

The Trans-Pacific Partnership (TPP)

Earlier this year, Auckland Fellows and Registrars met for an evening to listen to speakers and participate in discussions on the Trans-Pacific Partnership. This article, written by Dr Karen Bartholomew in her own time, was an outcome of that meeting.

Introduction

- New Zealand is currently involved in negotiating the Trans-Pacific Partnership Agreement (TPPA) with 8 other countries: United States of America (US), Australia, Brunei, Chile, Malaysia, Peru, Singapore, and Vietnam.
- Negotiations are sensitive, have been conducted in a confidential environment and there is little publically available information.
- The TPPA potentially contains provisions that could dramatically alter crucial aspects of New Zealander's lives.
- There are concerns about the effects free trade agreements (FTAs) like the TPPA on human rights, health, wellbeing and the environment.
- As health professionals we need to know what the TPPA is and how it could affect New Zealand; our health system, our patients and ourselves.
- The TPPA is complex, but we really do need to take the time to find out a bit more and to ask our professional organisations to advocate on our behalf.

What is the Trans-Pacific Partnership?

- Technically, the TPPA is an expanded version of an existing FTA between New Zealand, Chile, Singapore and Brunei. This FTA was formerly called the Trans-Pacific Strategic Economic (known as P4) and was signed in 2005.
- In practice, the US and four other countries are negotiating a new agreement based on the US template for FTAs, which is more radical than the P4 because it grants foreign investors (generally multinational corporations) more extensive rights, including over intellectual property. It also potentially allows them to restrict or influence the kinds of services, policies and laws that governments can have into the future.
- We are not the only ones affected by the TPPA. Some of the others parties involved are developing countries. Although most already have reasonably liberal trade policies, countries like Vietnam are especially vulnerable to pressure to accept TPPA provisions and clauses, like the provisions affecting pharmaceuticals detailed below. We have a responsibility as a high income country (and as good international citizens) to help protect vulnerable nations in our region.

This review by Dr Karen Bartholomew (Public Health Registrar) represents her own research and views and is not intended as and should not be interpreted as a policy statement officially endorsed by the NZ College of Public Health Medicine.

Proposed benefits of the TPP

- Free trade is considered highly significant for a small exporting country like New Zealand, particularly with important markets such as the US, India and China (with whom a FTA was signed in 2008).
- There are two purposes for a FTA like the TPPA:
 - To remove barriers to trade between signatory countries, and
 - To create a 'high quality' FTA that other Asia-Pacific countries will want to join.
- Because there are already many FTA's among the TPPA parties, it is thought that removal of trade barriers will, in practice, be limited. However, because New Zealand is one of four countries that does not already have a US FTA, it hopes to get *new* and *extended* access to US markets.
- The most common perception is that the TPPA will eliminate (or reduce) tariffs on our dairy products in the US. This could allow New Zealand companies (like Fonterra) to improve their economic gains in the US market, which are hypothesised to flow through to economic gain for New Zealand as a whole. However, New Zealand negotiators recognise this will be difficult as the US (like China) is very protective of its dairy market.
- It must be remembered that because the details of the TPP negotiations are not public, it is unclear exactly what (and in what magnitude, with what restrictions) might be achieved in terms of agricultural benefits.

Concerns about the TPP

- The US is the dominant player in the negotiations and an agreement will need approval by the US Congress. The influence of various 'big' industries (like the agriculture, tobacco, pharmaceuticals, insurance, food, and chemical industries) on the US negotiating position has been a concern; particularly the recent information about the extent of the industry Pharmaceutical Research and Manufacturers of America (PhRMA) contributions to US senators who support a hard line on PHARMAC in the TPPA negotiations.

