Reference pricing for pharmaceuticals: is the Australia–United States Free Trade Agreement affecting Australia's Pharmaceutical Benefits Scheme?

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Unless the federal government changes the course of our medicines policy with intention, Australia's pricing of patented pharmaceuticals is likely to follow inequitable US trends

Proposed amendments to the *National Health Act 1953* (Cwlth) are currently being considered by the Australian federal government. The National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2007 (the Bill) includes several changes that will limit reference pricing under the Australian Pharmaceutical Benefits Scheme (PBS). Here, I argue that these amendments have been influenced by the Australia–United States Free Trade Agreement (AUSFTA) and, further, that if US influence on Australian medicines policy continues, there are likely to be adverse consequences for all Australians, involving the erosion of scientific objectivity and equity in PBS processes and, eventually, the end of public-funded medicines.

What is reference pricing?

The PBS is an internationally respected system under which the federal government uses public funds to reimburse pharmacists (and thence manufacturers) the "health innovation" value of listed medications, as proven by scientific evidence assessed by pharmacoeconomic experts on the Pharmaceutical Benefits Advisory Committee (PBAC). This allows Australian patients to generally pay a relatively low standardised copayment (currently $30.70 for non-concessional patients) for all PBS medicines, patented and generic alike.

Under the current PBS system, once expert assessment has established that a new patented drug has better efficacy or safety than a different off-patent comparator for the same clinical indication, it is recommended by the PBAC for listing. The submission price is then further negotiated by the Pharmaceutical Benefits Pricing Authority (PBPA). If the PBAC's analysis merely establishes equal effectiveness, then, in a fundamental cost-minimisation process, the newly listed drug's initial reimbursement price is linked to the lowest in the relevant price reference group.

Reference pricing, in its most fundamental sense however, 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" assists patients wishing to obtain an alternative to a drug in one of these groups whose price has a high additional premium. Readily expanding categories of TGP reference pricing are a fundamental institutional manifestation of the evidence-based distributional justice — seeking a fair balance between price and proven community benefit — required to underpin public expenditure on medicines under section 101(3B[a]) of the National Health Act, as well as the principle of equity of access under the Australian National Medicines Policy.[1]

What are the amendments influencing reference pricing?

The Bill proposes amendments (new sections 85AB, 85AC) to the National Health Act that will divide the current PBS formulary into two. Medicines will be listed on the F1 formulary if there are no "bioequivalent" brands or drugs in reference pricing groups subject to the TGP Policy — these will mostly be patented or "innovative" medicines. The F2 formulary will cover generic medicines.

Once adopted, specific price cuts and disclosures will be imposed *only* on F2 generic medicines. New reference pricing groups subject to the TGP (in addition to the existing six) will have to meet the additional high standard (undefined in legislation) that they are "interchangeable on an individual patient basis" (proposed sections 84AG and 101[3BA]). Reference pricing — as it now operates after PBS listing to produce "flow-on" price drops — will be problematic when the trigger drug is in the F2 formulary (although the latter's existence may cause the F1 comparator to be redefined as an F2).

What lies behind these changes?

I am concerned that at least some of the impetus for this alteration of PBS fundamentals may have come from multinational patented-pharmaceutical companies through mechanisms established by the AUSFTA.

Annex 2C of the AUSFTA,[2] which focuses on the PBS and pharmaceuticals, has led to some positive changes, including public summary documents of PBS drug-listing decisions.[3] However, it also produced a new review mechanism that is triggered after PBAC rejection decisions,[4] with increased opportunities for industry pre-hearings and consultations with technical staff, as well as a Medicines Working Group (MWG) comprising high-level officials on medicines policy from both Australia and the US.[5]

Further, in the past few months policies have been produced for full PBS cost-recovery from industry[6] — despite such "user fees" and increased liaison mechanisms being criticised as creating conflicts of interest for the US Food and Drug Administration that significantly endanger public safety.[7]

Perhaps most significantly with respect to the Bill, Annex 2C.1 of the AUSFTA emphasises the principle of valuing pharmaceutical innovation through either the operation of "competitive markets" (the US position) or by "adopting or maintaining procedures that appropriately value the objectively demonstrated therapeutic significance of a pharmaceutical" (the Australian position).[8] The potential importance to Australian medicines policy of this ambiguous definition of innovation has been highlighted in this Journal[9] and elsewhere.[10]

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United States AUSFTA negotiators' instructions on Pharmaceutical Benefits Scheme reference pricing

The US Trade Representative, the Secretary of Commerce, and the Secretary of Health and Human Services were obliged 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. In so doing, the agencies shall provide periodic and timely briefings for the Committees of the House and Senate listed above, with an interim briefing no later than 90 days after enactment to address **negotiations to establish a US–Australia Free Trade Agreement** and, as appropriate, other current negotiations.[11] [emphasis added]

AUSFTA = Australia–United States Free Trade Agreement. ◆

We should not forget that the US negotiators to the AUSFTA, who previously worked very closely with senior members of the US patented-pharmaceutical industry on the Industry Functional Advisory Committee on Intellectual Property Rights for Trade Policy Matters, had an explicit legislative mandate to seek the "elimination" of PBS reference pricing (see Box).[11] The same legislation also required the US Department of Commerce to investigate the possible future dismantling of reference pricing in OECD (Organisation for Economic Co-operation and Development) countries.[12] In December 2005, in Paris, the US sought to implement this agenda through the OECD Project on Pharmaceutical Pricing Policies and Innovation.[13]

Australian AUSFTA negotiators provided reassurances about the Annex 2C.1 innovation principle before a Senate Select Committee on 21 June 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.[14]

However, when the AUSFTA MWG met for the first time in Washington, DC on 13 January 2006, Australia's Minister for Trade, Mark Vaile, stated that:

> … the core principle that we both agree on in this area … is recognising the value of innovation …[15]

To my way of thinking, this represents a restatement of Australia's position on objective, evidence-based assessment of health innovation, in accord with the National Medicines Policy.

