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Impact of the Australia-US Free Trade Agreement on the Australian Medicines Regulation and Prices

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Impact of the Australia–US Free Trade Agreement on the Australian medicines regulation and prices

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ABSTRACT The Australia–United States Free Trade Agreement (AUSFTA) came into force on 1 January 2005. Before and subsequently to the AUSFTA being concluded, controversy surrounded the debate over its impact on Australia's health policy, specifically on regulation of pharmaceutical patents and Australia's cost-effectiveness system relating to prescription medicine prices known as the Pharmaceutical Benefits Scheme (PBS). This article examines the expectations of both parties in the pharmaceutical sector with regard to the AUSFTA, as well as how successfully they were achieved. It seeks to analyse important relevant outcomes for regulators, the public and pharmaceutical industry, as well as lessons about how trade negotiations relating to health and medicines policy should be approached in future. To investigate whether AUSFTA-related regulatory changes may lead to higher medicines prices in Australia, we looked at recent PBS Public Summary Documents to discover examples of PBS-approved F1 (patented) drugs, over the period from July 2008 until June 2009, that failed to establish cost-effectiveness over F2 (generic) comparators (with mandated price cuts) and were thence cost-minimised. This period was chosen because the major price effects of the potentially AUSFTA-related *National Health Amendment (Pharmaceuticals Benefits Scheme) Act 2007* (Cth) came into effect from August 2008.

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INTRODUCTION

The Australia–United States Free Trade Agreement (AUSFTA) came into force on 1 January 2005.[1] Controversy has surrounded the debate over its likely impact on Australia's

health policy, specifically that relating to prescription medicine prices, as well as regulation of pharmaceutical patents and Australia's cost-effectiveness system known as the Pharmaceutical Benefits Scheme (PBS). What can be said for sure is that it is out of all proportion to the reciprocal changes (if any) required by the AUSFTA to US domestic policy in the same regulatory areas.

This article makes the case that Australia's medicines pricing system has undergone significant regulatory change as a result of the AUSFTA. It will investigate the idea that positive outcomes have included an increase in PBS transparency and the establishment of 'objectively demonstrated therapeutic significance' as an alternative to 'competitive markets' in the definition of pharmaceutical innovation.

The case will be made that legislative changes to Australian pharmaceutical regulation ascribed directly to the AUSFTA offer a more defined outcome than medicines price changes. The latter, it will be maintained, are influenced by a wide range of variables and will take time to aggregate into a significant impact on the Australian public purse.[2] One argument advanced here is that AUSFTA-initiated Australian legislative changes are likely to increase prices for patented medicines and reduce incentives for generic medicines firms to establish and expand in Australia, particularly by promoting 'evergreening' and by diluting PBS reference pricing. Both of these factors, it will be contended, from the point of view of the Australian public, may lead to a scientifically unjustifiable divergence of prices between patented drugs and already marketed comparitors against which those patented medicines have been proven to have only equivalent cost-effectiveness. Finally, by looking at the expectations of both parties before AUSFTA, as well as whether they were successfully achieved, the article aims to gather important lessons about how trade negotiations relating to health and medicines policy should be approached by Australia in future.

EXPECTATIONS

Before negotiating the substantive details of the AUSFTA, US negotiators were provided with clear objectives regarding Australia's pharmaceutical regulation and, specifically, the PBS. These included the 'elimination of government measures such as price controls and reference pricing'.[3] Also sought were the extension of Australian pharmaceutical patent life based on delayed marketing approval and parallel importation prohibitions.[4] Another US negotiating objective emerging from the IFAC-3 industry-trade advisory committee was that reward for pharmaceutical 'innovation' would become a major principle of Australian pharmaceutical regulation through linkage with a non-violation nullification of benefits (NVNB) lobbying provision. A further US objective (also arising from IFAC-3 discussions) was that Australian drug safety regulators (like their Canadian counterparts under the *North American Free Trade Agreement*) be required to notify current pharmaceutical patent holders of impending generic drug market entries.[5] The US negotiators had expectations that the Australian PBS evidence-based cost-effectiveness system would become more transparent and have an appeals process, as well as that opportunities would arise for privatisation of blood fractionation in Australia.