- There is marked information asymmetry in these negotiations. The details of the provisions up for negotiation have been made available to US advisory bodies (largely industry representatives) from the early stages of negotiation. No details have been made available to those whom these provisions may ultimately affect (groups or the general public; even opposition government parties do not have this information).
- A consortium of concerned academics have laid a complaint with the United Nations in March 2011, suggesting that withholding this information is a breach of human rights: the right to information and participation in public affairs, in order to make informed political decisions via the democratic process.
- While the issues of most concern relate to health, there are extensive provisions up for negotiation that will impact on other areas which are important to New Zealanders (and in the broadest conception, do also relate to health), including: human rights, indigenous rights, environmental protections, financial services, intellectual property, food standards and labelling, public services and so on.
- The TPPA is a very complex document, and lack of publically available information makes detailed analysis difficult.

Health related issues in the TPPA

- *Affordability of pharmaceuticals:* The Pharmaceutical Management Agency (PHARMAC) decides on behalf of District Health Boards which medicines are subsidised in New Zealand. A number of provisions proposed for inclusion in the TPPA relate directly to pharmaceutical pricing (see Pg4). If these provisions are incorporated there is likely to be increased cost of medicines (for the health system as a whole and for individual patients) and reduced access to medicines, particularly for those on low incomes.
- *Weakened public health and environmental related regulations:* The TPPA could give foreign companies the ability to sue governments about regulations and laws that they feel are barriers to commercial enterprise, free trade or competition (see the investor-state clause in the table Pg4). Experience in other countries suggests multinational corporations *will* utilise these provisions to sue, with targets for this form of action including: drinking water provision, tobacco and alcohol regulations, environmental protections and indigenous resources. For New Zealand there is a possibility of targeting our recent smoke-free gains (and those proposed by the Maori Affairs Select Committee last year), and our very early alcohol reforms. Industries (such as large US chemical and tobacco companies) are very active in this area. For example, even though Australia said no to investor-enforcement powers in its FTA with the US, Philip Morris is now using the back-door of an investment agreement between Australia and Hong Kong to sue Australia in a confidential international tribunal over its new plain packaging tobacco laws.

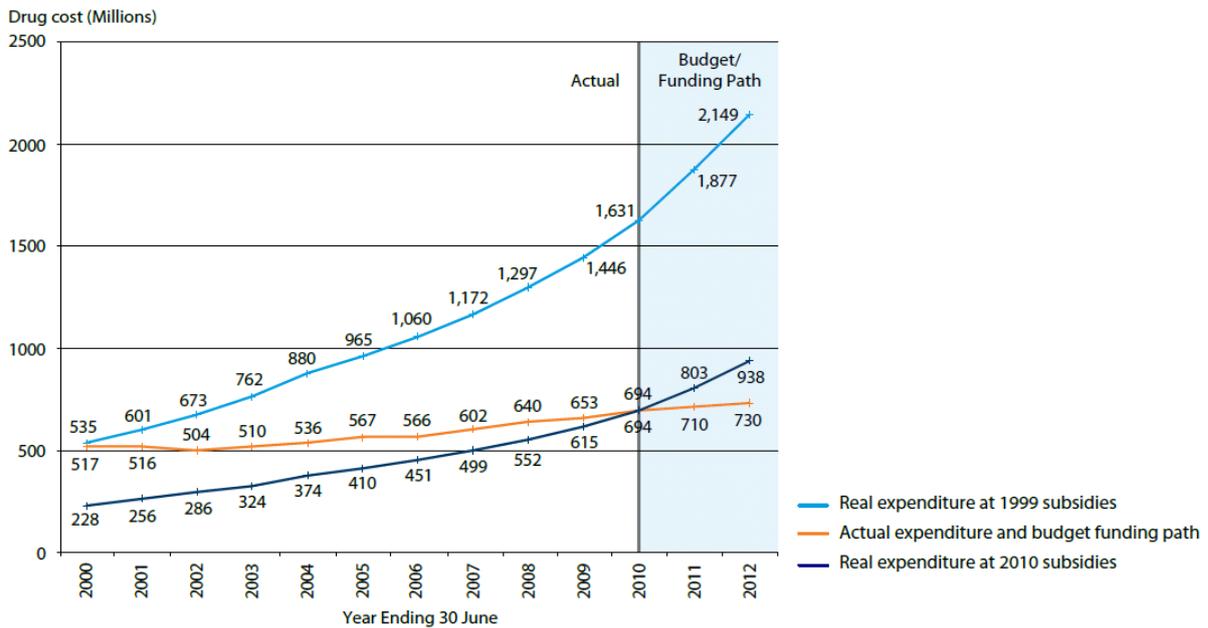
- *Concerns about ACC:* If ACC is privatised in the near future, the TPPA requires equal access to the workplace insurance market for the large US insurance companies. Provisions in the TPPA may also block a reversion to state control of ACC in the event of failed privatisation.
- *Concerns about foreign ownership of many health related services:* For example, aged care facility chains, drinking water provision, waste treatment services, public private partnerships to run hospitals, and so on.

