

# **Preliminary analysis of the final TPP Healthcare Transparency Annex: Annex 26-A: Transparency and Procedural Fairness for Pharmaceutical Products and Medical Devices**

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## **Introduction and background**

The intent of Annex 26-A of the Trans Pacific Partnership Agreement (TPP)<sup>2</sup> is to discipline national pricing and reimbursement schemes for pharmaceutical products and medical devices.

While the language of the Annex is framed around principles of transparency and fairness, the objectives of the pharmaceutical and medical device industries clearly go much further than this. The ultimate objective of the industry is expanded market access at monopoly prices dictated by industry: the target is mechanisms that impact on both market access and prices. The Annex was intended to achieve this objective through greater disclosure of information, greater industry participation, and ultimately more leverage for the industry in decision making regarding pricing, reimbursement and other decisions that impact on market share, such as the range of therapeutic indications for which a product is subsidised.

It is unlikely that the final Annex will go very far, at least in the first instance, towards achieving these industry objectives. The contents of the Annex have undergone quite a transformation since the first proposal, tabled by the United States, was leaked in 2011.<sup>3</sup>

The initial US proposal was based largely on text from the trade agreement between South Korea and the US (KORUS).<sup>4</sup> A later leaked draft from 2014<sup>5</sup> showed a significant ‘watering down’ of the original US proposal due to opposition by the non-US countries,<sup>3</sup> and some of the remaining concerns of public health and access to medicines advocates have been further mitigated in the final text.

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<sup>2</sup> See pages 26-9 to 26-12, Trans Pacific Partnership Chapter 26: Transparency and Anti-Corruption. (Subject to legal review and authentication). Retrieved 13 November 2015 from: <http://www.mfat.govt.nz/downloads/trade-agreement/transpacific/TPP-text/26.%20Transparency%20and%20Anti-Corruption%20Chapter.pdf>

<sup>3</sup> For a comprehensive account of the changes made to the draft Annex between 2011 and December 2014, see Gleeson, D. (2015). Commentary on the Leaked TPP Transparency Chapter Annex on Transparency and Procedural Fairness for Pharmaceutical Products and Medical Devices dated December 17, 2014 and released by Wikileaks in June 2015. Retrieved 13 November 2015, from: <https://wikileaks.org/tpp/healthcare/Analysis-Dr-Deborah-Gleeson/page-1.html>

<sup>4</sup> Lopert R, Gleeson D. (2013). The high price of “free” trade: U.S. trade agreements and access to medicines. *Journal of Law, Medicine and Ethics*, 41(1), 199-223.

<sup>5</sup> Trans Pacific Partnership. (2014, December). TPP Transparency Chapter Annex on Transparency and Procedural Fairness for Pharmaceutical Products and Medical Devices [Leaked draft released by Wikileaks, June 2015]. Retrieved 13 November 2015, from: <https://wikileaks.org/tpp/healthcare/>

Annex 26-A in its final form is in many respects closely modelled on Annex 2-C of the Australia-US Free Trade Agreement.<sup>6</sup> In contrast to KORUS, AUSFTA contains no provisions directly relating to pricing: it only pertains to the listing of pharmaceuticals for reimbursement.<sup>4,7</sup>

There are some important differences between AUSFTA Annex 2-C and TPP Annex 26-A. Unlike Annex 2-C, the TPP Annex covers medical devices, although Australia and New Zealand have succeeded in carving out medical devices from their obligations. Interestingly, the TPP Annex includes some additional flexibilities that did not appear in AUSFTA Annex 2-C. But the inclusion of an investor-state dispute settlement (ISDS) mechanism in the TPP, which AUSFTA did not contain, raises new risks that the Annex may lend weight to ISDS claims by pharmaceutical and medical device companies that countries have breached the obligations of the Investment Chapter. The TPP Annex also includes a consultation obligation which may not be circumscribed in the same way as the mechanism established under the AUSFTA.

### **Scope and coverage of Annex 26-A**

At the time when the TPP enters into force, the substantive procedural obligations of the Annex (which are listed in Paragraph 26-A.2) will only apply to Australia, Japan, New Zealand and the United States, which each have national healthcare programmes listed in the Schedule to Annex 26-A. But although the Schedule specifies that other TPP countries do not currently operate national healthcare programmes within the scope of the Annex, each of these countries has listed a national healthcare authority: if these national healthcare authorities introduce pharmaceutical pricing and reimbursement schemes in future, they may come under pressure to comply with the obligations in Paragraph 26-A.2.

Other parts of the Annex – the principles, consultation process and the obligations regarding dissemination of information to health professionals and consumers – will presumably apply to all countries since these are not limited to the national healthcare programmes listed in the Schedule to the Annex.