On the Australian side, negotiators took an essentially defensive stance. They sought no direct and specific reciprocal changes to US pharmaceutical policy (which they could have done), but instead placed greater emphasis upon preserving the essential elements of Australia's pharmaceutical cost-effectiveness regulatory system.[6]

> 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.[7]

Another core Australian expectation was preventing anticompetitive business behaviour that was specific to the pharmaceutical sector (for example, business and legal strategies amounting to 'evergreening' of soon-to-expire pharmaceutical patents).[8]

> We are not importing the Hatch-Waxman legislation into Australian law as a result of the free trade agreement … [Article 17.10.4] will not extend the time of the marketing approval process, and it does not add or provide any additional rights to the patent holders in that process … there is no injunction that can be applied under this article … .[8]

Australia's overall expectation about this sector was that it would receive commensurate returns for including the PBS in the AUSFTA, but that there would be no fundamental change to the Australian PBS cost-effectiveness processes (including reference pricing). The Australian government expected that the Pharmaceutical Benefits Advisory Committee (PBAC) would now have a 'review' but not an 'appeals' process. It expected that AUSFTA Annex 2C would not promote direct-to-consumer drug advertising in Australia and that a review would determine if privatisation of Australia's blood fractionation was in Australia's national interest. Australia expected that the competing definitions of pharmaceutical 'innovation' in Annex 2C would not override Australia's *National Medicines Policy*. Australia also had an expectation that NVNB provisions, particularly those linked to AUSFTA obligations related to Australian domestic health and medicines policy, would be restricted by the international law principle of good faith treaty interpretation.[9]

Australia introduced 'anti-evergreening' amendments to the *Therapeutic Goods Act 1989 (Cth)* as part of its AUSFTA implementing legislation. The US negotiators protested at this legislative confirmation of Australia's 'anti-evergreening' AUSFTA expectations (despite it being a legitimate specific problem in a particular industry sector).

> If Australia's law is not sufficient to prevent the marketing … where the produce or use is covered by a patent, Australia will have acted inconsistently with the Agreement. We also remain concerned about recent amendments to sections 26B(1)(a), 26C and 26D of the *Therapeutic Goods Act* of 1989. Under these amendments, pharmaceutical patents owners risk incurring significant penalties when they seek to enforce their patent rights. These provisions impose a potentially significant, unjustifiable, and discriminatory burden on the enjoyment of patent rights.[10]

LIVING UP TO EXPECTATIONS?

The AUSFTA resulted in many well-acknowledged statutory changes to Australian medicines policy.[2] AUSFTA Article 17.10.4, as mentioned, required as part of the AUSFTA implementing legislation a new s26B(1) *Therapeutic Goods Act* 1989 (Cth). This created a 'linkage' obligation for Australia's drug safety regulators to ensure the provision of certificates that any new generic market entrant has notified the patent holder, or will not infringe the relevant pharmaceutical patent. The same Act also contained (in a new s26C) a penalty for 'evergreening' and (in a new s26D) a mechanism for damages to be paid to the Australian federal government (which funds the PBS) for proven 'evergreening'. These were, as mentioned, all part of AUSFTA implementing legislation passed before the AUSFTA came into force. As the United States objected to some of these 'anti-evergreening' legislative protections but nevertheless entered the AUSFTA, the former can be regarded as a unilateral interpretive declaration of Australian legitimate expectations in this sector.

In subsequent legislation in 2006, the *Patents Act 1990 (Cth)* was amended so that springboarding of generics was locked in (s119A). Whether this was intended to or actually adequately counterbalanced the inhibiting effect of the above-mentioned AUSFTA 'linkage evergreening' changes is doubtful. As will be explained, the mix of post-AUSFTA legislation does not appear to have encouraged new generic companies to establish and/or expand research facilities in Australia.

