The Trans-Pacific Partnership Agreement (TPPA)  
Annex on Transparency and Procedural Fairness for Pharmaceutical Products and Medical Devices*  
(dated 17 December 2014)

Whereas the intellectual property chapter of the TPPA proposes to strengthen the monopoly rights of the originator pharmaceutical companies (PhRMA) over medicines, this ‘transparency’ Annex seeks to erode the processes and decisions of agencies that decide which medicines and medical devices1 to subsidise with public money and by how much.

This is the second time the Annex has been leaked. The first was in October 2011. The 2014 document dates from the negotiations in New York. This is one of the most controversial parts of the TPPA, on which decisions had been stalled for several years. While there are similarities between the 2011 and 2014 text, the latter is a based more directly on Annex 2-C of the Australia-US Free Trade Agreement (AUSFTA).2

This memorandum focuses on implications for New Zealand’s Pharmaceutical Management Agency (Pharmac), which was identified by the US pharmaceutical industry (PhRMA) as one of the principal targets of the TPPA.

New Zealand’s Trade Minister Tim Groser has repeatedly stated that the government will protect ‘the fundamentals’ of Pharmac:

We have laid down the fundamentals of a position which says our public health system is not up for negotiation, not part of any trade negotiation, and I can’t conceive of any New Zealand government that would change that view. Pharmac is an incredibly valuable institution that provides high quality medicines to many New Zealanders at very, very highly subsidised, reasonable prices. The fundamentals of that model are not up for negotiation.

The minister refused to release the text to support his promise: ‘to go beyond that and answer the obvious follow-up questions, I do not consider, as the New Zealand Trade Minister, to be in New Zealand’s interests and I will not negotiate it through the media.3

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1 Examples include artificial hips, pacemakers, cochlear implants, eye lenses, stints, surgical lasers, wheelchairs, sutures.
2 The relationship between this Annex and Annex 2-C AUSFTA may have particular implications for Australia if it is decided that existing FTAs shall run alongside the TPPA, with commercial interests able to avail themselves of the most favourable provision in each.
This leaked text shows the TPPA will severely erode Pharmac’s ability to continue to deliver affordable medicines and medical devices as it has for the past two decades. That will mean fewer medicines are subsidised, or people will pay more as co-payments, or more of the health budget will go to pay for medicines instead of other activities, or the health budget will have to expand beyond the cap. Whatever the outcome, the big global pharmaceutical companies will win, and the poorest and most vulnerable New Zealanders will lose.

**Pharmac**

Pharmac was established in 1993 and is governed by the New Zealand Public Health and Disability Act 2000. Section 47 describes its principal objective as:

> to secure for eligible people in need of pharmaceuticals, the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided.

The agency decides which medicines and medical devices to fund for use in community and public hospitals, negotiates prices with pharmaceutical companies, and sets subsidy levels and reimbursement criteria. In 2013, PHARMAC’s role was expanded to include the management of community medicines, pharmaceutical cancer treatments, the National Immunisation Schedule, management of all medicines used in DHB hospitals, and the national contracting of hospital medical devices.

Its bargaining power with the pharmaceutical industry comes from (a) its strictly capped budget, and (b) the conduct of the entire process within a single organisation. Gleeson et al summarise the functions as:

> Management of the formulary, assessment of comparative effectiveness and cost effectiveness, reimbursement decisions, price negotiation, procurement, management of the budget, and payment functions.  

Pharmac is recognised internationally as a highly successful model. The agency’s 2012 annual report estimated its cost containment strategies had saved New Zealand’s District Health Boards cumulatively more than $5 billion since 2000; it observed:

> ‘Medicines won’t cost more under TPP”. Radio New Zealand, 22 October 2014, also http://www.radionz.co.nz/news/national/257457/medicines-%27won%27t-cost-more-under-tpp%27

4 See Deborah Gleeson, Ruth Lopert and Papaarangi Reid, ‘How the Trans Pacific Partnership Agreement could undermine PHARMAC and threaten access to affordable medicines and health equity in New Zealand’, *Health Policy*, 112 (2013) 227-23 at 228
‘If not for PHARMAC, this funding would have had to come from other areas of health spending’.\(^5\)

