Submission on MBIE consultation document *Trans-Pacific Partnership Agreement Amendment Bill: Patent Term Extensions*

Name and organization

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Responses to consultation document questions

Manner of making a request for extension of term	
Q1	*Do you agree with the content of the proposed regulations regarding the manner in which a request for extension of term must be made? If not, why do you disagree?*
	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. This appears to be done under section 111A and 111B for patent term extension relating to delays during the granting process. **We agree with the content of the proposed regulations as written on this topic. But have a fundamental issue on the Regulations per se as they fail to address the considerably larger issue around New Zealand's obligations as a signatory to the Trans-Pacific Partnerships Agreement (TPP). We do have fundamental issues around sections 111C-1110 and disagree that the form and intent of the criteria for patent extensions for pharmaceutical substances per se and for biologics as written are suitable.** **Furthermore we believe that the definition of biologic as written is too narrow. The definition /interpretation of the term biologic (section 111C) also 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 other non TPP signatory 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 characterization 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 as currently defined in the TPP Amendment Bill. **Once these critical issues have been addressed and the other matters raised in our responses below then we are in principle supportive of the proposed manner in which a request for extension of term is dealt with under these proposed Regulations**
Q2	*Should the applicant for extension of term for unreasonable curtailment be required to declare that the marketing approval referred to in the request is the first marketing approval for the pharmaceutical substance involved, or should this be contained in the declaration from Medsafe? Why?*
	Assuming the above issues raised in response to Q1 where first addressed then we feel that this information should be contained in the declaration from Medsafe in its capacity as the Government body responsible for examination and record keeping of all market approvals for medicines in New Zealand.
Time limit for requesting extensions of term for unreasonable delays in patent grant	
Q3	*Which of the three options discussed do you prefer? Why do you prefer this option?*
	Assuming the above issues raised in response to Q1 where first addressed then we believe that option 1 is the best option as regards allowing no time limit on the right to request an extension to the patent term. This is in part due to the extreme complexity associated with the pharmaceutical research, development and commercialization process meaning that effective terms for the pharmaceutical patents are also prone to more uncertainty around the patent materials eventual commercialization timeframe. Allowing more flexibility for a patentee to apply for an extension therefore allows a continuation of investment in the innovation in its widest sense. We feel such an approach would see New Zealand uphold Article 18.4 of the TPP.
Q4	*Options 2 and 3 require the setting of time limits for making requests for extension of term. If either of these options was adopted, what do you think the time limit should be?*
	Not supportive of either Option 2 or 3.
Time limit for requesting extensions of term for unreasonable curtailment of the effective patent term	
Q5	*Which of the three options discussed do you prefer? Why?*
	We fundamentally have an issue with section 111F (*What is unreasonable curtailment*) and 111G (*Calculation of term of extension*) that would need resolution before a time limit on request for extension of term for unreasonable curtailment can be answered. **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 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.** **Furthermore, 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)) .** **We also disagree with the proposed method of calculating the length of extensions for pharmaceutical patents (section 111G), and also again 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.** **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 is also contrary to the need to provide robust incentives for companies to undertake research and development of new medicines. **Again, the approaches in Japan and the United States are informative. 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.** **Assuming the above issues were dealt with around a better definition and calculation of unreasonable curtailment for pharmaceutical patents then we would be supportive of Option 1. Again for the reasons stated in answer to Q3.**
Q6	*Options 2 and 3 would impose time limits by which a request for extension must be made. If one of these options was adopted, what do you think the time limits should be? Why?*
	Not applicable
Extensions of the time limit for requesting extensions of term for unreasonable curtailment of the effective patent term	
Q7	*Should the time limit for requesting extension of term for unreasonable curtailment be extendable? If so, what extension should be available?*
	Medicines New Zealand feel that should Option 1 as proposed under *Extension of term for unreasonable delay* be adopted (see Q3) and that therefore there would be no need to have an an extension of time limit.
Q8	*Under what circumstances should an extension be granted?*
	Not applicable
Disregarded Periods	
Q9	*Which of the two options discussed do you prefer? Why?*
	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. **We believe that a limit on the maximum length of extension available for grant delays as proposed in sections 111B(4) is both unnecessary and could undermine the intent of Article 18.46 of the TPP to compensate a patent owner for certain patent office delays.** **If there is any "unreasonable delay" by the patent office, it is only fair to fully compensate the rights holder for the loss of that time by granting an extension of the patent term without any limitation.**

	Any cap on the length of such an extension would be arbitrary and unfairly reward egregious patent office delays and could discourage patent applications by inventors in New Zealand. **We therefore feel this issue around the cap on patent term extension due to granting the patent needs to be resolved before we can comment on the best option for disregarded periods.**
Q10	*Considering the list of disregarded periods proposed in Appendix 1, are there any time periods on that list that you consider should not be disregarded? Why?*
	We feel this issue around the cap on patent term extension due to granting the patent needs to be resolved before we can comment on this matter.
Q11	*Considering the list of disregarded periods proposed in Appendix 1, are there any periods that are not on the list, but that you consider should be there?*
	We feel this issue around the cap on patent term extension due to granting the patent needs to be resolved before we can comment on this matter.
Procedure for opposition to extension of term for unreasonable curtailment of the effective patent term	
Q11	*Of the possible opposition procedures discussed, which do you prefer? Why?*
	None of the proposed methods is supported by Medicines New Zealand. 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 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. Therefore, 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.**
Q12	*If you do not prefer either of the procedures discussed, what other procedures could be used?*
	As stated in the answer to Q11 – we do not feel that an opposition process should be allowed as it is against the intent of the TPP specifically Article 18.48. **Furthermore given that the decision on eligibility for grant of a patent term extension is at the sole discretion of the Commissioner of Patents- then we feel that it is not clear what additional benefit will be derived from having such a procedure.**
Time limit for filing a notice of opposition to an extension of term for unreasonable curtailment of the effective patent term	
Q13	*What should the time limit be for filing a notice of opposition to an extension of term?*
	Not applicable. As stated in the answer to Q11 – we do not feel that an opposition process should be allowed as it is against the intent of the TPP specifically Article 18.48.

Q14	*Should the time limit for filing a notice of opposition to extension of term for unreasonable curtailment be extendable? If so, what extension should be available? Under what circumstances should an extension be granted?*
	Not applicable. As stated in the answer to Q11 – we do not feel that an opposition process should be allowed as it is against the intent of the TPP specifically Article 18.48.
Fees Set out above are tentative estimates of likely fee levels that would be charged in relation to requests for extension of term, and in relation to the filing of notices of opposition to extension of term.	
Q14	*Do you think that such fee levels are reasonable? If not, should the fees be higher or lower than the estimates given? Why?*
	On the information provided, and assuming our issues on the preceding questions are resolved in updated prosed regulations, then Medicines New Zealand is supportive of the fees level as proposed in terms of both their reasonableness and the rationale for setting the fees at that level.