Other unequivocally AUSFTA-initiated Australian domestic health policy changes related to transparency of the PBS process. These included the creation of Public Summary Documents (PSDs) about PBAC decisions. Pharmaceutical companies are now starting to refer to past PSDs in new submissions to cite the use of methodologies. Each PBAC agenda is now published and individuals and patient groups now can go to PBAC website and make comments about impending PBAC reviews. Another definite AUSFTA-related change has involved the creation of an independent review mechanism, this being a PBAC quality assurance exercise rather than an appeal process. This review process now has been utilised in regard to two drugs: teriparitide and imiquimod. In both of those cases the review organised by the independent convenor supported the relevant PBAC decision.

In relation to Australian blood fractionation, the Australian Flood Committee, established as a result of the AUSFTA, recommended against privatisation, and the Australian states additionally refused to agree to that outcome. The reason in each case was chiefly because biosecurity had become a major concern in relation to any move towards off-shore fractionation on Australian blood. Also relevant were unresolved safety concerns about paid blood donors and the importance of continuing voluntary blood donation to the Australian social fabric.

A more problematic area was the potential influence of the competing definitions of pharmaceutical 'innovation' inserted in AUSFTA Annex 2C.1. The then Australian Minister for Trade stated in relation to Annex 2C of the AUSFTA that 'the core principle that we both agree on in this area … is recognising the value of innovation'.[11] This begged the question, however, as Annex 2C.1 contained two competing definitions of pharmaceutical innovation. The first such definition required valuing pharmaceutical innovation through competitive markets (the US approach). The second permitted valuing pharmaceutical innovation through the operation of objectively demonstrated therapeutic significance (the Australian approach).[9] Australia's overall expectation in this respect (that domestic medicines policy would continue to be governed by the four principles of the *National Medicines Policy*) has not altered. The four key pillars of the Australian *National Medicines Policy* remain:

- timely access to the medicines that Australians need, at a cost that individuals and the community can afford;
- medicines meeting appropriate standards of quality, safety and efficacy;
- quality use of medicines; and
- maintaining a responsible and viable medicines industry.[9]

The Australian expectations in this respect are consistent with Australia's evidence-based concept of community value from pharmaceutical innovation underpinning all four points of the *National Medicines Policy*.

In relation to the PBS itself, some Australian legislative changes do not appear to sit logically with public statements about ensuring the integrity of the PBS evidence-based cost-effectiveness assessment process. A Freedom of Information application with regard to the AUSFTA Medicines Working Group (MWG) inaugural meeting points to an AUSFTA connection with 2007 Australian legislation limiting PBS reference pricing.

It revealed, for example, that an opinion editorial had been discussed at the MWG, which argued that innovative new pharmaceuticals submitted for PBS listing should be reference priced against innovation in other classes, rather than against generics.[9] The second meeting of the MWG on 30 April 2007 discussed the new F1 category, which as a result of intervening Australian legislation had now been structured along the lines proposed in the editorial the MWG had discussed at their previous meeting.[9]

Q3 As a result of the 2007 legislative amendments, from August 2008 new sections 85AB and 85AC to the *National Health Act 1953 (Cth)* fractured the PBS formulary into an F1 category (for prescription medicines with no 'bioequivalent brands', mostly patented medicines) and an F2 category, mostly for generic medicines. Compulsory price drops were imposed for drugs in the F2 category. There was to be no reference pricing between the two categories, and new reference-pricing groups would have to satisfy the criteria of 'interchangeable on an individual patient basis' (new sections 84AG and 101 [3BA]).

Under the F1-F2 PBS system, reference pricing still operates for specific categories of single brand drugs 'interchangeable on an individual patient basis' with multiple brand medicines, for example ACE inhibitors, angiotensin II receptor antagonists, calcium channel blockers, H_2 receptor antagonists, proton pump inhibitors, HMG Coenzyme A reductase inhibitors (pravastatin and simvastatin only). Reference pricing also continues to operate where enhanced cost-effectiveness is not established for a new drug submitted for PBS listing; the PBAC moves to cost-minimisation and the comparator happens to also be in the F1 (this happened recently for the sidenifil for pulmonary hypertension). But if one of those F1 drugs later moves to F2 (with compulsory price drops), there will be no reference pricing, and Australian taxpayers could well end up paying differing amounts for drugs with the same cost-effectiveness. New therapeutic groups for reference pricing can still be created and this happened in a recent Federal budgetary measure for atorvastatin and rosuvastatin.

