

The FTA and the PBS

A submission

to the Senate Select Committee on the
US-Australia Free Trade Agreement

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Executive summary

HIGHER DRUG PRICES

In a number of statements, government ministers have claimed that the US-Australia Free Trade Agreement will not have the effect of increasing drug prices and will not contribute to the long-term financial sustainability pressures on the Pharmaceutical Benefits Scheme. A close look at the FTA indicates that this is not the most likely outcome. The text of the Agreement is unbalanced and most of the measures increase the pricing power of US drug companies operating in Australia. It is inconceivable, based on past practice, that they will not make use of that new pricing power.

How much will this cost? American consumers, insurers and health programs pay two to three times as much for many important drugs as their Australian counterparts. Because most of the measures in the FTA apply to new drugs rather than existing ones, and because legislation will need to be enacted, regulations changed and new procedures put in place, there will be a substantial time-lag between the signing of the FTA and its full effect on prices. The full effect of the FTA on the pharmaceutical market is therefore unlikely to be felt for about five years.

By that time, however, it is plausible that the gap between US and Australian drug prices could be cut in half. We estimate, very conservatively, that Australia's PBS will have to pay at least one third more for its drugs with the FTA than without it. If the likely FTA effects are applied to 2003 figures, the extra cost to of the PBS to the government last year would have been around \$1.5 billion for the same drugs at the same levels of use and with no increase in the health benefit to Australian patients. Similar pressures would be felt by other buyers of prescription pharmaceuticals, particularly hospitals.

INTELLECTUAL PROPERTY MEASURES

Under the FTA, Australia is required to go much further in extending intellectual property rights than is required by our obligations under the existing rules of international trade. In a substantial number of measures, the previously accepted boundaries of the World Trade Organisation's Trade Related Aspects of Intellectual Property treaty have been pushed forward, greatly strengthening the power of the seller in the pharmaceutical marketplace.

The FTA concedes to the US standards on intellectual property rights (IPRs) that it would not have been able to obtain in the WTO or would have had to make considerable concessions to obtain.

The FTA throws away IPRs as a bargaining tool in the WTO with respect to other countries, most notably Europe and Japan. In other words, Japanese and European IPR owners also benefit from the IPR chapter.

This agreement aids the US strategy of using FTAs to divide and conquer countries that are interested in agricultural trade liberalisation. Both Cairns Group members and G-20 members are agreeing to FTAs (in the latter case the price of the FTA is departure from the group) thereby undermining their effectiveness as collective entities in multilateral bargaining over agriculture.

A number of other countries have rejected US trade pressure to redefine intellectual property laws as they affect the American pharmaceutical industry. They have, instead, sought to protect competition and their own export industries. Canada, for instance, has legislation before its Parliament to offer generic drug companies export potential for medicines used in HIV/AIDS. By complying with US-developed standards rather than the accepted norms of global trade, Australia is throwing away substantial export opportunities.

EFFECTS ON GENERIC COMPETITORS

The major trans-national originator drug makers do not compete on price. Even where several interchangeable drugs exist in a therapeutic field, prices stay the same or rise when alternative patented products are marketed. The only real price competition in the pharmaceutical market comes from generics manufacturers – those companies, usually much smaller, that make their own version of a medicine once it comes out of patent. When generic versions of a drug become available, prices usually fall dramatically.

Measures extending the large originator companies' rights in data protection will, in many cases, force generics makers to repeat clinical studies that have already been conducted. It is unlikely that ethics committees would approve such studies: to put patients at risk to provide data that are already well known would contravene basic international standards of human research ethics.

Other measures will also have the effect of delaying the development and approval of generic versions of drugs. The major companies will, therefore, have a longer period free of competition, during which they can enjoy much higher prices than they could achieve in a competitive environment.

A recent study by the Australia Institute found these measures were likely to delay the development of generic drugs in Australia by around three years. It estimated the cost of this to the PBS for the five drugs examined by the study was more than \$1.1 billion for the period 2006-2009.

THE PBAC APPEALS PROCEDURE

Under the FTA, Australia has undertaken to “make available an independent review process” by which a manufacturer can challenge PBS listing decisions made by the key committee, the Pharmaceutical Benefits Pricing Authority.

The government has repeatedly promised that this would not be able to set aside or overturn PBAC decisions. However, the realities of the FTA are that Australia is likely to face very large sanctions under the dispute resolution and enforcement sections of the FTA if it does not provide an appeals process that the US and its drug makers find acceptable. Any process that does not have the power to reverse decisions, and which merely returns a submission to the committee for further consideration, will not represent any advance for the American side or the US companies. According to several statements from the industry and the American side, an appeals process without power is not what they think they have secured.

Such a process will seriously compromise the negotiating position of the PBAC. At present, the committee commissions sophisticated economic evaluations of each new drug and decides whether the price requested by the company represents fair value in terms of the health benefits the drug is likely to provide. If the answer is no, companies must reduce their price or find new data to justify the price they want. Often, the price comes down.

If, rather than re-submitting to the PBAC, sponsor companies could go to an alternative forum to have the PBAC’s decision overturned or changed, the committee would find it far more difficult to enforce price discipline on major drug makers.

DISPUTE RESOLUTION AND ENFORCEMENT

Often, when trade negotiators cannot finalise contentious points of detail, they produce a text that is deliberately unclear on these matters and that can be sorted out later. These “constructive ambiguities” abound in those elements of the FTA that affect the pharmaceutical market and the PBS. These ambiguous clauses allow each side to claim a “win” and to secure endorsement from each nation’s legislatures. But further consultation and dispute resolution processes will be put in place to sort these matters out later, outside of public and parliamentary scrutiny.

Two such processes are included in this FTA: a consultative Medicines Working Group, and the overall disputes resolution processes.

The **Medicines Working Group** will comprise federal officials from each country. Decisions will effectively be binding on Australia unless the draconian provisions of the FTA’s enforcement processes are to be risked. The Australian parliament is being asked to endorse an agreement that does not specify what will happen to key elements of one of its central national health programs, the PBS; and that gives immense power to a non-

Australian group meeting behind closed doors, with no published agenda and no accountability to the Australian people, parliament or press.

Matters likely to be discussed by the Medicines Working Group include the PBAC appeals procedure, crucial technical aspects of PBAC economic evaluations, involvement of companies in PBAC decision-making, whether the Australian government will still be able to remove drugs from the PBS and demands about speed of listing. Most of these matters would potentially diminish the negotiating position of the PBS in dealing with overseas drug companies and would lead to higher drug prices.

If Australia does not comply with US demands, or does not change its laws, regulations and processes to put into effect the FTA and the judgements of the Medicines Working Group, the **disputes resolution and enforcement** processes will come into force. These involve the establishment of committees and working groups that “seek the advice of non-governmental persons or groups” – a measure that brings the industry and its lobbyists directly into the processes of administering and enforcing the FTA.

If Australia is found to be in breach, a fine can be set of up to 50 percent of the value of the benefit Australia is calculated to have gained by its breach. As some single drugs cost the PBS more than \$100 million a year, these fines are likely to be very large indeed. Ongoing penalties of up to \$US15 million may also be imposed for each instance of each breach.

And “benefits under the agreement” may be suspended. This means the US could deny Australia any or all of the access achieved under the FTA to its market for any Australian product, including primary products such as beef and lamb.

PRESSURES ON THE PBAC

As discussed above, the PBS listing process is a combination of valuation followed by negotiation, built on objective economic and clinical evaluation of their products. The PBS does not attempt to gain the lowest possible price: rather, it attempts to pay what it believes, based on the evidence of clinical safety and efficacy, is fair and consistent with what is paid for other medicines. It is a sophisticated and very successful program that has been copied by other countries. The PBS has provided Australia with very competitive drug prices. Local branch offices of global drug companies are under immense power from their overseas head offices to achieve prices closer to those ruling in the US; therefore, anything that weakens the power of the PBAC to reject unsatisfactory prices, and to hold out for better value, will inevitably cause costs to rise and add to the long-term problems of financial sustainability facing the PBS.

Australia’s ban on direct-to-consumer advertising of prescription medicines will become easier for companies to circumvent. This will add to the pressure on the PBAC to make new drugs available whatever the cost. It will also increase total cost as patients are

induced to switch to new, expensive drugs from older, cheaper ones or from no drug at all.

Company representatives will become involved in the actual meetings of the PBAC and its technical sub-committees, and will be able to make personal sales pitches to the meetings deciding on the value of their products. The FTA will reinforce companies' ability to seek higher prices for already-listed drugs, but there will be no capacity for the PBS to review prices downwards if (as often happens) drugs perform less well in the "real world" of actual clinical use than they did in the original clinical trials.

The combined pressures of all these measures on the PBAC and its members will be enormous and extraordinarily difficult to resist. The committee 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 *National Health Act*, it is difficult to see how the committee will be able to continue serving the public's interest properly under such conditions.

Introduction

MAIN POINTS

- The FTA will substantially increase the cost of the PBS. We will be paying more for the same drugs.
- It is plausible that the cost to government of the PBS is likely to rise by around 30 percent as a result of the FTA. For calendar 2003, this would have meant an extra cost of around \$1.5 billion with no increase in the health benefit to Australian patients. We believe this to be a conservative estimate.
- Other drug buyers, including public and private hospitals, will also have to pay more.
- To compensate for this drain on their budgets, public hospitals are likely to cut back on drug availability and on non-drug services such as elective surgery.
- Private hospitals will pass costs onto patients and insurance funds.
- Private health insurance premiums will rise.

COSTING THE FTA

The US-Australia Free Trade Agreement contains a large number of measures that effectively extend the intellectual property rights of US pharmaceutical companies, and that put them in a far more favourable position when negotiating with Australian government authorities for inclusion on the Pharmaceutical Benefits Scheme. These measures will have the inevitable result of substantially increasing the price paid for new drugs, not only by the PBS but also by hospitals, clinics and the general public. In turn, unless significantly greater funding is found from Commonwealth, state and private sources, this will cause distortions throughout the health system as money is taken out of non-pharmaceutical services to pay the higher drug bills Australia will face.

This effect will not be felt immediately. Many of the measures that will boost drug prices will not apply to items already listed, but the effect on the cost of the PBS will steadily increase as legislation, regulations and procedures are amended, and as new drugs are introduced and manufacturers are able to secure prices closer to those in their US home market. Because the bulk of PBS spending is always on relatively new drugs, the full effects can be expected within five to ten years.

