

The PBS in a globalised world: free trade and reference pricing

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Abstract

In January 2005 Australia implemented the Australia–United States Free Trade Agreement (AUSFTA). The agreement had placed domestic health policy and the Pharmaceutical Benefits Scheme (PBS) in particular, on the trade negotiating table. At the time Australians were told the PBS would not be undermined, but why was it included in a trade agreement? This article argues that recent reforms to the PBS partially delivered on an issue that the US has compelled its trade negotiators to ensure since 2002: the elimination of reference pricing. In Australia, reference pricing, as used by the PBS, had been credited with obtaining money when buying new medicines.

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THE DIFFERENCE IN PRICES for prescription medicines between Australia and the United States, combined with philosophical differences in the regulation of medicine markets, has created tension between Australia's Pharmaceutical Benefits Scheme (PBS), and US pharmaceutical companies and US trade policy. The central argument of this article is that the Australia–United States Free Trade Agreement (AUSFTA) became a focal point for this tension and created an impetus for change in Australia's processes for listing and pricing medicines. It is also argued that the AUSFTA, at least partly, contributed to the content of recent PBS reforms — one of which is likely to result in Australia paying more for new patented medicines. This paper aims to explore the influence of inter-

national trade agreements on domestic health policy in the specific setting of the AUSFTA. It builds upon previously published material on this topic^{1,2} by providing more detail on why the US might seek to interfere with Australian processes for listing and pricing medicines, and information on a contentious medicine pricing issue that has arisen since the PBS reforms. This paper reinforces the conclusion of earlier papers^{1,2} that the recent PBS reforms are likely to result in Australia paying more for new patented medicines.

AUSFTA and the PBS

As a bilateral trade agreement, the AUSFTA was designed to bring closer ties between Australia and the US by increasing trade and investment links.^{3–5} Primarily this was to be done by removing many of the market-based trade barriers between Australia and the US — in many cases these barriers were tariffs imposed on imports.³ However, concern over the potential content of the AUSFTA grew as it became clear that the US was interested in changing the PBS. As the trade negotiations progressed, the terminology used by government ministers to describe the relationship between the PBS and the AUSFTA ranged from assurances by Senator Kay Patterson, the then Federal Health Minister in 2003, that the PBS was not part of the trade negotiations⁶ to undertakings by the then Prime Minister, John Howard, that there was nothing in the AUSFTA that betrayed the PBS.⁷ In fact the PBS was an integral part of the AUSFTA, and Australian negotiators and Parliament agreed to change the PBS even though the changes had no apparent association with trade.

Government-commissioned modelling identified net economic gains from the AUSFTA for Australia, no adverse effects for the price of medicines purchased by the Australian Government through the PBS and no adverse effects on medi-

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cine prices paid by patients.⁴ However, there were dissenting views on the pharmaceutical provisions. Many of these were critical of the trade agreement affecting domestic health policy and expressed apprehension about the longer-term effects of the promises in the AUSFTA, particularly those that potentially impacted on the prices paid by the PBS to pharmaceutical manufacturers.⁸⁻¹⁵

AUSFTA and non-tariff market access for medicines

The inclusion of procedural changes to PBS processes of listing medicines was without Australian precedent, and even for the US, the AUSFTA's pharmaceutical provisions set a new benchmark for market access. The AUSFTA contained provisions on *non-tariff market access* for medicines. Specifically, access for pharmaceutical manufacturers to sell into Australia's pharmaceutical market was to be improved by changing Australia's domestic regulations and institutional processes. Examples of non-tariff market access include the creation of a review process for decisions made by the Pharmaceutical Benefits Advisory Committee (PBAC) and increased transparency of the operational processes and decisions of the PBAC. While there was little opposition to increased transparency of the PBAC, the question remains: why were reforms to domestic health policy included in a trade agreement? The US view of these inclusions in the AUSFTA was favourable. The Office of The United States Trade Representative (USTR) reported on its website:

Based on new guidance from Congress in the Trade Act of 2002, the Australia FTA was the first FTA to include specific provisions dealing with non-tariff market access issues related to pharmaceuticals. The Australia FTA achieves these objectives through provisions for increased transparency and accountability and enhanced consultation in the operation of Australia's Pharmaceutical Benefits Scheme (PBS) ...

