How the Australia-US free trade agreement compromised the pharmaceutical benefits scheme

Tom Faunce

Published online: 07 Jul 2015.

To cite this article: Tom Faunce (2015): How the Australia-US free trade agreement compromised the pharmaceutical benefits scheme, Australian Journal of International Affairs, DOI: 10.1080/10357718.2015.1048785

To link to this article: http://dx.doi.org/10.1080/10357718.2015.1048785

PLEASE SCROLL DOWN FOR ARTICLE

Taylor & Francis makes every effort to ensure the accuracy of all the information (the “Content”) contained in the publications on our platform. However, Taylor & Francis, our agents, and our licensors make no representations or warranties whatsoever as to the accuracy, completeness, or suitability for any purpose of the Content. Any opinions and views expressed in this publication are the opinions and views of the authors, and are not the views of or endorsed by Taylor & Francis. The accuracy of the Content should not be relied upon and should be independently verified with primary sources of information. Taylor and Francis shall not be liable for any losses, actions, claims, proceedings, demands, costs, expenses, damages, and other liabilities whatsoever or howsoever caused arising directly or indirectly in connection with, in relation to or arising out of the use of the Content.

This article may be used for research, teaching, and private study purposes. Any substantial or systematic reproduction, redistribution, reselling, loan, sub-licensing, systematic supply, or distribution in any form to anyone is expressly forbidden. Terms &
How the Australia-US free trade agreement compromised the pharmaceutical benefits scheme

TOM FAUNCE*

Australia’s Pharmaceutical Benefits Scheme (PBS) has unquestioned democratic legitimacy as a piece of public health policy. The PBS was approved by a majority of people in a majority of States in the 1940’s Constitutional referendum that added s 51 xxiIA to the Constitution. Legislation based on that power to establish the PBS was deemed constitutional by the High Court of Australia after a series of challenges against it by the professional association representing Australian medical practitioners. The PBS has since been operating for over half a century to provide evidence-based, cost-effective and equitable access to healthcare for Australians. The scheme’s success can partly be appreciated through lower average pharmaceutical prices for the government compared with other developed countries. The PBS is also popular with the public as listed medicines are available for a relatively low co-payment. Without the scheme, it is hard to imagine how the three main objectives of Australia’s National Medicines Policy would be met:

(1) timely access to the medicines that Australians need, at a cost individuals and the community can afford;
(2) medicines meeting appropriate standards of quality, safety and efficacy; quality use of medicines; and
(3) maintaining a responsible and viable medicines industry.

Yet the PBS has been so chewed over as a result of interference from US pharmaceutical companies gaining leverage through trade deals that its future efficacy has been called into question. In the paragraphs that follow, I briefly explain how the PBS works before explaining how it was compromised in the AUSFTA negotiations.

The PBS is the primary mechanism by which the safety, efficacy and affordability of pharmaceuticals in Australia is guaranteed. In terms of science-based health policy, before a new patented drug is listed on the PBS, it must obtain safety, quality and efficacy marketing approval from the Australian

*Tom Faunce is a Professor at the ANU College of Medicine, Biology and the Environment, and ANU College of Law, Australian National University. <Thomas.Faunce@anu.edu.au>

© 2015 Australian Institute of International Affairs
Therapeutic Goods Administration (TGA). Once this is done, the supplier may apply to have it listed on the PBS after scrutiny by an independent statutory committee—the Pharmaceutical Benefits Advisory Committee (PBAC), established under the 1953 National Health Act. The PBAC is required to consider applications against certain criteria set out in the legislation. The PBAC cannot recommend a new drug for listing if it is ‘substantially more costly than an alternative therapy’ unless it ‘provides a significant improvement in efficacy or reduction of toxicity over the alternative therapy or therapies’ (NHA 1953). Working through a hierarchy of evidence, the PBAC and its advisory subcommittee assess the cost-effectiveness of the submitted product against the cost of its most efficacious and safe already marketed comparator. If the product is deemed not cost-effective, in a cost-minimisation exercise its price is referenced down to that of the comparator. Reference pricing, in its most fundamental sense, then applies post-listing when new competitors (with lower prices) enter six groups presently established under the Therapeutic Group Premium (TGP) Policy. In this TGP system, the unusual criterion of ‘individual interchangeability’ assisted patients wishing to obtain an alternative to a drug in one of these groups whose price has a high additional premium. If the PBAC recommends against listing a particular pharmaceutical, the manufacturer can still access the market and promote its product, however, the patient will have to pay a higher out-of-pocket price. The PBS process is thus not a non-tariff barrier to trade.