It is beyond the scope of this submission to estimate accurately what that cost will be. However, a clue can be found in the difference in drug prices between the United States and Australia. A comprehensive study of international comparative drug prices was conducted by the Productivity Commission in 2001. This study examined 150 drugs accounting for 83% of PBS expenditure. According to the study's weighted average, prices for prescription drugs in the US are around three times (range 2.6 and 3.5 times) as high as in Australia. US prices are the highest of any of the eight countries examined; Australia's are in line with those in France, Spain and New Zealand but below those of Canada, Britain and Sweden.¹ These figures were accepted by the industry as accurate. Similar results were found last year in a more narrowly focussed study by the Australia Institute.²

It is plausible that, as a result of measures in the Free Trade Agreement, the difference in prices paid by the PBS and by US buyers could halve within five to ten years. In calendar 2003, the total cost to government of the PBS and the Repatriation Prescription Benefits Scheme (not including patient copayments) was almost \$5.2 billion.³ Since exchange rates have changed since 2001, it would be wise to base any calculations on the lower of the Productivity Commission's range of estimates.

On the basis of these assumptions, it is plausible that if the full effects of the FTA were in place in 2003, the PBS cost-to-government would have been around 1.3 times as high as it actually was: \$6.76 billion. In other words, the Australian government would have had to pay around \$1.56 billion more for the same drugs at the same levels of use and with no additional benefit to the nation's health.

There would be strong budgetary pressure on the government to transfer some of these costs to the individual consumer, either through higher PBS copayments, deleting drugs from the list, or both.

Because the PBS provides a powerful price benchmark in the Australian market, other purchasers – such as public and private hospitals, some clinics, and the private buyer – would experience similar percentage increases.

These increased prices would significantly reduce the amount of money available for treating patients, both with and without drugs. Unless public hospital funding was increased to compensate fully for the rise in drug prices, general services would have to be reduced. It is also probable that the number of items available on hospital drug formularies would fall: hospitals would no longer be able to afford their drug bills. But other services, such as elective surgery, would also be likely to be reduced. Hospitals would find it more difficult to buy and replace equipment, and to meet salary increases.

1. Productivity Commission. *International pharmaceutical price differences*. Research report. Ausinfo, Canberra 2001.

2. Lokuge B, Denness R et al. *Comparing drug prices in Australia and the USA*. The Australia Institute, Canberra 2003.

3. The actual amount was \$5,194,531,774. *PBS prescription and expenditure statistics year ending December 2003*. Department of Health and Ageing. Canberra 2003.

Private hospitals would also be affected, and would have to pass on these costs to individual patients and to private health insurance funds, whose premiums would rise. Many consumers would pay these increases, though others would not. But because private hospitals and insurers find it relatively easier than their public counterparts to pass on increased costs, the gap in service standards between public and private hospitals would widen.

Finally, because rising pharmaceutical prices already provide significant upward pressure on the cost price index, the measures in the FTA affecting drug prices would contribute to the national inflation rate.

Intellectual property and the PBS

MAIN POINTS

This section focuses on the intellectual property chapter of the FTA, including its implications for the PBS. There are four types of costs that are created by this chapter:

- Bargaining and strategic costs;
- Regulatory sovereignty costs;
- Competition costs;
- Dynamic efficiency costs

Depending on the quality of economic modelling, some of these costs may be picked up in a conventional modelling exercise. However, not all will be because they are costs that relate to dynamic processes. This submission provides examples of each of these types of cost, but it does not, for reasons of length, cover all cases in each category.

ASSUMPTIONS OF THE SUBMISSION

The arguments in this submission are underpinned by the assumption that intellectual property rights (IPRs) are not natural rights or primary human rights.⁴ Rather they are instrumental tools that governments use to regulate free markets, because without that regulation markets would not allocate an optimal level of resources to invention and creation. The assumption that IPRs are essentially regulatory in character has been part of English and Australian law for a long time. As the High Court pointed out in *Victoria Park Racing v. Taylor*, IPRs are “special heads of protected interests” that form an exception to general principles and values of market competition.⁵

One of the fundamental things that the US is attempting to accomplish with this and other FTAs is to turn IPRs into a natural right of investment. Essentially the US is creating a new paradigm in which the granting of monopoly rights is no longer seen as something that is special or exceptional, but rather something that is a permanent feature of the

4. See Peter Drahos, Intellectual Property and Human Rights [1999] (3) *Intellectual Property Quarterly*, 349-371.

5. (1937) 58 C.L.R. 479.

regulation of global knowledge markets. In this new paradigm, it will be US multinationals that will be the private regulators of global knowledge markets.⁶

BARGAINING AND STRATEGIC COSTS

Historically, Australia's strategy on international standards of intellectual property has been based on the fact that it has to participate in the international IPR regime, but its interests in that regime are those of a net intellectual property importer. Summarizing a history of indigenous policy development that goes back to the 1980s and the reports of the Industrial Property Advisory Committee of that time⁷, the position that Australia developed was to abide by but not argue for an extension of multilaterally agreed standards of IPRs, or, if necessary, agree to an extension of such standards if there were gains to it in other sectors (for example, agriculture). This strategy was based on a commitment to multilateralism. In the Uruguay Round of trade negotiations (1986–1993) Australia supported the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) while forcefully pushing its interests in agricultural trade liberalization through its leadership of the Cairns Group.

By signing the FTA with the US, Australia has signalled a fundamental change in the strategy that it has developed over the last few decades. In specific terms, the FTA has the following bargaining or strategic costs:

1. The FTA gives the US standards on IPRs that it would not have been able to obtain in the WTO or would have had to make considerable concessions to obtain.⁸
2. The FTA throws away IPRs as a bargaining tool in the WTO with respect to other countries, most notably Europe and Japan, *because the TRIPS MFN clause picks up the Australia - US FTA*.⁹ In other words, Japanese and European IPR owners also benefit from the IPR chapter.
3. The FTA aids the US strategy of using FTAs to divide and conquer countries that are interested in agricultural trade liberalization. The table below shows that both Cairns Group members and G-20 members are agreeing to FTAs (in the latter case the price of the FTA is departure from the group), thereby undermining their effectiveness as collective entities in multilateral bargaining over agriculture.

6. See Peter Drahos with John Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy?* Earthscan, London, 2002.

7. Industrial Property Advisory Committee, *Patents, Innovation and Competition in Australia*, Canberra, 1984.

8. On the use of bilaterals to ratchet up IPR protection see Peter Drahos, "BITS and BIPS: Bilateralism in Intellectual Property", 4 (2001) *Journal of World Intellectual Property* 791-808.

9. See Article 4 of TRIPS.

DIVIDING AND CONQUERING

The use of FTAs by the US to break up developing country groups

	G20	Ex –G20	Cairns Group	FTA with US?
Argentina*	Y		Y	
Australia			Y	Y
Bolivia	Y		Y	Proposed
Brazil*	Y		Y	
Canada			Y	Y (NAFTA)
Chile	Y		Y	Y
China*	Y			
Colombia		Y	Y	Proposed
Costa Rica		Y	Y	Y (CAFTA)
Cuba	Y			
Ecuador		Y		Proposed
Egypt	Y			
El Salvador		Y		Y (CAFTA)
Guatemala		Y	Y	Y (CAFTA)
Honduras				Y (CAFTA)
India*	Y			
Indonesia	Y		Y	
Malaysia			Y	Proposed
Mexico	Y			Y (NAFTA)
New Zealand			Y	
Nicaragua		Y		Y(CAFTA)
Nigeria	Y			
Paraguay	Y		Y	
Pakistan	Y			
Peru		Y		Proposed
Philippines	Y		Y	
South Africa*	Y		Y	Y (SACU) Being neg.
Tanzania	Y			
Thailand	Y		Y	Proposed
Uruguay			Y	
Venezuela	Y			
Zimbabwe	Y			
	19	7	17	

* Leaders of the G-20.

REGULATORY SOVEREIGNTY COSTS

In the past states have maintained very close control over their sovereignty over IPRs. For example, a survey of national intellectual property laws of more than 100 countries by the World Intellectual Property Organization in the 1980s revealed a huge diversity amongst

states on fundamental matters such as pharmaceutical patenting, patenting of software, plants and animals and so on.¹⁰

The effect of the IPR chapter in the FTA is to reduce the capacity of the Australian government to define standards of intellectual property regulation that suit Australia's industrial and public policy needs. Below are three of many possible examples.

Utility is a requirement of patentability. The idea behind the requirement is that the invention should have some practical use. Utility has proved difficult to apply in the context of the biotechnology industry where often patent applicants claim information the effects and application of which are not really known by them. The FTA obliges Australia to provide that an invention is useful if it has "specific, substantial and credible utility" (See Article 17.9.13). This wording picks up the Utility Guidelines that were issued by the US Patent and Trademark Office in January of 2001.¹¹ In effect, Australia has tied itself into a US standard of utility and its interpretation. Whether or not this suits Australian industry, especially the biotechnology industry, is an open question.

Compulsory licensing is an important regulatory tool that allows governments to bargain effectively with multinational companies in key sectors such as the pharmaceutical sector.¹² It is important to note that the US has over the years issued compulsory licences affecting many thousands of patents with no visible effects on investment.¹³ The FTA severely restricts the capacity of government to issue a compulsory licence compared to the TRIPS standard.

The compulsory licence provision also illustrates another point about the FTA. Almost certainly the US will not comply with this more restrictive standard in its own domestic law. There is a good argument that it does not comply with even the TRIPS standard of compulsory licensing. No smaller country, however, will take the US to dispute resolution in the WTO over this matter. In short, domestically the US will run an IPR regime that is more liberal in terms of access while insisting that its trading partners run an IPR regime that is more restrictive of access than its domestic one.

Parallel importation proved highly controversial in TRIPS and so for that reason TRIPS does not set a standard of parallel importation. Article 17.9.4 of the FTA allows for the possibility that in the case of patents, the patent owner may contractually restrict the importation of patented products that it has placed on the market. This is essentially the current Australian position. However, if Australia

10. See 'Existence, scope and form of generally internationally accepted and applied standards/norms for the protection of intellectual property', World Intellectual Property Organization, WO/INF/29 September 1988

11. See 66 Fed Reg 1092 January 5 2001.

12. On the importance of compulsory licences see Carlos Correa, *Public Health and Patent Legislation in Developing Countries*, 3, 2001, *Tulane Journal of Technology and Intellectual Property*, 1, 43-49.