Government procurement of pharmaceutical products and medical devices (i.e. direct procurement or purchasing by public authorities such as government agencies or public hospitals) and associated formulary management and development is explicitly excluded from the Annex by Footnote 11. This means that, consistent with a New Zealand Government Fact Sheet,<sup>8</sup> PHARMAC's current activities with respect to hospital medicines appear not to be covered, as these seem to be procured rather than subsidised at the time of writing.<sup>9</sup>

Footnote 9 (which applies to the entirety of the Annex), provides an important clarification regarding the scope of the obligations:

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<sup>6</sup> See Annex 2-C of Chapter 2 (National Treatment and Market Access for Goods) of the Australia-US Free Trade Agreement, available at <http://dfat.gov.au/trade/agreements/ausfta/official-documents/Pages/official-documents.aspx>

<sup>7</sup> It is important to note, however, that for programmes that have a funding cap (such as PHARMAC, New Zealand's Pharmaceutical Management Agency), pricing is more integrally linked to listing than in programmes like Australia's Pharmaceutical Benefits Scheme, which is uncapped.

<sup>8</sup> New Zealand Government. (2015) Trans Pacific Partnership: Pharmaceutical and Medical Device Purchasing (Reimbursement): Fact Sheet. Retrieved 13 November 2015, from [http://tpp.mfat.govt.nz/assets/docs/TPP\\_factsheet\\_Pharmaceutical-and-Medical-Device-Purchasing-Reimbursement.pdf](http://tpp.mfat.govt.nz/assets/docs/TPP_factsheet_Pharmaceutical-and-Medical-Device-Purchasing-Reimbursement.pdf)

<sup>9</sup> It is unclear whether all hospital medicines will be procured in future or whether some may be subsidised.

For greater certainty, the Parties confirm that the purpose of this Annex is to ensure transparency and procedural fairness of relevant aspects of Parties' applicable systems relating to pharmaceutical products and medical devices, without prejudice to the obligations in Chapter 26 (Transparency and Anti-corruption) and not to modify a Party's system of health care in any other respects or a Party's rights to determine health expenditure priorities.

This footnote will be important in assisting countries to resist efforts to change their health care systems on the basis of the contents of the Annex.

### **Analysis of the contents and potential implications of Annex 26-A**

The remainder of this paper discusses the specific provisions of the Annex and their implications, particularly for Australia and New Zealand.

#### **Paragraph 26-A.1: Principles**

This paragraph states that "The Parties are committed to facilitating high-quality healthcare and continued improvements in public health for their nationals, including patients and the public".<sup>2</sup> It outlines a set of principles that countries have acknowledged as important in pursuing these objectives. These principles are likely to be understood as applying to all TPP countries since they are not specifically limited to the national healthcare programmes included in the Schedule to the Annex.

Overall, the interests of the pharmaceutical industry are given greater weight than those of the public in Paragraph 26-A.1. While 26-A.1 (a) notes "the importance of protecting and promoting public health", the "important role played by pharmaceutical products and medical devices in delivering high-quality health care" appears to be assigned at least equal weight. 26-A.1 (c) mentions "timely and affordable access to pharmaceutical products and medical devices", but this is linked to the industry demands for "transparent, impartial, expeditious, and accountable procedures" rather than to the ability of health care authorities to control costs. 26-A.1 (b) and the first half of 26-A.1 (d) closely reflect pharmaceutical industry discourse. In some cases, the industry discourse reflected in the principles appears to condition the interpretation of the more public health-oriented language.

The phrase "adopting or maintaining procedures that appropriately value the objectively demonstrated therapeutic significance of a pharmaceutical product" in the second half of 26-A.1 (d) is borrowed from AUSFTA Annex 2-C. This was intended to reflect the use of comparative cost effectiveness analysis (and therefore therapeutic reference pricing) in the Australian context.

The Principles are not legally enforceable. 'Soft' language is used: the Parties "acknowledge the importance" of the Principles. Since the Annex is not subject to the TPP's state-to-state dispute settlement provisions (see Paragraph 26-A.6), the compliance of one state with the principles cannot be enforced by another using the dispute settlement process provided for in Chapter 28.

The investor-state dispute settlement (ISDS) mechanism in the TPP's Investment Chapter<sup>10</sup> cannot be used to directly enforce the implementation of the provisions in the Annex either. However, it is possible that the principles enshrined in the Annex could lend weight to an ISDS case brought by an

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<sup>10</sup> Trans Pacific Partnership (2015) Chapter 9: Investment. Retrieved 13 November 2015, from: <http://www.mfat.govt.nz/downloads/trade-agreement/transpacific/TPP-text/9.%20Investment%20Chapter.pdf>

investor based on a claim that certain obligations in the TPP's Investment Chapter had been breached.<sup>11</sup>