These legislative changes have restricted the evidence-based nature of the PBS cost-effectiveness system. Thus, they could well provide an example of the AUSFTA (or public or covert negotiations related to it) appearing to facilitate (if not directly require) regulatory changes that did not live up to public statements about Australian expectations about ensuring the integrity of PBS processes.

IMPACT OF REFERENCE PRICING CHANGES ON MEDICINES PRICES

The argument that the AUSFTA has led to higher medicines prices in Australia is predicated on at least two controversial assumptions. The first (mentioned previously) is that the US negotiators' desire to see Australian PBS reference pricing altered somehow translated, either through covert higher-level governmental arrangements or the AUSFTA MWG, into the 2007 F1-F2 PBS amending legislation. The second, assuming the validity of the first, is that these AUSFTA-promoted F1-F2 PBS changes have put in place a mechanism that will in time lead to higher Australian medicines prices.

The most obvious place to find such a potential AUSFTA-initiated difference is to look at cost-minimised F1 drugs (no proven cost-effectiveness) that have been through the PBAC process with an F2 comparitor since the PBS formulary was fractured into the F1 and F2 categories. Thus, we looked at the PSDs to discover examples of PBS-approved F1 drugs with F2 cost-minimisation comparators (be they F2A or F2(T)) over the period from July 2008 until June 2009. These times were chosen, as the major price effects of the *National Health Amendment (Pharmaceuticals Benefits Scheme) Act 2007* came into effect from August 2008.

Using Medicare Australia's public data, the aggregate services (based on the number of prescriptions filled) and overall Government contribution for the service of these specific drugs (the F1-approved drug and its F2 comparator) products was collected and analysed for such examples. An Average Cost to the Government was discerned based on Total Government Cost divided by Total Services. The analysis of these results included an examination of the equi-effectiveness of each cost-effective pair and, more importantly, the clear differences in average price to the Government. This analysis thus aimed to provide case studies of differences in the potential Government cost that could have been saved under the previous reference pricing system before the F1/F2 bifurcation process in 2007.

Tables 1 and 2 provide illustrative examples of two such cost-minimisation drugs approved for PBS F1 listing after the F1/F2 reforms: Levetiracetam and Pramipexole. Levetiracetam was approved for extension of listing in the PBS F1 category to include treatment of primary generalised tonic clonic seizures and generalised myoclonic seizures in November 2008. Pramipexole was approved for listing without restriction in the PBS F1 category to allow use as monotherapy (early stage) or in combination with levodopa (advanced disease) in July 2008.

Q4 Both drugs were progressed initially through expert PBAC evidence-based evaluation of their 'health innovation' (objectively demonstrated therapeutic significance) with close comparators in the F2(T) category (Lamotrigine for the former and Bromocriptine for the latter). Levetiracetam was found to have a therapeutic equivalency of 2887 mg to every 296 mg of Lamotrigine. Pramipexole was determined to possess a therapeutic equivalency of 2.8 mg to every 20.8 mg of Bromocriptine. As may be seen from Tables Q5 1 and 2, each F1 drug had an overall higher average cost per unit to the Australian Government (and thus the Australian taxpayer) than drugs thatg expert assessment of pharmacoeconomic evidence had shown offered clinically equivalent efficacy and safety. This is not a rational divergence, that is, there is no logical or transparent reason for this divergence in price. If such divergence becomes a significant feature of the PBS, then (given the assumptions mentioned earlier) it will confirm a significant negative impact on the evidence-based nature of Australian medicines policy and potentially on the prices to government (the Australian taxpayer) for F1 category PBS-listed prescription medicines.