An Australian report suggested using a similar model there could have saved A$1.6 billion a year.\(^6\)

It is not surprising that Pharmac has long been in the sights of the US pharmaceutical industry. In 2011 its submission to the US government on the TPPA singled out Pharmac as ‘an egregious example’, whose ‘sole focus on driving down costs’ for pharmaceutical products and medical devices ‘thus comes at the expense of the respect for intellectual property, transparency to the public and patient access to better health outcomes’.\(^7\)

The US annual Report on Special 301 (which deals with intellectual property issues) made it clear that Pharmac remains a target for US interests who have powerful influence in the TPPA:

*With respect to New Zealand, U.S. industry has expressed serious concern about the policies and operation of New Zealand’s Pharmaceutical Management Agency (PHARMAC), including, among other things, the lack of transparency, fairness, and predictability of the PHARMAC pricing and reimbursement regime, as well as the negative aspects of the overall climate for innovative medicines in New Zealand.*\(^8\)

The US annual Trade Estimates Report for 2015 said:

*These concerns have been exacerbated as PHARMAC expands into areas of funding that were previously unregulated, including medical devices.*\(^9\)

It is Pharmac’s precedent value rather than the value of New Zealand’s market, which explains the pharmaceutical industries’ determination to undermine its effectiveness. New Zealand taxpayers and New Zealanders’ health are collateral damage in a much bigger game plan.

**Coverage of the Annex**

7 PhRMA, ‘The Need for a Strong Pharmaceuticals Chapter in the Trans-PacificPartnership Free Trade Agreement’, 11 April 2011
8 Michael Froman, *Special 301 Report*, USTR, Washington DC, 2015, p.25; see also
The Annex applies very specifically to a ‘national health care program’ that makes recommendations/decisions about listing pharmaceutical products or medical devices for reimbursement, or the sum of that reimbursement, where these programmes are run by a ‘national health care authority’.  

The Annex does not apply to direct government procurement of pharmaceuticals and medical devices.

‘National’ is presumably chosen to preclude such programmes that are run by states and provinces, which are politically sensitive in the US and Canada. In effect, the US has excluded almost all its own programmes, while targeting New Zealand, as it did with the AUSFTA. In its own Q&A to reassure domestic constituencies:

Q. Are any existing or future U.S. health care programs subject to the pharmaceutical provisions of the U.S.-Australia FTA?

A. USTR has worked closely with all relevant U.S. agencies to ensure the FTA does not require any changes to U.S. health care programs. Procurement of pharmaceutical products by the Veterans Administration (VA) and the Department of Defense (DoD) is excluded from the Pharmaceutical Annex of the agreement, and U.S. agencies already comply with other provisions of the FTA dealing with government procurement, so no change to current practice will be required.

Procurement of pharmaceutical products by state Medicaid agencies is excluded because coverage and reimbursement decisions are made by state officials, not by federal health authorities.

The FTA’s transparency obligations may apply to certain pharmaceutical reimbursement decisions under Medicare Part B, and current Medicare practice is already consistent with the FTA. Medicare Part D, which will take effect in 2006, will not be covered since coverage and payment decisions are not directly made by Federal health authorities.

Four countries have listed their ‘national health care authorities’ in a Schedule to the Annex. For some reason, Pharmac is not listed. But

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10 Paragraph X.6
11 Footnote 3.
13 Australia (Pharmaceutical Benefits Advisory Committee with regard to its determinations on listing products for reimbursement under the Pharmaceutical Benefits Scheme); Japan (still considering how to define its national healthcare authority); US (Centres for Medicare and Medicaid Services with respect to Medicare national coverage determinations); Singapore (Drug Advisory Committee of Ministry of Health with respect to its role in the listing of pharmaceutical products, but the Ministry of Health does not currently operate a healthcare programme within the Annex).
any programme that fits the description is bound by the Annex, whether or not it is listed.

The main rules

The proposal has four main sections, which are discussed further below.

1. **Principles** (X.1): a number of ‘important’ principles governments promise will underpin these programmes, and which will be used as the basis for interpreting the obligations in the Annex.

2. **Procedural fairness** (X.2): a number of rules that governments must ensure are applied when operating these programmes.