Safeguards introduced into the Minimum Standard of Treatment (MST)<sup>12</sup> and Expropriation and Compensation<sup>13</sup> sections of the final TPP Investment Chapter are intended to reduce the risk of such disputes, but it is not clear how effective they will be. For example, Article 9.6.4 states "For greater certainty, the mere fact that a Party takes or fails to take an action that may be inconsistent with an investor's expectations does not constitute a breach of this Article, even if there is loss or damage to the covered investment as a result". The words "the mere fact" mean that an argument that an action is inconsistent with an investor's expectations *alone* is not sufficient grounds for an ISDS case. Some scholars argue that introducing this supposed safeguard is actually a retrograde step: in recognising that a breach of expectations *on its own* is not sufficient to constitute a breach of MST, the clause in effect establishes that expectations may actually be relevant in this context.<sup>14</sup>

Safeguards intended to prevent claims on the basis that a subsidy or grant has not been issued, renewed or maintained, or has been modified or reduced,<sup>15</sup> contain similarly weak and problematic language. Other safeguards intended to protect TPP countries' right to regulate to protect health and the environment are undermined by wording that potentially negates their effectiveness, such as "otherwise consistent with this Chapter" (Article 9.15) and "except in rare circumstances" (Annex 9-B 3 (b)).<sup>16</sup>

Even if there is little chance that an ISDS claim using the Annex 26-A principles (as part of an argument that the minimum standard of treatment has been breached or that expropriation has occurred) would succeed, it remains a concern that the pharmaceutical and medical device industries could use this avenue to attempt to deter TPP countries from, for example, introducing tighter cost controls for patented products, or re-directing research and development funding in ways that reduce expected profits. A previous draft of the TPP Investment Chapter indicated that Australia was seeking to exclude certain Australian health programmes and agencies (the Medicare Benefits Scheme, the Pharmaceutical Benefits Scheme, the Therapeutic Goods Administration and the Office of the Gene Technology Regulator) from ISDS. These exclusions were not adopted in the final text of the Investment Chapter – which is unfortunate given the weak safeguards that have replaced them.

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<sup>11</sup> It is important to note also that intellectual property is included in the definition of investment in the TPP.

<sup>12</sup> See Article 9.6: Minimum Standard of Treatment. Trans Pacific Partnership (2015) Chapter 9: Investment. Retrieved 13 November 2015, from: <http://www.mfat.govt.nz/downloads/trade-agreement/transpacific/TPP-text/9.%20Investment%20Chapter.pdf>

<sup>13</sup> Article 9.7: Expropriation and Compensation. Trans Pacific Partnership (2015) Chapter 9: Investment. Retrieved 13 November 2015, from: <http://www.mfat.govt.nz/downloads/trade-agreement/transpacific/TPP-text/9.%20Investment%20Chapter.pdf>

<sup>14</sup> Johnson L and Sachs, L. (2015) The TPP's Investment Chapter: Entrenching, Rather than Reforming, a Flawed System. Columbia Centre on Sustainable Investment. Retrieved 11 December 2015, from <http://ccsi.columbia.edu/2015/11/18/the-tpps-investment-chapter-entrenching-rather-than-reforming-a-flawed-system/>

<sup>15</sup> TPP Article 9.6.5 and 9.7.6

<sup>16</sup> For a thorough treatment of the flaws associated with the Investment Chapter safeguards, see Johnson L and Sachs, L. (2015) The TPP's Investment Chapter: Entrenching, Rather than Reforming, a Flawed System. Columbia Centre on Sustainable Investment. Retrieved 11 December 2015, from <http://ccsi.columbia.edu/2015/11/18/the-tpps-investment-chapter-entrenching-rather-than-reforming-a-flawed-system/>; and Kawharu, A. (2015) Expert Paper #2 TPPA: Chapter 9 on Investment. New Zealand Law Foundation. Retrieved 11 December 2015, from <https://tpplegal.files.wordpress.com/2015/12/ep2-amokura-kawharu.pdf>.

Peru has negotiated side letters with both the United States and Australia that include specific, almost identical clarifications regarding the way Paragraph 26-A.1 will be interpreted between Peru and each of these countries:

The Parties recognize that with regard to paragraph 26-A.1 (Principles) of the Annex, it is understood that “high-quality healthcare” does not refer to specific final outcomes in a Party’s healthcare system, including the selection of specific pharmaceutical products. (US-Peru side letter)<sup>17</sup>

This suggests that Peru considered its Viceministry of Public Health to be covered by the Principles of the Annex even though the Schedule to the Annex notes that Peru does not currently operate a ‘national healthcare programme’ that is in scope. Peru clearly had concerns that without these side letters, the Principles outlined in the Annex might be interpreted in such a way as to require “specific final outcomes...including the selection of specific pharmaceutical products”.<sup>17</sup>

Peru’s efforts to limit and clarify the interpretation of the Principles suggest there is reason for concern about how the Principles might be interpreted and used. It is not clear whether this concern centres around: (i) their potential to bolster an ISDS claim made by a pharmaceutical or medical device manufacturer, (ii) the potential for pressure to be applied through the consultation process outlined in Paragraph 26-A.4, (iii) the potential for pressure applied bilaterally outside of the implementation and enforcement mechanisms of the TPP<sup>18</sup> or (iv) all of the above.

