being talked about with US negotiators from the outset. This occurred even while the government made assurances clearly designed to convince Australians that the PBS was not up for grabs in the FTA.[12]

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8 See *House Hansard*, 26 May 2003, p. 14869 (Vaile) and *House Hansard*, 13 August 2003, p.18408 (Vaile).

9 Transcript of the Prime Minister the Hon John Howard MP, Ryde Business Forum, Sydney, 21 November 2003, found at: www.pm.gov.au/news/speeches/speech589.html accessed 26 July 2004

10 *Senate Hansard*, 2 December 2003, p. 18638 (Campbell)

11 Chief Negotiator Mr Stephen Deady told this committee that, 'discussions' on the PBS commenced in the first round of negotiations in March 2003. *Transcript of Evidence*, 21 June 2004, p.23 (Deady).

12 According to the AMA, their expressions of concern early in the piece that the PBS was on the table in the FTA negotiations were met with denials that the PBS was part of the negotiation process. *Transcript of Evidence,* 21 June 2004, p.30 (Haikerwal, AMA).

4.9 Having noted its concern about the way this issue has been handled by the Australian government, this committee must acknowledge the political reality that the PBS entered the negotiations at the insistence of US trade negotiators. US Congress requires American trade negotiators to seek "the elimination of government measures such as price controls and reference pricing which deny full market access for United States products" in overseas markets.[13] As an example of a reference pricing system that affects market prices, albeit one that does not discriminate on the basis of country of origin, Australia's PBS was a clear target for US trade negotiators bound to follow this Congress directive. It could be argued that US negotiators could not sign up to a trade agreement that did not show that at least some attempt had been made to open up the listing and pricing arrangements of the PBS to market competition.

4.10 This committee considers it most unfortunate that the Australian government has allowed provisions affecting the PBS to be included in a trade agreement. However, now that this has occurred, our task is to examine closely the relevant provisions and assess the possible impact and implications for the PBS into the future. Any outcome that would diminish the ability of the PBS to provide affordable, equitable access to pharmaceuticals for all Australian consumers would be an unacceptable trade off for possible gains in other areas of the economy.

The current system: Pricing and listing arrangements of the PBS

4.11 The pricing and listing arrangements of the PBS are crucial to its ability to contain costs. The Productivity Commission has summarised PBS listing and pricing arrangements as follows:

> Before a new pharmaceutical can be listed on the PBS, the supplier first must obtain marketing approval from the Therapeutic Goods Administration (TGA). The TGA analyses the product's quality, safety and efficacy before awarding marketing approval. The approval specifies, amongst other things, the approved uses (indications) for the pharmaceutical. Pharmaceutical manufacturers also must be licensed by the TGA and ensure that their manufacturing processes comply with principles of Good Manufacturing Practice.
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> Once approved for sale, suppliers may seek to have their products listed on the PBS by applying to the Pharmaceutical Benefits Advisory Committee (PBAC). The PBAC is a statutory committee of independent experts that reviews applications against a number of criteria including: the need for the product; the outcomes and costs of a particular pharmaceutical when weighed against other available therapies; and whether any restrictions should be imposed on new listings (such as limits on the number of items that may be prescribed or restrictions on the indications for which a PBS subsidy is available).

13 (US) Trade Act of 2002, 107-210, §2102(b)(8)(D). Deputy Trade Representative Josette Sheeran Shiner confirmed that this section applies to pharmaceuticals in evidence before a Joint Session of the (US) Senate Finance Committee, Subcommittees of Health and Trade, April 27 2004, "International Trade and Pharmaceuticals", p.5

> In reviewing applications for listing, the PBAC is required to consider both the effectiveness and cost of therapy involving the use of new pharmaceuticals. Under the *National Health Act 1953*, the PBAC cannot recommend listing unless the pharmaceutical provides 'a significant improvement in efficacy or a reduction in toxicity over the alternative therapy'. To this end, an important feature of Australia's system for listing new pharmaceuticals on the PBS is the reliance on requiring evidence that new pharmaceuticals offer significant benefits over those available from alternative forms of therapy. If the PBAC recommends that an item be listed on the PBS, the Pharmaceutical Benefits Pricing Authority (PBPA) will recommend a reimbursement price which may include a price-volume arrangement. According to Professor David Henry (a former member of the PBAC), the price at which a pharmaceutical is considered to be of acceptable cost-effective [*sic*] (that is, the cost of the item is justifiable based on the clinical outcomes which it is likely to deliver) by the PBAC has typically been the starting point for negotiations with manufacturers.
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> The reimbursement price is the maximum amount that the Government will reimburse to pharmacists, and it may be set with reference to the price of identical or similar pharmaceuticals that are already available under the PBS.
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> The PBPA recommends to the Government the price at which pharmaceuticals should be listed on the PBS. DHAC negotiates, on behalf of the Government, with pharmaceutical manufacturers the price of the pharmaceuticals using the PBPA recommendations as its basis. The Government then makes the final determination on whether to list a product at a particular price (although it cannot list a new pharmaceutical unless the PBAC has made a positive recommendation).
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> …
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> The PBPA also conducts annual reviews of the prices of products listed on the PBS. Also, suppliers may request a price review or seek to have pharmaceuticals already listed on the PBS approved by the PBAC for use to treat other conditions.[14]

FTA provisions relating to the PBS

4.12 Mr Stephen Deady told this committee that Australian negotiators went into negotiations on the FTA with "an absolutely clear mandate to protect and preserve the fundamentals of the PBS".[15] Nevertheless, the final FTA contains two sections directly relevant to the operations of the PBS.

4.13 **Annex 2C** of the agreement sets out specific commitments in the area of pharmaceuticals. The key parts are:

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14 Productivity Commission, *International Pharmaceutical Price Differences*, Research Report, July 2001, pp.4-5 (footnotes omitted)

15 *Transcript of Evidence*, 21 June 2004, p.12 (Deady, DFAT)

1. Agreed Principles: Sets out agreed four agreed principles emphasising the value of 'innovative pharmaceuticals'.

2. Transparency: sets out requirements for transparency of process for listing and pricing of pharmaceuticals under federal healthcare programs. They include giving applicants rights to provide submissions, get detailed information on the basis for decisions and have access to an independent review process.

3. Medicines Working Group: Establishes a Medicines Working Group comprising of federal government officials to "promote discussion and mutual understanding of issues relating to this Annex, including the importance of pharmaceutical research and development to continued improvement of healthcare outcomes."

4. Regulatory Cooperation: Agrees to advance existing dialogue between the TGA and the US Food and Drug Administration with a view to making innovative medical products more quickly available to their nationals.

5. Dissemination of Information: Provides that pharmaceutical manufacturers may use internet sites to 'disseminate…truthful and not misleading information' on their pharmaceuticals to medical practitioners and consumers.

4.14 An **exchange of side letters on the PBS** clarifies the commitments Australia has made regarding the operation of the PBS. Key points are:

1. Australia will give applicants for listing on the PBS an opportunity to consult with officials prior to submission of application; an opportunity to respond to PBAC reports; an opportunity for a hearing before PBAC; and sufficient information about reasons for a PBAC decision to facilitate an application to the Pharmaceutical Benefits Pricing Authority.

2. Australia will provide an opportunity for independent review of PBAC decisions not to recommend a drug for listing.

3. Australia will make selection, listing and pricing process more expeditious by: reducing the time required to implement PBAC recommendations; introducing procedures for more frequent revisions of the Schedule of Pharmaceutical Benefits; and making available expedited procedures for processing applications not requiring an economic evaluation.

4. Australia shall provide opportunities to apply for an adjustment to a reimbursement amount.

Areas of concern

4.15 Submissions concerning these sections of the FTA were received from consumer organisations, professional bodies, industry groups and academics as well as many individuals.[16] Several state governments also raised questions about Australia's commitments on the PBS.[17] In a general sense, their concerns centred on the possibility that Australia's FTA commitments will open Australia's PBS to institutionalised pressure from the US government (on behalf of the US pharmaceutical lobby) to recognise the value of "innovative pharmaceuticals" in the PBS listing and pricing system. This would be contrary to current practices that have kept prices down by emphasising cost-effectiveness in comparison with alternate treatments as a prerequisite for listing.

4.16 The following section sets out point by point the major specific concerns that have been raised regarding these sections of the FTA, and the government's response to those concerns. It then considers the more generalised issue of whether Australia's commitments FTA commitments on pharmaceuticals, taken together, provide a 'foot in the door' for the US pharmaceutical lobby to exert greater pressure on Australia's policies than at present to the long term detriment of the PBS.

Agreed principles

4.17 Witnesses to this inquiry have expressed concern that the agreed principles set out in Annex 2-C (1) are unbalanced and unduly reflect the agenda of US pharmaceutical companies in their emphasis on the value of 'innovative pharmaceuticals' rather than affordable access to medicines.[18] In addition, the principles leave out the principle of the Doha Declaration on the TRIPs Agreement that trade agreements should be interpreted and implemented so as to protect public health and promote access to medicines for all.[19] At a glance it would seem that the principles set out in Annex 2-C do indeed reflect the agenda of the US pharmaceutical lobby. The question is whether they impact on Australia's ability to set its own domestic policies that emphasise other priorities as well as those set out in this agreement.

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16 Submissions relating to the PBS were received from, among others (submission numbers in brackets): the Doctors Reform Society (407), the Australian Consumers Association (522), the Australia Institute (171), the Public Health Association of Australia (369), Dr Thomas Faunce et al (129), Dr Ken Harvey (80), the Australian Medical Association (105), Catholic Health Australia (405), the National Centre for Epidemiology and Population Health (445), Healthy Skepticism (467), Generic Medicines Industry Association (75), Medicines Australia (140), Australasian Society for HIV Medicine (349), National Association of People with HIV/AIDS (175), Australian Nursing Federation (147), Queensland Nurses Union (54).

