Medicines New Zealand

Foreign Affairs, Defence and Trade Select Committee
Parliament
Wellington

24 March 2016

Dear Committee Members,

Our apologies for a delayed written submission (attached) on the International treaty examination of the Trans-Pacific Partnership Agreement (TPP). However, Medicines New Zealand has been seeking guidance and confirmation on a number of matters relating to the intellectual Property and Transparency chapters from government officials since late 2015 and into early 2016.

A Ministry of Business, Innovation and Employment Trans-Pacific Partnership Agreement (TPP) Implementation workshop on 23 March 2016 granted us clarification we were seeking.

Given this unfortunate delay in obtaining the necessary clarification from officials, we hope that the committee may still be in a positon to accept our written submission.

We can provide additional evidence requested by the committee and would like to give an oral submission to the committee as part of its deliberations.

Yours sincerely,

Hon Heather Roy
Chair, Medicines New Zealand

Submission

To:

Foreign Affairs, Defence & Trade Select Committee

On:

The Trans-Pacific Partnership Agreement (TPP)

By:

Medicines New Zealand

24 March 2016

Medicines New Zealand has publically stated support for the TPP, with the proviso that: (i) a balanced and realistic position is taken by New Zealand for suitable intellectual property (IP) protection on innovative products including innovative medicines and vaccines and; (ii) that more transparent and timely decisions on Government procurement of medicines for New Zealand patients is achieved.

Unfortunately recent dialogue with Government officials indicates New Zealand is taking a narrow interpretation of matters around intellectual property and transparency around medicines procurement.

This seems, in most cases, to be at odds with the majority of TPP countries' interpretations and/or positions and OECD norms, especially on IP provisions.

Our rational and views are as follows:

Patent Term Extension

The New Zealand Government's proposed two year maximum limit for pharmaceutical patent term extension, including an unwillingness to take into account delays experienced by the patentee in carrying out the necessary studies and clinical trials to establish the safety and efficacy of the pharmaceutical substance, is unacceptable to Medicines New Zealand. Furthermore it is not in line with other TPP signatory countries such as Australia, USA and Japan (all up to five years).

1. Patent term extension, negotiated in the TPP, benefits all New Zealand companies that use patents as a form of IP protection in export markets i.e. the 11 other countries in this Free Trade Agreement (FTA).

2. The New Zealand Government has taken the view that under the TPP they are only required to compensate pharmaceutical patent owners a patent term extension for "unreasonable curtailment" due to processing delays caused by Medsafe only.

3. The New Zealand Government is not proposing to take into account any delays experienced by the patentee in carrying out the necessary studies and clinical trials to establish the safety and efficacy of the pharmaceutical substance.

4. The narrow definition of 'unreasonable curtailment' (which seems to be in alignment with what Singapore has also proposed) is unacceptable to Medicines New Zealand as it is not in line with other TPP signatory countries perspectives or positions.

5. Importantly, all OECD Countries with the exception of Canada, have reasonable provision for patent term restoration. However, Canada agreed to implement patent term restoration legislation as part of the trade deal with Europe (EU) in the previous year.

Regulatory Data Protection (RDP) small molecule medicines and biologics

An increase in data protection (or marketing protection terms) above five years aligns with international best practice, and would not see an increase in expenditure as highlighted by historical evidence from Canada and Japan. The protection period for highly novel and efficacious biologics in New Zealand is currently five years, compared to eight years in EU and 12 years in United States (US).

The current data protection limitations and mechanism proposed by the New Zealand Government, under its TPP obligations for both small molecules and in particular biologics, is unacceptable to Medicines New Zealand. For biologics it does not represent an eight year marketing protection period, only five years with "…other measures and market circumstances" being proposed to reach an eight year end point. This is an extremely liberal interpretation of what actually constitutes robust data protection.

1. Other forms of IP protection (i.e. regulatory data protection or market protection) relate to biologics which are highly innovative and efficacious molecules.

2. Patents are not always an effective form of IP protection for these complex molecules. Such molecules also require regulatory data protection.

3. Most OECD countries have extended data protection for biologics to encourage investment in these important new medicines. **This had no material effect on the price of medicines to Governments.**

    a. In 2006 Canada changed its regulations in a way that increased their RDP term from 0 years to eight years. Investment in medicines, as a percentage of total health budget, **decreased.**
    b. Japan increased data protection in 2007 to eight years. Expenditure on medicines since the increase have been in line with growth in health care spending as a percentage of GDP. Pharmaceutical spend decreased in 2010 - a year when health care spending increased.

Transparency Annex and PHARMAC decision making processes

Medicines New Zealand is not seeking an end to PHARMAC, either as a result of current TPP outcomes or future trade negotiations. However, there is room for improvement in both the transparency of PHARMAC's decision making processes and timeliness of funding decisions.

Medicines New Zealand is not supportive of the New Zealand Government's proposed interpretation of the Transparency Annex of the TPP. This represents no more than a *status quo* for the way in which PHARMAC already makes funding decisions.

Medicines New Zealand is seeking:

1. Stakeholder access - stakeholders should have meaningful opportunities to provide input to the PHARMAC decision-making process at the appropriate stages.

2. Supply of additional information from companies - the scientific information on which decisions are based should be shared between PHARMAC and medicines and vaccine applicants to speed up decision making. For example, at the time of PTAC meetings science and technical input can be sought from companies.

3. Timelines - funding decisions should be made within a predetermined and transparent timeframe of no more than 18 months from date of submission.

4. System of review for appeals – an independent expert review panel to ensure consistent decisions and due process are followed by PHARMAC.

5. New Zealand Government has indicated that under the TPP, PHARMAC will:
   (i) **Not** need to deliver a timeline on funding decisions if any application falls over two budget cycles or "until it has budget available"
   (ii) **Exclude** all hospital medicines including cancer medicines (currently in Schedule H of the Pharmaceuticals Schedule) from a review process.
   (iii) Run the appeals process as an **internal process**, with potential for cost-recovery as an option.

Conclusion on the Trans-Pacific Partnership Agreement (TPP)

- Medicines New Zealand broadly supports the TPP ratification by New Zealand, because of the tangible benefits to a range of New Zealand export industries.
- However, the narrow interpretation that seems to be adopted by the New Zealand government on IP and transparency provisions appears to have deleterious implications for both: (i) New Zealand patients access to the best in class innovative medicines, and; (ii) how New Zealand is viewed internationally regarding its

commitment to global standards on IP protection for both international and domestic companies and institutes involved in medicines research.

- As an organisation we cannot therefore support the current proposed interpretations and proposed applications of TPP as it relates to medicines and the IP and Transparency Chapters.

Medicines New Zealand is the industry association representing companies engaged in the research, development, manufacture and marketing of prescription medicines.

Medicines New Zealand works to:

- Demonstrate the value of medicines, within the context of total healthcare
- Ensure access for all New Zealanders and their medical advisors to new medicines
- Encourage and support continuing advancement in medical science and its application in health

Ensure the industry, through Medicines New Zealand, is recognised by the health sector and the community generally as a key partner in maintaining the good health of all New Zealanders.

A central objective for Medicines New Zealand is to promote the benefits of a strong research based medicines industry in New Zealand.