

Preferential Trade Agreements and National Medicines Policies: a comparison of the AUS-FTA, KORUS-FTA and negotiations for the CHINA-AUSFTA.

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Abstract

This paper, for the first time, compares the controversial medicines provisions in the two important United States preferential trade agreements: with Australia and with South Korea. It examines the forces behind them and their likely impacts. It also investigates why, despite what appear to be strong positive social and financial reasons for doing so, Australia appears to lack interest in negotiating any favourable medicines provisions in its impending trade negotiations with China. The argument presented here is that these medicines provisions provide a useful case study of the extent to which what are nominally termed free trade agreements are actually preferential, pro-corporate monopolistic deals involving probable deleterious impacts on public health.

Introduction

The recent Australia-United States Free Trade Agreement (AUS-FTA) was the first time a part of what is euphemistically termed a free trade agreement (FTA) was used to restrict a public pharmaceutical pricing reimbursement scheme, and hence impact on Australian national health policy. The case has elsewhere been made that Annex 2C and various intellectual property protections in Chapter 17 of the AUS-FTA arose as a result of intense and successful lobbying from the U.S patented pharmaceutical industry.¹ While Annex 2C does not contain any explicit provisions favouring patented drugs over

¹ Faunce T, Doran E, Henry D, Drahos P, Searles A, Pekarsky B, Neville W, "Assessing the impact of Australia-United States Free Trade Agreement on Australian and global medicines policy" 2005 Glob & Health 1:15, Senate Select Committee report p107.

generics, it has been suggested to have facilitated recent amendments hindering price referencing within the Australian Pharmaceutical Benefits Scheme (PBS).² The pro-monopolistic and anti-free trade role of the so called TRIPS-plus provisions in Chapter 17 is equally controversial.³

Korea has also just entered into an FTA with the US (KORUS-FTA), containing a chapter on pharmaceuticals similar to Annex 2C and an intellectual property chapter with so-called TRIPS-plus provisions similar to Chapter 17 of the AUSFTA . While some concessions were gained, both are widely regarded as being even more burdensome and intrusive than the AUS-FTA. The KORUS-FTA medicines chapter targets the Korean drug price formularies in a similar manner to the PBS and achieves an even clearer articulation of policy and regulatory preference for patented medicines over generic pharmaceuticals.

An FTA between Australia and China is currently being negotiated and pharmaceuticals have so far not been included in talks. This is remarkable given that China is predicted to become the second largest producer of pharmaceuticals by 2020 and already produces a substantial proportion of the active product ingredients (APIs) for Australian pharmaceuticals.⁴ Given the growing size of China's generic pharmaceutical industry and Australia's comparative advantage in regulatory, niche drug discovery and clinical trials expertise, there is evidence to suggest that the inclusion of a pharmaceuticals chapter and some protections for generics in the intellectual property chapter would greatly benefit both parties.

This paper aims to analyse and compare the pharmaceuticals and IP provisions of the AUS-FTA and KORUS-FTA through an examination of the negotiations leading up to the agreements, the final texts, and their impacts on domestic health policy. The success

² Faunce T, "Reference pricing for pharmaceuticals: is the Australia-United States Free Trade Agreement affecting Australia's Pharmaceutical Benefits Scheme?" 2007 MJA 187(4).

³ Faunce T, Lexchin J, "'Linkage' pharmaceutical evergreening in Canada and Australia" 2007 Australia and New Zealand Health Policy 4:8.

⁴ Zhou EY, "China Pharma Basking in its Spotlight" 2007 Genetic Engineering and Biotechnology News 27(5) <http://www.genengnews.com/articles/chitem.aspx?aid=2049&chid=4> accessed September 2007.

of each party's trade agenda and goals will be considered, as well as the extent to which the US pro-competitive free market trade agenda was successful in impacting national medicines policies. The positive and negative ways in which trade deals influence domestic health policy will be analysed through these examples, as well as the means by which Australia can strengthen its role in negotiations to ultimately achieve the best healthcare outcome. Finally, China's pharmaceutical industry will be discussed in light of the potential for its inclusion in an FTA with Australia.

1. Background to the AUS-FTA Medicines Provisions

This initial section seeks to examine how the Australian government came to agree to including its domestic medicines policy in a preferential trade deal, something that no developed nation had previously agreed to do. This will form the foundation for a comparison in the following section of the relevant provisions in the KORUS-FTA and the AUS-FTA. In negotiating the pharmaceuticals chapter of the AUS-FTA, particular attention was paid to the PBS, particularly its drug price reimbursement mechanisms. In order to understand the FTA negotiations and resulting text, it is therefore necessary to consider the functioning of the PBS.

The PBS

The PBS has long been recognised as a successful articulation of Australia's public health policy and values. Based on principles of the National Medicines Policy, it has been operating for over half a century to provide fast, effective and affordable access to healthcare for Australians.⁵ The success of the PBS pricing and listing mechanisms could be seen through lower average pharmaceutical prices compared with other developed

⁵ See Australian Government, "National Medicines Policy and the PBS statement" <http://www.health.gov.au/internet/wcms/publishing.nsf/Content/health-pbs-general-govtpolicy.htm-copy2> accessed September 2007.

countries,⁶ resulting in both taxpayers and consumers paying less for listed drugs. It is also popular with the public as listed medicines are available for a relatively low co-payment of approximately AU\$30.⁷

The low costs of medicines are achieved through the PBS pricing and listing mechanisms, parts of which have recently been amended. Before a new patented drug is listed, it must obtain marketing approval from the Australian Therapeutic Goods Administration (TGA). Once this is done, the supplier may apply to have it listed on the PBS to an independent statutory committee – the Pharmaceutical Benefits Advisory Committee (PBAC) set up under the *National Health Act 1953*. It is required to consider applications against certain criteria set out in the legislation. For example, 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.”⁸ If the PBAC recommends against listing a particular pharmaceutical, the manufacturer can still access the market and promote its product, however the consumer will have to pay a higher out-of-pocket price.