17 New South Wales Government (*Submission 69*), Queensland Government (*Submission 66*), Victorian Government (*Submission 66*), Western Australian Government (*Submission 142*)

18 See, for example, *Transcript of Evidence*, 4 May 2004, p.87 (Harvey)

19 Dr Ken Harvey, *Answer to question on notice*, 4 May 2004, no.2

4.18 Government officials have assured this committee that the agreed principles are not exhaustive and do not bind any party to the agreement to a particular course of action. Dr Ruth Lopert told the committee that:

> I think it is really important to recognise that these are statements of principle and they do not confer or imply any rights to any of the parties. They also do not convey any specific obligations on the parties and they are indeed consistent with the current principles and practices underlying the operation of the PBS.[20]

4.19 Dr Lopert further stated that these principles:

> …are not intended to encompass all important principles and practices underlying the operation of the PBS. They are not intended to encompass all important principles to which Australia or indeed the US subscribe – they are not exhaustive. They do not prevent the continued priority being accorded to fundamental principles that are articulated in a national drug policy, particularly in relation to affordable and timely universal access to medicines, innovative or otherwise. They do not preclude the continued recognition of the importance of public health as encompassed by Doha paragraph 6.[21]

4.20 It has been put to this committee that these agreed principles are more important than Dr Lopert suggests. Some say that, if a dispute arose in the future on whether Australia was meeting its obligations in this area, a three-member panel appointed to adjudicate would use the agreed principles set out in the text to interpret the agreement and would not necessarily take account of social justice considerations not set down as part of the agreement.[22] While this committee appreciates officials' assurances that the principles are not designed to be exhaustive, it must note with some concern the possibility that this part of the agreement could have unintended consequences should a dispute ever arise. If the agreed principles set out in Annex 2-C will not carry at least some weight in the future interpretation of this agreement, it is curious that US negotiators would not agree to inclusion of wording health enshrining the principles of equitable access to essential drugs.[23] If they serve no purpose, why are they included at all?

Independent Review of PBAC decisions

4.21 The most significant change to PBS listing processes under this agreement is that, where PBAC recommends against listing a drug, the sponsor company will be able to apply for an independent review of PBAC's decision. Although companies can currently re-submit an application to the PBAC if their product is not listed on the first

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20 *Transcript of Evidence*, 21 June 2004, p. 19 (Lopert, DoHA)

21 *Transcript of Evidence*, 21 June 2004, p. 19 (Lopert, DoHA)

22 *Transcript of Evidence*, 21 June 2004, p.9 (Faunce)

23 *Transcript of Evidence,*4 May 2004, p.91 (Harvey)

application, this independent review is a new, additional mechanism in the PBS listing process. This committee has heard many witnesses express concern that the independent review of PBAC decisions could lead to more drugs being listed at higher prices than would otherwise be the case. Other concerns have related to the possibility that the independent review could undermine the authority of PBAC or the principles on which PBAC's decisions are based.

4.22 At the time of this committee's hearings, the government could not provide information on what form this review would take. We were told that it was undertaking consultations with key stakeholders on this very issue, including who and how many people will do the review and what the terms of reference and procedural rules will be.[24] Health Minister Tony Abbott was reported in the press as saying that the government would not necessarily give the committee this information as it will not "bow in worship" to a Senate committee.[25] A public consultation document was finally released on 25 July 2004, after the House of Representatives had voted on the implementing legislation and only one week before it was to be introduced into the Senate. Neither Mr Abbott nor his department actually forwarded this document to this committee, despite repeated requests to departmental officers to provide further information on the independent review once they became available. The committee did not have the chance to question officials about the document, which is in any case only an initial discussion paper on how a review might operate, not a full blueprint of how it will work. This committee takes strong exception to a government asking the parliament to pass this legislation while full information on the implementation of a key aspect of the agreement is not available.

4.23 During public hearings, officials did give several assurances about what the independent review will *not* be able to do. First, DFAT and DoHA officials stressed that nothing in the FTA requires Australia to change the legislation governing the operation of the PBS.[26] According to DoHA, this means that the independent review will not have the capacity to overturn PBAC decisions. Dr Lopert told the committee that:

> …without change to the National Health Act there is no capacity whatsoever for any review mechanism to overturn a recommendation of the PBAC. The PBAC will remain the only body which may recommend to the Minister for Health and Ageing whether a drug may be listed on the PBS.

4.24 Second, Mr Deady said that the side letter on the PBS limits Australia's commitment to providing an independent review only of PBAC decisions not to list a drug.[27] According to Dr Lopert, this is important because PBAC can impose

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24 *Transcript of Evidence*, 21 June 2004, p.42 (Lopert, DoHA)

25 "Pact with US approved but drug scheme doubts", *The Weekend Australian*, 17 July 2004

26 *Transcript of Evidence*, 21 June 2004, p.13 and p.16 (Deady, DFAT) and *Transcript of Evidence*, 21 June 2004, p.18 (Lopert, DoHA)

27 *Transcript of Evidence*, 21 June 2004, p.38, p.39 (Deady, DFAT)

conditions on a recommendation for listing, including that a drug be listed only at a price comparable to an equivalent drug. She assured the committee that the conditions imposed on a recommendation to list, including pricing conditions, cannot be challenged under this review process, as these conditions do not amount to a decision not to list a drug.[28] In other words, where PBAC recommends a drug be listed at a price less than the manufacturer is seeking, the manufacturer will not have recourse to the independent review.

4.25 Mr Deady further assured us that individual decisions of the independent review could not be taken to the dispute resolution panel set up under chapter 21 of this agreement for adjudication. He stated unequivocally:

> There is no capacity under the agreement for a particular decision of the review or decision of the PBAC to be challenged under the agreement.[29]

4.26 What DFAT and DoHA told this committee during hearings appears consistent with the AMA's stated position, which stipulates that:

> The "independent review process" of PBAC recommendations required by the FTA must be truly independent and not dominated by any sectional interest, be that industry, professions, consumers or government. Any such reviews should:
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> - focus on the issues of concern and not re-open the whole application;
> - be undertaken by a specialised subcommittee comprising experts relevant to the subject of the requested review;
> - consider only information originally provided to the PBAC, and relevant to the requested review;
> - report back to PBAC and not directly to government;
> - be pragmatic and facilitate, not delay, the PBAC approval processes for PBS listing of pharmaceuticals.[30]

4.27 This position was picked up by JSCOT in its report, which included a recommendation along similar lines.[31]

4.28 The consultation paper released by the health minister on 25 July suggests that the review mechanism in contemplation will be along these lines. Among other things, that document states that the review will:

- Be independent of the applicant, the PBAC and staff or contractors of DoHA involved in any prior evaluations

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28 *Transcript of Evidence*, 21 June 2004, pp.51-52 (Lopert, DoHA)

29 *Transcript of Evidence*, 21 June 2004, p.41 (Deady, DFAT)

30 Australian Medical Association Federal Council Resolution of 28 May 2004

31 Joint Standing Committee on Treaties, *Report 61: The Australia-United States Free Trade Agreement*, Recommendation 5, p.90

- Only be available at a sponsor's request where an application to PBAC has not resulted in a recommendation to list
- Be conducted by an expert with relevant expertise appointed by a convenor. The expert may consult in private with the applicant, PBAC, DoHA or other experts following consultation with the review convenor. Any person consulted would be identified in the reviewer's report.
- Report back to PBAC
- Be conducted to a timeframe that does not delay PBS processes
- Consider only issues identified by the applicant that reflect PBAC's reasons for rejecting the application
- Have access to all information placed before PBAC as well as PBAC deliberations, but will not consider new data.

4.29 Although this document suggests that DoHA has taken on board stakeholder concerns in designing this review process, it unclear how anyone can guarantee at this stage that this additional mechanism will not have any impact on the operations of the PBS. Pharmaceutical companies seeking PBS listing will naturally use every available avenue available to exert pressure on PBAC to list their products. This review mechanism provides one more step through which they can seek to influence PBAC recommendations. How the availability of an additional review affects the effectiveness of the companies' lobbying and public relations strategies and the ability of the PBAC to withstand such pressure in cases where a drug is not considered cost-effective remains to be seen.

4.30 The committee accepts that DFAT and DoHA understand that the commitment to provide an independent review does not automatically mean that the independent review mechanism will have the power to override individual listing decisions of the PBAC or the principles on which those decisions are based. What is not clear is whether this understanding of the commitment would be open to challenge if the US were not satisfied with a review mechanism along these lines. Australian officials have told us that this is their understanding of the commitment, but cannot speak for the US and cannot necessarily predict how the US will act in the future.

4.31 This committee will continue to have reservations about the commitment to institute an independent review mechanism until it can be proved that a mechanism along the lines set out by the AMA and in DoHA's discussion document does not make PBS listing processes unwieldy and will not be open to challenge by the US. It would also expect close monitoring of the impact of this review mechanism on the operations of the PBS as a whole. Any suggestion that the review mechanism could be used to pressure PBAC to list drugs on grounds other than their cost-effectiveness and superiority to other available treatments would undermine the government's assurances to date that the fundamental architecture of the PBS will not be affected by this agreement.

Increased transparency of PBS pricing and listing processes

4.32 In addition to the independent review mechanism, some of the other transparency commitments under Annex 2-C(2) will require adjustments to current procedure. The side letter on the PBS suggests that companies seeking to have a drug listed on the PBS will be guaranteed the opportunity to consult with officials and provide further written submissions at certain stages of the listing process, be given the opportunity of a hearing in front of PBAC, and be given 'sufficient information on the reasons for PBAC's determination…to facilitate any application to the Pharmaceutical Benefits Pricing Authority'.[32]

4.33 Some of the transparency commitments under Annex 2-C reflect current practice. Currently, sponsors making submissions to PBAC are provided with the section of the minutes of the PBAC meeting that provides detailed information on the basis of PBAC's recommendation on their application.[33] Where PBAC recommends against listing a drug, it provides the company with specific issues that should be addressed in any revised application. Companies have the opportunity to meet with the chair of PBAC or health department officials to clarify these issues.[34]

4.34 Giving pharmaceutical companies the opportunity of a hearing with PBAC on their application is new. DoHA's public consultation document sets out a number of points detailing how it intends implementing this requirement.[35] It says, *inter alia*, that hearings should be confined to specific issues, limited in scope, duration and frequency, and that Medicines Australia will develop a code of practice to guide applicants in the most appropriate circumstances for seeking a hearing before PBAC. This committee is concerned that the points contained in this document are too vague to ensure that pharmaceutical manufacturers having hearings before PBAC will not make PBAC's consideration process unwieldy if not unworkable. It is unconvinced that a code of practice prepared by an industry lobby group will be designed with the best interests of the government or Australian consumers at heart.

