Medicines New Zealand

Foreign Affairs, Defence and Trade Select Committee
Parliament
Wellington

21 July 2016

Dear Committee Members,

Medicines New Zealand is providing the following written submission (attached) on the Trans-Pacific Partnership Agreement (TPP) Amendment Bill 2016.

While Medicines New Zealand has been providing its views previously to the Committee on a number of matters relating to the Intellectual Property and Transparency chapters. The focus of this submission is on Intellectual Property.

We specifically make comment in this submission on components of the Bill that relate to intellectual property i.e. Part 1 (Amendment to Agricultural Compounds & Veterinary Medicines Act 1997) and Part 8 (Amendments to Patents Act 2013) of the TPP Amendment Bill.

We can provide additional evidence if required by the committee and we also request the opportunity to give an oral submission to the committee as part of its deliberations as we have provided a number of solutions/alternatives for proposed clauses as they relate to Part 8 of the Bill.

Yours sincerely,

Hon. Heather Roy
Chair, Medicines New Zealand

Submission

To:

Foreign Affairs, Defence & Trade Select Committee

On:

The Trans-Pacific Partnership Agreement (TPP) Amendment Bill

By:

Medicines New Zealand

21 July 2016

Background:

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.

Medicines New Zealand's Views on the Trans Pacific Partnership Agreement

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.

Medicines New Zealand's High-level Views on the Trans Pacific Partnership Agreement Amendment Bill

From a review of the Bill, it appears that New Zealand is committed to taking a narrow interpretation of matters around intellectual property around human medicines/ pharmaceuticals.

This seems, in most cases, to be at odds with the majority of TPP countries' interpretations and/or positions and Organization for Economic Cooperation and Development (OECD) standards around human medicines.

Regulatory data protection, patents and other forms of intellectual property are not barriers to access to medicines, particularly when governments, the private sector and other stakeholders work together to achieve health outcomes.

In actuality, intellectual property facilitates access to today's medicines and incentivizes investment in tomorrow's treatments and cures for New Zealand patients. Without a strong system supporting innovation – incentivized and underpinned by patents and other intellectual property rights – many of the therapeutic and preventive advances made over the past century (and those that are being developed now) would not have been realized.

Strong IP protection creates a framework for rapid dissemination of ideas and efficient technology transfer, resulting in faster launch and faster access to new medicines in developing countries and the introduction of many medicines that would not otherwise be available in those countries (in either brand or generic form). [1-3]

Patient compliance and health outcomes improve when mechanisms such as strong local intellectual property regimes incentivize innovators to develop a local market, as compared to generic medicine launches. [4]

It has also been established that countries that have economies with fair and strong intellectual property regimes are 30% more likely to benefit from access to new technologies as compared to those in weak intellectual property environments, as companies are encouraged to introduce new products faster. [5]

Furthermore, the spill over economic benefits into other related sectors of a strong IP regime in a given country can be significant. A recent study showed that a strong IP regime means that a country was 9-10 times more likely to host a clinical trial, and that strong IP protection regime can explain over 40% of the clinical trial intensity of a country. [6]

The size of the clinical trial market in New Zealand is estimated to be well over $100 million in value to the economy [7]. In the 2015/2016 year alone over 221 trials are underway of with the vast majority (86%) being funded by the innovative medicines industry. [8]

Given the above clear benefits of strong intellectual property regimes, it is concerning that New Zealand seems to be adopting relative narrow and weaker position on both patent term extension and regulatory data protection around its human medicines compared to other TPP signatory countries such as Japan, Australia, United States, and Canada.

Our specific views, concerns and alternative solutions for Part 8 of the TPP Amendment Bill Amendments to Patents Act 2013. Subpart 10A Extension of term are fully explained in Appendix 1 of the document. We do however summarise our main issues below as they relate to the TPP Amendment Bill.

Patent Term Extension

The New Zealand Government's proposed two (2) 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.

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 (five years only, no change) and in particular biologics ("five years data protection period" plus "three years using other other measures and market circumstances"), is unacceptable to Medicines New Zealand.