Reference pricing, which has been impacted by the recent amendments (to be discussed below), then allows the Pharmaceutical Benefits Pricing Authority (PBPA) to recommend a reimbursement price – that is the maximum amount the government will reimburse to pharmacists. This is determined by reference to the price of similar medicines already listed on the PBS, thereby avoiding high prices for new drugs which offer no new substantial benefits.⁹ It is an evidence-based system of evaluating pharmaceutical innovation on the basis of objectively demonstrated therapeutic significance, in line with the central Australian National Medicines Policy objectives:

⁶ Australian Government Productivity Commission, International Pharmaceutical Price Differences Research Report July 2001, p6. <http://www.pc.gov.au/study/pbsprices/finalreport/> accessed September 2007.

⁷ See <http://www.health.gov.au/internet/wcms/publishing.nsf/Content/health-pbs-general-howmuch.html-copy2>, accessed September 2007.

⁸ *National Health Act 1953, section 101(3B(a))*.

⁹ Sansom L, “The subsidy of pharmaceuticals in Australia: processes and challenges” 2004, 28(2) *Australian Health Review* 194.

- timely access to the medicines that Australians need, at a cost 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.¹⁰

The negotiations

It is important to recognise the background to this Annex of the FTA in order to understand its function. This is best achieved by reference to the negotiation process, including particular agendas, values and intentions articulated by both parties.

A major concern for Australian negotiators regarding the pharmaceuticals section of the FTA was stated by the government to be the preservation of the PBS. The extent to which this was taken seriously can be seen through statements made before the Senate Committees on the FTA, and through the final report of the Senate Select Committee on the Free Trade Agreement between Australia and the United States of America¹¹ (Select Committee report). The report states that most submissions to the inquiry were explicitly against the PBS being a part of any trade negotiations. The committee also agreed that “as a core social policy in Australia, the PBS should never have been on the negotiating table.”¹² The senate report also considered statements from some members of the US congress who clearly stated that trade negotiations should not be used to interfere with national health systems of other countries, and that domestic health policy should not be a part of any trade agreements.¹³ 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

¹⁰ Australian National Medicines Policy objectives, <http://www.health.gov.au/internet/wcms/publishing.nsf/Content/nmp-objectives-policy.htm> accessed September 2007.

¹¹ Senate Select Committee on the Free Trade Agreement between Australia and the United States of America, Final Report, 2004. http://www.aph.gov.au/Senate/committee/freetrade_ctte/ accessed September 2007.

¹² Senate Select Committee report, p102.

¹³ Senate Select Committee report, p102.

evidence to suggest that it was an issue from the very first round of negotiations or ‘discussions’.¹⁴

This is not surprising, as the US position on what it views as ‘price control mechanisms’ such as PBS reference pricing has been clear both through positions stated in negotiations, as well as through legislated agenda. For example, §2102(b)(8)(D) of the (US) Trade Act of 2002 lists, as one of its principal negotiating objectives, “*to achieve the elimination of government measures such as price controls and reference pricing which deny full market access for United States products.*” It was therefore imperative for US negotiators to attempt to target reference pricing within the PBS. US senators have made many references to the fact that Australians do not value “innovative” pharmaceuticals, which hinders the ability of manufacturers to recover their research and development costs.¹⁵ Although this theory has been disputed,¹⁶ as will be shown, it is still influential in US policy and has strongly influenced the KORUS-FTA. There is also evidence to suggest that in negotiating the pharmaceutical chapter of the AUS-FTA, the generic pharmaceutical industry was not consulted equally by the Australian negotiators, compared with the attention given to the multinational patented pharmaceutical industry by US negotiators.¹⁷ This is particularly evident in light of some of the intellectual property provisions agreed upon in chapter 17 of the AUS-FTA, including those relating ‘linkage evergreening’ which opposes the interests of the generics industry by hindering their access to the market.

¹⁴ The PBS was not discussed in official ‘negotiations’ but rather in what was called ‘discussions’ – see Senate Select Committee report, p103.

¹⁵ For example see Testimony of Deputy U.S. Trade Representative Josette Sheeran Shiner before the Committee on Finance Subcommittees on Health Care and International Trade United States Senate April 27, 2004, http://www.ustr.gov/assets/Document_Library/USTR_Deputy_Testimony/2004/asset_upload_file843_4364.pdf?ht= accessed September 2007.

¹⁶ Lexchin J, Light D W, “Foreign free riders and the high price of US medicines” 2005 BMJ 331 958-960.

¹⁷ Faunce T, “Challenges for Australia’s Bio/Nanopharma Policies: trade deals, public goods and reference pricing in sustainable industrial renewal” 2007 Australia and New Zealand Health Policy 4:9.