At the time of writing, Peru does not appear to have negotiated side letters with any of the other countries apart from the US and Australia. It is not clear at this stage whether all side letters have been made public.

#### **Paragraph 26-A.2: Procedural Fairness**

Paragraph 26-A.2 includes a set of substantive rules for the operation of ‘national health care programmes’. These cover issues such as: timeframes for listing pharmaceutical products and medical devices for reimbursement; disclosure of rules, guidelines and other information used to assess proposals; opportunities to comment during the decision-making process; provision of information to applicants and the public regarding the basis for a recommendation or determination regarding listing for reimbursement; and a process for review of recommendations or determinations not to list a pharmaceutical or medical device for reimbursement.

It is important to note that Paragraph 26-A.2 seems to only apply to “procedures for listing new pharmaceutical products or medical devices for reimbursement purposes, or setting the amount of such reimbursement”.<sup>2</sup> There is nothing in Para 26-A.2 that specifies that the obligations extend to

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<sup>17</sup> US-Peru Understanding Regarding Paragraph 26-A.1 of Annex 26-A on Transparency and Procedural Fairness for Pharmaceuticals and Medical Devices. Available from: <https://ustr.gov/sites/default/files/TPP-Final-Text-US-PE-Understanding-re-Transparency-and-Procedural-Fairness-for-Pharmaceuticals-and-Medical-Devices.pdf> The Australia-Peru side letters contain a very similar sentence, although the entry language is slightly different: “The Parties understand that in Paragraph 26-A.1 (Principles) of the Annex, the term “high-quality healthcare”...(remainder as per US-Peru side letters). See: Australia-Peru Transparency and Procedural Fairness for Pharmaceuticals and Medical Devices [Side Letters]. Available from <http://dfat.gov.au/trade/agreements/tpp/official-documents/Pages/official-documents.aspx>

<sup>18</sup> Such as, for example, the annual Special 301 Report which identifies countries which are seen by the United States Trade Representative as providing inadequate intellectual property rights (IPR) enforcement and market access for “persons relying on IPR”. Five TPP countries were placed on the “priority watch list” or “watch list” in the 2015 Special 301 Report: Chile, Canada, Peru, Mexico and Vietnam (see <https://ustr.gov/sites/default/files/2015-Special-301-Report-FINAL.pdf>).

procedures regarding widening access to already listed medicines (e.g. recommendations or decisions to subsidise already listed medicines for additional therapeutic indications or additional patient groups).

The Paragraph 26-A.2 obligations will in the first instance only apply to:

- Australia’s Pharmaceutical Benefits Advisory Committee (PBAC);
- Japan’s Central Social Insurance Medical Council;
- Certain activities of New Zealand’s Pharmaceutical Management Agency (PHARMAC)<sup>19</sup>; and
- The United States’ Centers for Medicare & Medicaid Services (CMS).

If/when other TPP countries introduce national pharmaceutical pricing and reimbursement schemes, they may come under pressure to comply with Paragraph 26-A.2, although there is no specific provision in the Annex that would force countries to do so. If middle income countries do bow to pressure to comply, this could result in a significant administrative and resource impost.

Paragraph 26-A.2 is sufficiently similar to AUSFTA Annex 2-C that implementing the obligations outlined therein will not require any changes to the Pharmaceutical Benefits Scheme in Australia.<sup>20</sup> While PHARMAC is already compliant with some of the requirements, Para 26-A.2 does introduce some new obligations for New Zealand.

**Paragraph 26-A.2 (a)** requires countries to “ensure that consideration of all formal and duly formulated proposals for such listing of pharmaceutical products or medical devices for reimbursement is completed within a specified period of time”. This provision is consistent with AUSFTA Annex 2-C and so requires no changes to be made to Australia’s Pharmaceutical Benefits Scheme. It is a new obligation for New Zealand’s PHARMAC which will need to introduce and adhere to statutory timeframes for the first time.

A summary of analysis of the financial impact of Annex 26-A on PHARMAC published on the website of the New Zealand Ministry of Foreign Affairs and Trade<sup>21</sup> states that:

As a result of this provision, PHARMAC may need to consider some funding applications more quickly (although under TPP, PHARMAC retains the ability to determine how long this ‘specified timeframe’ should be), and it may need to make more decisions (rather than leaving applications open for future consideration).

There are four areas of potential impact on PHARMAC:

- (i) A reduction in the degree of flexibility and autonomy available to PHARMAC to prioritise and re-prioritise its assessment of applications;

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<sup>19</sup> For PHARMAC, the Annex will only apply to PHARMAC’s role in the listing of a new pharmaceutical for reimbursement on the Pharmaceutical Schedule - not to medical devices, procurement of hospital medicines or procedures regarding widening access to already listed pharmaceuticals (by changing the listed therapeutic indications or patient groups).