4.35 Another required change is that the PBAC will provide public written information on its recommendations or determinations, while protecting confidential commercial information. According to DoHA representatives, this will provide more scope to put information into the public domain than at present.[36] DFAT has said:

> Currently the amount of information made available to the public is limited to brief explanations of the nature and principle reasons for PBAC's

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32 Minister for Trade, Side letter to AUSFTA of 18 May 2004, 1(d)

33 DFAT and DoHA, *Answer to Question on Notice*, 7 July 2004

34 *Transcript of Evidence*, 6 July 2004, p.80, (Lopert, DoHA)

35 Minister for Health and Ageing, *AUSFTA – Implementation of the Obligations to Improve Transparency of the Pharmaceutical Benefits Scheme: Public Consultation Document*, 25 July 2004, p.5

36 *Transcript of Evidence*, 21 June 2004, p.37 (Lopert, DoHA)

> recommendations. These are posted on the departmental website following each PBAC meeting. Substantially more details of the recommendation and the PBAC's reasoning may be made available in future, in particular to inform the independent review mechanism.[37]

4.36 The public consultation document released on 25 July suggests that providing more public information on PBAC recommendations will promote better understanding of the operation of the PBS. It outlines the following principles that, subject to further consultation, should guide implementation of this commitment:

- Details of all recommendations made by the PBAC should be available to the public in a timely manner following each PBAC meeting;
- The information should include the relevant clinical, economic and utilisation data justifying PBAC's recommendations;
- Material agreed as confidential should be protected.[38]

4.37 This document is only an initial consultation document, however, providing little detail and leaving key questions unresolved. There is no guidance, for example, on who needs to agree that material should be confidential or on what basis this will be determined.

4.38 During this committee's hearings officials assured us that:

> The transparency provisions of the Annex 2-C on pharmaceuticals are intended to provide greater transparency to both the applicant and the Australian public. Implementation of these transparency provisions will carefully balance the needs of the PBAC, prescribers, consumers and the pharmaceutical industry. [39]

4.39 DFAT also told this committee:

> They are about improving transparency… There is still flexibility there for future governments of Australia, certainly on a best-endeavours basis, to try and improve that timeliness also. So I think they do get to try to improve the PBS system also where that can be done.[40]

4.40 Some stakeholders have told this committee that greater transparency of the PBS listing process is a welcome development. A number of state governments

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37 DFAT and DoHA, *Answer to Question on Notice*, 7 July 2004

38 Minister for Health and Ageing, *AUSFTA – Implementation of the Obligations to Improve Transparency of the Pharmaceutical Benefits Scheme: Public Consultation Document*, 25 July 2004, p.5

39 DFAT and DoHA, *Answer to Question on Notice*, 7 July 2004

40 *Transcript of Evidence*, 21 June 2004, p.37, (Deady, DFAT)

expressed support for greater transparency of the PBAC and accelerated processes for getting medicines to market.[41]

4.41 Others have put the view that, while increased transparency overall is a good thing, this is an unbalanced transparency requirement. The Public Health Association of Australia, for example, wrote that:

> The PHAA strongly endorses transparency in decision-making. However, transparency under the FTA needs to be explicitly spelt out. It must not just mean that the Australian Government has to provide information to pharmaceutical companies about aspects of how, and on what evidence, the Pharmaceutical Benefits Advisory Committee (PBAC) has made its recommendations and the Government has made its decisions. Rather, it must explicitly include both this and transparency from the pharmaceutical companies of the submissions they have made to the PBAC, the government and any review mechanism, such that only material that is truly "business in confidence" is not made public.[42]

4.42 Likewise, the AMA expressed support for greater transparency across the PBS process for all parties involved, including pharmaceutical companies. According to the AMA, the "commercial-in-confidence" secrecy surrounding clinical research data presented to the PBAC is a major restraint on the quality use of medicines in Australia. The AMA stated that greater transparency across the whole PBS approval process is fundamental to the AMA's support for the AUSFTA.[43]

4.43 Some witnesses expressed fear that these transparency requirements, unbalanced as they are, will simply provide greater scope for lobbying from pharmaceutical companies who are likely to use every available avenue to exert pressure on PBAC to list their drugs at the highest possible price. The Western Australian government, for example, listed the increased transparency of PBAC processes without a corresponding improvement in transparency of information from manufacturers as one factor that could lead to pressure on drug prices.[44]

4.44 A number of academics, some of them former members of the PBAC, point out that pharmaceutical companies are very profitable and spend large amounts of money on public relations to gain positive media coverage of the benefits of their products. This can result in considerable public pressure on the PBAC to list a new drug. According to these academics:

> It is against this backdrop that the new provisions of the FTA need to be considered. The PBAC members, although unable to publicly defend themselves, have had the advantage that they are the only independent

41 See, for example, *Submission 508,* Queensland Government, p.8

42 *Submission 369*, Public Health Association of Australia, p.2

43 *Submission 105*, Australian Medical Association , p.2

44 *Submission 142*, Western Australian Government, p.4

> authority that has fully examined the data. Now it will have another authority (the review panel) that has the power (officially appointed) but no responsibility (it cannot legally list a drug on the PBS), which presumably will be unfettered in terms of the secrecy of its considerations and advice. This body will only consider drugs that have been 'rejected' by PBAC; when its advice differs from the PBAC, this will be seized on by all of the vested interests, who will use the media to undermine the integrity of the committee. The confidentiality provisions of the *National Health Act* will effectively prevent the committee from defending itself.
>
> Add to this the effects of the other provisions considered in this chapter, which are all directed at increasing the pressure to list (never not to list). This will be a grossly unfair process in which the PBAC, although still working under Section 101 on the *National Health Act*, will effectively be under siege: the number of interests attacking any negative decision will have multiplied both in number and in strength. Despite its present powers under the *Act*, it is difficult to see how the committee can continue to serve the public's interest properly under such conditions.[45]

4.45 As a matter of principle, this committee believes that any change to the PBS should be driven by domestic circumstances, not by the demands of a trading partner. On balance, however, the committee accepts that, carefully implemented, the transparency measures may not be harmful to the PBS and may even result in some improvements. This will only be the case if DoHA ensures that the transparency requirements are implemented in a balanced way. If more information about the rationale for PBAC decisions and the independent review process is to be made public, it is only fair that the submissions of pharmaceutical companies also be made public, including the relevant clinical data. The question of what material is legitimately 'commercial in confidence' must be resolved in a way that takes into accounts the interests of all stakeholders, not just the pharmaceutical companies.

4.46 One factor that should be noted here is that the additional transparency measures are likely to increase the administrative cost of running the PBS. The independent review mechanism as set out in the consultation document would require the government to pay for at least one convenor plus expert reviewers. It seems likely that the other transparency requirements will require at least some additional resources. It is most unfortunate that this extra cost is being incurred not to benefit Australian taxpayers but to satisfy US demands.

4.47 The effect of additional transparency measures over time must be monitored carefully. The government must take steps to ensure that any changes to current listing procedures do not undermine the ability of PBAC and the PBPA to gain maximum cost-effectiveness for Australian consumers. Any change that increases the negotiating power of pharmaceutical companies in the listing and pricing process would

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45 *Submission 44*, Professor Peter Drahos, Dr Thomas Faunce, Martyn Goddard and Professor David Henry, p.42

undermine the government's repeated assurances that drug prices in Australia will not rise as a result of this FTA.

Medicines Working Group

4.48 The medicines working group to be set up under Annex 2-C of this agreement has also caused some concerns among stakeholders giving evidence to this inquiry. The text of the agreement itself provides little detail about the group. DFAT's Guide to the Agreement simply states that the medicines working group:

> …will be similar to other Working Groups that will be set up to discuss other aspects of the Agreement. The Working Group will comprise appropriate government officials. The details of how the Working Group will operate and the frequency of meetings are yet to be decided.[46]

4.49 At the committee's last hearing, DFAT and DoHA were not much more forthcoming with details of this new institutional arrangement. The committee was told that the working group will not meet until after the agreement enters into force, the terms of reference will not be finalised until after the working group meets, and the precise way in which the terms of reference will be progressed is not clear.[47] The latest available statement is that:

> The Medicines Working Group will comprise officials of relevant Government departments. The timing, frequency and agenda of the MWG are not yet determined, and the first meeting of the MWG will not take place until after entry into force of the Agreement. Consultative mechanisms have not yet been determined. [48]

4.50 DFAT and DoHA also state that:

> The Medicines Working Group is limited to promoting discussion and mutual understanding of issues related to the topics outlined in Annex 2-C, but explicitly excludes consideration of regulatory cooperation issues referred to in paragraph 4 of Annex 2-C. The Medicines Working Group is not a decision making body and cannot consider any changes to the Pharmaceutical Benefits Scheme. [49]

4.51 Some stakeholders expressed the belief that this working group will simply open the door for the US government to continue pressuring Australia to 'recognise the value of innovative pharmaceuticals' by paying more for them. Among those to voice this concern was Dr Ken Harvey, who wrote:

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46 DFAT, *Australia-United States Free Trade Agreement: Guide to the Agreement*, March 2004, p.11

47 *Transcript of Evidence*, 6 July 2004, p.101 (Lopert, DoHA and Myler, DFAT)

48 DFAT, *Answer to question on notice*, 7 July 2004

49 DFAT, *Answer to question on notice*, 7 July 2004

> The medicines working group is yet another US strategy whereby pressure will be brought upon Australian DoHA officials to pay more attention to the principles of Annex 2-C (higher profits for American pharmaceutical companies) rather than PBS principles (equitable access to affordable drugs). Clearly, the US PhRMA published goal is to raise Australian drug prices. It is naïve to think that the provisions they have inserted in the FTA, such as the medicines working group, are not part of that strategy.[50]

4.52 Dr Thomas Faunce described the medicines working group as a "siege engine to figure out ways in which the pharmaceutical companies can exploit the terms of this agreement."[51]

4.53 Comments made about this working group in the US seem to justify these concerns to a certain extent, as negotiators on the US have described it as a forum to continue seeking the greater changes to the PBS's reference pricing system they did not achieve in the FTA itself. US Trade Representative Josette Sheeran Shiner told a US Senate Committee hearing that:

> Crucially, the FTA also establishes a Medicines Working Group that will provide a forum for ongoing dialogue on Australia's system of comparing generics to innovative medicines and other emerging health care policy issues.[52]

4.54 Senator Kyl told the US Senate that:

> During our meetings in Australia we suggested such a working group as a way to guarantee that, if our pricing concerns could not be resolved in the FTA, we could continue to discuss the issue. The subject matters that the group might consider are not limited by the agreement, and therefore can be expected to include the importance of market-based pricing.[53]

4.55 Having said that, this committee appreciates that these kinds of inter-governmental working parties are not unusual, and will normally not have any kind of authority in domestic policy making. In the normal course of things, these institutional arrangements will not achieve changes unless both parties want such changes. Provided it is only a forum for discussion and has no formal decision-making role, the medicines working group need not necessarily spell the end of the PBS as we know it.