The result – Annex 2C

Australian negotiators claimed that they went into negotiations “with an absolutely clear mandate to protect and preserve the fundamentals of the PBS.”¹⁸ However, the resulting agreement, as encapsulated in Annex 2C, contains provisions which directly impact the policy and function of the PBS. Three out of four of the Agreed Principles mention the need to recognise and promote “innovative pharmaceuticals” (Annex 2C 1(a), (c), (d)). The meaning of ‘innovative’ is left undefined, resulting in an inherent ambiguity. The text allows the word to be interpreted either through the US position of “competitive markets” or the Australian position of “adopting or maintaining procedures that appropriately value the objectively demonstrated therapeutic significance of a pharmaceutical.” The potential for conflict arising from this was recognised by the Senate Select Committee and by others since.¹⁹ It has also been criticised for not mentioning equitable and affordable access to medicines as encapsulated in the Australian Medicines Policy as well as required by 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.²⁰

The ‘transparency’ provisions under Annex 2C 2 contain requirements that listing 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, 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. This could potentially allow PBAC decisions to be

¹⁸ Senate Select Committee report p105.

¹⁹ Faunce T, Doran E, Henry D, Drahos P, Searles A, Pekarsky B, Neville W, “Assessing the impact of Australia-United States Free Trade Agreement on Australian and global medicines policy” 2005 *Glob & Health* 1:15, Senate Select Committee report p107.

²⁰ World Trade Organisation: Declaration on the TRIPS agreement and public health WT/MIN(01)/DEC/2. 20 November 2001.

overturned, or pressure applied to ensure the decisions are made based on principles of ‘innovation’ rather than cost-effectiveness.²¹

The agreement also establishes a ‘Medicines Working Group’ (MWG) which is to “promote discussion and mutual understanding of issues relating to this Annex” (Annex 2C 3(b)). This was seen as creating the potential for patented pharmaceutical companies to lobby for or against existing medicines policies, thereby diminishing the growth of the generics industry,²² for example, through the role of Medicines Australia, the lobby group representing the ‘innovative medicines industry in Australia’ in the MWG.

Although Australian representatives maintained that this group will not influence policy formulation, there is evidence from the first two MWG meetings that the US ‘competitive markets’ approach to innovation was encouraged. After the first meeting of the MWG in Washington, in a press conference at the office of the US trade representative in Washington, 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. We continue to monitor a number of different areas in the operations of our system in Australia, our PBS, or as you call it here in the United States, our formulary.”²³

This was seen as a first step leading to proposals to alter the pricing mechanism of the PBS.²⁴

The IP Provisions – Chapter 17

The AUS-FTA also contains many contentious Intellectual Property (IP) provisions (chapter 17). These include ‘linkage evergreening’ provisions (article 17.10.4) which

²¹ Harvey K, Faunce T, Lokuge B, Drahos P, “Will the Australia-US Free Trade Agreement undermine the Pharmaceuticals Benefits Scheme?” 2004 MJA 181, p257.

²² Faunce T, “Challenges for Australia’s Bio/Nanopharma Policies: trade deals, public goods and reference pricing in sustainable industrial renewal” 2007 Australia and New Zealand Health Policy 4:9 p4.

²³ Vaile M: Deputy Prime Minister and Minister for Trade, Joint press conference at the office of the United States Trade Representative, Washington DC, 7 March 2006 http://www.trademinister.gov.au/transcripts/2006/060306_us_jt.html accessed September 2007.

²⁴ Faunce T, “Challenges for Australia’s Bio/Nanopharma Policies: trade deals, public goods and reference pricing in sustainable industrial renewal” 2007 Australia and New Zealand Health Policy 4:9 p5.

require a patent holder to be notified as soon as an intended generic product marketing approval is sought, and marketing approval be prevented. This impedes the ability of the generic to access the market, as their marketing and regulatory approval (based on safety and efficacy) is now linked to possible patents claimed by the brand name manufacturer.²⁵ Such delays in generics accessing the market have been predicted to lead to high price increases in both PBS and non-PBS drugs, raising costs for both Federal and state governments, as well as consumers.²⁶

Implications for PBS and Australian health policy

The impacts of the AUS-FTA on national medicines policy and the PBS can arguably now be clearly seen. In August this year (after minimal parliamentary debate), the *National Health Amendment (Pharmaceutical Benefits Scheme) Act 2007* was passed, amending key provisions of the *National Health Act 1953*. What has been called “in substance, the Medicines Australia policy proposals”²⁷ for changes to the PBS reference pricing system, the legislation effectively creates two PBS pricing formularies, F1 (comprising patented and ‘innovative’ drugs) and F2 (comprising generics). Reference pricing no longer occurs between the two formularies, and thus there is no price linking between the patented and generic medicines.²⁸ The pricing of new medicines in the F1 formulary is therefore not assessed based on objectively demonstrated therapeutic significance, as they are shielded from other existing drugs, favouring market entry for “innovative” patented medicines. This appears to contradict the National Medicines

²⁵ Faunce T, Lexchin J, “‘Linkage’ pharmaceutical evergreening in Canada and Australia” 2007 *Australia and New Zealand Health Policy* 4:8.

²⁶ Harvey K, Faunce T, Lokuge B, Drahos P, “Will the Australia-US Free Trade Agreement undermine the Pharmaceuticals Benefits Scheme?” 2004 *MJA* 181, p258.

