

Will the Australia–United States Free Trade Agreement undermine the Pharmaceutical Benefits Scheme?

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In January 2003, the Pharmaceutical Research and Manufacturers of America lobbied the US negotiators for the Free Trade Agreement with Australia (AUSFTA) to seek a commitment from the Australian government to “refrain from trade distorting, abusive, or discriminatory price controls” in relation to the operation of its Pharmaceutical Benefits Scheme (PBS).¹ In October 2003, President George Bush allegedly told Prime Minister John Howard that raising Australian prices for pharmaceuticals manufactured in the United States was important for ensuring that consumers in all countries, not just US consumers, paid for the high research and development (R&D) costs.² AUSFTA was signed by both governments in May 2004. If we presume at least some of this rhetoric influenced the provisions of AUSFTA, what implications will these provisions have for our PBS?

Is Australia paying its way with pharmaceutical R&D?

Australian drug prices are currently about three to four times lower than those in the United States.³ The PBS has kept Australian drug prices low by several strategies. Pharmacoeconomic analysis and reference pricing are used to determine the true worth of the benefits of a new drug, while national bargaining power is used to counter the increasingly prolonged price-setting monopoly accorded to pharmaceutical patent holders.⁴ The Australian Productivity Commission has established that the greatest price differences between Australia and the US are for aggressively marketed new drugs involving small molecular variations and minor additional patient benefit (so-called “me-too” drugs). PBS prices for new drugs providing genuine benefit are much closer to US prices.³ Further, over the past few years the Australian Department of Industry, Tourism and Resources has administered a \$300 million Pharmaceutical Industry Investment Program that provides additional rewards for those pharmaceutical manufacturers undertaking research and development in Australia. From 1 July 2004, a Pharmaceuticals Partnerships Program will take over from the Pharmaceutical Industry Investment Program and provide an additional \$150 million over the next 5 years.⁵ In short, the opinion of the Pharmaceutical Research and Manufacturers of America — that Australia “does not pay its way” with respect to pharmaceutical innovation — is not substantiated by the evidence.

ABSTRACT

- The Australia–United States Free Trade Agreement (AUSFTA) contains major concessions to the US pharmaceutical industry that may undermine the egalitarian principles and operation of the Pharmaceutical Benefits Scheme (PBS) and substantially increase the costs of medicinal drugs to Australian consumers.
- AUSFTA’s approach to the PBS excessively emphasises the need to reward manufacturers of “innovative” new pharmaceuticals, instead of emphasising consumers’ need for equitable and affordable access to necessary medicines (the first principle of our National Medicines Policy).
- Several features of AUSFTA may bring pressure to bear on the Pharmaceutical Benefits Advisory Committee (PBAC) to list “innovative” drugs that the committee initially rejected because the evidence for cost-effectiveness was not compelling.
- Intellectual property provisions of AUSFTA are likely to delay the entry of PBS cost-reducing generic products when pharmaceutical patents expire.
- We support the many concerned health and consumer organisations who have asked the Senate either not to pass the enabling legislation, or to delay its passage until a fairer deal in terms of public health can be obtained.

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The arguments put forward by this organisation are also undermined by the fact that US pharmaceutical companies spend two to three times more on marketing, administration and lobbying than they do on R&D, and that their profits are about twice their R&D costs.⁶ Based on an analysis of revenue disbursements across the industry, what US companies are asking for when they demand higher drug prices under AUSFTA is a greater Australian contribution towards monopoly profits.

The Pharmaceutical Research and Manufacturers of America has a reputation for vigorously opposing public policy that may have an impact on the profitability of its members. In the fiscal year July 2003 – June 2004, it spent US\$150 million on influencing public policy (a 23% increase over the previous year). Typical line-items included US\$17.5 million to fight price controls and protect patent rights in trade negotiations with foreign countries, and US\$15.8 million to fight “a union-driven initiative” in Ohio that would have lowered drug prices for people lacking the relevant insurance.⁷ In the 1999–2000 US elections, the pharmaceutical industry spent US\$20 million on campaign contributions, of which US\$15 million went to the Republican Party. There are now 675 pharmaceutical lobbyists on Capitol Hill, more than the number of US Congressmen!⁸

The PBS was established under the *National Health Act 1953* (Cwlth). Progressive amendments have emphasised that its basic



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principles relate to the need to ensure universal access to affordable, essential medicines.⁹ Given that background, it's not surprising that the AUSFTA negotiations relating to our PBS should have been fiercely contested. Australian Trade Minister Mark Vaile announced: "The PBS, in particular the price and listing arrangements that ensure Australians access to quality, affordable medicines, remains intact."¹⁰ However, members of the US Congress congratulated US Trade Representative, Ambassador Bob Zoellick, on securing a deal that made Australians pay a greater proportion of R&D costs for US drugs.¹¹ The key question is, "Who won?". The answer lies in what AUSFTA says about the PBS.