13. See F. M Scherer, *The Economic Effects of Compulsory Licensing*, The Monograph Series in Finance and Economics, New York University, 1977.

wished to change this position it would find itself in a trade dispute with the US. It is worth noting that the Ergas Committee observed that in the context of copyright consumers would be better off without restrictions on parallel importation.¹⁴ The World Health Organization expressly recommends that countries not place restrictions on parallel importation.¹⁵ This may also be an area where the US domestic position does not square with the standards it is seeking to impose on other states.¹⁶

COMPETITION COSTS

In practice, competition routinely and usually fails in the pharmaceutical market. This market failure was analysed in a 1999 report commissioned by the pharmaceutical industry itself and written by a firm of Sydney pharmacoeconomic consultants who do most of their work for major drug companies.¹⁷ The report pointed to a number of reasons why the normal operation of a free market does not work in pharmaceuticals. These include restricted competition as a result of high entry and development costs facing new manufacturers; the consumer's lack of information; the failure of existing sellers to compete in a market-oriented way and the centrality of patented medicines as a cost driver; the growth of a powerful oligopoly of large corporations formed by takeovers and mergers; and various technical problems with applying free-market theory to health care. Suppliers have immense market power and use this power by acting as a pricing cartel; individual buyers have very little, so the cartel flourishes.

A basic tension arises between the competitive process, which depends on the diffusion of information, and intellectual property, which enables the private appropriation of information.¹⁸ IPRs function as a form of private tax on other competitors in the market place. They allow the holders of those rights to collect royalties and fees from competitors and consumers. The only justification for allowing these private taxes is if there are clear dynamic efficiency gains. In the case of IPRs in the FTA there are clear losses in terms of the interference with competitive markets, but with either no corresponding gains or uncertain gains. There are many examples of this in the FTA including the following:

14. Review of intellectual property legislation under the *Competition Principles Agreement*, Final Report by the Intellectual Property and Competition Review Committee, 2000, Commonwealth of Australia, 60.

15. See Globalization, TRIPS and access to pharmaceuticals, *WHO Perspectives on Medicines*, March 2001.

16. An example of the way in which the US position in the FTA does not square with what is happening in its own Congress can be found in the work of a bipartisan group of the US Senate led by Senator Byron Dorgan, who have introduced a bill to "allow legal and safe importation of prescription medicines by both individuals and for personal use and licensed pharmacists and wholesalers for re-sale." Dorgan B. Media release, 21 April 2004, US Senate, Washington DC.

17. Davey P, Lees M et al: *Report on the Australian system of pharmaceutical financing and delivery*. Medical Technology Assessment Group, vol 1 pp 45-47. Sydney November 1999. The study was jointly commissioned by Eli Lilly and the Pharmaceutical Guild of Australia.

18. For a discussion of the many complexities see Drahos and Maher (eds) Special Issue of *Information Economics and Policy*, 'Innovation, Competition, Standards and Intellectual Property: Policy Perspectives from Economics and Law' (2004), 16, 1-158.

Application to existing subject matter. The FTA applies to all IPRs in existence upon the date that the FTA comes into operation (See Article 17.1.9). Extending the benefits of the FTA to owners of existing IPRs carries with it only social welfare losses. In the case of Australia, Gruen et al estimated the social welfare losses of a similar provision in TRIPS and only for patents.¹⁹ They concluded that the welfare losses might be as high as \$3.8 billion.

Since that study patenting and the use of copyright by US, European and Japanese companies have gone up dramatically.²⁰ It follows that the costs of extending the benefits of the FTA to IPRS in existence in 2004 is likely to be much higher than the estimates in the Gruen study of 1996. *It is also worth asking whether the losses in the IPR Chapter alone throw the overall result of this FTA into the debit column for Australia.*

Barriers to entry. IPRs form one of the most important barriers to entry in markets.²¹ By increasing barriers to entry the price effects of competition may be delayed or, depending on the industry structure, may never arrive. IPRs act as a barrier to entry in many industries (for example, computer software, semi-conductor chips, publishing). The IPR chapter of the FTA contains US style standards of copyright, trade mark and patent protection that will over time affect a number of Australian industries. An example in the next chapter of this submission relates to makers of generic pharmaceuticals.

Throwing away export opportunities. Other states such as India and Argentina are resisting US trade pressure to comply with rules that favour US industries at the expense of their domestic industries. Argentina and Brazil have at different times both rejected demands by the US to change aspects of their domestic intellectual property systems. India has taken full advantage of the transition rules in TRIPS in order to avoid disadvantaging its pharmaceutical and chemical industries. It is also a reasonable assumption that the Indian pharmaceutical and chemical industries, which have strong export interests, along with the Indian government will take full advantage of the flexibilities available to them under the current IPR regime. Canada also has draft legislation before its Parliament (Bill C-9) that implements the Decision on the Implementation of Paragraph 6 of the Doha Declaration. This legislation offers Canadian generic companies export potential for medicines related to the HIV/AIDS crisis. These states are keeping a weather eye on US attempts to set the rules of game and doing their best to preserve export opportunities for their industries. In Australia the acceptance of this FTA suggests

19. Nicholas Gruen, Ian Bruce and Gerard Prior, *Extending Patent Life: Is it in Australia's Economic Interests?*, Industry Commission, Commonwealth of Australia, 1996.

20. On the growth in patenting see the Trilateral Offices website.

21. See J. Bain, *Barriers to New Competition*, Cambridge, Mass, 1956.

that the Australian attitude amounts to one of meek compliance with the wishes of US multinationals.

DYNAMIC EFFICIENCY COSTS

Australia's concessions in the IPR chapter come at a time when there is an emerging view within the US that IPR protection has gone too far. This debate has been triggered by various abuses of IPRs (witness the antitrust litigation brought against Microsoft or the many class actions being brought against US pharmaceutical companies alleging abuses of the patent system).²² The Federal Trade Commission in recent hearings found widespread concern in the US that the patent system is failing.²³ Industry figures from the computer software, hardware and internet business have all expressed frustration at the diversion of time and resources to the patent system in the form of litigation and establishing defensive portfolios.

Australia has signed onto a set of US standards in the FTA at a time when there is considerable doubt in the US about the suitability of those standards for a truly dynamic and effective knowledge economy.

IPRS & DISPUTE RESOLUTION

One of the neglected aspects in the public discussion surrounding the FTA has been the arrangements for dispute resolution to be found in Chapter 21 of the FTA. There are six crucial points to make concerning this Chapter:

- Australia as a medium size trading entity should be supporting a multilateral approach to dispute resolution and in particular seeking to influence the evolution of WTO law. It should not be participating in the proliferation of non-transparent bilateral fora that FTAs such as this one represent. FTAs create forum shifting opportunities for the US.
- At a practical level it has to be asked where Australia's chances of success in trade litigation are likely to be the best – in bilateral or multilateral fora? The US has a highly sophisticated public-private partnership system for trade litigation that depends on, amongst other things, the resources of more than 80,000 US trade associations.²⁴ Australia best chances against this system of litigation are in the WTO rather than in a one-on-one contest.

22. *Collusion and Other Anticompetitive Practices: A Survey of Class Action Lawsuits Against Drug Manufacturers*, 3rd edn, January 2004, Families USA.

23. See <http://www.ftc.gov/opp/intellect/index.htm> For the FTC's recommendations see executive summary, <http://www.ftc.gov/os/2003/10/innovationrptsummary.pdf> full report <http://www.ftc.gov/os/2003/10/innovationrpt.pdf>.

24. For an excellent account of this system see Gregory Shaffer, *Defending Interests: Public-Private Partnerships in WTO Litigation*, Brookings Institution Press, Washington DC, 2003.

- The remedies in Chapter 21 include the possibility of cross-retaliation and this obviously favours the Party with the larger market.
- The Chapter allows for submissions from “nongovernmental persons”. In practical terms this may do more to enhance the participation of large corporations in disputes than any other actor. Similar kinds of proposals by the US in the WTO have been resisted by many countries because of fears about the practical effects of the proposal.²⁵
- Chapter 21 expressly allows the possibility of a non-violation nullification and impairment complaint for IPRs. In other words, a US intellectual property owner could instruct the US to bring an action against Australia where Australia had taken an action that resulted in a lessening of the economic value of the relevant IPR (for example, by issuing warnings about a patented biotechnological product).
- Chapter 21 offers the US an opportunity to influence the development of Australian domestic law, including intellectual property. It can argue that particular decisions of our courts represent a *systemic* failure to protect or enforce intellectual property rights and therefore this warrants a dispute resolution action. This FTA creates the real possibility that the US rather than Australian courts will have the final say on vital areas of domestic law.

25. See G. Shaffer, *The World Trade Organization under Challenge: Democracy and the Law and Politics of the WTO's Treatment of Trade and Environment Matters*, 25 *Harv. Envtl L. Rev* 1, 67-70 (2001).

Patents and Generics

MAIN POINTS

- Price competition in prescription drugs depends on the ability of generic drug makers to compete. Originator companies do not compete on price.
- Australia has already granted patent extensions that give major drug companies a more favourable situation in Australia than in most other countries, including the US.
- Under existing circumstances, patents on many high-cost, high-volume drugs will soon expire.
- Measures in the FTA will delay development of generic versions of drugs, probably by about three years or more.
- This will cost the PBS hundreds of millions of dollars a year.

COMPETITION AND GENERICS

Because price competition between originator companies is almost unknown, the position in the marketplace of generics manufacturers – which compete aggressively on price – is of the greatest importance and should be safeguarded.

For a number of years, US-based drug makers have aggressively and successfully sought extensions to their intellectual property rights in Australia and around the world. A principal argument has been that the time taken for regulatory approval eats into patent life, and that patents should be extended to compensate for this.