Documents obtained under a Freedom of Information application (organised by Pat Ranald, Australian Fair Trade and Investment Network, 2007) reveal almost nothing of what was said at the first AUSFTA MWG meeting. One disclosed document, presumably discussed, was an opinion editorial in *The Australian*, which argued that: "Truly innovative cures should be referenced against innovation in other classes, rather than against generics"[16] — an approach that seems to reflect the US "competitive markets" method of valuing innovation. The second meeting of the MWG on 30 April 2007 discussed the new F1 category, which had now been structured along the same lines proposed in the editorial the MWG had discussed at their previous meeting (International Trade Law Symposium, Canberra, 4 May 2007, personal communication). The official Australian Government website only disclosed that the MWG "discussions were constructive and informative".[17]

I believe this evidence suggesting a possible, non-transparent link between the definition of innovation in AUSFTA Annex 2C.1, the MWG, and the new F1 PBS category, with its sequestration from post-listing reference pricing against generic medicines, has disturbing implications for sovereignty over Australian public health policy.

The PBS beyond Australia

In its recent free trade negotiations with the US, the South Korean Government demanded a process similar to Australia's current system of evidence-based cost-effectiveness and reference pricing.[18] Article 5.2 of the Republic of Korea–United States Free Trade Agreement, after recognising each nation's differing approach to medicines policy, indicates that if South Korea establishes a reimbursement system for pharmaceuticals or medical devices where the amount paid is not based on "competitive market-derived prices", then it has to "appropriately recognize the value of patented pharmaceutical products" (Article 5.2 [b][i]). Article 5.1 (c) and (e) respectively mention PBS-type "sound economic incentives" as a method of facilitating access to patented medicines and PBAC-style "transparent and accountable" procedures as a means of promoting health innovation. However, Article 5.7 creates a Medicines and Medical Devices Committee, similar to the AUSFTA MWG. Will the parallels continue?

The end of public-funded medicines?

In Australia, it is likely that creating an F1 PBS category where patented drugs are insulated from post-listing reference pricing against generics and required price drops may, in the short term, tempt governments to increase the extent of patient cost-sharing (perhaps through differential means-tested copayments) for high-cost patented medicines. If the proposed amendments are adopted, the incentives for pharmaceutical products to remain within the price-protected F1 class are likely to lead to much more aggressive pharmaceutical patent battles in Australia (taking advantage of intellectual property changes introduced by Chapter 17 of the AUSFTA) that could delay the introduction of cheaper generic medicines.[19] The consequent widening discrepancy between initial listing prices for patented medicines and their therapeutically equivalent generic comparators may become unconscionable.

The evolving higher prices for F1 patented medicines could also provide additional arguments for patented-pharmaceutical industry lobbyists to claim that the PBS is "unsustainable" and that we need to move to a privately financed prepaid insurance system, such as medical savings accounts (a form of medicines superannuation).[20]

If, however, a future Australian government wants to retain public funding of patented medicines and contain PBS expenditure, it could remove, or rigorously define according to established PBAC records, the criteria of "interchangeable on an individual patient basis". It also needs to be clarified that this concept will not interfere with the initial choice of cost-effectiveness comparator, initial cost-minimisation, or the creation of therapeutic relativity sheets that are used by the PBPA to assess post-listing industry requests for price rises. Without such clarification, and a robust mechanism for shifting F1 drugs to the F2, the proposed changes

to the PBS threaten a shift away from the fundamentally evidence-based method of valuing the health innovation of a patented pharmaceutical after listing. They may, instead, push it more towards valuing F1 products through the operation of markets that are nominally competitive, but readily distorted by collusion and advertising.

Much will depend on whether the government protects and supports the independence of officials involved in pharmacoeconomic analysis and vigorous price negotiations with patented pharmaceutical manufacturers (both at first listing and over time), in the MWG and, if necessary, in AUSFTA Chapter 21 dispute resolution procedures.

My concern is that the haste with which this legislation is progressing might lead to this policy choice being delegated to technical experts in finance, or working groups with private interests, rather than being made part of a systematic public debate about the kind of health care system all Australians want to have, and the trade-offs they are prepared to make against strategic objectives of trade or international public policy.

If the Australian regulatory and policy environment for medicines continues to further resemble the inequitable US system, we will similarly have unaffordable innovative products and worse health outcomes (despite low-cost generics) for citizens lacking private insurance with extensive coverage.

Competing interests

I am Director of an Australian Research Council (ARC) grant investigating the impact of international trade agreements on Australian medicines policy. The ARC was not involved in writing this paper.

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