Seven AUSFTA provisions that impact on the PBS

The 1000-page AUSFTA contains seven areas of concern regarding the PBS. Four are detailed in Annex 2-C (Pharmaceuticals), the fifth is contained in a side-letter between Trade Minister Vaile and Ambassador Zoellick, the sixth resides in Chapter 17 (Intellectual property rights) and the seventh is in Chapter 21 (Dispute resolution procedures).¹²

1. Interpretive principles

Three of the four interpretive principles set out at the beginning of Annex 2-C (dealing with pharmaceuticals) focus primarily on enhancing the rights of manufacturers of "innovative" pharmaceuticals. They contain no unqualified assertion of consumers' rights to equitable and affordable access to necessary drugs. This is the core principle of the PBS as well as Australia's National Medicines Policy, and is supported internationally in the Doha Declaration on the Trade Related Intellectual Property Rights (TRIPS) Convention and Public Health, which states: "Trade agreements should be interpreted and implemented to protect public health and promote universal access to medicines."¹³ The AUSFTA interpretive principles also do not explicitly emphasise the crucial role of generic manufacturers in protecting public health by moderating prices when patents have expired or in health emergencies.

2. Transparency provisions

Annex 2-C 2(f), under the heading "Transparency," allows US pharmaceutical applicants (but not consumer or public health organisations) to ask for an independent review of a decision by the Pharmaceutical Benefits Advisory Committee (PBAC) not to list a drug. In briefings, representatives of the Department of Health and Ageing have argued that the proposed review process will not be able to overturn a PBAC decision. However, it seems inevitable that such reviews will increase pressure on the PBAC to list drugs at higher prices, or primarily as a reward for innovation in research and development instead of cost-effectiveness. Ironically, the "transparency" provisions of this section continue to enshrine the "commercial-in-confidence" right of pharmaceutical applicants to deny public access to their PBS submission, despite increasing evidence that some drug companies withhold vital information needed to make informed decisions about treatment.¹⁴ We agree with expert pharmacovigilance opinion that "commercial confidentiality" should be confined to details of manufacture and formulation, not to clinical trial methods, data, or results.¹⁵

3. Medicines Working Group

The agreement sets up a "Medicines Working Group" between health officials from each country. In an almost direct reference to dismantling PBS reference and premium group pricing policies (as encouraged by the US Trade Act 2002), Deputy US Trade Representative Josette Shiners recently declared in testimony to the US Senate Finance Committee that this Group "will provide a forum for ongoing dialogue on Australia's system of comparing generics to innovative medicines and other emerging health care policy issues."¹¹ Representatives of the Department of Health and Ageing insist that this "dialogue" will not influence Australian pharmaceutical policy formulation in areas such as reference pricing. Once again, US officials appear to have a different view of the likely impact of the Medicines Working Group than do Australian officials.

4. Disseminating information via the Internet

Provision 2.5 in Annex 2-C permits a pharmaceutical manufacturer to disseminate pharmaceutical information via the Internet (ie, via links on sites frequently used by Australian patients). This appears to be a "toehold" strategy to eventually facilitate direct-to-consumer advertising (DTCA) in Australia. DTCA is legal in the US but not in Australia. It has been associated with a substantial increase in patient demand for and use of products often not in accord with best clinical practice.¹⁶ Spokespersons for the Department of Health and Ageing argue that this clause contains nothing new and merely reiterates the current legal situation in both countries. The question as to why this and several other intellectual property and PBS matters are specifically mentioned in AUSFTA (if they contain nothing new) has not been satisfactorily answered.

5. Adjustment to PBS prices

An exchange of letters between Trade Minister Vaile and Ambassador Zoellick notes that Australia shall provide opportunities for pharmaceutical manufacturers to apply for an adjustment to PBS prices. Representatives of the Department of Health and Ageing argue that provision for price adjustments by the Pharmaceutical Benefits Pricing Tribunal has been available for some time and this clause also adds nothing new.¹⁷ There is concern, however, that if this clause is interpreted in the light of the principles at the beginning of Annex 2-C outlined above, it will provide greater opportunities for US companies to seek price rises for "innovation," as distinct from cost-effectiveness.