The Australian government complied with the US demands with the *Intellectual Property Laws Amendment Act 1998*, which amended the *Patents Act 1990* to extend pharmaceutical patents for up to five years, allowing a maximum patent life of 15 years from the date of first regulatory approval. This applied only to those patents covering the pharmaceutical substance itself, not those covering such aspects as the manufacturing processes. Typically, a single drug may be protected by as many as 50 to 100 patents.

A *quid pro quo* for this major concession by Australia was to permit generics drug manufacturers, when a patented drug enters this new patent extension period, to begin the work needed to bring its own version eventually to market.²⁶ This is known as

26. The Bolar provisions permit the use of technology of a patented pharmaceutical to perform work that would assist in the marketing or regulatory approval of a generic product while the patent is still in force.

“springboarding” and has become an important stimulant of price competition in the Australian pharmaceutical market. It takes an average of three to five years for a generics competitor to perform the work needed to produce its own version of a drug; so, without springboarding, the 1998 measure would have had the effect of extending patent life not by up to five years but by up to ten.

The FTA will give the major US manufacturers an even more favourable position in the Australian market than they currently enjoy – one which already gives them considerably longer patent periods than those enjoyed in comparable countries, including Britain and the United States itself.²⁷

The patent extensions of 1998 were not required under TRIPS. Argentina, which was also the subject of trade pressure on data exclusivity, refused to bow to US pressure on the issue.²⁸ The FTA goes much further than TRIPS in the area of pharmaceuticals. The TRIPS, plus concessions that Australia made in 1998, have simply resulted in the US and its pharmaceutical industry asking for and gaining more concessions. Examples of this include:

- Article 17.9.8 provides for the possibility of further extension of the patent term, including for pharmaceutical patents. This extension would be in addition to any extension that Australia already provides under section 70 of the Patents Act for pharmaceutical patents.
- The restrictive provision on compulsory licensing (see the earlier discussion) has more serious long-term implications for access in the pharmaceutical sector than in other sectors. Brazil’s use of its compulsory licensing laws to meet its HIV/AIDS crisis has been a crucial factor in its successful management of this particular public health crisis.
- The provisions on data exclusivity have been extended to apply to agricultural products for ten years (not required by TRIPS) and include new uses of existing products (not required by TRIPS).
- The trend of the IPR Chapter to foreclose future regulatory options for Australia is illustrated by Article 17.10.1(c). The aim of this provision (not required by TRIPS) is to stop third persons (eg generic companies) from using marketing approvals in other countries as the basis for seeking marketing approvals in Australia.

Bolar provisions are an acknowledgment that 20-year patent terms provide sufficient monopoly protection to recover research and development costs; at the end of the 20 years, these provisions aim to ensure generic competitors are able to market their lower priced products to consumers as soon as patents expire.

27. Department of Industry, Tourism and Resources. Discussion paper on patent extensions and springboarding, and the effect of generic pharmaceuticals manufacturers in Australia. DITR, Canberra, September 2002.

28. See *Therapeutic Goods Legislation Amendment Act 1998*.

- Article 17.10(5) links data exclusivity and marketing approval to the term of the patent. In effect, Australian authorities will be required to track and interpret patent product and use claims of patent owners (these claims need not necessarily be valid, that being a matter for the courts) and take steps to prevent the marketing of those patented products and uses.

At present, if a generics maker can come up with a new use for a drug, or a new formulation, it can legally use the original trial data without having to repeat the research that has already been performed. That capacity will be being seriously eroded by the FTA. Generics makers will, in many cases, have to repeat studies that have already been done, and the results of which have in many cases, been published in the medical press. It is doubtful that ethics committees either in Australia or overseas would be prepared to approve such trials. All clinical drug trials involve some risk to the participant; to require people to undergo this risk when the scientific questions have already been answered would contravene basic international charters of human research ethics.

The effect of these provisions will be to keep competition from generics drug makers out of the marketplace for longer. It will also add substantially to the cost of bringing a generic version of a drug to market.

Medical authorities will almost certainly not have the expertise to deal with problems such as overly broad patent claims. This kind of provision creates enormous advantages for large pharmaceutical companies and provides an incentive for broad claiming. The principle that *it is better to have a weak patent in strong hands rather than a strong patent in weak hands* applies here.

Another crucial issue is the relationship between this provision and compulsory licensing. If this provision continues to operate in those cases where a compulsory licence has been issued there will be no point in applying for one because marketing approval will still be a matter for the patent owner's consent. This would also seem to preclude Australian generic manufacturers from taking advantage of the WTO Doha Declaration and Decision on Implementation of Paragraph 6. The WTO scheme relies on the issue of compulsory licences and is intended to allow states with pharmaceutical manufacturing capabilities to help address the needs for medicines by developing countries.

IMPACT ON THE PBS

Of those drugs soon to run out of their principal patents, 12 appear in the list of 100 highest-cost drugs on Australia's Pharmaceutical Benefits Scheme.

SOON-TO-EXPIRE DRUGS BY PBS COST (2003)

PBS rank	Drug name	Volume	Cost to govt (\$)	Total cost (\$)
1	Atorvastatin	6 155 051	336 972 471	390 198 446
2	Simvastatin	5 232 938	311 387 241	347 808 232
5	Olanzapine	666 036	142 426 548	146 123 654
6	Pravastatin	1 862 235	108 546 906	122 207 982
14	Sertraline	2 391 775	68 692 626	94 250 839
19	Amlodipine	2 136 527	49 656 992	61 893 252
27	Lansoprazole	823 726	36 616 909	43 805 529
44	Fluticasone	810 231	24 851 450	32 652 200
48	Enalapril	1 094 697	22 455 007	28 796 159
52	Lisinopril	1 086 881	21 240 852	29 296 376
85	Quinapril	619 033	12 313 588	16 108 957
100	Fosinopril	466 509	9 299 411	12 221 224

Source: Department of Health & Ageing, PBS expenditure and volume, 12 months to December 2003

Even though the PBS pricing system does not take maximum benefit of generic competition – and needs reform for that reason – a recent study by the Australia Institute of high-cost drugs that had recently become subject to competition found the PBS made savings of around 35% by the fourth year after the entry of generic competition. On the basis of the estimate that the measures contained in the FTA would delay generic competitors entering the marketplace for an average of around three years, the study calculated that the cost of delays, for five drugs that are soon to be subject to competition, would add more than \$1.1 billion to the cost of the PBS for the period 2006-2009.²⁹ Clearly, this amount would be multiplied many times as these delays applied to more and more drugs.

EFFECTS ON INDUSTRY POLICY

Because price competition depends on the health of generic manufacturers, any measures that might drive any of these companies out of business in Australia, or seriously restrict their activities, should be viewed with concern. Intellectual property concessions that favour the large originator drug makers have already undermined the financial stability of several of these companies, reduced their capacity to compete and threatened their long-term viability. Already, several makers of generic prescription drugs are believed to be losing money on their Australian operations.

Some generic makers have responded to this situation by seeking strategic alliances with originator companies. Competition has already suffered as a result. Some manufacture product under contract from major companies, with whom they would previously have been in full competition. Another growing strategy by which originator companies meet the challenge of expiring patents is to grant a marketing and manufacturing licence to a generic “competitor” several months before patent expiry, allowing this “authorised”

29. Lokuge B, Faunce T, Denniss R. *A backdoor to higher medicine prices? Intellectual property and the Australia-US Free Trade Agreement*. Australia Institute, Canberra November 2003. The five drugs were simvastatin, atorvastatin, pravastatin, sertraline and flitotide.

generic version to become established in the marketplace ahead of rivals. Details of any financial deal between the two companies are seldom revealed, but they have the effect of maintaining higher prices for longer and holding full competition at bay.

This agreement will make matters worse. By keeping generic makers out of the market for longer, and increasing their costs, the incentive for them to seek alliances with the majors will increase. Some may go out of business in Australia altogether. The independence of the generics industry, and its capacity to compete, is already in retreat. The FTA could turn the retreat into a rout.

The Appeals Procedure

MAIN POINTS

- Details of a process to give drug companies the right of appeal against unfavourable PBS listing decisions have been left vague in the text.
- The outcome will be subject to a bilateral working party of bureaucrats which will effectively commit Australia to its decisions.
- The likely end result is an appeals process that can overturn or set aside listing decisions.
- If Australia fails to amend its laws in this way, very large fines and trade sanctions are likely.
- The negotiating position of the PBS, in its dealings with drug companies over price, will be seriously undermined.

BACKGROUND

Major pharmaceutical drug companies have for a number of years proposed that there should be a procedure to give them an alternative forum to appeal against, and overturn, unfavourable listing decisions by the Pharmaceutical Benefits Advisory Committee. Successive Commonwealth government have rejected these proposals whenever they have been put.

An appeals process would substantially weaken the position of the PBAC in securing favourable prices for Australia, and would inevitably damage the long-term sustainability of the PBS. The PBS listing process is a mix of objective, evidence-based clinical and economic evaluation and hard-nosed negotiation. Anyone dealing with US-based global drug companies knows they are the toughest of opponents. They do not easily accept lower prices than they might achieve in the United States home market and are aggressively hostile towards government purchasing programs that use market power, clinical evidence and regulatory capacity to secure lower prices and other concessions, such as price-volume agreements, targeted use of drugs and restrictions on promotion. Australia's PBS has been a world pioneer in demonstrating how the health authorities of a small nation can use economic evidence, combined with their market power to balance the immense power of global corporations that, in the absence of government intervention, act as a pricing cartel. Such schemes have now been implemented in many nations, and while they have been of immense importance in bringing important medicines to people who would otherwise have been unable to afford them, there has undoubtedly been an impact on corporate profits.

The PBAC is part of a negotiating process. It conducts intensive economic evaluation of the value of each new drug and, by comparing it with existing therapies, decides whether the Australian health system's money would be wisely spent on it or whether that money would be better spent on something else. These decisions are never easy, but they are absolutely necessary if we are to maintain a health system that uses limited dollars in ways that do the most good.

Sponsor companies understandably try to obtain the highest price they can. If the committee rejects a submission on grounds of inadequate cost-effectiveness (in other words, if the drug is not worth the money in terms of health outcomes) it is usual for the company to re-submit, either with improved data or, more usually, with a lower price. This is how the system works: like any good negotiator, the PBAC has to be able to walk away from a deal. An appeals process would remove that capacity to walk away from a deal that is bad for Australia.