²⁷ Faunce T, “Challenges for Australia’s Bio/Nanopharma Policies: trade deals, public goods and reference pricing in sustainable industrial renewal” 2007 *Australia and New Zealand Health Policy* 4:9 p6.

²⁸ Department of Health Fact Sheet: PBS Reform, 2007

http://www.health.gov.au/internet/wcms/publishing.nsf/Content/pbs_reform_02feb07.htm accessed September 2007. Also see Schedule 1 of the *National Health Amendment (Pharmaceutical Benefits Scheme) Act 2007* for the legislative changes.

Policy objectives²⁹ as well as the views put forward by the Australian negotiators of the FTA as discussed earlier. In outlining the changes late last year, the Australian Health Minister admitted that “Generics Medicine Industry Association is not, as I understand it, especially happy with these changes.”³⁰

These changes appear to reflect almost exactly the intentions articulated by US negotiators during the negotiations of Annex 2C of the AUS-FTA described earlier. This suggests that although assurances to the contrary were given, the US policy of the elimination of price control mechanisms has prevailed, altering a popular and core aspect of Australian national medicines policy.

2. A comparison of Medicines Provisions in the AUS-FTA and the KORUS-FTA

The pharmaceuticals chapter of the KORUS-FTA is described by the US Trade Representative as “a shared commitment on access to innovative medicines.”³¹ It is recognised as having been modelled on Annex 2(c) of the AUS-FTA, but has been described as even more restrictive.³² The main issues seen to impact medicines, and thus the areas which have garnered criticism, are the restrictions on formulary pricing, and the intellectual property provisions, which are seen to go beyond what is accepted under the TRIPS agreement. However, the KORUS-FTA can also be seen to have broader implications in many other areas.

²⁹ Faunce T, “Challenges for Australia’s Bio/Nanopharma Policies: trade deals, public goods and reference pricing in sustainable industrial renewal” 2007 Australia and New Zealand Health Policy 4:9 p7.

³⁰ Abbott T, Press Conference - PBS reform, Commonwealth Parliamentary Offices, Sydney 16 November 2006. <http://www.health.gov.au/internet/ministers/publishing.nsf/Content/health-mediarel-yr2006-ta-abb161106.htm> accessed September 2007.

³¹ USTR, “US-Australia FTA Summary of the Agreement” http://www.ustr.gov/Trade_Agreements/Bilateral/Australia_FTA/US-Australia_FTA_Summary_of_the_Agreement.html accessed September 2007.

³² Sean Flynn & Mike Palmedo, “Analysis of the KORUS FTA Pharmaceuticals and IP Chapters”, Program On Info. Just. & Intell. Prop. Br. (May 25, 2007). <http://www.bilaterals.org/IMG/pdf/pijip05252007.pdf> accessed September 2007.

Medicines and medical devices

While the AUS-FTA Annex 2(c) is entitled ‘Pharmaceuticals’ and deals exclusively with this, the equivalent KORUS-FTA chapter refers to ‘Medicines and Medical Devices’ (chapter five). This broad category is defined in article 5.8 as “pharmaceutical, biologic, medical device, or diagnostic product” and potentially encapsulates much more than its Australian equivalent, by including expensive ‘medical devices’ such as cochlear implants.³³

Restricting drug formularies

Annex 2(c) of the AUS-FTA was the first time a part of an FTA with the US sought to control existing national pharmaceutical reimbursement schemes based on formularies under the guise of a non-tariff barrier to trade.³⁴ Although the final version of the Annex did not contain any explicit restrictions relating to the current Australian system, the arguably ambiguous reference to “innovation” remains. One of the agreed principles (Annex 2(c) 1(a)) refers to “the need to promote timely and affordable access to innovative pharmaceuticals...”

Article 5.2 of the KORUS-FTA deals with this issue in a much more straightforward manner. In determining price reimbursements, the Party’s determination must be “based on competitive market-derived prices” (article 5.2(b)), or if it is not, the Party must then “appropriately recognize the value of the patented pharmaceutical product or medical device in the amount of reimbursement it provides.” While recognising the fact that Korea seeks to maintain its pricing formulary, this article prescribes the way in which the pricing decisions are made. If pricing reimbursement determinations are not based on “competitive market-derived prices” the article nevertheless ensures that the value of patented products is “appropriately recognised” in any determination. It allows some

³³ As suggested by Sean Flynn & Mike Palmedo, “Analysis of the KORUS FTA Pharmaceuticals and IP Chapters”, Program On Info. Just. & Intell. Prop. Br. (May 25, 2007), p2. http://www.bilaterals.org/article.php3?id_article=8424 accessed September 2007.

³⁴ Faunce T, Doran E, Henry D, Drahos P, Searles A, Pekarsky B, Neville W, “Assessing the impact of Australia-United States Free Trade Agreement on Australian and global medicines policy” 2005 Glob & Health 1:15.

room for the use of comparators in pricing (in allowing manufacturers to apply for an increased amount of reimbursement based on relative safety or efficacy – article 5.2 (b)(ii)), but is far from both the PBS model of reference pricing, and the Korean ‘positive list’ formulary. Overall, this article still mandates that patented drugs are favoured over generics – a bolder articulation of US policy than Annex 2C of the AUS-FTA.