4.56 This was the view taken by the AMA, which said:

> The AMA notes and endorses assurances we have been given that the Medicines Working Group envisaged as part of the AUSFTA will be

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50 Dr Ken Harvey, *Answer to question on notice,* 4 May 2004, no. 19

51 *Transcript of Evidence*, 5 May 2004, p.89 (Faunce)

52 Josette Sheeran Shiner, Evidence to a Joint Session of the (US) Senate Finance Committee, Subcommittees of Health and Trade, April 27 2004, "International Trade and Pharmaceuticals", p.5

53 *Congressional Record – Senate*, 15 July 2004, p.S8208 (Senator Kyl)

> merely a consultative forum, and have no role in either rule-making or decision-taking.
>
> We would be very concerned if this group of federal health officials from the US and Australia assumed any role in either rule-making or decision-taking, which would constitute a breach of Australian sovereignty.[54]

4.57 Overall, the committee appreciates the point made by Australian negotiators that the medicines working group is simply a consultative forum which will discuss issues of mutual concern without having any decision making authority. Nevertheless, it would be naïve to believe that the US will not use this as a forum to put pressure on Australia's drug pricing system in line with US trade policy. This raises the question of how the government can guarantee that it, or indeed a future government, will be able to withstand that pressure in circumstances that cannot be predicted now. With the scant detail provided to date about how the medicines working group will operate, the government is asking this committee to take on trust that it will be able to look after the best interests of Australian consumers in the face of intense pressure from our most powerful trading partner.

4.58 The lack of information provided to this committee about the Australian government's approach to the medicines working group is unacceptable. It is simply not good enough to ask parliament to pass an agreement that effectively gives the executive *carte blanche* to do what it likes in further talks with the Americans without reference to the legislature. If Australians are to be convinced that this agreement is in their interest and will not ultimately undermine a key pillar of the Australian health system, parliament must be kept informed of any further talks that take place in forums like the medicines working group.

New pressure points on the PBS

4.59 The committee accepts that Australian officials have told us in good faith that none of the commitments entered into in the FTA will change the fundamental architecture of the PBS or lead to higher drug prices in Australia. Looking point by point at the commitments set out in the text, it is true that no one of them guarantees that US pharmaceutical companies will immediately be able to demand more for their drugs. However, the committee remains concerned that these commitments could have implications in the long term that cannot be accurately predicted or measured now but may over time have this very effect. By allowing the PBS to enter a trade negotiation in the first place, the government has opened the door to forces that it ultimately may not be able to control.

4.60 Without doubt the US objective in including these commitments in the PBS is to benefit US pharmaceutical manufacturers by pushing for higher drug prices in the long term. Pharmaceutical industry advocates in the US have long argued that the high cost of pharmaceuticals in the US is due because of other countries' price controls.

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54 *Submission 105*, Australian Medical Association, p.3

They claim pharmaceutical manufacturers cannot charge prices abroad that factor in the cost of research and development, and therefore R&D costs are being borne by American consumers alone. They suggest that making pharmaceuticals in other countries more expensive would make them cheaper in America. Although dismissed as 'specious' and 'absurd' [55] even by some members of Congress, this argument is nevertheless the basis for a vigorous campaign by the USTR to drive up pharmaceutical prices worldwide.

4.61 It would be naïve in the extreme to think that the American pharmaceutical lobby will be happy to rest with what has been agreed to in this FTA and will not push for further changes. This has been openly stated in Congressional debate by Senator Kyl. He told the US Senate that what has been negotiated through the FTA is 'an important first step' to ensuring that Australians pay more for research and development. He suggested that this FTA 'makes suitable progress' on pushing Australia to embrace a free market pricing system for drugs, but has not yet fully achieved this goal. Importantly, he suggested that this agreement lays the groundwork for further work, saying:

> It will…begin an important dialogue with our Australian friends about the importance of R&D and of paying for R&D.[56]

4.62 While the Australian government may honestly believe its FTA commitments will not be detrimental to the PBS, its formal commitments do give a powerful trading partner institutional arrangements to continue exerting pressure for change. While no single one of the specific commitments will create immediate and measurable price rises for the PBS, the new measures may well over time alter the bargaining power between the PBS and pharmaceutical companies. This may have long term ramifications that are not in the interest of Australian consumers.

4.63 Professor Ross Garnaut put his concerns about including PBS related commitments in a trade agreement persuasively as follows:

> One thing that worries me in particular about the PBS is that there is clearly a very big divergence in expectations between American and Australian political interests about the effects of what has been negotiated on the PBS. We have not yet seen all the details about how this will be implemented, but I know that there is an expectation in industry and relevant parts of the US polity that there will be change as a result of these provisions. Now we have received assurances from the Australian trade minister that there will be no changes in Australia. If you just looked at the words that we have seen so far in the agreement, you would reasonably conclude that a strong and determined Australian health minister, supported by his government, could resist change, but the new processes are likely to generate pressure for change, backed by the US government in some cases. Not every Australian trade minister or Australian government is able to or sees benefit

55 *Congressional Record – House of Representatives*, 13 July 2004, p.H5615 (Mr Brown)

56 *Congressional Record – Senate*, 15 July 2004, p.S8208 (Senator Kyl)

> in resisting great pressures from the United States. So the political process of consideration over pharmaceutical questions will be affected. That does not mean that there will be change with certainty, but some American expectations will be disappointed if there is not change, and that disappointment will have consequences.[57]

4.64 From all accounts this is the first time that measures affecting a country's pharmaceutical scheme have been specifically included in a trade agreement.[58] It is a precedent-setting move, and, in this committee's view, a dangerous one. Government officials have assured us that its commitments under this agreement can be interpreted so as to ensure that the fundamentals of the PBS are not seriously affected. But the Australian government is only one of the parties to this agreement. How can it guarantee that, should a dispute ever arise on Australia's implementation of this part of the agreement, a three-member panel of trade lawyers would share the Australian government's view of what the commitments mean?

4.65 This government has gambled that it will be able to control the pressure this part of the FTA will inevitably bring to bear on the PBS in perpetuity, contrary to the wishes of our most politically powerful trading partner. Verbal assurances that the PBS will not be adversely affected are all very well, but this committee would like to see concrete steps to monitor the impact of the FTA related commitments on the operations of the PBS. This should include an independent audit of the implementation of the new transparency arrangements to assess both their cost and their impact on PBS listing process and outcomes. It should include an ongoing system for monitoring the price of pharmaceuticals listed on the PBS. If there is no system in place to monitor the PBS after these changes are made, the Senate cannot be expected to be satisfied that the PBS has not been compromised.

Intellectual property and pharmaceuticals

4.66 Many witnesses told this inquiry that the changes most likely to impact on drug prices in Australia in the short term are found in Chapter 17 of the agreement. These relate to patent law and the marketing approval process for generic drugs. The availability of generic medicines has a direct impact on drug prices, as they provide competition and thus lower prices for pharmaceuticals. PBS data shows that on average the price for a drug falls by 30% when generics enter the market.[59] Any change that delays the introduction of generic pharmaceuticals effectively extends a

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57 *Transcript of Evidence*, 15 June 2004, p.30 (Garnaut)

58 Deputy US Trade Representative Josette Sheeran Shiner confirms that "the US-Australia FTA [is] the first to include special provisions addressing market access for pharmaceuticals". Testimony before a Joint Session of the (US) Senate Finance Committee, Subcommittees of Health and Trade, April 27 2004, "International Trade and Pharmaceuticals", p.5

59 *Submission 142*, WA Government, p.5

patent holder's monopoly for a particular medication and keeps the price of that medication higher.

4.67 The availability of generic drugs is an essential factor in the PBS's ability to contain pharmaceutical prices, as they provide a lower-cost benchmark against which to assess the value of new drugs. They are also important to containing state governments' costs for pharmaceuticals in public hospitals. According to the Western Australian government, medicines are the second most expensive item after salaries in the health budget, and a small increase in costs would have a significant impact on health spending.[60] The availability of generic medicines is particularly important in hospitals where generics are used extensively. [61]

4.68 This committee has received a substantial volume of evidence about the possible impacts of the FTA provisions linking pharmaceutical patents with marketing approval. Many witnesses have said that these provisions are likely to result in delays to the introduction of generic drugs in Australia. One submission asserted that DoHA representatives had conceded that delays in the introduction of generic pharmaceuticals can be expected.[62] If true, this would result in Australians paying more for certain drugs while marketing approval for generic equivalents was delayed. Even minor delays could have significant costs.

4.69 The CIE Report had the following to say on the implications of a delay in generic drugs reaching the market:

> If generic versions of products under patent were reaching consumers prior to patents expiring, the required changes to the marketing approval process would be expected to increase the price of pharmaceutical products – as the generic versions, which cost less than their patented equivalents, would be prevented from entering the market.[63]

4.70 The CIE went on to say that it is extremely rare for a generic drug to enter the market while a patent is current, so the impact of the changes will be minimal. It notes that the way the changes are implemented in legislation is critical to making an assessment of their likely impacts. [64] This committee is therefore very concerned to examine the detail of this part of the agreement and attendant legislative changes.

4.71 It is noteworthy that most of the submissions to this inquiry were prepared before the actual text of the implementing legislation was introduced to Parliament.

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60 *Submission 142*, WA Government, p.5

61 *Submission 142*, WA Government, p.5

62 *Submission 171*, Australia Institute, p.2. No source is given in the submission for this statement.

63 Centre for International Economics, *Economic Analysis of AUSFTA*, report prepared for DFAT, April 2004, p.42

64 Centre for International Economics, *Economic Analysis of AUSFTA*, report prepared for DFAT, April 2004, p.42

Some papers that have been extensively cited by stakeholders concerned about this aspect of the FTA were prepared well before negotiations were finished. Without in any way denigrating those who have expressed concerns about this aspect of the agreement, it is fair to say that some of the concerns aired both before this committee and in the media relate to fears of what might have eventuated rather than the actual negotiated outcome or the actual legislative changes.

