

Analysis of the June 2011 leaked TPP Transparency Chapter Annex (Annex on Transparency and Procedural Fairness for HealthCare Technologies)

A comparison with the text of Annex 2-C of the Australia-US Free Trade Agreement and Chapter 5 of the Korea-US Free Trade Agreement

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Submission to the Department of Foreign Affairs and Trade, 7 September 2012

Introduction

Increasingly intrusive provisions regarding pharmaceutical coverage programs can be observed across The Australia-US Free Trade Agreement (AUSFTA), the Korea-US Free Trade Agreement (KORUS) and the 2011 leaked US proposal for the Trans Pacific Partnership Agreement (TPP).

AUSFTA Annex 2-Cⁱⁱ represented the first *attempt* by the US to use a bilateral free trade agreement (FTA) as a vehicle to undermine the conduct of a trading partner's pharmaceutical coverage and reimbursement program in order to enhance market access for the pharmaceutical industry. The USTR's negotiating objectives included the elimination of 'price controls' and reference pricing used within Australia's Pharmaceutical Benefits Scheme.ⁱⁱⁱ

While the inclusion of a pharmaceuticals annex in the AUSFTA set a regrettable and unacceptable precedent in legitimizing intrusion into domestic policy space, PBS decision making and pricing mechanisms remained intact and the US' overall objectives were not met. This conclusion is not an endorsement of the AUSFTA annex, nor is it promoting the AUSFTA annex as a precedent for other countries. Nevertheless it is important to understand the content and context of the AUSFTA text and to recognize how seemingly subtle differences in wording between Annex 2-C and texts of subsequent free trade agreements can give rise to substantial differences in impact.

Both Chapter 5 of KORUS^{iv} and the 2011 US proposal for the TPP Transparency Annex^v represent a far greater intrusion into national decision-making on pharmaceuticals and medical devices, and a substantial reduction in governments' flexibility to ensure that medicines can be made available to all at affordable prices. In the TPP, however, for the first time the constraints attempted in AUSFTA and prosecuted in KORUS regarding the establishment and operation of pharmaceutical reimbursement programs are being pursued in developing countries.

The 2011 leaked TPP Transparency Chapter Annex on Transparency and Procedural Fairness for HealthCare Technologies (hereafter referred to as the TPP Annex) articulates a number of proposals that are likely to constrain TPP countries' domestic policy flexibilities in developing and operating therapeutic formularies, setting coverage and reimbursement policies, and applying and enforcing other price moderating mechanisms. While several TPP countries do not yet have such programs in place, the draft provisions have the capacity to seriously circumscribe the ways in which they might develop these in future, thereby limiting their scope to respond market failure, regulate drug prices, and facilitate affordable access.

This brief examines differences in the text pertaining to pharmaceuticals and medical devices between AUSFTA, KORUS and the TPP. It describes how subtleties in the text of AUSFTA preserved key policy settings in Australia and largely left the Pharmaceutical Benefits Scheme intact. These subtleties are not reflected in subsequent texts, including KORUS and the 2011 US TPP proposal.

Critical differences in the text of AUSFTA Annex 2-C, KORUS Chapter 5 and the June 2011 TPP Annex

Scope

AUSFTA Annex 2-C applies to pharmaceutical products only, whereas KORUS Chapter 5 and the US TPP Annex apply to both pharmaceuticals and medical devices. Both KORUS and the TPP Annex are broader in scope than AUSFTA Annex 2-C.

Language referring to pharmaceuticals (and medical devices)

There are subtle but important differences in the language referring to pharmaceutical products (and medical devices) between AUSFTA, KORUS and the TPP Annex. The Agreed Principles of AUSFTA Annex 2-C refer to *"innovative pharmaceuticals"*. This language allowed Australia to retain flexibility in how innovation was determined, and to continue the practice of identifying and assigning value based on the evidence based assessment of therapeutic significance of pharmaceuticals in comparison with existing products.