Korea announced its intention to create a ‘positive list’ in May 2006, a move met by strong opposition from KORUS-FTA US negotiators who refused to attend a Pharmaceutical and Medical Device Working Group meeting. In a public statement by a US trade representative, the US saw the decision to create the list as “inconsistent with both the mandate of the Pharmaceutical Working Group and the market-opening spirit of the FTA.”³⁵

This is not the first time that the US has used trade negotiations with Korea to impose higher drug prices. Since 1999, the US has been negotiating market access in the pharmaceutical sector with Korea.³⁶ One aspect of the negotiations was to pressure Korea to adopt the “A-7 pricing system” for all new innovative medicines, that is the average ex-factory price in the A-7 countries – US, UK, Germany, France, Italy, Switzerland and Japan.³⁷ This has been criticised, as the result requires Koreans to pay much higher prices relative to their average income per person than any of the other A-7 countries. Furthermore, Korea also pays more for patented drugs than the US does in absolute terms.³⁸

³⁵ Statement of Assistant USTR Wendy Culter on the Conclusion of the Second Round of Negotiations of the KORUS FTA, 14 June 2006
http://www.ustr.gov/Document_Library/Press_Releases/2006/July/Statement_of_Assistant_USTR_Wendy_Culter_on_the_Conclusion_of_the_Second_Round_of_Negotiations_of_the_KORUS_FTA.html accessed September 2007.

³⁶ USTR Trade Policy Agenda and 2004 Annual Report of the President of the United States on the Trade Agreements Program,
http://www.ustr.gov/assets/Document_Library/Reports_Publications/2006/2006_Trade_Policy_Agenda/asset_upload_file936_9071.pdf accessed 17/09/07.

³⁷ USTR Trade Policy Agenda and 2004 Annual Report of the President of the United States on the Trade Agreements Program, Bilateral and Regional Negotiations, p168.

³⁸ Sean Flynn & Mike Palmedo, “Analysis of the KORUS FTA Pharmaceuticals and IP Chapters”, Program On Info. Just. & Intell. Prop. Br. (May 25, 2007), p2.
http://www.bilaterals.org/article.php3?id_article=8424 accessed September 2007, Flynn S, Treat S, “A

Korea's price reimbursement system is part of its universal National Health Insurance (NHI) system which relies heavily on its generics industry to control the costs of medicines. It is quite similar to the Australian PBS in that it uses a formulary (referred to as a 'positive list' and reference pricing – aspects which the US also saw as barriers to trade.³⁹ The formulary also allowed patients to be steered towards generic drugs, thus encouraging the industry to thrive. This is in obvious conflict with article 5.2(b) of the KORUS-FTA which would not allow generics to be favoured over patented drugs. Much stronger than the Annex 2C provisions, there is little room to argue that any price reimbursement system favouring the growth of a generics industry can exist without breaching these provisions.⁴⁰

It is also interesting to note that before the final text of the KORUS-FTA was released, there was some concern regarding the viability of the US drug formulary programs.⁴¹ These are used extensively to negotiate drug prices in the US at the state level, as well as by private insurance companies. Drug prescription benefits which are available through US Medicare are negotiated by private firms contracted by the government. Many US agencies such as Department of Defense, Veterans Administration and Medicaid purchase drugs through price negotiating programs. Medicaid is run through state governments under federal guidelines providing health insurance. These would clearly be threatened by the articles of the KORUS-FTA. However, due to public concern during the negotiations,⁴² these programs have been exempted. For example, “government

drug Deal Gone Bad” 2007 http://www.tompaine.com/print/a_drug_deal_gone_bad.php accessed September 2007.

³⁹ Flynn S, “‘Annex 2C-plus’ provisions in the Korea-US FTA Pharmaceuticals Chapter” 2007 Program On Info. Just. & Intell. Prop. <http://www.wcl.american.edu/pijip/documents/pijip04172007.doc?rd=1> accessed September 2007.

⁴⁰ See also Sean Flynn & Mike Palmedo, “Analysis of the KORUS FTA Pharmaceuticals and IP Chapters” 2007 Program On Info. Just. & Intell. Prop. Br. http://www.bilaterals.org/article.php3?id_article=8424 accessed September 2007.

⁴¹ See for example Shaffer E, “The U.S.-South Korea Trade Agreement: Affordable Medicines and Tobacco Control Under Fire” 2007 <http://www.expertclick.com/NewsReleaseWire/default.cfm?Action=ReleaseDetail&ID=16061> accessed September 2007.

⁴² For example see Flynn S, “Access to Medicines Issues in the US-Korea Free Trade Negotiations” 2007 Program on Information Justice and Intellectual Property, p3 <http://www.wcl.american.edu/pijip/documents/korea02112007.doc?rd=1> accessed September 2007.

procurement of pharmaceutical products for healthcare” (referring to the US Department of Defense and Veterans Administration drug procurement programs) appear to be exempt by a footnote under article 5.2. This section also explicitly refers to “health care programs operated by its [the Party’s] central level of government” thereby excluding, and thus protecting Medicaid which is run on the state level. For even greater clarification, article 5.8 contains a definition of “health care programs operated by a Party’s central level of government”, which includes a footnote stating that “Medicaid is a regional level of government health care program in the United States, not a central level of government program.”

The result is that the provisions do not apply to US government pricing programs, thereby protecting access to affordable medicines within the US, while continuing to apply to the Korean ‘positive list’ formulary.