This expert cost-effectiveness assessment system in the PBS system has been improved by a succession of progressive and conservative governments to become highly respected nationally and internationally (and almost universally supported by Australian medical practitioners) as a successful articulation of a scientific approach to ensuring maximum public benefit from government expenditure on medicines. However, this system was explicitly targeted for dismantling by US pharmaceutical companies under the AUSFTA (Faunce, Bai, and Nguyen 2010).

US pharmaceutical corporations attack reference pricing

The US pharmaceutical negotiators in the AUSFTA received their riding instructions in the Medicare Prescription Drug Improvement and Modernization Act 2003 (US). This specifically prohibited the US government from using its bulk buying power for Medicare beneficiaries (as the Australian government does under the PBS) from negotiating medicines price discounts. A Conference Agreement on the legislation obliged the United States Trade Representative, the Secretary of Commerce, and the Secretary of Health and Human Services to analyse whether the AUSFTA presented an opportunity to bear in mind the negotiating objective set forth in the Bipartisan Trade Promotion Authority Act of 2002 to achieve the ‘elimination of government measures such as price controls and reference pricing which deny full market access for United States
products’. A further study on how to dismantle science-based reference pricing not only in Australia but in all OECD countries was also required.

The US attacked PBS reference pricing through Annex 2C of The AUSFTA. An ‘annex’ in a trade agreement is a provision that only applies to one party. In Annex 2C the US juxtaposed its constructive ambiguity that Australia’s pharmaceutical policy should reward innovation through the operation of competitive markets with our own approach that innovation should be based on scientific evaluation of the benefits patients received from the new product compared on a cost-effectiveness basis with existing products.

US negotiators had for some time worked closely with senior members of the US patented-pharmaceutical industry on the Industry Functional Advisory Committee on Intellectual Property Rights for Trade Policy Matters (IFAC-3) to develop draft AUSFTA provisions that would achieve this end. The Australian government, on the other hand, had a much more defensive approach to advancing its industries or to protecting is public health and environment in trade and investment negotiations. Stephen Deady, Australia’s chief AUSFTA negotiator highlighted this passive approach, in stating in 2004:

we went into these negotiations with an absolutely clear mandate to protect and preserve the fundamentals of the PBS. That is what this agreement does ... there is nothing in the commitments that we have entered into in Annex 2C or the exchange of letters on the PBS that requires legislative change.

The Senate Select Committee report on the AUSFTA concluded that ‘as a core social policy in Australia, the PBS should never have been on the negotiating table’. The committee also noted that although the Australian public was assured that the PBS was never going to be on the negotiating table, there is evidence to suggest that it was an issue from the very first round of negotiations or ‘discussions’.

US pharmaceutical corporations attack the Australian generics industry

The AUSFTA also contained requirements (particularly in Ch 17 on increasing patent monopoly privileges—hardly a free trade goal) that our Therapeutic Goods Act 1989 (Cth) be amended to create a mechanism where our quality, safety and efficacy regulator (the TGA) had to notify existing patent holders if a generic was seeking to enter the market. This risked the patent holder using such notification to utilise a variety of evergreening techniques to keep the generics out of the market. To prevent this, a section of the Therapeutic Goods Act 1989 (Cth) was amended to allow financial penalties if the mechanism was used for evergreening. In addition, the Australian generics industry was hindered by an increase in the length of patent terms and the addition of a period where patented quality, safety and efficacy data was not released in general as should be the immediate social trade-off for a patient monopoly (Faunce 2007b; Faunce, Bai, and Nguyen 2010).
In preparing to negotiate the intellectual property Chapter 17 of the AUSFTA, Australian-based stakeholders in the generic pharmaceutical industry were not consulted with anything like the care and detail utilised by the US in the IFAC-3 system (Faunce 2007b). This is particularly evident in light of the apparent ready acquiescence by Australian negotiators to some of the Chapter 17 TRIPS-plus patent term extensions, data exclusivity and ‘linkage evergreening’ provisions which directly opposed the commercial interests of the Australian generics industry. Further, at this time Australian generics medicines were subjected to compulsory price drops which undercut their profit margins in a small market and made them ripe for takeover by foreign multinationals. Which is in effect what happened.