In both KORUS and the TPP annex, the language of *"innovation"* is replaced with terminology referring to *"patented and generic pharmaceutical products and medical devices"*. This wording provides no flexibility in its interpretation – whether a product is patented is no indication of whether it confers an additional benefit over existing therapies – and appears to preclude the assessment of innovation based on therapeutic significance.

Basis for determining the reimbursement amount

The AUSFTA text articulates that the *"value of innovative pharmaceuticals"* may be based either on *"the operation of competitive markets"* or *"the objectively demonstrated therapeutic significance of a pharmaceutical"* [Annex 2-C Art. 1(d)]. This reflected the existing evidence-based decision making processes of Australia's Pharmaceutical Benefits Scheme (PBS) and meant that Annex 2-C did not result in changes to the formulary listing and pricing processes of the PBS.

In contrast, the KORUS text requires reimbursement amounts to be based on “*competitive market derived prices*” or to “*appropriately recognize the value of the patented pharmaceutical product or medical device*” [Art. 5.2(b)]. Given that in industry parlance, every new molecular entity in possession of a patent is deemed to be innovative, this supplants an assessment of therapeutic benefit or value for money with an assertion of patent status as the basis for determining price and value.

The TPP Annex mirrors KORUS in abandoning references to “*valuing innovation*” and “*objectively demonstrated therapeutic significance*”, adopting instead references to the value of “*patented and generic pharmaceutical products and medical devices*”. TPP Annex Art. X3(d) specifies that the determination of reimbursement amounts must have:

“a transparent and verifiable basis consisting of competitive market-derived prices in the Party’s territory, or an alternative transparent and verifiable basis consisting of other benchmarks that appropriately recognize the value of the patented or generic pharmaceutical products or medical devices at issue”.

While the full implications of this wording are not yet entirely clear, concerns have been expressed that references to “*in the Party’s territory*” could prevent countries from using external (international) reference pricing – the setting of a drug’s price based on the price(s) paid in one or more reference countries (noting that this is a pricing mechanism which can be highly disadvantageous where the reference countries have higher GDPs, and leads to prices that reflect neither opportunity cost nor therapeutic value).^{vi} Of far greater concern however are references to “*competitive market-derived prices*” and “*benchmarks that appropriately recognize*” the value of patented products. (A market-derived price for a product protected by a monopoly is simply a price set by the rights holder. Who will set the benchmarks and what will be deemed ‘appropriate’?). These are intended to undermine both the use of therapeutic reference pricing (by which the price of a drug is referenced to that of another conferring similar therapeutic benefit, irrespective of patent status - a practice which is argued by industry as undermining the value of patents) and the application of value for money assessment, thereby undermining any rational calculus of opportunity cost through the use of evidence-based formulary listing and pricing processes.

Procedures allowing manufacturers to apply for increased reimbursement

The side letter to AUSFTA Annex 2-C states that “*Australia shall provide opportunities to apply for an adjustment to the price of a pharmaceutical under the PBS*”, however no criteria are specified, enabling flexibility in the application of this provision. KORUS and the TPP Annex, however, specify that manufacturers can apply for increased reimbursement over a comparator, or for additional indications [see KORUS Art. 5.5.2(b) and (c) and TPP Annex Art. X3(e) and (f)]. The implications of this are not entirely clear but it appears to provide less flexibility in the interpretation.

Requirement to publish regulations

KORUS introduced a requirement to publish proposed regulations and provide opportunities for “*interested persons and the other Party*” to comment [Art 5.3], which had no counterpart in AUSFTA.

KORUS further includes a set of onerous obligations regarding the publication of such regulations that would be likely to frustrate policy making and allow undue influence in the process by industry.

Paragraph X.2.1 of the TPP Annex refers to Articles XX.2 (Transparency-Publication) – presumably text from the main body of the Transparency Chapter, which is not publicly available. However, X.2.2 specifies that *“To the extent possible, each Party shall allow reasonable time between publication of final regulations of general application at the central level of government respecting any matter related to the reimbursement for pharmaceutical products or medical devices and the effective date of such regulations”*. It is therefore highly likely that the TPP will require a similar set of onerous obligations to KORUS.