3. **Dissemination of information** (X.3): allowing the manufacturers to provide information directly to consumers over the Internet.

4. **Consultation with other parties** (X.4): an obligation to respond to concerns from other parties about implementation of the Annex.

Enforcement

At first glance, the Annex appears relatively benign. Paragraph X.7 says it is not enforceable through the TPPA’s state-state dispute settlement process. That gives false comfort for three reasons:

(i) **Certification**: Compliance will be a target of the US certification process, whereby the US will not exchange diplomatic notes to bring the TPPA into force unless the other Party has changed its laws, policies and procedures, including regulations and operational guidelines of Pharmac, to the US understanding of what is required under the agreement. Legislators from five TPPA countries, including leaders of four NZ parliamentary parties recently signed an open letter calling on their governments to prevent the US holding governments to ransom in this way.\(^{14}\)

The US has used certification most extensively in the past to force changes to countries’ pharmaceutical laws and practices. It is particularly worrying that the legislation being promoted in the US Congress to grant the President Fast Track (Trade Promotion) authority, which restricts their ability to amend the final deal, proposes to give Congress greater influence over certification than in the 2002 version. The Bill as approved by the Senate says

*CONSULTATIONS PRIOR TO ENTRY INTO FORCE:* Prior to exchanging notes for the entry into force of a trade agreement, the United States Trade Representative shall consult closely and on a timely basis with Members of Congress and [relevant committees]*

\(^{14}\) [www.tppnocertification.org](http://www.tppnocertification.org)
... and keep them fully apprised of the measures a trading partner has taken to comply with those provisions of the agreement that are to take effect on the date that the agreement comes into force.\textsuperscript{15}

\textit{Inside US Trade} links these stronger powers to objections from Senator Orin Hatch that the US Korea FTA was allowed to come into force without South Korea having fulfilled what the US said were its obligations to set up an independent review process for decisions on the rates for reimbursing pharmaceutical providers of particular medicines under its national health programme.\textsuperscript{16} PhRMA complained at the time that Korea’s appeal mechanism only related to a limited category of medicines.\textsuperscript{17} As Ranking Member of the Senate Committee on Finance, Hatch is a key player in Congressional TPPA debates and has written frequent letters to the White House demanding extreme intellectual property provisions in the TPPA.\textsuperscript{18}

(ii) **Investor-state disputes**: Other TPPA states are the only ones that seek to enforce the Annex directly, and that has been expressly prevented.

However, the Investment chapter allows investors from the other TPPA countries to bring an investor-state dispute if they claim another party, such as New Zealand, has violated the investors’ rights under the investment chapter. ‘Investment’ includes intellectual property, such as medicine patents, and foreign owned businesses that are established in New Zealand.

The biggest risk is the obligation to provide ‘fair and equitable treatment’, which investors may claim includes a legitimate expectation that governments will comply with their obligations in making regulatory and administrative decisions. They could launch a claim for many millions of dollars compensation, including expected future profits, if they believed New Zealand’s process in general, or in specific cases, violated their expectations under the Transparency Annex and adversely affected the value or profitability of their investment.

Article II.6.3 of the leaked TPPA Investment chapter (dated 20 January 2015) says a determination of a breach of another provision in the agreement (such as this Annex) does not

\textsuperscript{15} Senate Bill: ‘Bipartisan Congressional Trade Priorities and Accountability Act of 2015, SEC. 4. CONGRESSIONAL OVERSIGHT, CONSULTATIONS, AND ACCESS TO INFORMATION, (a) (2)


\textsuperscript{17} ‘PhRMA Charges Korea Out of Compliance with FTA Drug Provision’, \textit{Inside US Trade}, 2 March 2012

\textsuperscript{18} See letters on www.tppnocertification.org
establish a breach of the fair and equitable treatment obligation, but that would not prevent this kind of claim. The investor would not be relying on a breach of the Annex *per se*, but of its legitimate expectations of the government’s regime.\(^{19}\)

Equally, New Zealand could face an ISDS dispute should it change its approach to subsidising medicines or medical devices in ways that an investor from a TPPA country says negatively affected their investment, including loss of future profits.