6. Intellectual property provisions

Several intellectual property provisions of AUSFTA are likely to delay the introduction of cost-effective generic drugs. Others prevent our generic drugs industry from alleviating public health crises in neighbouring countries (Article 17.9.6). Article 17.9.8 of AUSFTA locks in the preferential patent term extensions accorded to pharmaceuticals. Article 17.10.4 takes the radical step of linking and indefinitely "preventing" market approval by the Therapeutic Goods Administration if any type of patent has been "claimed" over the relevant drug. This facilitates litigation replacing innovation in Australia, as it has in the US and Canada. Original patent owners will seek to "evergreen" their exclusive rights over "blockbuster" (high sales volume) pharmaceuticals, with speculative and

Recommended clarification of the Australia–United States Free Trade Agreement concerning the Pharmaceutical Benefits Scheme (PBS)

- That, in the introduction of Annex 2-C (Pharmaceuticals), it is also agreed that, “This agreement shall be interpreted and implemented to protect public health and promote universal and affordable access to necessary medicines, and that nothing in this agreement shall inhibit the sovereign rights of Australia as an exporting country to alleviate public health crises in neighbouring regions”.
- That the “experts” involved in any Pharmaceutical Benefits Advisory Committee (PBAC) “review process” are broadly representative of all PBS stakeholders: government, health professionals, consumers and the pharmaceutical industry.
- That the discussions of the “Medicines Working Group” be made fully transparent by posting all agenda items, discussion and recommendations on the PBS website.
- That, in the interests of ensuring genuine rather than “selective” transparency in PBAC processes, all documentation submitted by a pharmaceutical applicant should be made available to the public on the PBS website.
- That the capacity of generic manufacturers to rapidly “springboard” their cheaper products from existing data on the expiry of a patent be unequivocally protected.
- That an independent study be jointly funded by both parties to determine the public health impact of all the intellectual property and PBS changes, including Clause 5 of Annex 2-C, “Dissemination of information by the Internet.”

ultimately spurious “claims” over the process or capsule rather than the active ingredient.

Research at the Australia Institute in Canberra has estimated that if such changes succeed in delaying by 24 months market entry of generic versions of just the top five PBS expenditure drugs due to come off patent, this could increase the cost of the PBS by \$1.5 billion over 2006–2009.¹⁸ Delayed entry of generic drugs will not only affect the prices of PBS-listed medicines and hospital medicines supplies, but also non-PBS products sold in Australia. These include pharmaceuticals purchased by private and public hospitals and over-the-counter medicines not covered by government subsidies or safety nets. The end result will be much higher pharmaceutical costs for the federal and state governments as well as consumers and the potential collapse of the PBS.

7. Dispute resolution

Chapter 21, on dispute resolution, gives a panel of three trade lawyers nominated by the Parties (Article 21.7) the power to interpret compliance with obligations in AUSFTA, including the provisions that shift the focus of our PBS towards greater rewards for drug “innovation”. Faced, for example, with determining whether the PBS “review mechanism” actually fulfils AUSFTA obligations, the panel will rely on the interpretive “principles” set out at the beginning of Annex 2-C. As previously mentioned, these principles are heavily weighted towards the agenda of the US pharmaceutical industry’s emphasis on “innovation,” “R&D” and “transparent, expeditious and accountable procedures”, as well as “competitive markets”. The principles contain no unqualified reference to universal access to affordable, essential medicines. In addition, Article 21.2 (c) allows a damages claim if a “benefit” the United States could reasonably have expected to accrue under

AUSFTA is not realised, even though no specific provision has been breached. The upshot of this is that PBAC decisions not to “list” “innovative” new US drugs (because they are not cost-effective) will be made in the shadow of possible US trade retaliation in important areas such as manufacturing and agriculture.

Conclusion

The medical profession and the Australian public deserve to know specifically what Australia was promised in return for taking the unprecedented step of including the PBS in a trade deal. The US had no legitimate or scientifically valid reason to ask for changes to the PBS under a free trade agreement, and Australia would have been well within its rights to unequivocally refuse to make any concessions.

Our world-respected PBS is crucial to ensuring the continuance of an egalitarian and compassionate healthcare system in Australia. It is also an important international exemplar, particularly to many developing nations (including Papua New Guinea) suffering public health crises involving HIV/AIDS, which could be alleviated by cheap generic medicines. We support the many health and consumer organisations¹⁷ that asked the Senate to refuse to pass the amendments to legislation required to implement AUSFTA — either to block AUSFTA in its entirety or delay its implementation until a fairer deal is negotiated. With AUSFTA in place, we may well have begun the journey to destruction of our PBS.

Competing interests

None identified.

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