<sup>20</sup> It is possible that the United States could apply political pressure for additional changes during the certification process, before the TPP comes into effect. It seems very unlikely that Australia would agree to such changes, given its very strong opposition to the earlier US proposal for the Annex.

<sup>21</sup> New Zealand Ministry of Foreign Affairs and Trade (2015) Cost to PHARMAC of Implementing the Transparency Annex of TPP. Retrieved 24 November 2015, from <http://www.tpp.mfat.govt.nz/assets/docs/TPP%20-%20Analysis%20of%20Impact%20of%20Transparency%20Annex%20on%20PHARMAC.pdf>.

- (ii) New and unnecessary administrative costs: in addition to one-off establishment costs, PHARMAC estimates that it will cost \$910,000 annually to administer the consideration of funding applications within set timeframes;<sup>21</sup>
- (iii) Potential for increased lobbying from the pharmaceutical industry for shorter timeframes; and
- (iv) Requests for consultations from other Parties, especially the US, under Para 26-A.4.

Two features of the legal text assist in mitigating the impact of the provision on PHARMAC. First, the time frame is not specified in the text but left to be determined by each country. New Zealand has not yet indicated the length of the timeframe it plans to adopt. Second, Footnote 13 specifies that “In those cases in which a Party’s national health care authority is unable to complete consideration of a proposal within a specified period of time, the Party shall disclose the reason for the delay to the applicant and shall provide for another specified period of time for completing consideration of the proposal”. This allows the flexibility which is critical to PHARMAC’s effectiveness to be retained to a greater degree. The New Zealand Government fact sheet<sup>8</sup> states: “This exception is noteworthy given PHARMAC may assess applications over multiple budget cycles or defer a final decision until funding is available.” Despite the exception, the NZ Government has calculated that additional costs will be incurred, and the requirement to introduce and adhere to specified timeframes, however flexibly implemented, introduces a new norm that may facilitate industry lobbying and pressure from other Parties to the agreement.

**Paragraph 26-A.2 (b)** mandates disclosure of “procedural rules, methodologies, principles and guidelines” used to assess proposals. The most recent leaked draft showed considerable disagreement over the wording of this provision.<sup>3</sup> The final wording is identical to AUSFTA Annex 2-C.

A negotiator’s note which was included in brackets in the 2014 draft has been deleted from the final text of the Annex. This negotiator’s note stated “For greater certainty, it is understood that subparagraph (b) refers to procedural rules, methodologies, principles and guidelines of general application.” This made it clear that the disclosure requirement would not apply to the application of these rules, methodologies, principles and guidelines to the assessment of specific proposals for listing pharmaceutical and medical devices. The absence of this clarifying note in the final text introduces some uncertainty that the industry is likely to be quick to exploit, particularly with respect to PHARMAC. It is worth noting, however, that the identical provision in AUSFTA has always been interpreted to apply at the level of general application, and TPP countries should insist on retaining this interpretation.

**Paragraph 26-A.2(c)** is very similar to the relevant provision in AUSFTA.<sup>3</sup> The provision requires countries to “afford applicants, and where appropriate, the public, timely opportunities to provide comments at relevant points in the decision-making process”. The difference to AUSFTA is the inclusion of “where appropriate, the public”. A footnote specifying that each Party can define the “persons or entities that qualify as an ‘applicant’” allows some flexibility – although this flexibility does not extend to the definition of “the public”. This provision will not require changes for Australia, which already provides opportunities for the public to provide comments to the Pharmaceutical Benefits Advisory Committee at the time when an application is being considered. The NZ Government fact sheet appears to indicate that PHARMAC is already considered compliant with this provision.<sup>8</sup> Whether New Zealand’s interpretation will be accepted by the US or whether NZ will be pressured during the certification process to provide additional opportunities for industry input is open to question.

**Paragraph 26-A.2 (d)** mandates the provision of written information to applicants “sufficient to comprehend the basis for recommendations or determinations regarding the listing of new pharmaceutical products or medical devices for reimbursement by national healthcare authorities”. Unlike the comparable provision in AUSFTA, there is no mention of a specified period in which this information must be provided, nor that the information must be “detailed”. The final TPP provision is therefore an improvement over its AUSFTA predecessor. While the meaning of the phrase “sufficient to comprehend” may be contested, a particular interpretation cannot be enforced by another TPP Party since the TPP’s state-to-state dispute mechanism does not apply. Pressure for a certain interpretation could however be applied during certification, or through the consultation process under Paragraph 26-A.4.

**Paragraph 26-A.2 (e)** provides for a review of determinations or recommendations. Two alternative processes are outlined: (a) an independent review process (as provided for in AUSFTA) and (b) an internal review process. The earlier push by the US for an appeal process has been abandoned and the two review options with which it has been replaced allow far more flexibility. Importantly, whichever review process is adopted, it is only available for review of decisions *not to list* a pharmaceutical or medical device<sup>22</sup> for reimbursement – not for pricing recommendations or determinations.

