INTERNATIONAL GENERIC AND BIOSIMILAR MEDICINES ASSOCIATION

March 30, 2016

Business Law
Building, Resources and markets
Ministry of Business, Innovation & Employment
PO Box 1473
Wellington 6140
New Zealand

Re: Targeted Consultation Document – Implementation of the Trans-Pacific Partnership Intellectual Property Chapter

Submitted via email: tpp.ip.policy@mbie.govt.nz

Dear Madam or Sir,

The International Generic and Biosimilar Medicines Association (IGBA) is pleased to provide the following recommendations to the Government of New Zealand with regard to the proposed introduction of patent term extensions (PTEs) to compensate for any unreasonable delay as a result of Medsafe's marketing approval process.

The IGBA represents companies that are actively engaged in the global manufacturing and trading systems for medicines. We support enhanced cooperation between regulators to foster the global trade in medicines, as well as measures aimed at the elimination of barriers to trade in medicines in order to increase access for patients.

From a global perspective, the IGBA remains concerned regarding the scope and wording of intellectual property provisions included in the final TPP text, which goes beyond the international standard established by the World Trade Organization Agreement on the Trade-Related Aspects of Intellectual Property Rights (WTO TRIPS Agreement). This includes the inclusion of patent term extensions in the final text.

There are several steps New Zealand can take to limit the potential impact of the proposed domestic PTE system, as outlined below. In addition, care should be taken in drafting to ensure the system is designed in a manner that avoids ambiguity and loopholes regarding when a patent or product is eligible for exclusivity. Based on the international experience of IGBA members, it is

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clear that any ambiguities will be exploited by originator companies to attempt to expand the scope of protection and delay the entry of generic medicines

Implementation
The TPP is a forward-looking agreement, and the start date for eligible products should therefore be limited to innovative molecules approved after the date in which the agreement comes into force. No extensions should be made available for existing pharmaceutical products.

Applies to a Single Patent
The US PTE system applies to a single patent. Any potential implementation of PTE in New Zealand should also apply only to a single patent. It should be made clear that only pharmaceutical products containing new active moieties are entitled to protection, that they may benefit from the extended protection from only one patent, and that the patent must be a truly foundational patent. This will normally be a composition-of-matter (compound) patent. If a composition-of-matter patent has not been issued, process or use patents should only be eligible for protection if they arise from the patent application in which the active ingredient was first disclosed/patented.

Limit Maximum Length of Extension
The maximum length of a PTE in the United States is 5 years. The TPP treaty text does not specify a minimum or maximum length of a PTE. While many countries have implemented systems permitting up to 5 years of exception, there is no treaty obligation for New Zealand to do so. It is notable that Canada is implementing a maximum extension of 2 years under the Comprehensive Economic and Trade Agreement (CETA) it has signed with the European Union, and this implementation is consistent with the final TPP treaty text. An even shorter length of extension, such as 6 months, could also be considered by New Zealand.

Limit Maximum Length of Monopoly Created by PTE
The total market monopoly for a drug cannot be extended beyond 14 years of FDA approval in the United States. The TPP treaty text does not specify a minimum or maximum length of monopoly that could be provided to a product that obtains a PTE. As such, a much lower maximum length – possibly in line with the length of domestic data protection – could be considered.

No Paediatric Extension Should Be Granted
The US does not provide for a PTE with a paediatric extension. As such, no special PTE considerations should be provided for paediatric trials.

Submission Filing Should Trigger Calculation
The PTE calculation of the extension in the US begins with the submission filing date. New Zealand should adopt this approach.

Include Due Diligence Requirement
Under the US system, an applicant loses time during which it did not act with attention and timeliness during the regulatory review period. A requirement for due diligence by the applicant should also be required in New Zealand.

Limit Time to File Submission
In the US an application for a PTE must be filed within 60 days of market authorization. As New Zealand has national authority over patent laws as in the US, the US approach would be appropriate.

Transparency
The system should be implemented in a transparent manner with the New Zealand public able to understand the basis for decisions to grant PTEs and to challenge the grant of extended protection in appropriate circumstances.

Export Exception for Full Period of Extension
New Zealand should implement a provision allowing for the export of generic pharmaceuticals during the full period of patent term extension, even though such a provision may have little practical effect as a result of the current lack of pharmaceutical manufacturing in New Zealand. Both Canada and the European Union are moving forward with such export provisions in their domestic regimes through the implementation of CETA. There is nothing in the TPP treaty text that prohibits the inclusion of such a clause in domestic law.

Interplay Between PTE and PTA Systems
The consultation document also includes consideration of the design of a new patent term adjustment (PTA) system, which would be required as part of TPP implementation. The IGBA notes that the consultation document is silent on the interplay between the PTE and PTA systems. We recommend that the Government of New Zealand give careful consideration to the interplay between these two systems and the safeguards that need to be implemented to ensure that the total cumulative period of extension for PTE and PTA do not exceed the PTE period.

Conclusion
Thank you for reviewing the recommendations of the International Generic and Biosimilar Medicines Association. The IGBA would be pleased to discuss these recommendations in greater detail via phone or Skype.

Sincerely,

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President, Canadian Generic Pharmaceutical Association
Redacted s.9(2)(a) OIA 1982
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Cc: Vivian Frittelli, Chair, IGBA