Transparency

Both Annex 2C of the AUS-FTA and Chapter 5 of the KORUS-FTA address the notion of ‘transparency’ in any healthcare program reimbursing pharmaceuticals. As discussed earlier, the Annex 2C provisions created mechanisms allowing further review of PBAC decisions, calling into question the authority of well established government healthcare institutions.

The KORUS-FTA transparency provisions are similar, but go further, providing additional requirements, for example that the parties “within a reasonable, specified period, provide applicants with meaningful, detailed written information regarding the basis for recommendations or determinations.”

Article 5.7 requires the establishment of a “Medicines and Medical Devices Committee” similar to the AUS-FTA MWG. Whether or not this committee will play a similar role has yet to be seen.

A major difference is the requirement that Korea establish an independent review process which appears to allow pharmaceutical companies to challenge decisions regarding pricing or formulary listing (article 5.3 5(e)). While this appears similar to the Annex 2C equivalent, a confirmation letter from the Korean government to the US trade representative states that in implementing this section, Korea will establish an independent review body.⁴³ This body will be entirely separate to government health care authorities that are involved in price reimbursement schemes and decisions, and will be comprised of “professionals with relevant expertise and experience” with no pecuniary or personal interest in the outcome of the decisions. It is unclear whether this body will have the power to overturn pricing decisions, however it can be assumed that it is unlikely for it to have been established to serve a purely advisory role.

Intellectual Property Provisions

The KORUS-FTA includes what have been described as ‘TRIPS-Plus’ intellectual property protections, which work to delay generic competition and allow patented drugs to extend their life span. These include changes to data exclusivity (art 18.9.1), linkage requirements (art 18.9.4), mandatory extensions of patents (art 18.8.6), and patent requirements for new uses of known products (art 18.8.1).

Article 18.9 allows for five years of data exclusivity for new pharmaceutical products and three years for those containing “a chemical entity that has been previously approved”. This prevents generic manufacturers from accessing the data from clinical trials conducted by the patented equivalent, which would allow them to prove that their product is ‘bioequivalent’ to the brand name drug. Bypassing the need to repeat clinical trials to prove safety and efficacy, generic manufacturers can use data from the original patent to prove that their drug will behave in the same way. Their early access to the data allows

⁴³ Confirmation letter from the Korean Minister for Trade Hyun Chung Kim to US Trade Representative Susan Schwab June 30 2007, http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Republic_of_Korea_FTA/Draft_Text/asset_upload_file511_12725.pdf accessed September 2007.

generics to obtain marketing approval, and be ready to market their product as soon as the patent term expires. Data exclusivity provisions prevent generic manufacturers from applying for approval based on the original data during the period of exclusivity, thereby delaying their access to the market. While the TRIPS agreement allows for protection of data from 'unfair commercial use' it has been argued that there are other ways in which this can be done.⁴⁴ These provisions once again hinder the Korean government's ability to further the generic industry.

The KORUS-FTA also contains 'linkage' provisions, which function to prevent health authorities from giving market approval to generic drugs while the brand name is still under patent. A number of Special 301 Reports issued by the USTR show that the US had a primary goal of forcing Korea to adopt linkage provisions:

The United States encourages Korea to address its lack of an effective coordination system between its health and patent authorities to prevent the issuance of marketing approvals for unauthorized patent-infringing copies of pharmaceutical products. The United States will work with Korea to make progress on these and other IPR issues through the upcoming Free Trade Agreement negotiations.⁴⁵

Article 18.9.4 provides a similar mechanism to the AUS-FTA equivalent, whereby a patent owner is notified of a request for marketing approval, and after notifying the approving authority, marketing approval is prevented. However, unlike the AUS-FTA article 17.10.4, the patent holder must first have notified the regulatory authority as covering the particular product. This encourages regulatory oversight of a list of approved pharmaceutical patents, helping to avoid patent 'evergreening'.

Recent US Democrats deal with USTR

⁴⁴ For example see Flynn S, "Access to Medicines Issues in the US-Korea Free Trade Negotiations" 2007 Program on Information Justice and Intellectual Property, p4
<http://www.wcl.american.edu/pijip/documents/korea02112007.doc?rd=1> accessed September 2007.

⁴⁵ USTR, "2006 Special 301 Report"
http://www.ustr.gov/Document_Library/Reports_Publications/2006/2006_Special_301_Review/Section_Index.html accessed September 2007.

It is interesting to note that in May 2007 a new deal regarding trade agreements between the US Democrats and the Bush Administration was reached.⁴⁶ The democrats negotiated concessions in a number of areas including patent extensions, linkage provisions, and to some extent in data exclusivity – thereby eliminating some of the ‘TRIPS-plus’ provisions.⁴⁷ This deal was predicted to have an impact on the KORUS-FTA (among other forthcoming trade agreements).⁴⁸ However, although it was reached prior to the completion of the KORUS-FTA, the negotiated concessions with respect to IP did in fact influence the final agreement.⁴⁹ For example, patent extensions were to be made optional, using terms such as ‘may’ instead of ‘shall’,⁵⁰ yet in the final version, this is not the case. However, chapter 16 of the United States – Peru Trade Promotion Agreement, does appear to have taken on these changes.⁵¹

If subsequent trade agreements do incorporate the concessions gained through this deal, a much more flexible approach to negotiating and protecting patent provisions could be achieved – perhaps including a return to TRIPS-only standards.