4.72 A paper written for the Australia Institute before the text of the FTA was finalised set out two key areas of concern about what the negotiations on IP could lead to. These are: first, that linking marketing approval to generics to patent expiration as per the US system would provide loopholes that pharmaceutical firms could use to block generic competitors from entering the market. Second, providing extensions to the 'data exclusivity' period would delay the entry of generic drugs since generic drug manufacturers rely on test data produced by patent holders to gain marketing approval. Based on US experience, and on what US negotiators had sought and achieved in other Free Trade Agreement negotiations, the authors suggested that:

> The changes being sought by US drug companies would see this effective monopoly extended for two to three years by creating legal obstacles to the rapid approval of generic competitors to patented medicines at the end of the 20 year patent life.[65]

4.73 The AUSFTA has not produced all the changes to Australia's patent regime that US negotiators may have sought or hoped. It is clear from DFAT's evidence to this committee that negotiations on this part of the agreement were long and hard.[66] The wording finally agreed upon is different to that of other US free trade agreements.

4.74 According to DFAT, the FTA does not require any changes to Australia's patent extension regime or to our regime for the protection of pharmaceutical test data.[67] However, Australia has committed to take measures linking patent expiration with marketing approval. Exactly what effect these changes will have on generic drugs entering the market has been a matter of some debate. Since this is the key change to Australia's existing practice required by the FTA, the committee examines it in detail below.

Marketing approval for generic drugs

4.75 One factor enabling prompt entry of generic drugs to the Australian market after a patent has expired is the practice of 'springboarding'. Springboarding allows a generic drug to gain marketing approval on the basis of test data supplied by the patent holder. This means that generic manufacturers can avoid the duplicating the

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65 Dr Buddhima Lokuge, Dr Thomas Faunce, Richard Denniss, "A backdoor to higher medicine prices? Intellectual property and the Australia-US Free Trade Agreement", Australia Institute, November 2003, (*Submission no. 171b*), p.23

66 *Transcript of Evidence*, 6 July 2004, p.97 (Deady, DFAT)

67 DFAT, *Answer to question on notice*, 18 May 2004, no. 22

costly and time-consuming process of drug testing and enter the market quickly with a cheaper product once the patent and a five-year 'data exclusivity' period has expired.[68]

4.76 Australia's current rules allow a generic drug manufacturer to seek TGA marketing approval even if the patent has not expired. The TGA assesses applications for marketing approval purely on safety and efficacy grounds and is not required to examine patent issues. It is not the role of the TGA to prevent marketing where the patent might be infringed.[69] Effectively, a generic manufacturer can obtain marketing approval based on the patent holder's test data and be ready to enter the market as soon as a patent expires. In cases where a generic manufacturer considers a patent is invalid or that marketing their product would not infringe that patent, they might even release the product onto the market regardless of the claimed patent. It would then be up to the patent holder to sue the generic manufacturer for an infringement of the patent, and a court would decide whether their claim was valid.

FTA provisions relating to marketing approval of generic drugs

4.77 When asked to identify what provisions in the FTA were likely to lead to higher drug prices, several experts pointed to article 17.10.4.[70] This article provides that where a party to the agreement permits the practice of springboarding:

> (a) That Party shall provide measures in its marketing approval process to prevent those other persons from:
>
> (i) marketing a product, where that product is claimed in a patent; or
>
> (ii) marketing a product for an approved use, where that approved use is claimed in a patent,
>
> during the term of that patent, unless by consent or acquiescence of the patent owner; and
>
> (b) if the Party permits a third person to request marketing approval to enter the market with:
>
> (i) a product during the term of a patent identified as claiming the product; or
>
> (ii) a product for an approved use, during the term of a patent identified as claiming that approved use,
>
> the Party shall provide for the patent owner to be notified of such request and the identity of any such other person.

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68 This is explained in more detail in Appendix 4, Dr Kate Burton and Jacob Varghese, *The PBS and the Australia-US Free Trade Agreement*, Parliamentary Library Research Note no. 3, 21 July 2004

69 Dr Kate Burton and Jacob Varghese, *The PBS and the Australia-US Free Trade Agreement*, Parliamentary Library Research Note no. 3, 21 July 2004 (Appendix 4)

70 *Transcript of Evidence*, 21 June 2004, pp.4-6 (Faunce, Lokuge)

4.78 In other words, part (a) requires Australia to 'provide measures' in its marketing approval process to prevent entry of generics into the market during the life of a patent. Part (b) requires Australia to 'provide for' patent holders to be notified of an application to market a generic drug during the life of the patent.

4.79 This commitment prompted great concern among both academics and the generic drug industry in Australia as it appeared a significant diversion from current practices and one which could seriously delay the entry of generics onto the market. Before seeing the legislation, the Generic Medicines Industry Association (GMiA) submitted that:

> Article 17.10.5[71], if not implemented carefully, would enable [large pharmaceutical] companies to further protect and in some cases extend patent life by various legal stratagems.[72]

4.80 GMiA took issue with the wording of the agreement, saying that:

> The current wording of this paragraph requires that marketing of a generic equivalent must be prevented where the product or use is "claimed" in a patent. [73]

4.81 Dr Thomas Faunce also expressed concern about the possibility that a drug being "claimed in a patent" would be grounds to prevent marketing approval:

> The reason why 17.10.4 is so disadvantageous to the generic industry in Australia is that all that has to happen is that a patent is claimed, it does not say what type of patent.[74]

4.82 According to GMiA:

> Whether a product or use is claimed in a patent is not always clear from the terms of the patent itself and it is certainly not possible to identify in every case, whether such a claim is made. [75]

4.83 Many stakeholders were concerned that this provision of the FTA appears to require the TGA to refuse marketing approval of a generic version of a drug that is 'claimed in a patent'. As noted above, it is currently up to the courts, not the TGA, to determine whether a product or use is claimed in a patent, and whether that patent is valid. Courts have sometimes overturned the validity of a patent. As GMiA points out, forcing generic manufacturers to wait for possibly invalid patents to lapse or for a

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71 This number refers to the draft text, which was renumbered as 17.10.4 in the final text.

72 *Submission* 75, Generic Medicines Industry Association, p.2

73 *Submission* 75, Generic Medicines Industry Association, p.2

74 *Transcript of Evidence*, 21 July 2004, p.5 (Faunce)

75 *Submission* 75, Generic Medicines Industry Association, p.2

court ruling that a drug is not claimed by a valid patent before gaining marketing approval would delay the entry of generics onto the market. [76]

4.84 GMiA's submission further suggested that making marketing approval dependent on proving that a drug was not 'claimed' in a patent would encourage the practice of 'evergreening'.[77] This is where patent holders attempt to prolong their monopoly over a particular drug by filing patents for a new use or delivery system shortly before the original patent for the drug compound expires. They then use these new patent claims to assert that production of a generic version of the drug would be infringing their patent rights even after the patent for the compound itself expired.

4.85 According to the Canadian generic drug industry, the practice of evergreening in Canada has made it "virtually impossible" to bring out a generic version of a drug there.[78] This is because Canadian legislation allows pharmaceutical patent holders to gain an automatic 24-month injunction preventing marketing approval of a generic drug where there is an allegation of patent infringement. Pharmaceutical companies can thus 'evergreen' their patent monopoly by lodging any number of additional patents for specific aspects of a drug and use these to gain an injunction preventing generic competition while the patent claims are litigated. As a consequence, entry of generics can be delayed for 24 months for each patent claim, regardless of the merit (or lack thereof) of the patent claims.

4.86 Similar provisions apply in the US. When a generic manufacturer seeks marketing approval in the US it must certify either that the patent covering the product has expired or will expire or that the patent is invalid and will not be infringed. In the latter case, the patent owner must be notified, and has 45 days to bring an infringement suit. If the patent owner brings a suit, they can get an automatic injunction preventing marketing approval of the generic for 30 months. These provisions have led to abuse of the patent system in the US through evergreening tactics that delay the introduction of generic drugs, a fact acknowledged by President Bush.[79]

4.87 Without question, changing Australia's marketing approval process in a way that allowed evergreening patent claims to prevent marketing approval of generic drugs would have serious consequences for the generic drug industry and drug prices in Australia. The issue then is whether the actual legislative changes required by the FTA will stop generics gaining marketing approval while patent claims are resolved.

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76 *Submission* 75, Generic Medicines Industry Association, p.2

77 *Submission* 75, Generic Medicines Industry Association,, pp.2-3

78 *Submission* 75, Generic Medicines Industry Association, Attachment, p.ii

79 *Transcript of Evidence*, 21 June 2004, p.5 (Faunce)

Legislative changes

4.88 The legislation required to implement this commitment has been carefully framed to minimise the changes to Australia's current marketing approval process. The FTA implementation bill[80] basically institutes one new step in the marketing approval process. Companies seeking to register a drug will be required to certify either: a) that they do not intend to market the drug in a manner that infringes a patent, or; b) that they have notified the patent holder of their intention to market a drug in a manner that infringes a patent. Where other listing requirements are satisfied, the TGA must proceed to list the goods without inquiring into the correctness of the certificate and is protected from injunction for relying on that information. The bill creates a new criminal offence with a significant penalty[81] for giving a false or misleading certificate.

4.89 Essentially, this means that the TGA will not be put into a position of checking whether a drug is claimed in a patent, and will not be required to deny marketing approval to a drug even where a patent is claimed. It will be up to generic drug manufacturers to check the existence or non-existence of a patent and certify to the TGA that they have done this. Provided they believed they would not be violating a patent when they marketed the drug, they would simply certify this to the TGA. If they did intend to market a product in violation of a current patent, they would also need to certify to the TGA that they had notified patent holder of their intention. Issuing a false or misleading certificate would be a criminal offence, although this would appear to apply only where a false or misleading certificate was intentionally or recklessly provided, not where due diligence had been carried out and a false certificate was mistakenly provided.[82]

4.90 The important difference between this process and that which has caused delays in generic drug entry in the US and Canada is that the legislation does not provide scope for patent holders to gain an automatic injunction preventing the TGA granting marketing approval of generics while patent claims are resolved in the courts. Even in the event that a generic manufacturer certified that they did intend marketing in violation of a patent, the TGA would nevertheless be required to register the drug provided that the generic manufacturer had notified the patent holder of their intention.