These investor-state tribunals are widely criticised for their expense, pro-investor bias, conflicts of interest of arbitrators, lack of formal legal precedents and predictable rulings, the absence of any appeals, and extravagant awards with compound interest.\(^{20}\)

Australia clearly anticipated that risk when it proposed this ‘Annex on Health’ (Annex II-M) in the January 2015 leaked investment chapter:

> The following measures of Australia shall not be subject to the dispute settlement procedures under Section B (Investor-State Dispute Settlement) of the Investment Chapter: measures comprising or related to the Pharmaceutical Benefits Scheme, Medicare Benefits Scheme, Therapeutic Goods Administration and Office of the Gene Technology Regulator.

Square brackets indicate that the other parties had not accepted that Annex.

\((iii)\) **Pressure through Consultation and committee oversight**: The Annex (Paragraph X.4) says a government must give ‘sympathetic consideration’\(^{21}\) to a written request from another Party to consult on any matter relating to the

\(^{19}\) Nor would could it be relying on a prior determination that the Annex had been breached, because the Annex makes no provision for a state-state dispute that would make such a determination. ‘Investment’, draft chapter of the Trans-Pacific Partnership Agreement, 20 January 2015, https://wikileaks.org/tpp-investment/

Annex. Consultations must occur within 3 months of receiving the request. A stronger version, presumably from the US, would require a Party to consult when it receives a written request to do so. Health and ‘other’ officials would be involved in such consultations.

The TPPA is also likely to establish a Committee that will conduct regular reviews of a state’s compliance with its obligations. That would allow the US to maintain pressure on countries to comply with its interpretation of the Annex.

**Principles (Paragraph X.1)**

The four principles are the reference points for interpreting and applying a state’s obligations under the Annex. They are full of code words like ‘high quality health-care’, ‘continued improvements in public health’, which appear positive from a public health perspective, but they actually provide entry points for PhRMA to contest processes and decisions. There is only one bracketed position remaining in this paragraph.

The principles stress
- ‘the important role played by pharmaceutical products and medical devices in delivering high quality health care’;
- ‘the importance of research and development, including associated innovation, research and development’ of those products,
- through ‘timely and affordable access’, consistent with the needs of patients and the public’
- using ‘transparent, non-discriminatory, expeditious and accountable procedures’; and
- recognising the value of products and devices ‘through the operation of competitive markets’ or procedures that ‘appropriately value the objectively demonstrated therapeutic significance’.

There is an important point of disagreement between the parties, indicated by square brackets, over whether the procedures for ‘timely and affordable access’ must also be ‘impartial’. ‘Impartial’ is an imprecise term. It could mean any potential risk of pre-judgement, such as the same people (including officials) being involved directly or indirectly in the process of listing and deciding subsidies; representatives of ministries who have an interest in ensuring Pharmac’s cap is maintained; medical experts with stated

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21 This term is used in various WTO instruments, but has never been subject of interpretation in a WTO dispute.
views regarding the appropriate approach to balancing the various criteria; requiring advisory boards to comprise people with no involvement in the health sector or ministry;\textsuperscript{22} or a lack of definitive guidelines that allows subjective decisions. If it were included, the government and Pharmac could face constant pressure over their processes.

The additional wording on Paragraph X.1(c) on procedures for ‘timely and affordable access’, that this is ‘without prejudice to a Party’s right to apply appropriate standards of quality, safety and efficacy.’ This is another ambiguous and contestable term. What is ‘appropriate’ depends on who is defining it and against what criteria. In this context, the New Zealand government has the right to apply ‘appropriate’ standards, but it does not mean it has autonomy to decide what those standards are without that decision being challenged.\textsuperscript{23}

Decoded this means funding new on-patent medicines at the high cost that is said to be necessary to reward research and development, and incentivise investment and innovation.

It encourages pharmaceutical companies to deluge Pharmac with (often self-funded) studies that purport to show the efficacy of their product and require decisions within a short time frame that will be subject to review.

References to patients and the public can become a manipulative means of appealing to people with illnesses for which PhRMA offers highly expensive treatments that have the potential to bust Pharmac’s capped budget.