3. The negotiations for an AUS-China FTA

⁴⁶ USTR, Trade Facts, http://www.ustr.gov/assets/Document_Library/Fact_Sheets/2007/asset_upload_file312_11283.pdf accessed September 2007.

⁴⁷ Committee on Ways and Means Republicans, Press Release “Agreement will allow us to move the American trade agenda forward” May 10 2007 <http://republicans.waysandmeans.house.gov/news/PRArticle.aspx?NewsID=56> accessed September 2007.

⁴⁸ Weisman SR, “Democrats and White House reach trade compromise” 2007 International Herald Tribune, <http://www.iht.com/articles/2007/05/11/news/trade.php> accessed September 2007.

⁴⁹ Press release, “Statement by AFL-CIO President John Sweeney On the Proposed Korea-U.S. Free Trade Agreement” 2007 AFL-CIO <http://www.aflcio.org/mediacenter/prsptm/04032007a.cfm> accessed September 2007. Also see Joo H, “Korea-United States Free Trade Agreement Signed” Dynamic Korea 2007 http://www.dynamic-korea.com/news/view_news.php?main=KTD&sub=ECO&uid=200700173713&keyword= accessed September 2007.

⁵⁰ Love J, “KEI Statement on IPR/Health aspects of bipartisan “New Trade Policy” 2007 Knowledge Ecology International http://www.keionline.org/index.php?option=com_content&task=view&id=48&Itemid=1 accessed September 2007.

⁵¹ USTR, “United States – Peru Trade Promotion Agreement”, Chapter 16, http://www.ustr.gov/Trade_Agreements/Bilateral/Peru_TPA/Section_Index.html accessed September 2007.

On 18 April 2005, after the completion of a joint FTA Feasibility Study showing potential for significant economic benefits, Australia and China agreed to begin negotiations on an FTA.⁵² While so far pharmaceuticals have not been considered in the discussions, there are compelling reasons to believe that the inclusion of a chapter on pharmaceuticals in the final FTA will be greatly beneficial to both countries.

As one of the world's largest manufacturers of generic pharmaceuticals, China has a pharmaceuticals industry predicted to become the world's 5th largest by 2010, and largest by 2050.⁵³ Foreign drug investors see the Chinese drug market as having great scope for growth, with a population of over 3.1 billion, ageing at a projected 3% a year, as well as a very low relative research base, with approximately 97% of manufactured drugs being copies of foreign products or 'generics'.⁵⁴ Currently, all the top 20 multinational pharmaceutical companies have set up wholly owned subsidiaries or joint-ventures in China.⁵⁵ While the Chinese market holds huge potential for a large pharmaceutical research and development (R&D) base, the market is currently quite fragmented, partly due to bureaucratic obstacles in centralising the industry, as well as inconsistent intellectual property standards deterring both local and foreign manufacturers.⁵⁶ The result is that currently China has only patented two "innovative" drugs.⁵⁷

⁵² Department of Foreign Affairs and Trade, "Australia-China Free Trade Agreement Negotiations" <http://www.dfat.gov.au/geo/china/fta/> accessed September 2007.

⁵³ PriceWaterhouseCoopers, "China – Prescription for Growth" 2004 p2 <http://www.pwc.com/Extweb/pwcpublishations.nsf/docid/4D287C2BE1191F4A80257131004D6464> accessed September 2007.

⁵⁴ PriceWaterhouseCoopers, "China – Prescription for Growth" 2004 p 2, 3. <http://www.pwc.com/Extweb/pwcpublishations.nsf/docid/4D287C2BE1191F4A80257131004D6464> accessed September 2007.

⁵⁵ Zhou EY, "China Pharma Basking in its Spotlight" 2007 Genetic Engineering and Biotechnology News 27(5) <http://www.genengnews.com/articles/chitem.aspx?aid=2049&chid=4> accessed September 2007.

⁵⁶ PriceWaterhouseCoopers, "China – Prescription for Growth" 2004 p 2-4. <http://www.pwc.com/Extweb/pwcpublishations.nsf/docid/4D287C2BE1191F4A80257131004D6464> accessed September 2007.

⁵⁷ China Economic Information and Agency. The Internal and External Environments Facing the Domestic Pharmaceutical Industry. Beijing 2002, http://professional.tdctrade.com/content.aspx?data=Professional_content_en&contentid=175150&src=IN_RepAna&w_sid=194&w_pid=840&w_nid=11028&w_cid=175150&w_idt=1900-01-01&w_oid=180 accessed September 2007.

Conversely, Australia possesses the regulatory expertise (through the well established mechanisms of the TGA), high quality research institutions, and a strong and growing R&D base.⁵⁸ As well as great potential to enhance the generics industry in Australia, there is much scope to develop the “innovative” pharmaceutical market, leading to large global exports.

As with Australia, but unlike many parts of Europe and the US, China has not only invested heavily in biopharmaceutical sciences, but has also ensured liberal policies towards globally contentious issues such as therapeutic cloning. This is an area which still lacks global consensus, making international collaborative research difficult. As Australia has recently legalised therapeutic cloning by lifting the ban on somatic cell nuclear transfer (SCNT) last year, there is much potential for collaborative research and development in this area through partnerships and joint ventures, which could be greatly facilitated by an FTA.