... The provisions of the pharmaceutical annex to the Agreement will help improve market access for pharmaceuticals in Australia by improving the transparency and accountability of Australia's PBS system.¹²

A further commitment in the AUSFTA to aid non-tariff market access was the creation of a new body, the Medicines Working Group (MWG), to discuss health policy in Australia and the US. The USTR reported:

... In the agreement, Australia committed to the principle of appropriately recognizing the value of innovative pharmaceuticals. The US and Australia also agreed to establish a Medicines Working Group to discuss emerging health policy issues.¹²

The pharmaceutical provisions were in keeping with US practice to influence the policies, regulations and institutional structures of its trading partners.¹⁵⁻¹⁹ But why would the US be motivated to change the Australian PBS? The motivation stems from the way the respective countries provide prescription medicines to their nationals.

Prescription medicines in Australia and the US

Compared with the US, prescription drug regulation in Australia favours public provision and, in particular, the prices the PBS pays manufacturers for medicines are determined more by institutional processes than market forces. The PBS is a central component of Australia's medicines policy and it uses regulations (eg, as contained in the *National Health Act 1953* [Cwlth]), institutions (eg, the PBAC), and reference pricing and pharmaco-economic techniques to meet its aim of obtaining necessary medicines at prices both the community and patients can afford.

Reference pricing is one of several pricing tools used by the PBS. It is where the price the PBS pays for a new medicine is referenced or tied to the prices of medicines that have similar health effects. In Australia, this once meant that the price of a new patented medicine could be referenced to an existing medicine that had similar effects — even if the existing medicine was a cheaper generic. According to US trade legislation, reference pricing is a form of price control¹³ and it is a view that is rarely challenged. Yet in effect, consumers practice a ver-

sion of reference pricing, albeit less sophisticated than that used in the PBS model, every time they compare prices and products before making a purchase.

Regulation, institutions, reference pricing and other pricing techniques used by the PBS have provided value for money for some expensive prescription medicines.² This success has been evidenced by low average prices paid by the government to manufacturers for many medicines, compared with the prices paid by other developed countries.¹⁴

While the PBS is viewed favourably by most Australians, departments within the US Administration and US pharmaceutical companies have been openly critical.^{15,16} If US, and other, pharmaceutical companies want to sell their medicines in Australia in profitable quantities, their drugs need PBS listing. This is one of the fundamental differences between Australia and the US. The US has many Health Maintenance Organisations (HMOs) that negotiate price deals with pharmaceutical companies. Multiple buyers have less market power than a single large buyer. In Australia, the PBS (through the Pharmaceutical Benefits Pricing Authority [PBPA]) is the *only* institution permitted to make pricing deals for benefit-paid medicines that have PBS listing. This shifts the PBS toward having *monopsonistic* (sole buyer in a market) buying powers. Effectively, if an expensive medicine fails to be listed on the PBS, it may be sold in Australia (depending on approval from Australia's Therapeutic Goods Administration [TGA]), but it will not receive a PBS reimbursement, leaving the patient to pay the full amount. For expensive medicines, high prices for patients will limit the drug's Australian sales. When the PBS obtains value for money the flip side is that pharmaceutical companies receive prices that they consider to be too low. Although disputed, the low prices paid to pharmaceutical manufacturers by the PBS, and some OECD (Organisation for Economic Co-operation and Development) countries, are argued to hinder pharmaceutical research and development and result in higher medicine prices for US patients.¹⁵

Attempts to influence Australian policy

There is no doubt that the US sought to influence Australia's procedures — reference pricing in particular — for government purchases of prescription medicines during the trade negotiations. The US position is legislated in the US Trade Act 2002 which requires US trade negotiators to eliminate the use of reference pricing:

(8) REGULATORY PRACTICES.—The principal negotiating objectives of the United States regarding the use of government regulation or other practices by foreign governments to provide a competitive advantage to their domestic producers, service providers, or investors and thereby reduce market access for United States goods, services, and investments are . . .