Specifically, for biologics it does not represent an actual eight year marketing protection period using data protection as it is only a data protection period of five years and then also employing non-data protection period options i.e. "…other measures and market circumstances" being proposed to reach an eight year end point. These measures include: use of the patent (a different form of IP); the time it takes Medsafe to consider biosimilar applications after the five year data protection period, and; the "natural lag" for biosimilars to be developed and come to the New Zealand market following the marketing of the innovator biologic (in New Zealand).

In our view this, this is an extremely liberal interpretation of what actually constitutes robust regulatory data protection and not in the spirit of the TPP agreement.

1. While patents exist for innovative biologics, 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 actually 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.

We do note with some interest that Part 1: Amendments to Agricultural Compounds and Veterinary Medicines Act proposes that data protection period increase for "innovative agricultural compounds" from five years to 10 years, effective from the date of registration.

Most interestingly, the Ministry of Primary Industries were not supportive of this data extension and noted that "…there is no compelling reason to increase the basic length of the data protection term." [9]. However we do note that the 10 year is aligned exactly to a number of TPP signatory countries data protection periods for similar compounds (including US, Japan, Canada, and Australia) [10].

Conclusions on the Trans-Pacific Partnership Agreement (TPP) Amendment Bill

- 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.
- It is disconcerting that under this Bill the New Zealand government is proposing to extend data protection for "innovative agricultural compounds", including veterinary medicines, to 10 years from five years. There is no use of "other measures" (as is the case with novel biologic human pharmaceuticals). This five year additional extension of data protection base level is in direct contrast to no material extension to regulatory data protection base level period for innovative small molecule and biologics medicines for humans.
- As an organisation that aims to ensure access for all New Zealanders and their medical advisors to new medicines, we therefore cannot support the current proposed interpretations and proposed applications of TPP as it relates to medicines and the IP clauses proposed in the Bill.

References:

[11 Kyle, M and Qian ,Y (2014) *Patents and the Global Diffusion of New Drugs.* National Bureau of Economic Research Working Paper No. 20492.

[2] Kyle, M and Qian ,Y (2014) *Intellectual Property Rights and Access to Innovation: Evidence from TRIPS*. National Bureau of Economic Research, Working Paper No. 20799.

[3] Ryan, M.P. (2007). *Pharmaceutical Foreign Direct Investment, Technology Transfer, Health Competitiveness, and the Jordan-United States Free Trade Agreement*. Report from George Washington University Law School, Creative and Innovative Economy Center (May, 2007).

[4] Charles River Associates (2013). *The wider value delivered to patients, healthcare systems and competitors when innovators launch new products* (Charles River Associates Ltd, April, 2013).

[5] Global Intellectual Property Center (2016) *Infinite Possibilities: IP as a Development Tool: Supplementary Statistical Analysis to the U.S. Chamber International IP Index* .US Chamber of Commerce.

[6] Pugatch, M (2015). *BCI- Measuring the Global Biomedical Pulse*. Pugatch Consilium Ltd.

[7] New Zealand Health Select Committee (2011) *Enquiry into improving New Zealand's environment to support innovation through clinical trials*. Report of the Health Committee Forty-ninth Parliament June 2011

[8] US National Institute of Health (2016) www.clinicaltrials.gov

[9] Ministry for Primary Industries (MPI) (2012): *Regularity Impact Statement – data protection for agricultural compounds*. ISBN 978-0-908334-96-4 (online).

[10] Covec (2009) *Study of data protection for agricultural compounds and veterinary medicines* (Report prepared for NZFSA).

APPENDIX 1:

Specific comments on *Part 8 of TPP Amendment Bill : Amendments to Patents Act 2013*

Subpart 10A Extension of term

Sections 111A and 111B. Patent extension on ground of unreasonable delay in granting patent

Article 18.46 of the TPP requires that a Party provide the means to adjust the term of the patent to compensate for unreasonable delays.

With no limit on the maximum length of extension available for grant delays as proposed in sections 111A & B Medicines New Zealand is supportive of the regulations as written and fell they are in line with Article 18.46 of the TPP Agreement.