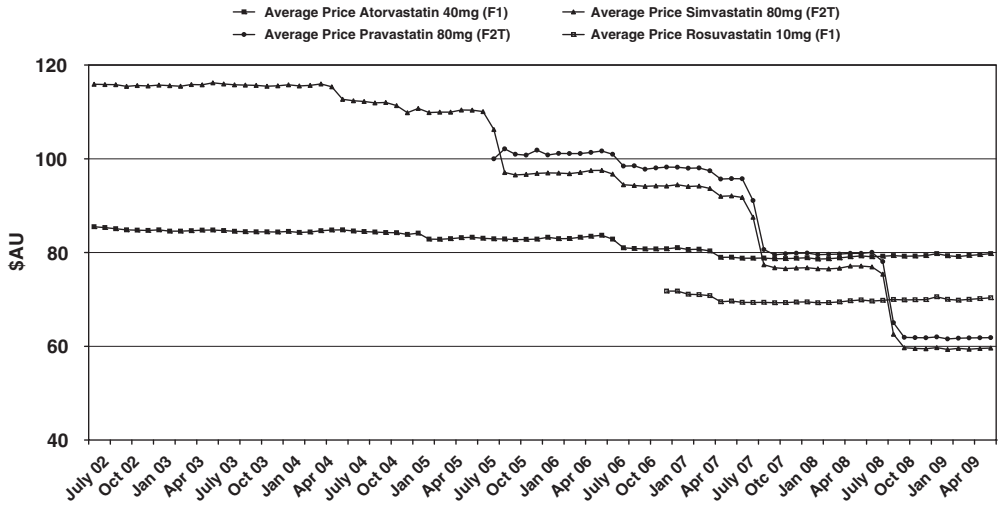
Additionally, the following two graphs Q6 (Figures 1 and 2) show changes in overall Average Price of major drugs in different Anatomical Therapeutic Chemical (ATC) groups. Here, Average Price represents Total Cost to government and patients (the latter collectively via co-payments), divided by Total Number of Prescriptions. The figures depict the differences in Average Price trends within one ATC group between those classified as F1 and F2 drugs.

Table 1: Example of cost-minimisation drug approved for PBS F1 listing after the F1/F2 reforms – Levetiracetam

	Volume of prescriptions	*Total Government Cost*	*Average Cost to government per unit*
Levetiracetam (F1)	160994	20448127	127.0117334
Lamotrigine (F2(T))	184092	16034860	87.10242705

Table 2: Example of cost-minimisation drug approved for PBS F1 listing after the F1/F2 reforms – Pramipexole

	Volume of prescriptions	*Total Government Cost*	*Average Cost to government per unit*
Pramipexole Hydrochloride (F1)	43079	2750903	63.85716939
Bromocriptine (F2(T))	14062	564320	40.1308491



Q9 **Figure 1**: Lipids average price, 10–14 July 2002 to 10–14 June 2009.