. . . (D) to achieve the elimination of government measures such as price controls and reference pricing which deny full market access for United States products.¹³

The expectation that this objective was pursued in the AUSFTA was confirmed by US Trade Representative, Josette Shiner:

Trade Promotion Authority (TPA) granted by Congress in the Trade Act of 2002 introduced a new trade negotiating objective — requiring the Administration to seek to address price controls and referencing pricing systems maintained by foreign governments that discriminate against American products, including pharmaceuticals.

USTR pursued that objective in trade negotiations with Australia . . .¹⁷

There is nothing improper with these US objectives. The US attitude to trading partners using reference pricing has been made clear in numerous public documents, including US legislation. And there is nothing improper with the US pursuing its stated objectives on reference pricing in trade deals with any country including Australia. What is of concern is whether, and to what extent, Australian policy was influenced by the US view on reference pricing.

AUSFTA and reference pricing

The closest the AUSFTA came to directly referring to the pricing of innovative medicines was a promise to *recognise the value of innovative pharmaceuticals*.¹⁸ Nowhere in the pharmaceutical provisions is the term *reference pricing* mentioned. However, the AUSFTA introduced a mechanism whereby the US could ensure its views on Australian pharmaceutical pricing policies could be raised in an official context through the MWG. The MWG was to be attended by federal government officials from both Australia and the US.¹⁸ During trade negotiations Australian officials saw the MWG as a discussion group to keep Australian officials informed about national and international pharmaceutical issues — they did not see it as having any influence over PBS decisions or health policy.¹⁹ However, the US expressed its understanding of the MWG as a forum where, among other issues, Australia's system of comparing generics with innovative pharmaceuticals and other health care policy issues would be raised.^{19,20} Testimony from Deputy US Trade Representative to a US Senate Committee summarised the US view on the MWG:

Crucially, the FTA also establishes a Medicines Working Group that will provide a forum for ongoing dialogue on Australia's system of comparing generics to innovative medicines and other emerging health care policy issues.¹⁷

The first MWG meeting was on 13 January 2006 in Washington and the second, in Sydney, was held on 30 April 2007. There is limited information on what was discussed at the meetings (ie, transcripts are not available) or how, or if, these discussions had broader influence over Australian policy. Nonetheless, there is evidence that at the initial MWG meeting, Australia was encouraged to follow a US-style competitive markets approach when valuing innovative medicines.²¹ During this meeting, a newspaper opinion piece by a Coalition government member²² was discussed that recommended reform of the PBS by restricting the use of reference pricing for innovative drugs — reform that

would prevent innovative drugs being compared, for pricing purposes, against generic medicines.²¹

Australia weakens its use of reference pricing

Without any reference to the AUSFTA, 23 months after the trade agreement came into force and nine months after the first MWG meeting, the Australian Government announced reforms for the PBS. The then Health Minister, Tony Abbott, announced in 2006 that the single PBS formulary would be separated the following year into two sections (F1 and F2) and prices paid by the PBS for some generic medicines would be cut. Industry commented that the latter would create *headroom* for new innovative drugs.²³

The PBS reforms sought to alleviate two policy problems for the government.

1. With many patents on expensive medicines coming to an end, Australia was already paying too much for some generic drugs.

2. Australia needed to position itself to meet demand for new and expensive medicines in the future.²⁴

Splitting the single formulary into F1 and F2 required modification to the National Health Act with the creation of two new sections: 85AB and 85AC. The Act outlined the criteria for a drug to be listed in F1 and essentially this would only occur for drugs for which there is no bioequivalent or biosimilar alternative. This will usually mean the first drug of its kind and most likely a drug protected by a patent. Drugs will be in F1 if they are not “interchangeable on an individual patient basis” with therapeutically equivalent products.