Sections 111C to 111O Extension of patent term for pharmaceutical substances

We disagree with the form and intent of the criteria for patent extensions for pharmaceutical substances *per se* and for biologics as written. Furthermore we believe that the definition of *pharmaceutical substance* and biologic as written is too narrow.
When considering subject matter restrictions on eligibility for extension, we urge the Select Committee not to propose overly broad restrictions that will ultimately harm the environment for innovative medicines in New Zealand.

Beyond patents on pharmaceutical substances, other types of pharmaceutical patents, such as patents on new uses, new delivery mechanisms, new formulations or new combinations, provide innovative solutions by using existing active ingredients in new therapeutic areas. Therefore, granting the extensions for any type of patent directed to a pharmaceutical substance represents a more robust way of incentivizing and protecting valuable innovation. Without such equal treatment, innovative pharmaceutical companies will have less incentive to introduce improved therapies in New Zealand. Patients, and the society at large, will bear a higher cost in the long term because more effective and safer medicines may not be available as a result.

In particular, the proposed limitations set forth are unduly restrictive as to biologics. It provides that extensions are available only for patents regarding substances produced using recombinant DNA technology, but many useful biologics are produced through other means.

Further, the definition /interpretation of the term biologic (section 111C) appears to limit biologics to "recombinant DNA molecules." Without doubt, this definition is much too narrow, particularly when viewed in comparison to the relevant definitions used in other TPP signatory countries (Japan, USA) and territories (EU) .

For example, the European Union defines a "biological medicinal product" as "a product, the active substance of which is a biological substance. A biological substance is a substance that is produced by or extracted from a biological source and that needs for its characterisation and the

determination of its quality a combination of physico-chemical-biological testing, together with the production process and its control." Section 3.2.1.1(b), Part I, Annex I to Directive 2001/83/EC.

Furthermore, Japan has in Article 2.9 of its Pharmaceutical Affairs Law, defined biological products as products including ingredients derived from human or biological (excluding plants) source materials (such as cells, tissue, blood, body fluid, etc.), which are specifically designated by the authorities to require particular attention from a public health point of view.

Finally, in the United States, a biological product is defined as "virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings." *See* Public Health Service Act § 351(i), 42 U.S.C. § 262(i)

Therefore, we believe the patent term extension rules should not be limited to pharmaceutical substances *per se* and to the biologics described in the Document.

Section 111F: What is Unreasonable curtailment

We disagree with section 111F(2) that any delays not directly attributable to the Regulator (Medsafe) , including delays that are outside the direction or control of Medsafe, would be excluded from these time periods.

Article 18.48 obligates New Zealand to make available patent term adjustment to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process. From a practical perspective, certain delays, even though they are not directly attributable to Medsafe, are in fact necessary to obtain the marketing approval from Medsafe and are thus indeed the "result of the marketing approval process."

The corresponding approaches in Japan and the United States provide useful examples for approaches that are fully aligned with the intent of Article 18.48. The pharmaceutical patent term extension in Japan takes into consideration the date of commencement of relevant clinical trials. Further, in the United States, the patent term extension period is based on the regulatory review period, which is in turn composed of a "testing phase" and a "review phase." For a drug product, the "testing phase" begins on the effective date of an Investigational New Drug ("IND") Application and ends on the date a New Drug Application (NDA) is submitted to the Medsafe equivalent of the United States, the Food and Drug Administration (FDA). The "review phase" for a drug product is the period between the submission and the approval of the NDA. The patent term extension calculation in the United States is based on the sum of one-half of the time in the "testing phase" plus all of the time in the "review phase" minus any time during which the applicant did not act with due diligence. The above approaches by Japan and the United States more appropriately compensate patent owners and encourage the rigorous clinical research and development necessary to ensure that the drug product is effective and safe.

Consistent with the goals of Article 18.48 of the Agreement and the approaches of other TPP signatories noted above, we strongly urge New Zealand to ensure that the definition of "unreasonable curtailment" also covers delays incurred through diligent efforts to complete the necessary clinical trials to secure marketing approval from Medsafe.

Sub-Section 111F(1)(b) Unreasonable Curtailment

We do not agree that the definition of "unreasonable curtailment" should apply different time periods for small molecule pharmaceuticals and biologics. In requiring that a Party provide the means to adjust the term of the patent to compensate for unreasonable delays, Article 18.48 of the TPP does not distinguish between small molecule pharmaceuticals and biologics.