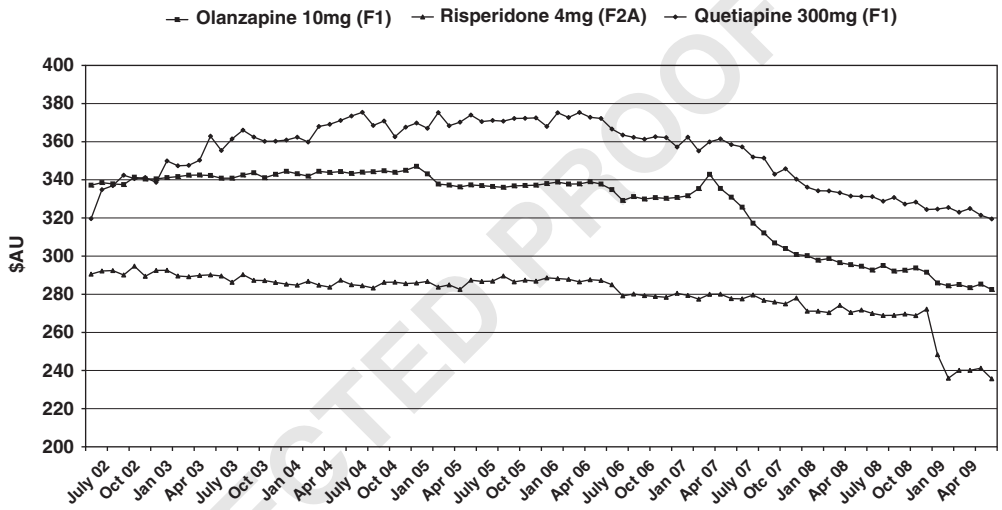


Figure 2: Psycholeptics average price, July 2002 – June 2009.

Figure 1 shows the Average Price changes in Serum Lipid Reducing drugs. Of these, Atorvastatin and Rosuvastatin are F1 drugs, whereas Simvastatin and Pravastatin have been classified within F2(T). Remembering that these are medications with closely aligned clinical and cost-effectiveness, it can be seen that, over time, government and patients have been paying an increasingly disproportionate amount for the F1 classified medications without the necessary (according to the *National Health Act 1953* (Cth)) expectation that they are paying for increased cost-effectiveness (or a greater level of objectively demonstrated therapeutic significance).

Figure 2 shows the Average Price changes in Psycholeptic drugs. Of these, Olanzapine and Quetiapine are F1 drugs, while only Risperidone is an F2(A). Figures 1.3 and 1.4 Q7 show changes in overall Average Price of major drugs in different ATC groups. Q8

Here again, Average Price is Total Cost to government and to patients (via co-payments), divided by Total Number of Prescriptions. The figure depicts the differences in Average Cost trends within one ATC group between those drugs in this class classified as F1 and F2. The increasing divergence once more is due to the creation of the F1-F2 category and is not an outcome of increased scientifically proven cost-effectiveness of drugs in the F1 category. To the extent that the F1-F2 bifurcation is an outcome of the AUSFTA (and this remains contentious so long as detailed minutes of the AUSFTA negotiations and MWG meetings are unavailable) then this presumptively represents a negative AUSFTA impact on Australian medicines prices that is likely to continue and be exacerbated.

IMPACT OF EVERGREENING REGULATORY CHANGES

Pharmaceutical evergreening is a concept of legal sociology rather than patent law. It describes a wide range of tactics whereby rent can be prolonged from soon-to-patent-expire pharmaceuticals.[12]Examples of 'evergreening' tactics include potentially misleading or deceptive advertising; patent extensions for delayed regulatory approval (in the absence of criteria requiring that the manufacturer did not itself prolong the regulatory process); data exclusivity claims (which impede access of generics to the safety data disclosed to regulators that they need to prepare for 'springboarding' into the market on patent expiry); threatened or actual legal action against generics; licensed generics and 'keep out' payments to generics and patent claims over incremental product modifications with marginal obviousness.[12]

Most of the 'evergreening' debate about the AUSFTA involved the so-called 'linkage evergreening' provision in article 17.10.4 of the AUSFTA. This, in effect, required Australia's drug safety regulators to check whether a generic drug was infringing a patent. As mentioned, the inclusion of this so-called TRIPs-Plus provision provoked Australian 'anti-evergreening' legislative amendments.[12] This, in turn, provoked criticism from the United States.[10] It is difficult to see that the US criticism is justified by international trade law. It is well recognised that the World Trade Organisation TRIPS agreement permits regulation of problems (such as 'evergreening') that arise primarily in one industry sector.[13]

Data-exclusivity protections (the period, as mentioned, that a regulatory agency (for example the US FDA or Australian TGA) cannot access data from original patented drug when considering application by a generic manufacturer) were in place in Australian legislation prior to the AUSFTA as a result of the *Therapeutic Goods Act 1989* (Cth) s25A (though article 39.3 of TRIPS only obliged regulators to protect against unfair commercial use of confidential data on new chemical entities). AUSFTA article 17.10.1 (a) 'locked-in' this requirement, although only at levels allowing a maximum of 5 years data exclusivity from the date of TGA approval.