The first option, an independent review process, has already been introduced in Australia as a result of the AUSFTA. The independent review process implemented in Australia cannot re-make a recommendation of the Pharmaceutical Benefits Advisory Committee (PBAC) and can only recommend that a determination be reviewed.

The second option, an internal review process, involves a “substantive reconsideration of the application” but this is mitigated by the fact that the review can be conducted by the same expert or group of experts that made the initial recommendation/determination. Footnote 16 includes additional flexibilities: Parties are not required to provide more than one review, or to include other proposals or the assessment related to other proposals in the review. As the New Zealand Government points out, “This means that PHARMAC’s process of prioritising all applications is not subject to review”.<sup>8</sup> Parties can also choose to review either a draft or final recommendation or determination. There are few requirements for how the review process must be implemented outlined in the text and none in publicly available side letters at the time of writing.

The establishment of a review process will undoubtedly involve administrative overheads for PHARMAC, however as the NZ Government notes,<sup>8</sup> there is nothing in the text that prevents PHARMAC from using cost-recovery (i.e. requiring applicants to cover the costs) for the reviews themselves. In addition to the \$4,503,550 in one-off establishment costs for implementing the obligations of the annex, the New Zealand Government has estimated \$310,000 annually for providing information to support the internal review function and \$724,000 for the costs of the review process itself.<sup>21</sup> A footnote clarifies that “PHARMAC may be able to operate the review process on a cost recovery basis”<sup>21</sup> (ie applicants cover the cost of a review) but it is not clear whether the costs of providing information to support the internal review function could be recovered from industry.

**Paragraph 26-A.2 (f)**, which requires countries to provide written information to the public about recommendations or determinations, is the sole provision in the Annex that is arguably in the public interest. Both Australia and New Zealand already provide such information to the public via the

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<sup>22</sup> Note medical devices are not covered by Para 26-A.2 for either Australia or New Zealand.



internet: Australia publishes summaries of Pharmaceutical Benefit Advisory Committee Outcomes<sup>23</sup> and New Zealand publishes minutes of the quarterly Pharmacology and Therapeutics Advisory Committee (PTAC) meetings.<sup>24</sup>

### **Paragraph 26-A.3: Dissemination of Information to Health Professionals and Consumers**

The objective of the United States in including Paragraph 26-A.3 in the Annex was to oblige countries to permit pharmaceutical companies to disseminate information about approved pharmaceuticals to health professionals and consumers over the internet. But the very important clause “As is permitted to be disseminated under the Party’s laws, regulations and procedures”, borrowed from AUSFTA Annex 2-C, enables those TPP countries that currently prohibit Direct to Consumer Advertising (DTCA) to continue doing so.

Currently New Zealand and the US are the only countries amongst the Parties to the TPP that allow DTCA. A move to prohibit DTCA in these countries would not necessarily be non-compliant with Paragraph 26-A.3, but could be perceived to affect an investor’s rights under the Investment Chapter, and could therefore be subject to an ISDS claim. Similarly, a move to reduce or limit the extent of advertising aimed at prescribers could also be contested through ISDS.

Curiously, a requirement in the leaked draft of the Annex dated December 2014<sup>5</sup> that the information disseminated “includes a balance of risks and benefits and encompasses all indications for which the Party’s competent regulatory authorities have approved the marketing of the pharmaceutical product” has been made optional in the final text (“A Party may require that the information includes a balance of risks and benefits...”). While the requirement remains in the text that information must be “truthful and not misleading”, it is unclear to what extent governments that allow DTCA will be able to prevent the common practice of advertising based on unbalanced, selective or partial information.

### **Paragraph 26-A.4: Consultation**

Paragraph 26-A.4 requires countries to “give sympathetic consideration to” and “afford adequate opportunity for consultation regarding a written request by another Party to consult on any matter related to this Annex”. Such consultations are expected to take place within 3 months (“except in exceptional circumstances or unless the consulting Parties otherwise agree”).<sup>2</sup> Consultations are to involve “officials responsible for the oversight of the national healthcare authority or officials from each Party responsible for national healthcare programmes and other appropriate government officials”.<sup>2</sup>

Footnote 17 is very important in narrowing the scope of the obligation. It states that “Nothing in this paragraph shall be construed as requiring a Party to review or change decisions regarding specific applications.” However, since the most recent leaked draft, the footnote has been truncated. The previous bracketed wording [*or any aspect of national health care or healthcare subsidy programmes*] has been removed from the footnote. Since negotiating documents will not be available for over four years, it will be some time before the reason for its removal becomes clear. The removal of this important clarification is unfortunate.

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<sup>23</sup> Australian Government Department of Health (n.d.) PBAC Outcomes [web page] <http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/pbac-outcomes>

<sup>24</sup> PHARMAC (n.d.) PTAC Minutes [web page] <http://www.pharmac.health.nz/about/committees/ptac/ptac-minutes/>

It is important to note that an obligation to consult does not imply an obligation to introduce changes, and compliance with matters raised by other Parties is not enforceable through the TPP's state-to-state dispute settlement procedures.