Until the Australia-US free trade negotiations, the most recent rejection of a PBAC appeals process came from a review of the committee's procedures conducted in 2000 by Senator Grant Tambling, then the Parliamentary Secretary for Health. The members of that review were Senator Tambling, as chair; Mr Dudley Schleier, chairman of the Australian Pharmaceutical Manufacturers' Association (now Medicines Australia) and CEO of Pfizer; Mr Will Delaat, deputy chair of the APMA and CEO of Merck Sharp & Dohme; Professor Don Birkett, then chair of the PBAC; Professor Lloyd Sansom, then chair of the Australian Pharmaceutical Advisory Council; Mr Martyn Goddard, a consumer representative and consumer member of the PBAC; and Mr David Borthwick from the Department of Health and Aged Care.

The final report of the review rejected the idea. During the discussion, it was made clear that one of several objections by the government was that the procedure would involve a loss of control over its own budget:

Providing a mechanism for allowing appeals against the merits of PBAC decisions would provide a sponsoring company with an alternative avenue in which to put its case in the event that it had significant concerns with the merits of a PBAC decision. This could provide a more complete assurance that all relevant aspects of listing submissions will, at the end of the day, have been fully considered.

Industry has observed that the scope for appeals under PBAC arrangements is narrower than that provided for in relation to applications for the registration of drugs. Several years ago the *Therapeutic Goods Act 1989* was amended to allow negative drug registration decisions by the Therapeutic Goods Administration (following advice of the Australian Drug Evaluation Committee) to be subject to appeal to the Administrative Appeals Tribunal (AAT).

On the other hand, there are a number of factors which can be raised as militating, to a greater or lesser extent, against such an appeals mechanism:

PBAC recommendations to list a particular drug or indication are not final. Once a recommendation has been made the Parliamentary Secretary (as delegate for the Minister for Health and Aged Care) retains a discretion to reject it. In the case of recommendations

involving a potential annual cost in excess of \$10 million per annum, approval must also be sought from the Prime Minister and the Minister for Finance and Administration. Any decision made on appeal against a rejection of an application by PBAC would not, therefore, guarantee the applicant listing.

PBAC decisions to list a particular drug or indication involve policy considerations, including the availability of Government funds for the subsidy of medicines. As such, these decisions may have significant Budgetary implications or policy ramifications for the Government, the merits of which are arguably not for an external body to determine.

Decisions made by the TGA, on the basis of advice from the ADEC are, on the other hand, made on the basis of factual and scientific criteria, which are either met or are not met. The *Therapeutic Goods Act 1989* sets out the processes and criteria for the registration of drugs. It provides a clear basis on which to make an appeal against registration decisions by TGA delegates and the results of appeals against registration decisions have no funding implications for the Government.

PBAC members are technical experts with a range of medical and pharmacological qualifications. Individual listing decisions are not made in isolation, but rather by reference to other decisions taken in relation to similar or comparable drugs in a particular therapeutic class. A review by the AAT would not encompass either the technical expertise embodied in PBAC or the whole context in which recommendations are made and the PBS administered.

The purpose of the PBS is to provide a benefit to members of the public. The fact that in so doing, a benefit may accrue to the manufacturer and/or supplier of the product subsidised, is incidental and does not confer a right upon the manufacturer or supplier. This is distinguishable from the TGA arrangements, which are set up in relation to regulation of industry, and do confer a right upon the sponsor to market or distribute a product.

There are processes in place for the review of PBAC decisions:

- manufacturers or sponsors are free to resubmit applications for listing, and in practice this occurs quite frequently. Resubmissions may be on the same basis as the original submission, but containing additional data or argument. Alternatively they may seek approval on a narrower basis than originally proposed; and
- The scope for appeals to the ADJR provides an avenue for ensuring that the process by which decisions are taken is able to be scrutinised.

At the first meeting, it was made clear that the Government would not wish to legislate for a formal appeals process against the merits of PBAC decisions. The Department pointed out that there was no other area involving budget outlays that was subject to judicial review.

Industry sought some other mechanism of appeal where applications had been rejected for important drugs. It was suggested that some form of mediation could occur, such as a round-table meeting of stakeholders (eg patient groups, the sponsor, medical specialists, PBAC members) to discuss other factors which could influence the PBAC to reconsider a decision. Any outcome from such mediation would be required to be considered by the PBAC at its following meeting. It was decided that the APMA would investigate how such a proposal could operate.³⁰

30. Tambling, G et al. *Final report of the review of pbs listing arrangements by Senator Tambling review group*. Department of Health & Aged Care, Canberra, 2000 (unpublished).

Round table meetings, involving representatives of the PBAC, the sponsor company, consumers and clinicians have become a regular but not routine feature of the PBAC's procedures, taking place perhaps five or six times a year. They are not binding on the committee but have proved useful in helping the PBAC find a way through difficult situations in which there is a high community need for a drug of marginal or unfavourable cost-effectiveness. These meetings may be requested by either the company or the committee, but both must agree for a meeting to take place. Drugs that have been successfully listed following such meetings include new treatments for Alzheimer's disease and hepatitis C.

APPEALS AND THE FTA

The industry, however, was unsatisfied with this and continued to press for a binding appeals mechanism. In a submission presented to the US Deputy Trade Representative early in 2003, shortly before the negotiations with Australia began, the industry lobby group Pharmaceutical Research and Manufacturers of America (PhRMA) said, in relation to Australia and the PBS:

Certain market access barriers of concern include pricing and reimbursement practices that fail to recognise the value of patented, innovative medicines researched and developed by US pharmaceutical manufacturers. Transparency, appropriate dispute settling mechanisms and meaningful consultation is also an important factor in market access and commercial predictability. We are pleased that the Australian government is currently considering options to improve transparency to the Pharmaceutical Benefits Scheme process as it is hoped that this will lead to the improvements in transparency and consultation that are of such great importance to PhRMA member companies.³¹

When the FTA text was released it specified an appeals (or review) process, despite previous strong rejections by the present government of such an approach. The Australian government has undertaken to:

Make available an independent review process that may be invoked at the request of an applicant directly affected by a recommendation or determination.³²

The exchange of letters between Mr Vaile and the US Trade Representative, Mr Zoellick, said:

Australia shall provide an opportunity for independent review of PBAC determinations, where an application has not resulted in a PBAC decision to list.³³

In public statements, the industry lobby group, Medicines Australia, immediately welcomed this measure. In a media release the group's CEO, Mr Kieran Schneeman,

31. Pharmaceutical Research and Manufacturers of America. *National trade estimate report on foreign trade barriers (NTE) 2003*. PhRMA, Washington 2003.

32. Annex 2-C: Pharmaceuticals. 2-C-2(f).

33. Exchange of letters on the PBS; March 1 2004.

said, left no doubt that the industry believed it had at last been successful in obtaining a PBAC appeals process:

He said one of the most important improvements is the agreement to an appeals system that would act as an important safe-guard to ensure Australians have the best chance of accessing a range of new generation medicines for diseases and illnesses such as cancer, diabetes and mental health problems. “We are pleased that industry, consumers and medical specialists can now rest assured there is a system of review to ensure the best decisions are made for all Australians, with access to the best therapies to treat and cure illness,” he said.³⁴

The US government saw things similarly. US trade law requires specialist advisory committees to advise the President and the Congress on all aspects of trade and trade agreements. The Industry Sector Advisory Committee for Chemicals and Allied Products, which includes representatives of PhRMA, Eli Lilly and Schering-Plough, welcomed this aspect of the agreement:

We are pleased to see that Australia will be making improvements in its Pharmaceutical Benefits Scheme (PBS) procedures, particularly the establishment of an independent process to review determinations of product listings.³⁵

The Australian government’s interpretation is less easy to discern. In its *Guide to the Agreement* the Department of Foreign Affairs and Trade said simply:

In the interests of greater transparency and accountability, Australia has agreed to establish a review mechanism that will be made available to companies when an application to have a drug added to the PBS has been rejected by the PBAC. The detail of how the review process will operate will be worked out in the context of Australia’s legal and administrative framework.³⁶

Statements by the Minister for Trade, Mr Vaile, on this matter have been equally cryptic. On the national television *Meet the Press* program, according to a transcript released by his department, the Minister was asked how an appeals process would work:

BRIAN TOOHEY: Let's see what happens. Just on the PBS, which is also an important one – at the moment one of the key things for containing costs, budgetary costs of this scheme, is that an expert, an independent panel – the pharmaceutical benefits advisory committee – has the final say on what drugs get on that list. The US drug companies are very, very keen to get expensive but not cost-effective drugs on to that list. Can you give a guarantee that the final say on what goes on that list will remain with the existing advisory committee?

MARK VAILE: It does. It remains with the existing advisory committee and they make

34. Schneeman K. *Medicines Australia welcomes FTA announcement*. Media release, Medicines Australia. Canberra 9 February 2004.

35. Gamble G et al. *The US-Australia Free Trade Agreement: Report of the Industry Sector Advisory Committee for Chemicals and Allied Products (ISAC-3)*. 12 March 2004.

36. Department of Foreign Affairs and Trade. *Australia-United States Free Trade Agreement: Guide to the agreement* (2) National treatment and market access for goods (including Pharmaceutical Benefits Scheme). DFAT Canberra 2004. www.dfat.gov.au/trade/negotiations/us_fta/guide/2.html accessed 20 April 2004.

their recommendations to the minister. What we've agreed to do is to inject an independent review – in terms of a transparency measure. But the decision-making process remains the same. We have said all along and the Prime Minister has said all along that as a result of this negotiated agreement, prices of pharmaceutical products to the Australian public will not change, will not increase.

BRIAN TOOHEY: What about the taxpayer? If the Americans get their way...

MARK VAILE: Just on that, we as a Government have a vested interest in maintaining the sustainability and the viability of the Pharmaceutical Benefits Scheme. We started that over 12 months ago with some changes proposed in the budget.

BRIAN TOOHEY: The final say will still stay with the existing...