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80 The amendments to the *Therapeutic Goods Act 1989* are found in Schedule 7 of the US Free Trade Implementation Bill 2004

81 The maximum penalty is a fine of 1,000 penalty units, which is currently $110,000

82 According to the Explanatory Memorandum, the *Criminal Code Act 1995* (the Criminal Code) provides that 'recklessness' is the necessary mental element which would apply to the false or misleading nature of the certificate provided by the applicant… Recklessness can be established by proving intention, knowledge or recklessness. (See subsections 5.6(2) and 5.4(4) of the Criminal Code). US Free Trade Agreement Implementation Bill 2004, Explanatory Memorandum, para 225.

4.91 Government officials have said that this certification process is simply a technical legal requirement that gives effect to Australia's commitment to 'provide a measure in our marketing approval process to prevent persons from marketing a product that is claimed in a patent'.[83] According to Dr Lopert:

> Under the current legislation, if the generic manufacturer then places that generic version of the product on the market while the patent is in force, they are in breach of current IP laws. What they are required to do under this process is simply to certify to the TGA that they will not do that. It does not affect the TGA's process of marketing approval; it is merely a certification to the TGA that they will not proceed to actually put the drug in the marketplace until any patents covering the product have expired.[84]

4.92 Dr Lopert further stated that this new requirement will not promote the practice of evergreening:

> …evergreening is a practice that pharmaceutical companies will pursue if they believe it is in their interests to do so. There is nothing in this legislation that either promotes or discourages evergreening. Evergreening is the practice of registering additional patents as a result of slight changes – that is, changes in additional uses, changes in methods of production or changes in the colour or the presentation that a company may seek in order to prolong the patent protection of a product. This legislation neither encourages it nor prevents it; it does not affect it.

4.93 It is true that this legislation does not affect pharmaceutical companies' ability to file extra patents at the end of the original patent life in an attempt to prolong patent protection. That is a matter of patent law, which is unchanged by these new provisions. What it could potentially do is to increase the incentive for pharmaceutical companies to file additional patents if it provided an opportunity to use these additional patents to delay the entry of generics onto the market. This possibility appears to be limited by the wording of the new section 26B(1)(a) that requires manufacturers simply to certify that they will not market the goods "in a manner, or in circumstances, that would infringe a patent".[85] Presumably, if a manufacturer intended only to market a generic drug after the original patent for the drug compound had expired, and did not intend marketing it for additional uses covered by other patents, they could still provide a certificate under s26B(1)(a) and would not need to notify the patent holder. However, this is a matter that the committee would like clarified in the legislation.

4.94 The requirement to notify patent holders of an intention to market a generic while a patent is in force seems odd at first glance, as marketing a drug in violation of a patent is illegal anyway under current law. However, under the current procedures, there are times where, if it is unclear whether a drug is covered by a valid patent, a

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83 *Transcript of Evidence*, 6 July 2004, p.82 (Deady, DFAT)

84 *Transcript of Evidence*, 6 July 2004, p.83 (Lopert, DoHA)

85 FTA Implementation Bill 2004, Schedule 7 part 6

generic manufacturer will bring a generic version to market knowing that they could be sued by the patent holder and the validity or otherwise of the patent would be determined by a court.

4.95 According to the negotiators, the requirement to notify of an intention to bring a drug to market while a patent stands is simply an additional requirement inserted into the marketing approval process at the request of US negotiators, but not one that will diminish the integrity of our marketing approval process.[86] Medicines Australia, representing (mostly international) research-based pharmaceutical manufacturers, asserts that these provisions merely provide greater transparency to the existing law. Their submission says:

> Notification provisions on their own do not delay or impede the capacity of generic manufacturers to prepare for generic production.[87]

4.96 It is true that notification procedures do not on their own delay the introduction of generics. It is the *effect* of this new notification requirement on litigation tactics used by patent holders to maintain or extend their effective patent monopoly or on the business strategies of generic manufacturers that could result in delays. It is obvious that the US intention in seeking a notification requirement is to forewarn patent holders of possible competition so that they could commence pre-emptive litigation to prevent a generic drug coming to market before a court determines the validity of the patent. Under current arrangements, the generic manufacturer can bring a drug to market and make a profit from it until the patent holder can gain an injunction. While the new legislation does not allow a court to prevent the TGA giving marketing approval to a generic, a court could order the generic manufacturer not to market their product before litigation was finalised. The new notification requirement may dissuade generic manufacturers from taking a risk in bringing generics to market before the patent claim is settled. This would be to the detriment of the PBS, which benefits from accessing cheaper generic drugs before litigation is settled.

4.97 This committee appreciates that the implementing legislation has been framed with the intention of minimising the potential for patent disputes to impact on the marketing approval process. What is less certain is how the tactics of generic manufacturers will be impacted by the new administrative procedures, especially in cases where a patent is unclear or they wish to challenge the validity of a patent. This issue has been considered in a paper by parliamentary library researchers as follows:

> One difficulty is that 'infringement' is not always clear. For example, a patent may have expired on one use of the drug but not another, as new patents are filed for newly discovered uses. Similarly an active patent may not be valid because it does not fulfil one of the requirements for

86 *Transcript of Evidence*, 6 July 2004, p.97 (Deady, DFAT)

87 *Submission 140*, Medicines Australia, p.21

patentability, such as novelty or inventiveness. These are complex legal issues that only the courts can resolve.

Under the certification scheme, generic manufacturers would have three options before applying to springboard. They could:

- certify that they will not infringe, if they believe that to be the case
- apply for a court declaration to settle the uncertainty before certifying, or
- notify the patent holder of the application and certify to that effect.

Taking [the] first option would risk a fine if the certification is later found to be false or misleading. However, it might be a safe option where the patent has clearly expired, or where other generics are on the market already.

Where the issue is particularly complex, the last two may be the only options. The second option involves the commencement of litigation. The third option allows the patent holder to consider litigation. In either case, litigation of these matters would be happening before rather than after the generic has entered the market. Currently, generic manufactures have much more control over when any litigation takes place, with the option to enter the market first.

In practice, it is unclear that this shift, on its own, would make a significant difference in practice. A reduction in control over timing may have adverse consequences for generic manufacturers' litigation and business tactics. It may also increase the likelihood of early injunctions being ordered against generic manufacturers that delay their initial entry to market. The complexity of the scheme, costs of litigation and risk of penalties for false and misleading certification might theoretically deter generic manufacturers from entering a generic drug on the market. On the other hand, the regulatory and IP environment for generics is already complex, so the new scheme might be accepted as a relatively small technical change in an uncertain business. Overall, the effect of these subtle technical changes on the time it takes for generics to enter the market are difficult to predict. [88]

4.98 Before the legislation was released, Dr Faunce et al expressed the view that:

Tighter IP provisions…would create uncertainty for generic producers. It would provide multinational pharmaceutical corporations with additional opportunities to engage smaller generic producers in preemptive legal disputes over IP.[89]

88 Dr Kate Burton and Jacob Varghese, *The PBS and the Australia-US Free Trade Agreement*, Parliamentary Library Research Note no. 3, 21 July 2004 (Appendix 4)

89 Dr Buddhima Lokuge, Dr Thomas Faunce, Richard Denniss, "A backdoor to higher medicine prices? Intellectual property and the Australia-US Free Trade Agreement", Australia Institute, November 2003, (*Submission 171b*), p.8

4.99 Having seen the legislation, Dr Thomas Faunce continued to contend that the new s26B will inhibit generic drug companies' commercial decisions about whether to seek to enter the market near the end of patent expiry. He identified as inhibiting factors:

> 1) the expense of doing an exhaustive search for both product and process patents, many of which may be complicated by spurious "evergreening" patents designed to prolong monopoly rights at the expiry of the compound by "claims" to patent rights over method of delivery etc. Companies do this already of course, but if foreign trends are anything to go by patent offices in Australia will soon witness an inrush of complex patent "claims" making the task much more difficult.
>
> 2) The risk of filing a misleading certificate: this will expose the intended generic to a criminal penalty (under s26A) and invalidate its marketing approval. Effectively this now prevents a generic manufacturer banking on a period of profit making while it held the patent until the spurious "evergreening" patent claims could be worked out in the Federal Court. The fact that s26(1A) allows listing with[out] the TGA inquiring into the correctness of the certificate, does not solve the problem that if the original patent holder subsequently challenges the certificate as misleading because it fails to mention a "claimed" patent then the generic manufacturer will have committed a crime and the marketing approval would be invalid.

4.100 In her assessment for this committee, Dr Philippa Dee said:

> Now that the enabling legislation has been tabled, it is reassuring to see that Australia will not be providing drug innovators with the ability to take out injunctions. Nevertheless, the provisions do strengthen the enforcement of the current legislative framework preventing the marketing of generics while a patent is still in place. Whether this will have any effect depends on judgements about whether enforcement activity is useful.[90]

4.101 This committee has not heard directly from the generic drug industry since the legislation was released, however DFAT told us that GMiA had been consulted in preparing this legislation. DFAT said that while GMiA was still in the process of obtaining legal advice on the full ramifications of the bill and had not written formally to the government, their initial impression is that they do not expect the legislation to result in delays to the launch of generics.[91]

4.102 Altogether, this committee accepts that every effort has been made to construct legislation that will not cause delays to the entry of generic drugs onto the market. However, there will remain some uncertainty about their full impact unless and until the changes are actually implemented and we can see how they affect litigation strategies and outcomes. *Any* delay to the marketing of generic drugs as a

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90 Dr Philippa Dee, Supplementary note prepared for the Senate Select Committee on the Free Trade Agreement between Australia and the United States of America, 15 July 2004, p.7

91 DFAT, *Answer to question on notice*, 7 July 2004

consequence of these changes, however slight, will have a cost to the PBS, state governments and consumers.

4.103 The committee is concerned that there are no plans to monitor the entry of generics onto the market after these changes are introduced to assess whether the there are in fact any delays. DFAT simply told the committee that they would expect the industry to make any concerns known to the government.[92] With several high-volume medicines due to come off patent over the next few years, it is crucial to ensure that any changes to the legislative environment do not impede the process of bringing in generic competition. If there is no monitoring, how can the government be sure that the changes are not having an adverse impact on the speed at which generic drugs can come on to the market?

Different understandings of the FTA commitment?