The introduction of “interchangeability” overruled the test of “equivalence”, which had been used by the PBAC when reference pricing drugs. Interchangeability is a more stringent test and, therefore, it is less likely to group together drugs that may have otherwise been defined as equivalent. The more stringent test of interchangeability means that drugs which might be equivalent based on the outcomes of comparative clinical trials may not be interchangeable at the patient level.²

The F2 formulary contains drugs that have at least one additional product that is considered clinically “interchangeable” and this formulary is where most generics will be located. The F2 category was split into a further two groups: F2A and F2T. The F2A formulary had annual reductions in the price paid by the PBS of 2% for three years starting 1 August 2008. The F2T formulary had a 25% price reduction on 1 August 2008 although some patented medicines on this formulary will have the price reduction phased in over the remainder of the patent life.

The PBS reforms allowed reference pricing to continue within each formulary but, critically, not between F1 and F2. The restricted use of reference pricing combined with a reduced likelihood that the interchangeability test will group equivalent medicines together creates a financial incentive and an easier pathway for manufacturers to seek a listing in F1. Has a “rush” to F1 occurred? Information on formulary allocations published by the Department of Health and Ageing²⁵ as at 1 January 2009 showed that out of 691 drugs allocated to PBS formularies, most (63.6%) were listed in F1 and about 30% were listed in the two F2 categories. The remainder were not allocated to a formulary and were listed on the Combination Drugs List — a list which is separate to the F1 and F2 formularies (a combination drug is defined by the National Health Act as one that contains at least two medicinal preparations where at least one is listed on the PBS).

The new rules on reference pricing create a substantial impediment to the type of “complete” reference pricing Australia practised before the reforms. It has been argued that, post reform, pharmaceutical manufacturers targeting the F1 formulary will be more likely to seek comparison against a placebo and this could lead to a situation where Australia pays more for a medicine that is no better, or even less effective, than an existing treatment.² However, others have disputed this outcome by claiming that the PBS reforms do not prevent a new PBS F1 listing from being compared with an off-patent comparator in the F2 formulary for pricing purposes.²⁶ It is argued that if the new drug fails to offer superior

efficacy or safety, the PBS will offer the pharmaceutical manufacturer the same price as the comparator.²⁶ Yet, if this did occur, pharmaceutical manufacturers would view it as an unintended consequence of the PBS reforms.²⁷ The representative body of pharmaceutical manufacturers, Medicines Australia, has explained its understanding of pricing under the new F1 and F2 formularies as being one where F1 prices are:

determined by evidence-based medicine and cost-effectiveness analysis, while in F2 market competition determines price and that given the different markets, there should be no price linkage between F1 and F2 medicines at the time of price setting as well as price maintenance after listing.²⁷

Whether having a comparator in the F2 formulary establishes a basis for a price link between the F1 and F2 formularies is now being investigated by the Access to Medicines Working Group (AMWG) — a group comprised of members drawn from the Department of Health and Ageing and Medicines Australia. The AMWG's Interim Report has been released and discusses three options for addressing this pricing issue, and, as the AMWG acknowledges, all options would cause an increase in PBS expenditures.²⁷

Conclusion

By reason of the mandatory cuts in the price paid by the PBS for some medicines, Australia is now paying less for generic drugs as a result of the PBS reforms. However, the extent to which the savings on generics offset the higher prices the PBS is likely to be paying manufacturers for new patented drugs is unknown. The AUSFTA may not have directly targeted reference pricing as practised by the PBS, but it appears that it constructed, through the MWG, a mechanism for the US to have its views clearly heard. We may never know how much influence the opinions expressed at the MWG ultimately had on the development of the 2006 PBS reforms, but what is clear is that the reforms ultimately shifted Australia closer to a clearly stated US trade objective: the elimination of reference pricing.

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Competing interests

The author declares that he has no competing interests.

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