MARK VAILE: All this is a transparency measure. We've argued from day one, since this was brought up, that we do value on the therapeutic good of a drug, innovation in new drugs, and we bring them into our system as soon as we can so that people in Australian society can get a benefit from those drugs. We are not free riders on innovation or the cost of innovation anywhere in the world. We inject significant amounts of money into research and development in Australia as well.³⁷

So will there be an appeals, or review, process with any power? Any process that does not have the power to reverse or set aside decisions, and which merely returns a submission to the committee for further consideration, will not represent any advance for the American side or the US companies. It is not what they think they have secured. After all, any company whose submission is not accepted by the PBAC already has the option of re-submitting: that has always been the normal process and the course most sponsor companies already choose. Or they could take a case to the Federal Court under the *Administrative Decision (Judicial Review) Act*. The Court is empowered to decide whether the Committee has taken into account grounds it should not have considered, or has not taken into account grounds it should have considered. The Court may uphold the PBAC's decision or overturn it, and send the matter back to the committee for re-consideration. Sponsor companies have taken this action on several occasions, though the Court has in most cases upheld the PBAC's decisions.

On the other hand, the most obvious way of putting into place the kind of review process the Americans think they have would be to change Australia's *National Health Act 1953*. Section 101 of this *Act* specifies that the Minister for Health may not list a drug for subsidy unless the PBAC has recommended that the drug is cost-effective at the price requested, when compared to other existing therapies:

A drug or medicinal preparation shall not be declared ... to be a drug or medicinal preparation in relation to which this Part applies unless ... the Committee has recommended to the Minister that it be so declared.³⁸

This section of the *Act* spells out clearly what the committee must do, how it must proceed, and what its powers are. Nowhere is there any mention of an appeals process,

37. Vaile M et al. Interview with *Meet the Press*, Seven Network. 15 February 2004. Minister for Trade, Australia. www.trademinister.gov.au/transcripts/2004/040215_mtp.html . Accessed 20 April 2004..

38. National Health Act 1953. S.101(4). Parliament of Australia, Canberra.

though it is possible that some process could be put in place by regulation. Section 101 specifies that:

The regulations may make provision for and in relation to the procedure of the Committee.³⁹

It would be possible for the Minister for Health to appoint new members to the Committee, who could meet separately and could be charged with reviewing decisions complained about by sponsor companies. There may be no requirement for these new PBAC members to sit on the meetings of the main committee: for practical purposes, they could function as a quite separate body. However, the main committee would have to agree to abide by the review group's findings, or to submit to the government's desire for this to happen.

Changes to the regulation would have to be presented to the Senate for ratification and could be disallowed. A previous attempt by the government to change the regulations on PBAC membership, to provide for an industry representative, was rejected by the Senate in December 2000. However, disallowance of an element of a Free Trade Agreement could result in an action under the FTA's dispute and enforcement procedures, followed by substantial trade retaliation by the United States. Similarly, changes to Section 101 of the *National Health Act* itself would be politically problematic for the government, which has led journalists, the public and medical experts to believe the *Act* would not be changed. Such an amendment would also, of course, have to pass the Senate but, if it was held by the United States to be a significant measure under the Agreement, substantial trade retaliation could be expected.

The wording of the Agreement on the appeals/review process appears to be a "constructive ambiguity" that is clearly being interpreted by the US side differently from the way it is being presented by the Australian government. Such ambiguities are by no means unknown in the world of trade negotiations: where the parties cannot agree to a firm position, they may decide on deliberately ambiguous wording that will require certain matters to be worked out later through dispute resolution procedures. The processes of dispute resolution and enforcement are central to the understanding of the probable effects of the Free Trade Agreement on the PBS and the pharmaceutical market, and will be discussed in a separate chapter of this submission.

39. National Health Act 1953. S.101 (5).

Disputes Resolution and Enforcement

MAIN POINTS

- A Medicines Working Party will be set up to resolve outstanding issues.
- Its agenda is not known and it will be out of sight of the Australian parliament and press.
- If Australia does not change its laws and procedures to comply with the wishes of the Medicines Working Party and any formal subsequent disputes resolution procedures, large fines and trade sanctions could be imposed.
- The US drug industry will have substantial input to any disputes resolution agenda and process.

CONSTRUCTIVE AMBIGUITIES

Many of the most serious questions about just how the Free Trade Agreement will affect the Australian pharmaceutical market and the PBS remain unanswered in the text. On many major points that affect the pharmaceutical market, the agreement is ambiguous or unclear. So much is unspecified, and so much depends on later processes and consultations with the United States, that it is impossible to know just what the Australian government has conceded or will be forced to concede in the future.

It would be very dangerous indeed to assume, where the text is unclear on a point of importance to the US pharmaceutical industry, that the United States will not take all avenues open to it to resolve these matters in its own, and its industry's, favour. The likely impact of this on Australia, and the PBS, is worrying.

This lack of clarity bears all the hallmarks of “constructive ambiguity”. Not infrequently, trade negotiators who are unable to finalise contentious points of detail, agree on ambiguous wording. These ambiguous clauses allow each side to claim a “win”. Processes of consultation and dispute resolution are put in place that come into play once the main package has been ratified by each nation's legislature. In the case of the concessions on pharmaceuticals, this process potentially has major implications for Australia.

Two processes, to take place after the agreement is ratified, will commit Australia to an agenda of change that is not yet specified or clearly understood, and that for the most part will take place beyond the scrutiny of the Australian press and parliament. These processes are:

- A bilateral working group to pursue an unspecified further agenda in pharmaceuticals; and
- The overall disputes resolution procedures and the serious penalty clauses that will be invoked against Australia if we do not satisfy whatever demands these subsequent processes may put upon us.

THE MEDICINES WORKING GROUP

Annex 2-C, which deals specifically with pharmaceutical matters, specifies that:

- (a) The Parties hereby establish a Medicines Working Group.
- (b) The objective of the Working Group shall be to promote discussion and mutual understanding of issues relating to this Annex (except those issues covered in paragraph 4),⁴⁰ including the importance of pharmaceutical research and development to continued improvement of healthcare outcomes.²
- (c) The Working Group shall comprise officials from federal government agencies responsible for federal healthcare programs and other appropriate federal government officials.⁴¹

The Australian government has not been forthcoming about what this working Group will discuss and what it will commit Australia to. The *Guide to the Agreement* from the Department of Foreign Affairs and Trade says simply that:

Australia and the United States have agreed to establish a Medicines Working Group to enable further discussion of the issues covered by the Annex. It 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 detail of how the Working Group will operate and the frequency of meetings are yet to be decided.⁴²

The Australian parliament is being asked to endorse an agreement that does not specify what will happen to key elements of one of its central national health programs, the PBS; and that gives immense power to a non-Australian group meeting behind closed doors, with no published agenda and no accountability to the Australian people, parliament or press.

40. Paragraph 4 involves closer consultation between Australia's Therapeutic Goods Administration and the US Food and Drug Administration.

41. Free Trade Agreement, Annex 2-C-3: Pharmaceuticals: Medicines Working Group.

42. Department of Foreign Affairs and Trade. *Guide to the Agreement: 2. National treatment and market access for goods (including Pharmaceutical Benefits Scheme)*. DFAT Canberra 2003 (www.dfat.gov.au/trade/negotiations/us_fta/guide/2.html accessed 20 April 2004).

The issues on which the Medicines Working Group will make judgments binding on Australia are likely to include, but may not be limited to:

- Whether an appeals process is instituted with power to overturn, amend or set aside PBAC decisions, thereby effectively crippling the PBS negotiating position when dealing with US manufacturers;
- Whether such processes established under the FTA would extend to manufacturers based in countries other than the United States, or whether US companies would expect special treatment not extended to their competitors in Europe, Japan and elsewhere;
- The extent of the input to be given to sponsor companies in choosing comparator therapies for the purposes of economic evaluation and thus securing higher prices for their products;⁴³
- The nature and extent of direct company involvement in the considerations of the PBAC, its technical subcommittees and evaluators;
- The extent to which the Australian government will be required to give up its right to refuse to list, or to delay listing, a drug recommended by the PBAC;⁴⁴
- Whether the government will still be free to remove drugs from the *Schedule of Pharmaceutical Benefits*;⁴⁵
- What demands will be placed on the PBAC, the Pharmaceutical Benefits Pricing Authority, technical evaluators, support staff and technical committees to increase the speed of evaluation and listing;
- What processes will be put in place for companies to secure higher prices for drugs already listed, beyond the present need for them to apply for PBAC economic evaluation in the usual manner.

43. A comparator is the existing therapy against which a new drug must establish superior efficacy, safety or both in order to justify a higher price than that already paid for the comparator. Where there is more than one possibility, sponsor companies usually wish the comparator to be one that is the least cost-effective, thus justifying a higher price for their new medication. Subsequent manufacturers of new drugs in the same therapeutic field could then be expected to compare their own drug against this one, establishing a chain of cost-ineffective listings into the future.

44. Health Ministers and Australian Cabinets occasionally refuse to list drugs recommended by the PBAC; the most recent example was the government's decision not to list sildenafil (Viagra) on the grounds of excessive cost.

45. For instance, the government has removed nasal sprays and topical antifungals from the PBS list, even though the cost-effectiveness of these products was not in question.

DISPUTES RESOLUTION AND ENFORCEMENT PROCESSES

If Australia does not comply with US demands, or does not change its laws, regulations and processes to put into effect the judgments of the Medicines Working Group, the disputes resolution and enforcement procedures specified in Chapter 21 of the Free Trade Agreement will come into force.

The Joint Committee established to supervise the implementation of the agreement is empowered to:

Establish and delegate responsibilities to *ad hoc* and standing committees, working groups, or other bodies, and seek the advice of non-governmental persons or groups.⁴⁶

The Medicines Working Group, or another yet-to-be-specified body, could be given additional powers of dispute resolution and enforcement under Chapter 21 of the agreement.

If a US drug company, or the industry lobby organisation PhRMA, wished to gain a concession under the agreement, it can be expected to raise the matter with the US Trade Representative. The USTR regularly calls for such submissions from US interests; the record shows that the pharmaceutical industry responds more frequently than any other sector.

The USTR would then call for a formal consultation under the terms of the agreement. Again, the USTR would call for input from the industry:

Promptly after requesting or receiving a request for consultations pursuant to this Article, each Party shall solicit and receive the views of members of the public on the matter to draw upon a broad range of perspectives.⁴⁷

Despite the reference to “members of the public”, in most cases only the US industry and their Australian branch offices will be resourced to respond, or will even know such a consultation is taking place.