China is already showing great promise as a potential market for the Australian biotechnology and nanotechnology industries, for example through the patenting in China of BioSilicon™, a nanotech silicon drug delivery system manufactured by the Australian publicly listed company, pSivida Ltd. Furthermore, the CSIRO has been developing and acquiring patents for RNA interference (RNAi) gene silencing technology. Already holding patents in China, representatives from the CSIRO have stated that they see “a major market for its RNAi technology in China”.⁵⁹

It has previously been suggested that in establishing a pharmaceuticals chapter within a CHINA-AUSFTA, a Medicines Working Committee could be set up to facilitate dialogue about cooperative research, manufacture and distribution of pharmaceuticals.⁶⁰ The

⁵⁸ Department of Industry, Tourism and Resources, “Pharmaceuticals Industry Profile” <http://www.industry.gov.au/content/itrinternet/cmscontent.cfm?objectID=848F9330-F7BA-4D80-8578BCD96F96D993> accessed September 2007.

⁵⁹ O’Neil G, CSIRO, Benitec strengthen RNAi patent positions, 2005 Life Scientist <http://www.biotechnews.com.au/index.php/id:1743694923> accessed September 2007.

⁶⁰ Thomas Faunce, “Submission to Senate Foreign Affairs, Defence and Trade References Committee into Australia’s relationship with China” 2005

parties could also establish regulatory mechanisms similar to Australia's PBS, ensuring methods of comparing effectiveness and therapeutic significance of existing and new medicines. As both countries support the growth and prevalence of a generics industry, intellectual property provisions limited to the TRIPS agreement could be included, prohibiting data exclusivity provisions, and allowing for the 'springboarding' of generic drugs.

When the inclusion of pharmaceuticals related provisions offer such potential for great public benefit, it is surprising that Australia's trade negotiators are taking a relatively passive role in developing both domestic and international trade policy. For example, as discussed earlier, the US has strong legislative trade goals and agendas, as well as advisory committees such as the Industry Functional Advisory Committees (IFAC) set up under US trade legislation. These committees are legislated to provide the President and Congress with a report analysing the extent to which a particular trade agreement promotes US interests. For example, the IFAC on Intellectual Property for Trade Policy Matters (IFAC-3) provided a report on the IP chapter of the AUS-FTA during negotiations.⁶¹ If Australia fails to take an active role in negotiating trade deals, it is likely to will miss out on opportunities to gain significant benefit through the supranational normative systems provided by trade deals.

Discussion

The Australian and Korean trade agreements with the US were the first to include pharmaceuticals chapters. During negotiations for both, the US expressed a strong agenda to change the domestic health policies of each country, particularly by getting rid of price control mechanisms such as the Australian PBS and the Korean positive list formulary. Recent legislative changes to Australia's price referencing mechanisms show that despite

http://www.dfat.gov.au/geo/china/fta/submissions/4NMA_04_Thomas_Faunce~001B.pdf accessed September 2007.

⁶¹ Industry Functional Advisory Committee on Intellectual Property for Trade Policy Matters, "The US-Australia Free Trade Agreement, The Intellectual Property Provisions" 2004 USTR http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Australia_FTA/Reports/asset_upload_file813_3398.pdf?ht= accessed September 2007.

assurances from Australian negotiators, this core aspect of the PBS, and in turn Australian health policy, was in fact negatively affected by the AUS-FTA. Furthermore, this shows that the US successfully implemented its agenda of eliminating price control mechanisms through the use of a trade deal.

Similarly, the KORUS-FTA contains provisions obviously seeking to eliminate or hinder Korea's drug price formulary. Whether or not a similar impact on domestic health policy as that observed in Australia remains to be seen.

Unless changes are made (either through the bipartisan deal negotiated by the US democrats or otherwise), these two agreements may provide the model for future medicines provisions in FTAs. Measures must be developed to counter the negative aspects seen, and to ensure compliance with TRIPS and the Doha declaration. These may include, for example, the creation of a separate treaty protecting safety and cost-effectiveness of pharmaceuticals.

Another approach for Australia may be a clear articulation of domestic trade agenda in legislation (such as that of the US), which ensures that domestic health policy goals are maintained and promoted during trade negotiations. This could include, for example, the establishment of similar advisory bodies to the US IFAC committees, which could monitor and report on the protection of Australian interests during trade negotiations.

If the final terms of the agreement are found to conflict with the national trade goals or health policy, or if the promised gains are not proven, measures could be developed to remedy this, and amend the agreement accordingly. This could occur either through a stronger dispute resolution chapter of the agreement itself, or through recourse to the WTO.

Stronger protections, such as a constitutional right to health similar to that existing in South Africa, could also be considered. This would ensure that the right to healthcare is a consideration at the forefront of any trade negotiations.

The current negotiations with China allow for Australia to take a more active role in including a pharmaceuticals chapter and thereby allowing Australia to access the full potential of China's rapidly growing pharmaceuticals market.

Conclusion

The huge potential trade deals hold in influencing domestic and international health policy cannot be doubted. While offering great public gains for healthcare, they can also greatly restrict and impede successful domestic health policy, and Australia must consider and implement measures to protect domestic healthcare while capitalising on the benefits trade deals offer. The upcoming trade deal with China provides opportunities to learn from earlier agreements, and include a strong, beneficial pharmaceuticals chapter in the FTA.