Likewise, the needs of the ‘public’ links to the industry’s common strategy of funding and sometimes initiating public campaigns to secure the funding of particularly expensive medicines (such as Herceptin).

\textbf{‘Procedural Fairness’ (Paragraph X.2)}

The language of this provision reflects PhRMA’s common rhetoric, which is intended to make its interests sound normative.

\textsuperscript{22} This approach proved a disaster with the short-lived experiment of converting New Zealand’s public hospitals into Crown Health Enterprises with governing boards from outside the sector.

\textsuperscript{23} The comparable phrase in Annex 2-C in AUSFTA is: ‘without impeding a Party’s ability to apply…’. That could be read as allowing more constraints on the party that fall short of ‘impeding’. In practice the change of wording would make little difference.
Governments must ensure that national health care programs operated by national health care authorities that are subject to this Annex operate according to the following procedures:

a) **consideration of all formal proposals for listing of products and devices for reimbursement must be completed within a specified time.** This will put decision makers under tremendous pressure, especially when they have to make assessments of the products and conduct comparative pricing exercises;

b) **the general procedural rules and guidelines – and possibly methodologies and principles – used to assess such proposals must be disclosed.** This reduces the ability to exercise discretion in weighing up relevant considerations, and provides more opportunities for PhRMA and individual manufacturers to challenge the bases on which decisions are made.

c) **applicants must be given timely opportunities to comment at relevant stages of the decision making process.** Because of the criteria in the ‘principles’, manufacturers will demand access to many phases of decision making during which they can exercise pressure, add new ‘evidence’ to support their arguments that require further investigation under time pressures, and build an evidence portfolio to use in subsequent complaints if the decision goes against them.

*the public also has rights to comment ‘where appropriate’.* PhRMA is renowned for funding and often initiating public and often emotional consumer campaigns to demand that expensive medicines are subsidised. People involved in those campaigns have legitimate concerns, but the debates are rarely balanced with the opportunity cost to other health users of subsidising those medicines. That difficult trade-off or rationing is integral to the Pharmac model.

d) **give applicants written information on the basis for recommendations or determinations regarding the listing of new products or devices for reimbursement.** There is disagreement about the detail or the information to be provided. Clearly, the more detail, the more litigious the manufacturers can be.

g) **provide written information to the public about such recommendations or determination,** while protecting confidential information. This is intended to reinforce the public pressure referred to under (c).

**Review (Paragraph X.2(f))**

One of the most controversial issues is the provision of a review procedure for pharmaceutical companies to challenge a decision by a programme not to list a product or device for reimbursement. There are several major points of friction:
(i) how ‘independent’ the review process needs to be from the agency that made the original recommendation or decision, and whether it can be made by the same group of experts provided they undertake a substantial reconsideration of the application;

(ii) whether the state has the right to determine for itself the nature, scope and timing of the review, including whether an opportunity to comment on a draft final recommendation or determination would be adequate;

(iii) what a substantive reconsideration of the application might require, based on what new considerations and under what time constraints.

This review process extends far beyond Pharmac’s current processes. Combined with the other procedural requirements, it could come under enormous and repeated pressure. The review would doubtless seek to re-litigate decisions in terms to the ‘principles’ in para X.1, which could in turn inform domestic judicial review proceedings or an investor-state dispute where the manufacturer claims its legitimate expectations were violated.

Disseminating health information (Paragraph X.3)

A pharmaceutical manufacturer must be allowed to disseminate information about products that have approved for marketing in the country to the profession and consumers through a website registered in the country, and other locally registered sites linked to that site, to the extent this is permitted by the country’s domestic law. The information must be ‘truthful and not misleading’ about the products and be allowed to be disseminated under New Zealand’s laws, regulations and procedures. In addition, the information must include a balance of risks and benefits, and encompass all ‘indications’ (meaning the uses of that drug for treating a particular disease) for which the product has been approved for marketing.

Given this right to disseminate information is subject to domestic law, its purpose is not clear. However, it potentially affects New Zealand more than any other TPPA country, aside from the US. New Zealand is one of few countries in the world to allow the direct electronic marketing of such products. This provision would not directly prevent tighter rules or bans being introduced, but such a move could become subject to an investor-state dispute, as discussed above.