While we understand that "…the complexity of biologics means that applications for marketing approval require more expert advice and consultation and will therefore take longer to process than those for small-molecule pharmaceuticals…" in New Zealand, such delays do not in any way diminish the intent of this obligation to compensate the patent owners for the effective patent term lost due to the marketing approval process. Loss of effective term would be at least as significant for patents directed to biologics as for patents directed to small molecule pharmaceuticals; indeed, because the marketing approval process takes longer for biologics, there is all the more need for compensation of lost patent term for these medicines. **Therefore, we submit that the definition of "unreasonable curtailment" should not distinguish between small molecule pharmaceuticals and biologics as it currently does (see Section 111F(1)(b))** .

Calculations of Periods of unreasonable curtailments (sections 111F(1)(b) & section 111G

We disagree with the proposed method of calculating the length of extensions for pharmaceutical patents.

We submit that the proposed method fails to fully take into account the expensive, high-risk, and time-consuming research and development necessary to obtain regulatory approval of new medicines. For example, before the regulatory review period can commence, new drug candidates must undergo a lengthy, rigorous clinical "testing phase" to ensure the safety and efficacy of the drug. Therefore, the proposed method of calculating the length of extensions for pharmaceutical patents, which would allow no longer than a two (2) year extension, could fail to fully compensate the patent owner. This approach also is contrary to the need to provide robust incentives for companies to undertake research and development of new medicines and is inconsistent with best practice as described in response to Question 14 below.

Again, the approaches in Japan and the United States are informative. As noted in Question 11, the calculation of the length of pharmaceutical patent term extension in Japan also takes into consideration the date of commencement of relevant clinical trials. Further, as described, in the United States, the patent term extension period is based on the regulatory review period, which is in turn composed of a "testing phase" (clinical study phase) and a "review phase" (FDA review phase).

The patent term extension calculation in the United States is the sum of one-half of the time in the "testing phase" plus all the time in the "review phase" minus any time during which the applicant did not act with due diligence.

We believe the above approaches by Japan and the United States more appropriately compensate the patent rights owners for time lost due to the lengthy clinical development and regulatory review processes and encourage development of new medicines.

Section 111H Opposition to extension on the ground of unreasonable curtailment of effective patent term as a result of marketing approval process

As proposed, we disagree that third parties should be able to oppose decisions to extend patents for pharmaceuticals through the Commissioner of Patents.

First, while Article 18.48.3 of the TPPA allows New Zealand to provide for conditions and limitations, New Zealand is still obligated to give effect to Article 18.48, which seeks to compensate patent owners for unreasonable curtailment. Allowing third parties to oppose ministerial decisions to extend patents could significantly undermine the intent of Article 18.48, i.e., it could lead to patent owners not being sufficiently compensated for "unreasonable curtailment" of the effective patent term due to Medsafe's marketing approval process. Moreover, from a practical perspective, based on the format of the proposed amendments, the Commissioner of Patents would have very little discretion in making a decision on whether a patent is eligible for an extension; applying such rules to the application for extension is purely ministerial. Thus, it is not clear what value a third party could bring to the eligibility decision process. Finally, if the process were to be made adversarial, this would impose a significant administrative burden on the Commissioner of Patents.

Section 111I Exclusive rights of patentee are limited if extension granted on ground of unreasonable curtailment.

We disagree with the proposal that patent rights during the extended term should be limited in the manner proposed. The goal of Article 18.48 of the TPP is to compensate the patent owners for any effective term lost due to the marketing approval process. At the broadest level, we believe that the patent rights during the extended patent term should be the same as the patent rights as set forth in the originally issued patent as applicable to the product and the approved method of use of the product.

However, if the Government decides to limit the rights during the extended term to the therapeutic uses for which the substance was approved, the therapeutic uses should encompass both the initially approved and any subsequently approved therapeutic uses for the product.

We further believe that the patent rights in the extension should at least encompass both the particular substance specified in the application for extension as well as any variations thereof that would be permitted to be made in a generic version of the substance, provided such variations are encompassed by the claims in the patent.