PHARMAC and the TPPA

- PHARMAC uses a range of methods to price and purchase medicines. In order to get the most health improvement for New Zealanders PHARMAC utilises cost-effectiveness evaluation for new medicines, and reference pricing mechanisms (alongside other methods) to contain pharmaceutical expenditure for the health system as a whole.
- The graph on the next page demonstrates how successful PHARMAC is at cost containment.
- This system is regarded as exceptionally successful around the world.
- We are a small country with very a small pharmaceutical industry base. To curtail the ever increasing cost, and get the best value for money, we need PHARMAC and we should value what they do.
- Opponents of PHARMAC (generally from the pharmaceutical industry) seek to strip cost effectiveness from PHARMAC's consideration, preferring a platform that focuses on pharmaceutical innovation and quality.
- The work of PHARMAC is watched very closely by the rest of the world. Pharmaceutical industry profits have been affected by PHARMAC's processes in New Zealand, and the licensing process for generic medicines has also been able to affect the world price of some medicines.

The Trans-Pacific Partnership (TPP) Agreement and Public Health cont...

Impact of PHARMAC on drug expenditure over time



| Potential provision: | Potential effect: |
|-----------------------------------|--|
| Removal of reference pricing | Reference pricing and cost effectiveness evaluation systems (like PHARMAC) mean we can buy the most cost effective medicines for our populations. We have a very small pharmaceutical industry, so we don't have any national interest in keeping the reference prices a bit higher to protect that (unlike the UK and Australia). The challenge to reference pricing via the TPPA is a major concern for New Zealand. |
| Changes to patents | Possible clauses may include patent ever-greening, patent extensions and patent restoration. Pharmaceutical companies currently patent new drugs for 20 years. When patents expire generics can be generated. The details of the TPPA are still not clear, however there are several proposals which affect patents, such allowing companies to renew their patent for another 20 years by creating a new indication (use) for their product, or presenting it in a new form or dosage, so that it is under patent (and protecting their profits) indefinitely. |
| Extending data exclusivity | Data exclusivity grants makers of the first (branded) drug exclusive control of their clinical trial data, preventing the effective registration of generic versions of their products. In practical terms, this creates an absolute product monopoly for the duration of the exclusivity period (which stands even if the drug is not patented). In the US, this period is five years, plus an additional three years if the manufacturer presents a new product use. The US may require New Zealand to apply its same data exclusivity rules. This text has not yet been tabled in the TPPA, instead a 'placeholder' for this item was included in the 2007 version. |
| Limits on generics | There are different provisions in the TPPA which relate to the transport of generic medicines. Some clauses deal with parallel importation, and some with seizures of in-transit generics as a border control issue. These clauses are aimed at limiting the availability of generics, which is a significant issue of concern for New Zealand. |
| Removal of compulsory licensing | Compulsory licensing refers to public health needs, including in a public health emergency (eg pandemics) where governments can require companies to provide their data or sell their medicines cheaply (eg a vaccine). Experts feel that this provision is unlikely to be up for negotiation in the TPPA, but this is still not clear. |
| Transparency | PHARMAC doesn't decide what drugs can be sold in New Zealand, just which ones receive government subsidies. US PhRMA says PHARMAC's processes lack transparency and accountability. A Transparency chapter could guarantee them rights of input into decisions on policy and regulation, potentially including a seat on bodies that decide PHARMAC's pricing formula and creation of new categories of medicines that exclude cost-effectiveness criteria. |
| Investor-state dispute resolution | A provision which allows companies to sue governments directly in private international courts where their investment (including their intellectual property right) has been negatively affected. |

Where to from here?