Timeliness of listing and pricing processes

While AUSFTA Annex 2-C includes a provision requiring Australia to *“ensure that consideration of all formal proposals for listing are completed within a specified time”* [Art 2.2(a)]. KORUS and the TPP Annex both go further in extending this requirement to consideration of pricing or reimbursement decisions. This may force premature decision-making, where evidence is inadequate to make a well informed decision.

Transparency in decision making

Annex 2-C includes a requirement to *“disclose procedural rules, methodologies, principles and guidelines used to assess a proposal”* [Art 2.2(b)]. KORUS and the TPP Annex, however, include a disclosure requirement applying to decision criteria used to determine pricing or reimbursement (see Art. 5.5(b) of KORUS and X.3(b) of the TPP Annex). This may lead to the imposition of fixed thresholds and reduce countries’ ability to take into account specific circumstances, burdens of disease or public health priorities in decision-making.

Transparency to applicants

Where Annex 2-C requires federal health care programs to *“provide applicants with detailed written information regarding the basis for recommendations or determinations regarding the listing of new pharmaceuticals or for setting the amount of reimbursement by federal healthcare authorities”* [Art 2.2(d)], KORUS and the TPP Annex both include a similar clause which also requires such written information to include citations to any expert opinions or academic studies used in such determinations. The likely impact of this is unclear.

Transparency to the public

A specific obligation regarding transparency to the public was included in AUSFTA: *“provide written information to the public regarding its recommendations or determinations, while protecting information considered to be confidential under the Party’s law”* [Art 5.5(e)]. This created a treaty level obligation facilitating disclosure – of PBAC processes, evidence and outcomes – to an extent that the pharmaceutical industry had hitherto strongly opposed.^{vii}

Interestingly, KORUS does not contain such a public transparency clause, but it reappears in the TPP Annex: *“make available to the public written information regarding its recommendations and determinations relating to the reimbursement of pharmaceutical products or medical devices, subject to*

any requirements under the Party's law to protect information considered to be confidential" [Art. X.3 (h)].

KORUS contains a concerning clause requiring reimbursement decision-making bodies to be open to all stakeholders (including innovative and generic companies) [Art 5.3.5 (f)]. A similar clause does not appear in the TPP Annex. Both KORUS and the TPP Annex, however, include a requirement to "make publicly available the membership list of all committees" involved in pricing and reimbursement decisions [see KORUS Art 5.3.5(g) and TPP Annex Art X.3 (k)].

Contestability mechanisms

AUSFTA Annex 2-C includes the requirement to "*make available an independent review process that may be invoked at the request of an applicant directly affected by a recommendation or determination*" [Annex 2-C Art 2(f)]. The side letter further specifies that "*Australia shall provide an opportunity for independent review of PBAC determinations, where an application has not resulted in a PBAC recommendation to list*". As such, the review only pertains to listing decisions, not pricing.

As implemented, the independent review process established under the AUSFTA^{viii} cannot remake a decision of the Pharmaceutical Benefits Advisory Committee (PBAC), and serves essentially as an independent quality assurance mechanism. No new information or evidence can be presented, and the review can only consider specific issues pertaining to PBAC's determination. To date, PBS independent reviews have only been sought twice. On both occasions, the independent external reviewer supported the PBAC's view and the PBAC found no reason to revise its original recommendation.

The review process established by KORUS, in contrast, covers not only drugs and devices, but also both listing and pricing determinations. While in AUSFTA the right to review is limited to decisions to decline formulary listing, in KORUS there is no similar limitation, implying that any decision at variance with the outcome sought by the manufacturer may be subject to appeal – a situation that could rapidly become unworkable. Moreover, a side letter requires the establishment of a review body rather than a review process, implying that such a body would have the capacity to overturn the original decision.