The AUSFTA also included 5 years potential extra patent terms for delayed marketing approval (provided the delay was not due to the manufacturer failing to meet pre-existing regulatory requirements). The AUSFTA failed to include (but did not prevent) the capacity for generic manufacturers in Australia to manufacture product under patent for sale in overseas jurisdictions where the patent had expired. The Australian government, as mentioned, did pass legislation allowing springboarding of generic medicines. The creation of a PBS with an F1 category for patented drugs and an F2 category for generics (with compulsory price drops), however, may nullify much benefit from the 'springboarding' legislation by encouraging 'evergreening' tactics to keep medicines in the F1 category.

There have been no cases as yet where AUSFTA-related 'evergreening' provisions have directly resulted in the inhibition of

generic market entry. *Alphapharm Pty Ltd* v. *H Lundbeck A/S (2008) 76 IPR 618; [2008] FCA 559* was a case involving a generic purified racemate enantiomer in which the new certification arrangements for generic market entry and data exclusivity protections did appear to have an inhibiting effect.[14]

Taken as a whole, definite AUSFTA-related changes to Australian pharmaceutical intellectual monopoly privileges (IMPs) (such as extra patent terms for delayed marketing approval), as well potential AUSFTA-related regulatory changes such as the new F1-F2 categories have made the task of achieving profit in the Australian generic market more difficult. The compulsory F2 price drops, for example, are a major factor in profitability, given the small size of the market in Australia. Many AUSFTA-related changes in fact appear to have contributed to an unwillingness of generic manufacturers to establish research facilities in Australia, or to invest substantially in such facilities.[15]

LESSONS AND PROBLEMS THAT REMAIN

Five years after the AUSFTA, the Australian PBS system remains a world class example of evidence-based pharmaceutical cost-effectiveness analysis. Nevertheless, in relation to the fracturing of the PBS formulary and reduction of reference pricing we are left supporting the conclusion that the 'creation of the F1 category is likely to, over time, result in higher prices for some patented drugs than would have been the case under previous pricing arrangements'.[15]

In the face of ongoing lobbying by the multinational patented pharmaceutical industry strong ongoing Australian governmental, administrative and academic vigilance is required to protect its essential elements, particularly that of seeking a fair balance between price and proven community benefit in relation to public expenditure on medicines under section 101(3B[a]) of the *National Health Act 1953 (Cth)*. This will be particularly true in relation to prevention of pharmaceutical patent 'evergreening' in Australia and may necessitate the creation of a specialist multidisciplinary oversight regulatory body such as that operating in the same area under the aegis of Health Canada.

One benefit of the AUSFTA to global medicines policy (probably unexpected by the multinational patented pharmaceutical industry) is that Annex 2C.1 emphasised a choice of alternate definitions of pharmaceutical innovation. The first was the principle of valuing pharmaceutical innovation through the operation of competitive markets. This was the US negotiating position that requires (and permits) strong anti-trust laws to be effective. Strengthening of Australian laws against fraud and anti-competitive behaviour in the pharmaceutical industry could be a particularly positive outcome of the 'competitive markets' definition of pharmaceutical innovation of Annex 2C.1 of the AUFSTA.

The second (the Australian position) was that pharmaceutical innovation could also be valued by adopting or maintaining procedures that appropriately value objectively demonstrated therapeutic significance (requiring and permitting regulatory processes for expert evaluation of pharmacoeconomic evidence related to such 'health innovation'). As such, AUSFTA Annex 2C.1 now not only helps preserve the core science-based processes of the PBS system, but also helps frame the global debate on determining health technology innovation.

One illustration of this can be seen in Article 5.2 of the Korean–US Free Trade Agreement (KORUSFTA). The Koreans, having witnessed the debate over the PBS in the AUSFTA, determined to create regulatory space in the KORUSFTA for subsequent creation by them of a similar cost-effectiveness pharmaceutical evaluation process.[9]Article 5.2 KORUSFTA, after recognising each nations' 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 recognise the value of patented pharmaceutical products (Article 5.2 [b][i]). KORUSFTA 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.