4.104 Assuming that DFAT and DoHA are correct in telling this committee that there is no possibility that these provisions will delay the entry of generic pharmaceuticals while patent claims are litigated raises a second question. Will these provisions satisfy the US that Australia's commitments under the FTA have been met? If what US negotiators were after was a measure that would delay marketing approval while patent claims are settled, there is a chance they may not be satisfied with this measure. If there is any scope for doubt, it seems highly likely that the powerful US pharmaceutical lobby would pressure the US government to use the dispute resolution mechanism to push for further changes.

4.105 The US International Trade Commission report on the FTA suggests that the US side were expecting that the TGA would deny marketing approval to products still under patent. It says:

> The FTA also ensures that government product approval agencies deny marketing approval to patent-violating products. [93]

4.106 When asked about whether DFAT's understanding of these commitments conformed with US expectations, Mr Deady said that the Americans 'very knowingly' agreed to the exact wording of Article 17.10.4:

> You negotiate these things in good faith, and this was certainly thrashed around for a very long time with the Americans. I take great comfort from the fact that it is different from what they have negotiated in other agreements… They wanted additional wording in this article which we did not agree to. It stands the way it is; that was the negotiated outcome. I think that is the understanding of the United States. That is the language that was agreed to and that we have now given effect to.[94]

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92 *Transcript of Evidence*, 6 July 2004, p.100 (Deady, DFAT)

93 US International Trade Commission, *US-Australia Free Trade Agreement: Potential Economywide and Selected Sectoral Effects*, USITC Publication 3697, May 2004, p.115.

94 *Transcript of Evidence*, 6 July 2004, p.97 (Deady, DFAT)

4.107 Asked about whether any jurisprudence the Americans might set up under their preferred set of words in other agreements would apply in the case of this agreement, Mr Deady said:

> …the very fact that the language is different means that any panel would say, 'Hang on. There must have been a reason why the language is different in this agreement.' We would certainly highlight the language in other agreements, if it ever came to it – and that is what a panel's jurisprudence takes into account in these sorts of agreements.[95]

4.108 The committee respects Mr Deady's expertise and sincerity in offering this judgement. However, his opinion is one side of the story, and this committee is not in a position to clarify with the US side whether they are satisfied that Australia's new legislation satisfies their demands and will not be a cause for dispute down the track. No one can predict with absolute certainty that, if a dispute did arise down the track, a three-member panel would accept Mr Deady's argument and find in favour of Australia's interpretation of its commitment, regardless of the difference in wording between the AUSFTA and other US FTAs.

Other IP measures affecting pharmaceuticals

4.109 Witnesses to this inquiry raised concerns about several FTA IP provisions affecting pharmaceuticals that do not require changes to current legislation but do limit the flexibility of governments to make changes in the future. The committee considers some of these below.

Parallel importing

4.110 Article 17.9.4 of the FTA provides that patent owners shall have exclusive rights to prevent importation of a patented product. This is effectively a ban on 'parallel importing', which is when legally purchased patented goods are imported into a country without the authorisation of the patent holder. Although parallel importing is currently not allowed in Australia anyway, this provision locks Australia into this ban at a time when many governments around the world are looking to parallel importing as a way of promoting competition and containing drug prices. Dr Faunce told the committee that, while parallel importing is not allowed in Australia at the moment;

> …in a lot of other countries it is allowed. It is a major means of providing competition; and one of the only mechanisms – in fact the only mechanism – by which drug prices are ever lowered is increased competition. So provision 17.9.4, by absolutely preventing us from ever having parallel importing, is another mechanism whereby drug prices will rise in Australia through lack of competition.[96]

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95 *Transcript of Evidence*, 6 July 2004, p.98 (Deady, DFAT)

96 *Transcript of Evidence*, 21 June 2004, p.6 (Faunce)

4.111 DFAT's response to this concern was simply to reiterate that parallel importing is currently not allowed in Australia anyway, and that this provision simply reaffirms the status quo.[97] This ignores the point that by locking in the status quo, Australia is limiting its capacity to lift the ban on parallel importing should this be considered necessary to promote competition in the pharmaceutical sector in the future. Studies suggest that in the EU, where parallel importing is allowed, competition from parallel importation of certain drugs has helped contain drug prices.[98] Under the terms of the FTA, Australia will not be able to go down this path in future.

4.112 The parliamentary library paper at Appendix 4 has the following to say about parallel importing:

> These rights allow patent-holders to prevent products they have sold in one country to be exported to another. For example, if parallel importing is allowed and drugs are wholesaled cheaper in, say, China than in Australia, importers are able to import (legitimately purchased) drugs to Australia from China, resulting in a lower price of the drug for the PBS. Restrictions on parallel importing, on the other hand, allow drug companies and other IP holders to divide the world into several markets and sell their product at the most favourable price in each. As David Richardson of the Parliamentary Library has noted, this is effectively privatised protectionism.
>
> Globally, parallel importing has developed into a significant issue. Least developed countries have argued that restrictions on parallel importing make life-saving drugs too expensive for public health authorities to afford. In the US itself, where drugs are sold at higher prices than in Canada, consumers in northern states have been reported to be crossing the border in significant numbers to purchase drugs, performing their own small scale and illegal parallel importing. There have been increasing calls in the US to reduce the exclusive rights of patent-holders so that this can be done legally and in commercial quantities.
>
> AUSFTA requires that Australia maintain either:
>
> - a system of 'national exhaustion', in which exclusive importation rights of the patent-holder continue even after the product has been sold abroad, or
> - (at least) the current system in which the patent-holder may impose restrictions on the exportation of the product to Australia when it is sold in foreign countries.
>
> Over the last two decades Parliament has been progressively allowing parallel importing of other forms of IP, such as copyright over music, books and computer software. Similarly, Australian patent law now provides that

97 *Transcript of Evidence*, 21 June 2004, p.17 (Deady, DFAT)

98 For example, Mattias Ganslandt and Keith E. Maskus, "Parallel Imports of Pharmaceutical Products in the European Union", World Bank Research Working Paper no. 2630, 1999, accessed 16 July 2004 at: http://econ.worldbank.org/view.php?id=2240

> patent-holders cannot place certain anti-competitive restrictions on the sale of products.
>
> Given these trends, combined with escalating PBS costs and the competitive advantages that parallel importing may provide, it is reasonable to assume that future parliaments would have considered changes to patent law that would void restrictions on parallel importing. AUSFTA would remove this as an option for pharmaceutical reform. [99] [Footnotes omitted]

4.113 This committee is seriously concerned that the Australian government has effectively signed away its right to allow parallel importing should future circumstances make it in the public interest to do so. Even in the US, this part of the agreement has been criticised. This was a major sticking point during Congressional debate on the FTA because of the negative consequences for American consumers at a time when parallel importation is being considered as a way to drive down the high cost of pharmaceuticals there.[100] Some members also criticised the US administration for using a trade agreement to further the domestic agenda of big pharmaceutical companies. One member commented that:

> The last time I checked, re-importation of pharmaceutical drugs was a domestic health policy issue that should be debated in Congress, and we should be making domestic health policy in this Chamber, not the U.S. Trade Representative.[101]

4.114 This committee agrees that a decision to permanently ban parallel imports of pharmaceuticals, or any other product, should only be taken by parliament if it decides it is in our national interest after due consideration. It should not be forced on us as part of a trade deal. It is ironic that a "Free Trade Agreement" would contain an anti-competitive provision effectively limiting the free trade of certain goods. This is one provision the committee views as a negative for Australia.

Compulsory licensing

4.115 Article 17.9.7 of the FTA limits the circumstances in which governments can allow compulsory licensing. Compulsory licensing is when a government allows someone else to produce a patented product or process without the consent of the patent owner. Under current Australian law, this can be done by a court when it is satisfied that "the reasonable requirements of the public with respect to the patented invention have not been satisfied" and that "the patentee has given no satisfactory reason for failing to exploit the patent."[102]

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99 Dr Kate Burton and Jacob Varghese, *The PBS and the Australia-US Free Trade Agreement*, Parliamentary Library Research Note no. 3, 21 July 2004 (At Appendix 4)

100 See, for example, *Congressional Record, House*, 14 July 2004, pp.H5968 – H5720

101 *Congressional Record, House*, 14 July 2004, p.H5699 (Mr Stark)

102 *Patents Act 1990* s133(2)

4.116 Dr Thomas Faunce suggested that the FTA provisions on compulsory licenses in 17.9.7 of the agreement will have an effect on drug prices. He said:

> By effectively restricting the situations in which governments can issue compulsory licenses to particular manufacturers to produce cheap drugs, we are really giving a hostage to fortune in terms of public health. In an era where we are at risk of bioterrorist attack and unusual viral diseases such as SARS, this agreement essentially locks us out of compulsory licenses in all except very restricted circumstances…[T]his restriction is a breach of United States law…which requires any bilateral treaties such as this to respect the capacity of countries to use the flexibility to the full to implement the public health exceptions in the TRIPS Doha declaration.[103]

4.117 In response to this concern, Mr Deady said:

> My understanding is that this reflects current TRIPS commitments of Australia. In any event, just looking at the language makes it very clear that, despite what Dr Faunce…has said, there are exceptions in the case of public non-commercial use, legitimate government use, national emergency or other circumstances or circumstances of extreme emergency. There are exceptions that would allow future Australian governments to deal with these sorts of issues in an appropriate way.[104]

4.118 He also said that:

> There is nothing in [Article 17.9.7] that affects our existing WTO rights and obligations….these articles reflect the status quo in Australia. We have not taken on additional commitments with the United States as part of the FTA in this area[105]

4.119 Although there is nothing in the FTA implementation bill that changes the status quo in Australia, the wording in the FTA is significantly different to TRIPs. TRIPs neither lists nor restricts the circumstances in which compulsory licences can be issued provided that a number of conditions aimed at protecting the patent holder are met.[106] Some of these conditions are waived in "national emergencies", "other circumstances of extreme urgency", "public non-commercial use" or anti-competitive practices. In contrast, the FTA appears to limit compulsory licensing only to cases where it is needed to remedy anti-competitive practices or to public non-commercial use, national emergency or other circumstances of extreme urgency. This is a significant departure from TRIPs, and one which the government has not adequately explained.