The independent appeal process specified in Art. X.3(i) of the TPP Annex ("*make available an opportunity for independent appeal or review of recommendations or determinations relating to reimbursement for pharmaceutical products or medical devices*") is similar to that of KORUS, and would facilitate pharmaceutical company challenges to formulary decision-making, specifically where a decision to decline listing is made on the grounds of inadequate cost effectiveness or lack of evidence of value for money.^{ix}

Direct to consumer advertising (DTCA)

The AUSFTA text includes a provision that ostensibly legalizes direct to consumer advertising via the internet:

Each Party shall permit a pharmaceutical manufacturer to disseminate...through the manufacturer's Internet site...truthful and not misleading information regarding its pharmaceuticals that are approved for sale in the Party's territory...

However the intent is effectively obviated in Australia by the subsequent clause specifying:

...as is permitted to be disseminated under the Party's laws, regulations and procedures.

The inclusion of this clause allowed Australia to continue to prohibit all forms of DTCA.

KORUS and the TPP Annex both include a requirement to permit DTCA via the Internet, but without the textual qualification that allowed it to remain unimplemented in Australia. Evidence suggests that DCTA, which among OECD countries is permitted only in the US and New Zealand, can adversely affect demand, undermine rational prescribing, over-medicalize well populations, and increase overall expenditure on health.^x These risks would appear to substantially outweigh any putative benefits, particularly in contexts where regulatory enforcement is less than ideal.^{xi}

Ongoing engagement

The Medicines Working Group established under AUSFTA is a discussion forum with limited terms of reference, chaired by health officials,^{xii} and with no decision-making, advisory or even reporting role; it has met only twice since the conclusion of the agreement.

KORUS requires the establishment of a Medicines and Medical Devices Committee with a far more extensive and influential remit than the Medicines Working Group established under the AUSFTA. The committee established by KORUS will be co-chaired by health and trade officials (unlike the AUSFTA MWG which is chaired by health officials only), has a specific mandate for monitoring and supporting implementation of the KORUS pharmaceutical products and medical devices chapter, is required to meet at least once a year and reports to the Joint Committee. These arrangements will provide considerable scope for ongoing US influence in health policy-making in South Korea.

A placeholder *"for possible cooperative mechanisms"* remaining in the leaked TPPA Annex [Paragraph X.6.2] could become a forum similar to the Medicines and Medical Devices Committee established under KORUS, and with ongoing capacity to influence domestic policy making in ways that favour commercial interests.

US carve-out

Article 6 of AUSFTA Annex 2-C implicitly carves out most US programs, including Medicaid (although this is considered ambiguous by some as it is not explicitly mentioned). It may be argued that the text does not exclude Medicare Part B. Article 5.8 of KORUS also carves out most US programs, with a footnote that explicitly carves out Medicaid (*"for greater certainty, Medicaid is a regional level of government health care program in the United States, not a central level of government program."*)

The use of explicit references to reimbursement programs where decisions are made at "a Party's central level of government" in Paragraph X.7 of the TPP Annex effectively carves out many US programs, including Medicaid, however it may be argued that the leaked text does not adequately exclude parts of Medicare (especially Part B), the 340B program, or Medicare National Coverage Determinations (NCDs).

Nevertheless, the inclusion of the carveout suggests that the US recognizes that its proposal would have negative effects on its own reimbursement programs, if it were to be applied to programs in the US. The US appears to be pressuring other countries to accept these proposals despite anticipated negative effects on its own programs, and despite the limitations they would place on the development of such programs in countries which seek to introduce them in future.

Conclusions

This brief demonstrates that the texts of KORUS and the draft text of the TPP represent much greater intrusions than the AUSFTA into national decision-making on both medical devices and pharmaceuticals, and a substantial reduction in governments' flexibility to ensure that medicines can be made available to all at affordable prices.

While AUSFTA Annex 2-C set a regrettable and unacceptable precedent, it did not result in changes to pricing of pharmaceuticals, and the PBS was largely left intact.