If the matter was not resolved within 60 days, the matter would be referred back to the overarching Joint Committee and a three-person Panel would be established. Again, the industry is given a role:

The panel shall consider requests from nongovernmental persons or entities in the Parties’ territories to provide written views regarding the dispute that may assist the panel in evaluating the submissions and arguments of the Parties and provide the Parties an opportunity to respond to such submissions and arguments.⁴⁸

If the panel rules that Australia should implement the changes that had been requested by the US industry, Australia will be required to change its laws, regulations and processes

46. Chapter 21: Article 21-1: Joint Committee.

47. See 21-4: “

48. Article 21-8 (d)

accordingly. If it does not do so, the enforcement measures under the agreement will come into effect. This will involve a fine that is:

... set at a level, in US dollars, equal to 50 percent of the level of the benefit the panel has determined under Paragraph 3 to be of equivalent effect or, if the panel has not determined the level, 50 percent of the level that the complaining Party has proposed under Paragraph 2.⁴⁹

Some single drugs already cost the PBS over \$A100 million a year; consumers in the United States pay, on average, around three times as much for a drug as the PBS pays. Such fines could be very large indeed and would have a significant effect on Australia's health budget and on the money available to pay for Australian health programs.

And "benefits under the Agreement" may be suspended. In other words, the US could deny Australia any or all of the access to its own market for any Australian product, including primary products such as beef and lamb.

HOW MIGHT THIS WORK IN PRACTICE?

Imagine that in five years time an "innovative" US drug with high R&D costs is rejected for PBS listing. The drug's manufacturer wants this decision reviewed. The FTA specifies an "independent review process" for decisions that relate to the listing of new pharmaceuticals or their reimbursement. The meaning of "independent review" is undefined. Assume that the "review process" eventually established under the FTA (probably by its Medicines Working Group) allows for drug manufacturers as applicants, but not bodies such as the Public Health Association of Australia, or the Australian Consumers' Association. Assume also that Australian representatives have made sure it cannot overturn a PBAC decision. The US, however, buoyed by recommendations from the committee monitoring the FTA, now claims this "review mechanism" is inadequate. It threatens and then moves to invoke the dispute resolution mechanism.

Article 1 of the FTA's Pharmaceutical Annex outlines 'agreed principles' utilized by the dispute panel in interpreting the text. These emphasize "innovation", the importance of R&D and "competitive markets." Missing, however, is an unambiguous and unqualified statement of Australia's right to make a priority of "protecting public health" and, in particular, facilitating "access to medicines for all." These are the words that public health groups fought for and won in the WTO's *Doha Declaration* under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), but which the US is now circumventing through more restrictive bilateral FTAs.

A case that illustrates the likely outcome is the litigation between India and the US over India's obligation under TRIPS to create a temporary "mailbox" system for pharmaceutical patents before it moved to full protection in 2005. The need for cheap generic drugs to aid the health of its vast population makes pharmaceutical patents a deeply controversial issue in India. Indian negotiators had made sure the provision

49. 21-7.

contained a constructive ambiguity. The US, however, disputed the adequacy of India's implementation. The US took the matter to WTO dispute resolution and prevailed.

The overall US threat is that if this FTA panel decides that Australia is in breach of its obligations, then chapter 21 permits a "suspension of benefits" or "cross-retaliation" in other trade areas such as beef, or lamb, or manufacturing. In order to prevent this, the party found to be non-compliant may have to pay large amounts of monetary compensation.

Pressures on the PBS

MAIN POINTS

- The main PBS committee, the Pharmaceutical Benefits Advisory Committee (PBAC), will find itself under siege when it rules that a drug is not worth the money being asked.
- Many FTA measures will combine to put unprecedented pressure on the PBAC to list drugs at high prices.
- Australia's ban on direct-to-consumer advertising of prescription drugs will become easier for companies to circumvent.
- Confidentiality measures mean the PBAC will continue to be unable to respond to the industry's lobbying of medical and consumer groups, journalists and politicians.

BACKGROUND: HOW PBS LISTING WORKS

The FTA contains numerous provisions that in aggregate will have the effect of putting increasing pressure on the PBS and will undermine the decision-making of the principal committee – the Pharmaceutical Benefits Advisory Committee (PBAC). One major proposal, the proposed appeals or review mechanism, is the most obvious and is discussed in a separate chapter of this submission.

To understand fully how the Free Trade Agreement will lead to increased PBS costs, it is necessary to recognise the pressures that will be brought to bear on its key committee, the Pharmaceutical Benefits Advisory Committee. And to understand *that*, it's necessary to understand the way the PBS listing system operates.

In 1987, Section 101 of the *National Health Act 1953* was amended to require the PBAC to consider the cost effectiveness of a drug when deciding whether to recommend it for subsidy on the PBS. The new process based on that law change was introduced in 1993 and is encapsulated in a set of highly detailed *Guidelines* to be used by the pharmaceutical industry when making submissions.

The PBAC judges whether a new drug is cost-effective at the price the company requests. It does this by comparing it with an existing therapy (usually another drug). If the PBS is to pay a higher price for the new drug than for the old, Section 101 of the *National Health Act* requires that the committee has to be convinced that the new one is more effective, safer, or both.

The selection of the comparator drug is important. Not all older, already-listed drugs are of equal cost-effectiveness. Companies would usually prefer their drug to be compared with one against which their new product looks good – and which would allow them to claim a higher price.

Submissions received from a sponsor company go for detailed technical evaluation by an economist, epidemiologist and statistician, working within the Pharmaceutical Evaluation Section of the Department of Health and Aged Care, and/or to a contracted external evaluator.

The evaluator's report is sent simultaneously to the sponsor and to the PBAC's Economic Sub-Committee (ESC), which consists of independent expert pharmacoeconomists, clinical epidemiologists, statisticians, clinical pharmacologists and a representative of Medicines Australia (the industry peak body). The principal technical measures of value-for-money are the cost per life year gained or quality adjusted life year (QALY) gained with use of the new drug compared with the old one. This puts a dollar value onto how much the new drug is worth compared to the comparator, taking into account a wide range of factors including clinical effectiveness, side-effects, quality of life, and the cost savings if the drug helps avoid hospitalisation, doctor visits, tests and so on.

Sponsors are given the right to respond to the evaluation; this response is considered by the PBAC when making its recommendation regarding listing of a new drug to the Minister.

The ESC advises the main PBAC committee on whether the technical evaluation is valid but is not involved in the decisions themselves.

THE PBAC: COMPOSITION AND ROLE

The PBAC consists mainly of medical practitioners from a wide range of specialities, including general practice, as well as a consumer member and (more recently) an industry representative. The committee is independent of both the Department and the Minister and, legally, is the only body that can recommend whether a new drug should be listed on the PBS. The Minister may decline the PBAC's recommendation to list a new drug, but cannot list a drug in the absence of a positive recommendation from the PBAC.

The PBAC judges whether the drug, taking into account the technical evaluation as well as the clinical and social need, is worth the money the company is demanding, and what the specific clinical indication should be. If the PBAC decides the drug is not worth the money, the company will usually make another submission, either with a lower price, newer (and better) safety and efficacy data, or an indication more narrowly targeted at particular patient groups.

The PBAC recommendation formally goes to the Minister for Health; in practice it goes first to the Pharmaceutical Benefits Pricing Authority and the Health Department officials

who work with both committees. The PBPA is a five-person committee, one of whom is a representative of Medicines Australia. During this process, the precise conditions of pricing are hammered out, including any price-volume agreement (under which price discounts are given by the company after certain thresholds of usage are reached).

NEGOTIATION BUILT ON EVALUATION

The PBS does not attempt to gain the lowest price possible; it attempts to pay what it believes, based on the evidence, is a fair price. So although listing decisions are based on a sophisticated evaluation of a drug's clinical worth, the process necessarily remains one of negotiation. Often, companies would like a higher price than the one the PBAC thinks the government ought to pay; local branch offices are under immense pressure to achieve prices close to those in the US (or European) home markets. Therefore, anything that weakened the power of the PBAC to reject unsatisfactory prices and conditions, and to hold out for lower prices, would add substantially to prices, and would inevitably threaten the long-term financial viability of the PBS. Delays in listing of new drugs are usually because of failure to agree on what is a cost-effective price. This is best viewed as a purchaser/provider relationship than a regulatory relationship. The purchaser is entitled to 'hold out' for a better price, so long as this does not put the public's health at significant risk.

COMPROMISING THE PROCESS

A number of measures in the Free Trade Agreement will compromise PBAC activities. One, the proposed appeals or review mechanism, is the most obvious and is discussed in a separate chapter of this submission. But there are a number of others, all serious in themselves which, together, will undermine the PBAC's capacity to ensure value-for-money in PBS drug subsidisation, and damage the integrity and sustainability of one of Australia's central national health programs

The Exchange of Letters on the PBS and Annex 2-C on pharmaceuticals describes measures that will injure the capacity of the PBS to do its job; others are part of the existing procedures developed by PBAC in consultation with the pharmaceutical industry over several years..

- ***Direct-to-consumer advertising on the internet.*** Under the *Therapeutic Goods Act*, it is illegal for a manufacturer to advertise prescription medicines directly to consumers. Of all developed nations, only the United States and New Zealand allow such marketing. The reason is that consumers are often unable to make a balanced judgment about their own drug treatment when only one possibility is put before them. Even with this ban – which has been strongly supported by medical and consumer groups in Australia – doctors have to deal with demands by patients for prescriptions for new drugs that have been widely publicised, whether or not that drug is the best clinical option. In Australia and elsewhere, the industry has

bypassed the ban by exploiting a loophole involving the internet. Companies run press, radio and television advertising campaigns announcing “a new treatment” for a condition (such as arthritis or male erectile dysfunction) and urge potential customers to “ask their doctor about it” and to log onto an internet site. It may not be obvious to the customer that a site is operated by the company and is not independent: an example is the “Impotence Australia” website funded by Pfizer, the manufacturers of Viagra. These marketing techniques have been shown to be successful, sometimes dramatically so: the campaign involving the anti-inflammatory drug celecoxib (Celebrex), again marketed by Pfizer, led to extraordinarily high PBS-subsidised uptake involving an annual cost to government of around \$120 million. This loophole should be closed; it permits marketing that undermines both the PBS and the government’s Quality Use of Medicines programs. The Free Trade Agreement will prevent its closure.