Side letters between Australia and the United States<sup>25</sup> indicate that Australia will meet the requirements of Paragraph 26.A.4 through the Medicines Working Group (MWG) that was established under the AUSFTA:

Australia and the United States may satisfy the requirement to undertake consultations under Paragraph X.4 of the TPP Annex, if they undertake relevant consultations with respect to the obligations in Annex 2-C of the Australia-United States Free Trade Agreement under the appropriate mechanisms established under the Australia-United States Free Trade Agreement.

The Standard Operating Procedures of the MWG<sup>26</sup> are tightly circumscribed. Its objectives are limited to promoting discussion and mutual understanding and it is co-chaired by representatives of the respective health authorities.

But the consultation process outlined in TPP Annex 26-A.4 is not a body or committee but a requirement to consult based on a written request. It is possible that other countries might set up committees with terms of reference or operating procedures that can be tightly circumscribed like those of the MWG. However, no side letters have been published to date that include such arrangements that might helpfully limit the scope. The fact that Australia has insisted that the MWG serve to meet its obligations under 26-A.4 begs the question of whether other countries have more to worry about.

#### **Paragraph 26-A.5: Definitions**

This paragraph defines the terms 'national health care authority' and 'national health care programme' for the purposes of the Annex.

#### **Paragraph 26.A.6: Disputes**

Paragraph 26.A.6 simply notes that "The dispute settlement procedures provided for in Chapter 28 (Dispute Settlement) shall not apply. Other avenues, however, including the consultation mechanism and the investor-state dispute settlement mechanism, may be used to pressure countries to conform to certain interpretations or implement the obligations in certain ways.

#### **Schedule to Annex 26-A**

The Schedule to Annex 26-A sets out the national healthcare authorities to which the annex applies.

Australia has listed "the Pharmaceutical Benefits Advisory Committee (PBAC), with respect to PBAC's role in making determinations in relation to the listing of pharmaceutical products for reimbursement under the Pharmaceutical Benefits Scheme." Medical devices are not subsidised through the PBS and are therefore excluded from the scope of Para 26-A.2.<sup>27</sup>

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<sup>25</sup>Retrieved 14 November 2015, from: <http://dfat.gov.au/trade/agreements/tpp/official-documents/Pages/official-documents.aspx>

<sup>26</sup>Australian Government Department of Health. Australia - United States Free Trade Agreement Medicines Working Group - Standard Operating Procedures. Retrieved 14 November 2015, from: <http://www.health.gov.au/internet/main/publishing.nsf/Content/health-ausfta-sops>

<sup>27</sup> Many of Australia's medical device schemes are also funded and administered by the states and territories, so would not be in scope in any case, since the annex targets national programmes.

New Zealand has listed “The Pharmaceutical Management Agency (PHARMAC), with respect to PHARMAC’s role in the listing of a new pharmaceutical for reimbursement on the *Pharmaceutical Schedule*, in relation to formal and duly formulated applications by suppliers in accordance with the *Guidelines for Funding Applications to PHARMAC*.” Footnote 18 indicates “For the purposes of New Zealand, pharmaceutical means a “medicine” as defined in the Medicines Act 1981 as at the date of signature of this Agreement on behalf of New Zealand”. Only PHARMAC's role in the listing of a new pharmaceutical is covered by the Annex, i.e. medical devices are carved out. Procedures for listing hospital medicines are carved out by Footnote 11 where these are procured rather than subsidised.

Japan has listed the “Central Social Insurance Medical Council with respect to its role in making recommendations in relation to the listing or setting amount of reimbursement for new pharmaceutical products”.

The United States has listed “The Centers for Medicare and Medicaid Services (CMS), with respect to CMS’s role in making Medicare national coverage determinations”.

Side letters agreed between the US and Japan<sup>28</sup> emphasise the “valuable contribution of the medical device industry to the health of our societies and of our economies”, and commit Japan and the United States to “maintain at least the current level of consistency with Paragraph X.2 of the Annex with respect to the treatment of medical devices” by the programmes listed in the Schedule.

The eight remaining Parties have listed a national healthcare authority (presumably the national agency that would be responsible for subsidising pharmaceuticals and medical devices should such a national scheme be introduced in future). This seems short-sighted. At some point in the future, many of these countries are likely to consider introducing national schemes for pharmaceuticals and possibly also medical devices, and they may then face pressure to implement the procedural requirements of the Annex. At the very least, implementing the obligations would mean unnecessary administrative and human resource costs.

### **Concluding points**

I have previously argued<sup>3,4</sup> that it is inappropriate to have provisions like these in a trade agreement – the conduct of health programmes should be a matter for domestic and democratic policy making – and that the inclusion of such provisions sets a negative precedent for other trade agreements. It is a shame that the unanimous opposition to the first US proposal did not see the Annex abandoned altogether.