In the AUSFTA, key policy settings were retained for the PBS through:

- ensuring flexibility in the language regarding pharmaceutical products – e.g. “innovative” rather than “patented and generic” products – enabling Australia to apply its own definitions and assign value according to its own criteria;
- the inclusion of language enabling reimbursement amounts to be based on therapeutic significance rather than patent status;
- limiting the independent review process to negative listing decisions (not pricing) and limiting its scope to a quality assurance mechanism that can only result in a recommendation to review a listing decision, rather than overturn a decision;
- a clause permitting parties to retain any existing laws and regulations prohibiting direct to consumer advertising via the internet; and
- carefully crafted terms of reference for the Medicines Working Group (led by health officials, and limited to a discussion forum without decision making powers).

In contrast to the AUSFTA, the KORUS and TPP far more tightly prescribe the operation of pharmaceutical coverage and reimbursement programs. Specifically, these texts:

- preclude assessments of innovation based on therapeutic significance;
- include onerous obligations to publish regulations (facilitating pharmaceutical industry influence);
- extend opportunities for manufacturers of pharmaceuticals and medical devices to participate in decision making regarding listing, pricing and reimbursement;
- include review/appeals processes able to overturn listing and pricing decisions made by expert bodies;
- legalize direct-to-consumer advertising via the internet; and
- establish cooperative mechanisms for ongoing engagement which are likely to have ongoing capacity to influence formulary decision making.

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ⁱⁱ Annex 2C to the Goods Chapter of the Australia United States Free Trade Agreement, *available at*: https://www.dfat.gov.au/fta/ausfta/final-text/chapter_2.html

ⁱⁱⁱ Trade Promotion Authority Act, Public Law No. 107-210 (2002).

^{iv} Korea-US Free Trade Agreement, available from: <http://www.ustr.gov/trade-agreements/free-trade-agreements/korus-fta/final-text>

^v Trans Pacific Partnership. *Transparency Chapter – Annex on Transparency and Procedural Fairness for Healthcare Technologies*, June 22, 2011, available at: [http://www.citizenstrade.org/ctc/wp-content/uploads/2011/10/TransPacific Transparency.pdf](http://www.citizenstrade.org/ctc/wp-content/uploads/2011/10/TransPacific%20Transparency.pdf) (last visited Apr. 25, 2012).

^{vi} S. Flynn, M. Kaminski, B. Baker and J. Koo, "Public Interest Analysis of the US TPP Proposal for an IP Chapter, Draft Version 1.3, December 6, 2011," Program on Information Justice and Intellectual Property, American University Washington College of Law.

^{vii} R. Lopert and S Rosenbaum, "What is fair? Choice, Fairness and Transparency in Access to Prescription Medicines in the United States and Australia," *J Law Med Ethics* 35 (2007):643-56.

^{viii} <http://www.independentreviewpbs.gov.au/>

^{ix} D.H. Gleeson, K.S. Tienhaara and T.A. Faunce, "Challenges to Australia's National Health Policy from Trade and Investment Agreements," *Med J Aust* 196, vol. 5 (2012): 354-6.

^x S. Gilbody, P. Wilson and I. Watt, "Benefits and harms of direct to consumer advertising: a systematic review," *Qual Saf Health Care* 14 (2005):246-250, at 246; D.L. Frosch, D. Grande, M. Derjung and R.L. Kratitz, "A decade of controversy: balancing policy with evidence in the regulation of prescription drug advertising," *Health Policy and Ethics* 100 (2010):24-32; L. Toop, D. Richards, T. Dowell, M. Tilyard, T. Fraser and B. Arroll, *Direct To Consumer Advertising of Prescription Drugs in New Zealand: For Health or for Profit? Report to the Minister of Health Supporting the Case for a Ban on DTCA*, (Christchurch, University of Otago, 2003), *available at*: <http://www.chmeds.ac.nz/report.pdf>

^{xi} C. M. Flood. "The evidentiary burden for overturning government's choice of regulatory instrument: The case of direct-to-consumer advertising of prescription drugs", *U Toronto Law Journal* 60, No. 2 (2010):397-424

^{xii} <http://www.health.gov.au/internet/main/publishing.nsf/Content/health-ausfta-sops>