- ***An opportunity for a hearing before the PBAC while it is considering reports or advice from technical committees.*** Personal presentations to PBAC meetings have been sought before and have been repeatedly rejected by the government. Each two-day meeting considers up to 30 major submissions. Members, most of whom are medical and pharmacological specialists at the top of their professions, cannot afford more time than they currently spend on PBAC business, which involves a major workload. It would be difficult for company personnel to make an effective presentation in less than 20 minutes; this would cut the committee’s effective time for decision in half and would probably mean that the committee was no longer able to clear its agenda. Companies would have to wait considerably longer for PBS subsidy than they do now. It would be grossly improper for company representatives to take part in the committee’s actual discussion: the PBAC is, effectively, a government purchasing authority. These hurdles have been pointed out to the industry repeatedly and it is regrettable that they are still pushing for opportunities to influence committee decisions in this way.
- ***Make available expedited opportunities to apply for processing of applications not requiring an economic evaluation.*** Australia has been successful in implementing a vigorous evaluation of the cost-effectiveness of all new drugs being considered for PBS listing and has achieved value for money in pharmaceutical subsidisation as a result. There is already a process in place which allows the Department to triage submissions. This reduces workload by diverting truly ‘minor’ submissions (e.g. altered tablet size of an existing drug, generic equivalent of an existing drug that meets regulatory standards at an equivalent or lower price) away from the committees. However it is important to understand that many apparently ‘minor’ submissions require an economic evaluation. For instance a company may claim their new drug is equivalent to an existing product and they expect the same reimbursed price. In this situation close examination of the data has sometimes revealed that the new drug is inferior or the company has claimed ‘equivalence’ at an unusually low dose – which would provide them with a substantial windfall (at the public’s expense) when the drug is used at a higher dose in clinical practice. All such claims need careful examination by the technical

subcommittee of PBAC. Allowing this new provision will encourage pharmaceutical companies to by-pass the tough evaluation procedures whenever they feel they can get away with it.

- ***Provide written information to the public.*** It is important to stress that the factors that have prevented more openness in decision making are: (1) the secrecy provisions on the *National Health Act* and (2) the industry’s insistence on all submission material being considered ‘commercial in confidence’. For many years successive committees and department officials have urged a greater level of openness and direct accountability to the Australian public. They have always been prevented from publishing any but the sketchiest details by the industry. Protracted negotiations were needed to achieve the very limited information now available on the Department’s website about submission outcomes. The present, seriously non-transparent situation greatly benefits the industry: a company can say and publish anything it likes about a decision at any stage, but the committee, officials and the government are prevented from entering any public discussion to put the other side of the case. The industry has a clear run in lobbying consumer and medical groups, politicians and the media. It routinely marshals these interests to put public pressure on the PBAC to list a particular drug (see below). This is very one-sided. It is almost unknown for public professional or political pressure to be directed at a company to lower its price.
- ***Reduce time to implement PBAC decisions, where possible.*** This depends largely on the sponsor company’s position in negotiation with the PBPA and officials. As noted above this is a process of negotiation, not regulation and if the company is prepared to accept such measures as price-volume agreements for high-cost, high-volume drugs, the process can proceed. If not, the PBPA and the government retain the power to negotiate. Other delays have resulted in the process of formal approval by the Minister and the Cabinet, for budgetary or other reasons.
- ***More frequent revision and dissemination of the Schedule of Pharmaceutical Benefits.*** Because publication of the Schedule is tied to PBAC and PBPA meetings, this would involve more frequent meetings and, paradoxically, a delay in listings. This was closely examined during a review in 2000 of listing procedures conducted by Senator Grant Tambling, then Parliamentary Secretary for Health. The review drew up this potential timetable for six meetings for that year:

	Meeting 1	Meeting 2	Meeting 3	Meeting 4	Meeting 5	Meeting 6
Cut-off for major submissions	19 Nov 99	21 Jan	17 March	19 May	21 July	15 September
ESC meeting	18 Jan	21 March	16 May	18 July	19 September	14 November
Dept Evaluations to sponsors	18 Jan	21 March	16 May	18 July	19 September	14 November
Pre-PBAC Response	25 Jan	28 March	23 May	25 July	26 September	21 November
PBAC Meeting	3-4 Feb	6-7 April	1-2 June	3-4 August	5-6 October	30 Nov-1 December
Brief Advice to	By 25	By 28 April	By 23 June	By 25 August	By 27 October	By 22

sponsors	Feb					December
PBPA Meeting	Mid March	Mid May	Mid July	Mid September	Mid November	Mid January
Action close for new listings	About 20 April	About 20 June	About 20 August	About 20 October	About 20 December	About 20 February
Effective date of new listings	1 July	1 September	1 November	1 January	1 March	1 May

The report from the Tambling Working Party said:

The above table assumes the timing of the different stages of the process as currently agreed with the APMA).⁵⁰

It would mean, for example, that the applications for the third PBAC meeting in the year would be being submitted at about the same time as the ESC meeting was being held to consider the applications to the second meeting for that year of the PBAC and is also about the same time as the Pricing Authority would be considering pricing matters relating to recommendations from the PBAC's first meeting for the year,

Implications:

For Industry:

- No longer any surety that application will be considered at the scheduled meeting
- If listing or changes to listing of alternatives occur between submission date and PBAC consideration, sponsors may be asked to re-submit
- With different teams performing evaluation, consistency may be jeopardised
- Timing between the submission date and listing date where the PBAC recommends listing will not be different from the current timing where there are 4 meetings per year
- The maximum gain to industry would be 1-2 months.

For Government:

- Need to significantly expand resources of external evaluators, Pharmaceutical Evaluation section and PBAC secretariat
- Apart from cost, employing additional staff would be difficult as suitably qualified personnel are hard to find
- Working in two streams would create inefficiencies especially when similar drugs are being evaluated by different streams.⁵¹
- ***Consideration within a “specified” time.*** This is already achieved by the PBAC, which clears its agenda after each three-monthly meeting. Provided submissions are received by the cut-off date they will be dealt with at the subsequent meeting. But the meaning of the term “specified” is unclear.
- ***Disclose procedural rules, methodologies etc used to assess a proposal.*** This is already done. A very large range of materials, including the *Guidelines* for PBAC submissions, is publicly available.
- ***Afford applicants timely opportunities to provide comments at relevant points in the process.*** Again, this is routinely built into the system. At every stage in the process described at the beginning of this chapter, written input from sponsors is

50. Now Medicines Australia.

51. Tambling G et al. *ibid*.

requested. The only document not referred to sponsors before consideration by the PBAC is the report of the PBAC Economic Sub-Committee. The reason for this is that the timeline does not allow this; meetings would have to be delayed in order to accommodate this.

- ***Provide applicants with written information on basis for recommendations.*** In addition to receiving a copy of the evaluation of their drug, which they are able to respond to prior to the PBAC meeting, sponsor companies are told the result of their submission by telephone within about three days of every PBAC meeting. Within about two weeks they are given copies of the full and highly detailed minutes of the discussion of their submission by the PBAC. Upon request, they will be given a formal Statement of Reasons, a legal document that can form the basis of an appeal to the Federal Court under the *Administrative Decisions (Judicial Review) Act*.
- ***Sufficient information to facilitate an application to the Pharmaceutical Benefits Pricing Authority.*** This is already given.
- ***Australia should provide opportunities to apply for an adjustment to a reimbursement amount.*** This right exists at the moment: the PBPA frequently considers industry applications for higher prices if the company believes a drug is now worth more than the listed price, as a result of new clinical or other data. This process has been strongly criticised by the Australian National Audit Office, which said the industry's right to review prices upwards should be balanced by the government's right to review prices downwards if (as more often happens) post-marketing data show a drug is less safe or less effective than the original clinical trials indicated.⁵² There is nothing to prevent companies submitting a new submission, with new data, to the PBAC, but the industry has strongly fought any attempt by the PBAC to review prices once a drug is listed.

HOW THESE CHANGES WILL AFFECT THE PBAC AND ITS MEMBERS

The proposed review (appeals) mechanism is considered in a separate chapter. However, the review panel, combined with the mechanisms highlighted in this chapter, will have a cumulative effect on the PBAC members. It is important to understand the context in which PBAC makes its recommendations.

As noted earlier, the PBAC is the legally responsible entity and makes recommendations to the Minister for Health and Ageing and the Pricing Authority regarding which drugs should be listed, for whom, and at what price they can be considered 'cost-effective'. The Minister cannot declare a drug on the Schedule in the absence of a positive PBAC recommendation; so the committee, effectively, is on its own when it decides to reject a submission from a pharmaceutical company.

52. Australian National Audit Office. *Pharmaceutical Benefits Scheme* (Auditor-General Performance Audit Report No. 12, 1997-98). ANAO, Canberra 1997, pp. 58-59.

Saying ‘yes’ is easy. Saying ‘no’ brings the committee into conflict with a range of powerful interests. Pharmaceutical companies are very profitable and spend large amounts of money paving the way for the entry of their new products. The benefits of new drugs are often exaggerated, the adverse effects played down and there is extensive media coverage. Examples of this were the news stories written at the time sildenafil (Viagra) and celecoxib (Celebrex) were being launched in Australia. It has been our often-repeated experience as members of PBAC that medical specialists, patient support groups, lobbyists, journalists and politicians and lawyers (if an application goes to the Federal Court) all tend to take the same line – that the benefits of the drug are clear and that the product should be listed on the PBS. News coverage is biased, inaccurately representing the benefits, plays down the harms of treatment and ignoring the likely costs.⁵³

In this environment the PBAC, charged under law with assessing cost-effectiveness, may be a lone voice legitimately questioning the benefits of the new drug and asking whether it represents value for money. The experiences of two of the authors of this submission (MG and DAH) are that the committee will come under severe pressure while simply trying to do its job. The support of the Minister is not guaranteed, as the experience with the listing of celecoxib (Celebrex) (in 2000) showed.

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 authority that has fully examined the data. Now it will have another authority (the review panel) that has 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 of 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.

53 See for instance Moynihan R et al. Inadequacy of media coverage of benefits and harms of medications. *N Engl J Med* 2000; 342: 1645-1650.

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