Nonetheless, the TPP Healthcare Transparency Annex has undergone such a transformation during the negotiations, as a result of immutable opposition to the initial US proposal, that it no longer represents the serious impingement on the functioning of national pharmaceutical pricing and reimbursement schemes that it threatened to be. Most importantly, there are no provisions remaining that target pricing, and the Annex is not enforceable through the TPP’s state-to-state dispute settlement process.

The implementation of the Annex in its final form will require no changes to Australia’s Pharmaceutical Benefits Scheme, provided Australia successfully deflects any further pressure applied by the US during certification. While New Zealand’s PHARMAC will need to introduce a statutory timeframe for considering applications and a new review process, considerable flexibility is

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<sup>28</sup> US-Japan side letters: Transparency and Procedural Fairness for Pharmaceutical Products and Medical Devices. Retrieved 28 November 2015, from: <https://ustr.gov/sites/default/files/TPP-Final-Text-US-JP-Transparency-and-Procedural-Fairness-for-Pharmaceuticals-and-Medical-Devices.pdf>

built into the provisions, meaning that the impact on PHARMAC's existing operations will not be as extensive as initially feared. Provisions in other parts of the TPP such as the intellectual property chapter and the investment chapter are likely to have far greater impact.

However, the following concerns regarding Annex 26-A remain:

- Unlike the Australia-US Free Trade Agreement, the TPP includes an investor-state dispute settlement mechanism which provides the pharmaceutical and medical device industries with an avenue to bring claims, or threaten to bring claims, over pharmaceutical policy decisions they perceive as breaching their rights under the investment chapter. Various provisions in Annex 26-A may be used to support claims that the Investment Chapter obligations have been breached. While purported safeguards in the Investment Chapter aim to reduce the risk that such a claim would be successful, each of these safeguards contains flaws. The risk remains that an ISDS claim could be made, or that a company may threaten to use ISDS, in an effort to deter governments from regulating.
- The principles in Paragraph 26-A.1 are more heavily weighted in the interests of the industry rather than the public, and could help to bolster a claim made by a pharmaceutical or medical device company using the TPP's ISDS mechanism. All TPP countries appear to be exposed to this risk, not just the countries which have national healthcare programmes identified in the Schedule to the Annex. Countries could also face pressure over the interpretation of the principles through the consultation process in Paragraph 26-A.4, or through avenues outside the TPP, such as the annual Special 301 Report.
- For New Zealand, and for other countries which introduce national programmes for listing pharmaceutical products and/or medical devices in future, there will be significant administrative costs involved in implementing the obligations of Paragraph 26-A.2. New Zealand has estimated the cost of implementing the Annex at approximately \$4.5 million NZD in initial establishment costs and \$2.2 million each year in ongoing costs.<sup>8</sup> These costs are quite significant given that PHARMAC reported spending approximately \$28.7 million in operating costs in the 2014-2015 financial year.<sup>29</sup> In addition to these costs, PHARMAC may also face pressure on its pharmaceutical budget resulting from commitments in the intellectual property chapter, such as patent term extensions and patent linkage (and extended market exclusivity for biologics, should New Zealand bow to pressure from the US to provide longer than the existing five years). Developing countries that introduce subsidy programmes in future are more likely to find the costs associated with implementing the Annex prohibitive and are less likely to have the human resource capacity to administer the requirements without introducing opportunity costs in other areas of health policy.
- For New Zealand, certain provisions in Paragraph 26-A.2 may also constrain PHARMAC's flexibility and facilitate industry lobbying and pressure from other TPP Parties. This is particularly the case for Para 26-A.2 (a), the requirement to consider proposals within a specified period of time. Much will depend on how this is implemented in NZ and PHARMAC's ability to continue to resist pressure from industry and/or other TPP Parties to adopt and adhere to a short timeframe. The impact of the new review process (Paragraph

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<sup>29</sup> Pharmaceutical Management Agency (2015). Annual Report for the year ended 30 June 2015. Retrieved 11 December 2015 from <https://www.pharmac.health.nz/assets/annual-report-2014-2015.pdf>

26-A.2 (e)) will likewise depend on how well New Zealand is able to use the flexibilities in the legal text to design the process in such a way as to minimise its effects.

- Paragraph 26-A.3 does not prevent countries from prohibiting direct-to-consumer advertising of pharmaceuticals, but if a TPP country that has previously permitted pharmaceutical advertising subsequently prohibits or places new limits on it, this may be challenged using the ISDS mechanism.
- The consultation mechanism in Paragraph 26-A.4 obliges countries to consult on receipt of a written request from another party on matters related to the Annex. This consultation process cannot be used to force a country to review or change decisions about specific applications for reimbursement. But unless countries insist on establishing committees with limited terms of reference like the Medicines Working Group established under the AUSFTA, countries may face ongoing pressure over their implementation of the Annex and their health care decision making more generally.