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103 *Transcript of Evidence*, 21 June 2004, p.7 (Faunce)

104 *Transcript of Evidence*, 21 June 2004, p.18 (Deady, DFAT)

105 *Transcript of Evidence*, 21 June 2004, p.53 (Deady, DFAT)

106 TRIPs Article 31.

Patent extensions and data exclusivity

4.120 Article 17.10.1(a) of the FTA requires Australia to maintain a five-year "data exclusivity" period for pharmaceutical test data. As discussed in the library research paper at Appendix 4, data exclusivity periods in practice prevent the entry of generic drugs, as generic drug companies cannot rely on test data generated by a patent holder to register an equivalent product until the data exclusivity period has expired. Thus, a longer data exclusivity period would delay the introduction of generic drugs. While the five-year minimum requires no change to current Australian law, it does limit Australia's ability to reduce this in future. This goes well beyond our TRIPs obligations, as TRIPs does not set a minimum data-exclusivity period.

4.121 Article 17.9.8(b) requires that Australia will provide patent extensions in cases where delays in marketing approval curtail the effective life of the patent. Again, this is current practice in Australia and does not require legislative change. However, it is yet another area where the FTA goes beyond the TRIPs agreement. There is no requirement in TRIPs that governments provide patent extensions to compensate for regulatory delays in marketing new pharmaceuticals.

Export of generic drugs

4.122 Article 17.9.6 provides that export of drugs under patent can only be permitted for the purposes of gaining marketing approval in another country. According to Dr Faunce:

> That will stop the generic industry in Australia from exporting medicines to other countries and earning profits through that mechanism. In a sense it will affect drug prices here because we do not have a generic industry in Australia and so we have no means of competing against the major pharmaceutical companies that drive prices up.[107]

4.123 In response, DFAT said that the Australian generic industry has maintained the ability to export for marketing approval. Mr Deady said that the ban on exporting commercially while a patent is in place in Australia is status quo, and reflects the obligations of the TRIPs agreement.[108] DFAT also said that this agreement would not affect Australia's ability to export under compulsory licence if, for example, there were a national emergency in a country that could not produce necessary drugs domestically.[109]

4.124 This committee believes that, whether new or not, preventing generic pharmaceutical manufacturers from exporting to a country where the drug is not under patent is a blatantly protectionist measure that should not be borne. This measure limits the capacity of Australian generic manufacturers to make a profit in the global

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107 *Transcript of Evidence*, 21 June 2004, p. 6 (Faunce)

108 *Transcript of Evidence*, 21 June 2004, p.17 (Deady, DFAT)

109 *Transcript of Evidence,* 6 July 2004, p.129 (Quinn, DFAT)

marketplace by taking away export opportunities. It could undermine the profitability of the Australian generic drug industry and force jobs offshore. Whether this obligation is found in TRIPs or is new in the FTA, it is a highly undesirable restraint to free trade.

4.125 This committee is of the view that it is entirely inappropriate to go beyond our TRIPs commitments in negotiating a bilateral trade deal. US negotiators have been pushing for a 'TRIPs-plus' standard of patent protection in all its free trade agreements. This seeks to benefit US pharmaceutical companies by strengthening and prolonging their patent monopoly. The end result in the Australian FTA is considered a 'win' by the US International Trade Commission, which notes that: "The FTA also extends patent and trade secret protections beyond TRIPs and other applicable international agreements"[110] and identifies the pharmaceutical industry as a beneficiary.

4.126 While many of the pharmaceutical-related commitments do not require changes to existing patent law in Australia, they do limit future governments' ability to make changes in this area that could allow generic drugs to enter the market sooner. Perhaps more importantly, by making these commitments in a treaty with the US, Australia is effectively providing greater legitimacy to a strategy that the US has employed aggressively around the world to ramp up standards of IP protection for pharmaceuticals at the cost of developing countries seeking access to affordable medicines.

A sustainable generic drug industry?

4.127 Another difficulty with the intellectual property provisions is that Australia's commitments, whether to change the law or bind the status quo, could have unintended and unforeseen consequences for the viability of Australia's generic drug manufacturers. A viable generic medicines industry is essential to creating the competition needed to contain drug prices. It is important to the PBS's reference pricing system and hence to Commonwealth government expenditure on drugs. It is important to containing state governments' expenditure on drugs in public hospitals. There are currently only six generic drug manufacturers in Australia. Any changes that would undermine the viability of this industry and further limit competition would have implications for the cost of pharmaceuticals across the board.

4.128 The pharmaceutical-related provisions of the IP chapter are complex and may appear trivial, but the possible impacts over time for Australia's generic drug industry are important. The most obvious change for the generic industry is the additional step to the marketing approval process. Just how much of a burden this will be for manufacturers may not be known until the legislation is implemented. Whether any of the commitments binding the status quo will limit future development of this industry

110 US International Trade Commission, *US-Australia Free Trade Agreement: Potential Economywide and Selected Sectoral Effects*, USITC Publication 3697, May 2004, pp.115-116

also remains to be seen. This committee believes that the government must ensure that its FTA commitments do not work to the detriment of the generic drug industry in Australia.

Blood fractionation services

4.129 An exchange of letters attached to Chapter 15 (Government Procurement) deals with trade in blood plasma products and blood fractionation services. Procurement of plasma fractionation services has been excluded from coverage of the Government Procurement Chapter (Annex 15-E Services). The side letter provides that Australia will undertake a review of its blood fractionation arrangements by 2007. If, after this review, Commonwealth and state and territory governments reach an agreement to move to tender processes for fractionation services consistent with Chapter 15, Australia will remove the blood fractionation exclusion.

4.130 In Australia decisions on the blood supply are a joint responsibility of the Commonwealth, State and Territory Governments under the National Blood Agreement. Plasma fractionation services are purchased by the National Blood Authority on behalf of all governments. Australia has a longstanding policy of national self-sufficiency in blood and blood products sourced from voluntary, non-remunerated blood donation. The Australian Red Cross Blood Service is the sole collector of blood, and the bulk of that blood plasma collected is sent to CSL Limited (formerly Commonwealth Serum Laboratories) for fractionation.[111]

4.131 A review of blood fractionation services in March 2001 found that Australia's blood needs were best provided through the CSL as the national plasma fractionation provider.[112] The review, conducted by Sir Ninian Stephen, recommended that self sufficiency should remain an important national goal for Australia.[113]

4.132 As the Australian Red Cross Blood Service pointed out in its submission, self sufficiency in blood is important to reduce the risk of infectious agents such as Creutzfeldt-Jacob disease, West Nile virus or as yet unidentified pathogens or contaminants entering the blood supply.[114] Separate processing facilities for Australian blood plasma are advantageous because they ensure segregation of Australian plasma from other overseas sources as an additional risk management strategy.[115]

4.133 This committee has heard some concerns about the possibility that blood plasma fractionation services could be covered by the government procurement

111 *Submission 143*, Australian Red Cross Blood Service, p.6

112 *Submission 69*, New South Wales Government, p.3

113 *Submission 143*, Australian Red Cross Blood Service, p.9

114 *Submission 143*, Australian Red Cross Blood Service, pp.9-10

115 *Submission 143*, Australian Red Cross Blood Service, p.4

provision in future and the consequences that could follow from that. The NSW government expressed support for Australia's policy of self-sufficiency in blood products and suggested that:

> The implications of tendering for the supply of blood and blood products could lead to the Commonwealth Government losing its strong control and oversight role in this area, jeopardising the quality and high standard of Australia's blood supplies.[116]

4.134 The Australian Red Cross Blood Service also noted the benefits of self-sufficiency in blood products, including specifically the voluntary blood donation system. It stressed that any departure from this would impact on Australia's long standing policy and risk management strategy.[117]

4.135 DFAT has offered assurances that 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.[118] The side letter on blood plasma specifically provides that: 'A Party may require that blood plasma products for use in its territory be derived from blood plasma collected in the territory of that Party'. However, it is possible that blood derived from Australian donors could be sent to the US for fractionation. Baxter Healthcare, a possible competitor for CSL in blood fractionation services, confirmed that it would use overseas processing facilities if it were to provide blood fractionation services.[119]

4.136 Paragraph 4 of the side letter recognises the right of any party to require any supplier of blood plasma products or fractionation services to fulfil safety, quality and efficacy standards. However, it also states that: "Such requirements shall not be prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to trade. This caveat should not be taken as permitting the current Australian practices of self-sufficiency or quality and safety regulations to be overridden.

4.137 This committee firmly believes that the Australian government must ensure the integrity of Australia's blood supply. It should not only maintain the right to regulate for self-sufficiency, it must exercise that right. It must also protect the safety of blood products by ensuring that any facilities used to process Australian blood conform to Australian standards.

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116 *Submission 69*, New South Wales Government, p.3

117 *Submission 143*, Australian Red Cross Blood Service, p.5

118 DFAT, *Fact Sheet – Health*, www.dfat.gov.au/trade/negotiations/us_fta/outcomes/10_health, accessed 30 April 2004

119 *Transcript of Evidence*, 22 June 2004, p.40 (Coy, Baxter Healthcare)

Conclusion

4.138 Much of the debate over the impact of the FTA on pharmaceutical policies and prices in Australia has focused not so much on the text itself but on what might eventuate once the agreement is implemented.

4.139 This committee appreciates that Australia's negotiating team has negotiated long and hard in the face of considerable pressure to ensure that Australia's commitments in this area have much less impact on our existing law and policy than US negotiators would no doubt have liked. The committee does not doubt the sincerity of government witnesses who have told us that nothing in these changes will result in increased drug prices in Australia. It is clear that Australia's negotiators have come away with an agreement that they believe does not make specific commitments that will automatically push up the price of drugs in Australia. DFAT has told us that the concerns that witnesses to this inquiry have raised about specific sections of this agreement are unfounded. The committee sincerely hopes this is the case.

4.140 What most concerns this committee is the possibility that allowing Australia's pharmaceutical policies and IP laws to be up for grabs in this agreement could have unforeseen and unintended consequences down the track. This report has repeatedly noted that the FTA is in a sense a living agreement. Further work will take place in forums such as the working groups set up under it. Many of the details of what it means and how it will be implemented will be sorted out later, possibly with the help of the dispute-resolution mechanism. While we understand the Australian negotiators' interpretation of the agreement, we cannot predict the actions of the US or the dispute resolution mechanism into the future. Whatever happens, Australia must retain the flexibility to set its own health policies that are in Australia's national interest.