The 2009 Kennedy Report on Valuing Innovation in NICE Assessments is directly relevant to debates such as that under the KORUSFTA about how to value pharmaceutical innovation. It strongly promotes, for example, what is in effect the Australian, PBS evidence-based approach to assessing and valuing innovation through expert assessment of objectively demonstrated therapeutic significance. The Kennedy Report recommends disinvestment or compensation to the government if an alleged innovative product fails to offer value or meet expectations made when being evaluated for public funding. It recommends a working definition of pharmaceutical innovation, emphasising scrutiny of whether the relevant product significantly and substantially improves the way that a current need (including supportive care) is met.[16] Other commentators have recently reinforced this approach by supporting the view that empirical research suggests that patents are an ineffective incentive for innovation generally.[17]

In the meantime, pressure is likely to continue to be placed on the Australian government by the USTR through invocation (not necessarily with logical or justifiable legal support) of the AUSFTA linkage between medicines-related provisions and NVNB claims. This is most likely to arise from 'behind doors' lobbying using veiled threats of cross-retaliation (threatening a trade dispute in one trade area to obtain a result in a different sector) if planned or existing domestic policy is perceived to breach the 'spirit' of the relevant bilateral trade agreement. Formal dispute resolution proceedings may never be initiated or be intended to commence in such situations. Indeed, this type of use of NVNB claims is contrary to basic principles of international law.[18] This is because such usage falls outside the five requisite elements of a NVNB claim identified by WTO Dispute Resolution Panels: (1)that a 'measure' has been applied by a party subsequent to the entry into force of the relevant trade agreement; (2) that a 'benefit' was reasonably expected by the other party as being negotiated in return for some textual agreement; (3) that as a result of the application of the measure that benefit has been 'nullified or impaired'; (4) that the nullification or impairment was contrary to the legitimate or reasonable expectations of the complainant at the time of the negotiations; and (5) that such claims will only be used in extremely rare circumstances (for example proven bad faith during negotiations), due to their capacity to upset the certainty of the international trading order.[18]

Although provisions of the AUSFTA have resulted in some improvements to transparency in PBS processes (such as PSDs), other changes have not been so positive. The Pharmaceutical Benefits Pricing Authority Therapeutic Relativity Sheets, for example, in August 2007 included details of pricing arrangements. The December 2007 versions, however, merely contained the generic statement 'Special pricing arrangements apply'.[19]

Challenges that lie ahead for Australian medicines policy include increasing post-marketing surveillance and ceasing to disclose generic competitors price offers to others.[15] Data exclusivity will continue to be a problem for Australian medicines regulation and for the generic pharmaceutical industry. It hampers springboarding and compulsory licensing. The extent to which it is justified in hindering or preventing such wholly legal activities is likely to be the subject of trade

dispute proceedings in the future. Data exclusivity appears likely to be pushed to 12 years in the United States, and the Australian government may soon be lobbied to follow suit (again, not necessarily with any sound legal or evidentiary justification).[20]

The AUSFTA medicines provisions, particularly the support they indirectly provide to the continuance of the PBS as an evidence-based system for pharmaceutical cost-effectiveness assessment may begin to have an unintended positive influence on US health policy debate. A recent academic survey of drug regulation is the United States, Europe and Australia, for example, recommended that 'well defined and consistent comparative effectiveness research is a much more rational and predictable way for payers to make purchasing decisions than for administrators to impose price cuts arbitrarily, to shift costs to individual patients, or to ration needed technologies and services according to ability to pay'.[21]

Another positive outcome of the AUSFTA medicines debate may be that Australian negotiators of medicines provisions in subsequent trade agreements will generate a more positive agenda through association with the equivalent of a generic industry functional advisory committee. Such a committee, for example, might be instrumental in promoting the idea of export-under-patent provisions and processes and committees for sharing of safety and cost-effectiveness expertise in the impending trade deals between Australia and (respectively) India, Japan, South Korea and China.

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