A number of people and organisations have been discussing the TPPA and the potential impact for New Zealanders.

- The Public Health Association (PHA) and the New Zealand Medical Association (NZMA) have both commented on the TPP and health.
- The New Zealand Nurses Organisation (NZNO) has put out a joint press release on the TPPA, which can be found [here](#).
- The Association of Salaried Medical Specialists (ASMS) has several discussion pages on their website, including a TPPA discussion found [here](#), and a dialogue on the role of PHARMAC [here](#).
- Pharmacy Today has a commentary from a law expert assessing how similar clauses in the Australia-US FTA have impacted the Pharmaceutical Benefits Schedule (PBS), the Australian equivalent of PHARMAC, found [here](#).
- There have been editorials in various newspapers, such as the argument in favour of PHARMAC by Gareth Morgan, see the Health Cheque website [here](#).
- Law Professor Jane Kelsey's (University of Auckland) book, *No Ordinary Deal*, is a very readable account of the TPP, and includes a chapter on public health that covers Australia's experience under the Australia US FTA with its Pharmaceutical Benefits Scheme and other public health policies. See synopsis [here](#).
- The websites www.TPPWatch.org and www.TPPdigest.org have a number of resources, including factsheets and a discussion of the TPP, Te Tiriti o Waitangi and Māori.
- We can also raise awareness with colleagues, colleges and professional bodies.

References

Faunce, T. A., & Townsend, R. (2011). The Trans-Pacific Partnership Agreement: Challenges for Australian health and medicine policies. *Medical Journal of Australia*, 194(2), 83-86.

PHARMAC. (2010). *Annual Review 2010*. Wellington: Pharmaceutical Management Agency.

Acknowledgements

Kind thanks to Professor of Law Jane Kelsey and Dr Zaheer Babar, both from the University of Auckland, and to Peter Maybarduk of the Global Access to Medicines Programme, for their peer review and comments on this article.

Kind thanks to Dr Babar for allowing adaptation of part

of his presentation: Babar ZU. Trans-Pacific Partnership Agreement and Access to Medicines in New Zealand. Public Health Physicians Meeting, Greenlane Clinical Centre, Auckland 26th May 2011.

Dr Karen Bartholomew has recently been elected as the registrar representative on the College policy committee.

Upcoming Workshops

Health Quality & Safety Commission Forums and Workshop in October

Quality Forums: Improving Together: consumers, clinicians & services

The Health Quality & Safety Commission will hold the first of its quality forums in Auckland and Christchurch in October. The forums are open to people working in health, as well as health consumers and groups representing consumer interests. There is no charge to attend.

Beverley Johnson, who heads the Board of the Institute of Patient and Family Centered Care in the United States, will be the keynote speaker at the two fora. The Commission has brought her to New Zealand to share her experiences of working with hospitals and health organisations to improve consumer involvement and leadership.

Auckland Forum: Tuesday October 4th 9am to 5pm Ko Awatea, Middlemore Hospital, Auckland

Wellington Forum: Thursday October 6th 9am to 5pm Cashmere Club, Garden Room, Colombo St, Christchurch,

Workshop on consumer engagement: Improving together: strengthening the consumer voice

The Health Quality & Safety Commission is hosting a workshop in October for people who have an interest in or a responsibility to enhance their organisation's engagement with consumers.

The workshop will be presented by Beverley Johnson who will use a local case study and work with participants to create a plan for the implementation of a consumer group to provide advice to your organisation.

Who should attend: Chief Medical Officers, Directors of Nursing, Quality & Risk Managers, clinical leaders and senior clinical staff, and health managers from public and private health organisations.

Auckland Workshop: Monday October 3rd 9am – 3.30pm, Ko Awatea, Middlemore Hospital, South Auckland. For more information see <http://www.hqsc.govt.nz/page/27856/register-to-hear-beverley-johnson/?tab=2349§ion=9214>