Annex 2C’s statement of agreed principles did not mention the Doha Declaration on the Trade Related Intellectual Property Rights Agreement (TRIPS) Agreement and Public Health to promote public health by facilitating access to affordable medicines.

The ‘transparency’ provisions under Annex 2C contain requirements that listing PBS proposals are completed within a specified time, that procedural rules, methodologies, principles and guidelines used to assess a proposal be disclosed, and that applicants are given opportunities to provide comments. Furthermore, PBS applicants and the public are to be provided with detailed information about the determinations made, and an ‘independent review process’ is to be available to an applicant directly affected by a recommendation or determination. The legislative form that this review process took framed it more as a quality assurance exercise for PBAC decisions, with no new evidence and no overturning of PBAC decisions permitted.

The medicines working group as a vehicle for dismantling reference pricing

Annex 2C also established a ‘Medicines Working Group’ (MWG) ostensibly to ‘promote discussion and mutual understanding of issues relating to this Annex’. This seemingly innocuous provision appears to have been the engine room for US lobbying that PBS reference pricing in particular was altered as required by US interests (Faunce 2007b, 4). Australian representatives maintained that this group did not influence policy formulation. This political position is understandable given the challenge to democratic sovereignty that was going on here. After the first meeting of the MWG in Washington, in a press conference at the office of the US trade representative in Washington in 2006, Australia’s trade minister Mark Vaile stated that:

the core principle that we both agree on in this area and that is recognising the value of innovation and the importance of ongoing innovation as far as pharmaceuticals are concerned as the fundamental central principle in what we’re doing.
This was at best statement of a constructive ambiguity in Annex 2C. Pharmaceutical innovation could be valued either by the market (the US approach) or by science (the Australian approach). A Freedom of Information Act application revealed that a policy whereby patented and generic medicines were put into different PBS formularies was discussed at a MWG meeting, and US negotiators followed up on legislation about this policy in the second meeting (Faunce 2007b). It is thus not surprising that in 2007, only two years after the AUSFTA came into force, the PBS formulary was cracked in half, seriously compromising reference pricing.

In August 2007 (after minimal parliamentary debate lasting no more than two week for both houses combined), the National Health Amendment (Pharmaceutical Benefits Scheme) Act 2007 (Cth) was passed, amending key provisions of the National Health Act 1953. My understanding is that private consultants with established contacts in patented pharmaceutical lobby groups were heavily involved in the drafting process for this legislation. Its target was ostensibly to lower the prices available to Australian generic manufacturers but really to alter reference pricing (Faunce 2007b). The legislation effectively created two PBS pricing formularies. F1 comprises single brand, mostly patented and ‘innovative’ drugs and F2 comprises multiple brand, mostly generic medicines. Reference pricing no longer occurs between the two formularies (Faunce 2007a). The pricing of new ‘innovative’ medicines in the F1 formulary risks diminishing the extent to which the PBS processes now can be said to be based on objectively demonstrated therapeutic significance. In outlining the changes late last year, the then Australian Health Minister Tony Abbott admitted that ‘Generics Medicine Industry Association is not, as I understand it, especially happy with these changes’.

What did Australia get in return for having the PBS included in the AUSFTA? This is a question that has long exercised my mind. We certainly didn’t get the access in beef, lamb, rice or sugar our farmers requested. So why on earth did the Australian government of the time allow the PBS to be included in the AUSFTA?

The conclusion I am gradually coming to is that we allowed the US to fiddle around with our democratically legitimate, science-based PBS in return for keeping Investor State Dispute Settlement (ISDS) out of the AUSFTA. If this was the covert agreement, it must have occurred at the highest levels between then Australian PM John Howard and US President George Bush jnr. If so, it represents one of John Howard’s great legacies and is worthy of mention at the time Australia is being pressured into including IDSD in the TPPA.

Disclosure statement

No potential conflict of interest was reported by the author.
References


