Submission on consultation document: ***Implementation of the Trans-Pacific Partnership Intellectual Property Chapter***

Your name and organisation

Name	Dr Graeme Jarvis
Organisation	Medicines New Zealand

Responses to consultation document questions

1	**Have the overarching objectives been framed correctly for this policy process? If not, what would be more appropriate objectives?**

We thank the Ministry of Business, Innovation and Employment ("Ministry") for taking important steps in this Consultation Document ("Document") and are grateful to the Ministry for seeking advice from various stakeholders on the New Zealand Government's implementation of the Trans-Pacific Partnership Agreement (TPP) intellectual property (IP) chapter (Chapter 18).

We note that Article 18.4 of the TPP lists the public policy objectives of the TPP IP chapter and states that "the Parties recognise the need to: (a) promote innovation and creativity; (b) facilitate the diffusion of information, knowledge, technology, culture and the arts; and (c) foster competition and open and efficient markets, through their respective intellectual property systems, while respecting the principles of transparency and due process, and taking into account the interests of relevant stakeholders, including right holders, service providers, users and the public." As such, we recommend that the Ministry's overarching objectives encompass all the objectives listed above, including promotion and rewarding of innovation and creativity.

We further note that the Document does not fully address several areas where the current IP laws of New Zealand are not compatible with the obligations set forth in the IP chapter of the TPP. These areas include data protection for new pharmaceutical products other than biologics (Article 18.50 of the TPP), data protection for biologics (Article 18.51 of the TPP) and effective patent enforcement mechanisms for pharmaceutical products (Article 18.53 of the TPP).

With respect to data protection for small molecule and biologic drugs, we are concerned that the Government has stated the view in its TPP Intellectual Property (IP) Fact Sheet that these obligations "can be met within existing policy settings and practice." We request that the Ministry provide greater clarity as to what those policy settings and practices are and provide an opportunity for stakeholders to comment on the sufficiency of such policies and practices. For example, while the current laws of New Zealand provide five years of data protection for biologic drugs, it is unclear what "other measures" exist to deliver a "comparable outcome in the market" of eight years of protection in the market, consistent with its TPP obligations under Article 18.51.1(a) and (b).

While we are aware that the Ministry proposes that "other measures" include using the patent protection period, biosimilar application process timeframes via Medsafe , and natural lag in biosimilars coming to the New Zealand market – none of these provide innovators or biosimilar manufacturers with the business certainty that they need to deem that these are "comparable" to providing eight years of effective market protection.

	Finally as regards patent linkage, no reference is made to this in the Targeted Consultation Document. However the Government's TPP IP Fact Sheet acknowledges that "New Zealand will need to provide for 'patent linkage'", this same Fact Sheet also states that "New Zealand's current law and practice is sufficient in this area". We hope the Ministry will provide greater clarity on the aforementioned issue and an opportunity to comment before an implementing bill is put forward.
Technological protection measures	
2	**Do you agree with the exceptions or limitations proposed for TPMs? What would be the impacts of not providing these exceptions? Please be specific in your answers**.
	N/A
3	**Do you agree that the exceptions proposed for TPMs should apply to both prohibitions (i.e. circumventing a TPM and the provision of devices or services that enable circumvention)? Why / why not?**
	N/A
4	**Do you agree that, if our proposals are implemented, the current exception allowing a qualified person to circumvent a TPM that protects against copyright infringement to exercise a permitted act under Part 3 would no longer be required? Why / why not?**
	N/A
5	**Are there any other exceptions or limitations to the TPM prohibitions that should be included in the Copyright Act? Please explain why any additional exceptions would be necessary.**
	N/A
6	**Would there be a likely adverse impact on non-infringing uses in general if the exception for any other purpose that does not infringe copyright was not provided for? Please be specific in your answers.**
	N/A
7	**Should there be a regulation-making power to enable the exception for any other purpose that does not infringe copyright to be clarified, and if so, what criteria should be considered?**
	N/A
Patent term extension for delays in patent grant	
8	**Do you agree with the proposals for patent term extensions for unreasonable grant delays? Why / why not?**
	With the exceptions noted below, we agree with the Ministry's proposals to implement TPP's obligation to provide for patent term extensions for unreasonable grant delays. We believe it is fair and just for New Zealand to harmonize its patent system with the other Parties to the

	TPP in this manner. Further, we believe patent term extensions for unreasonable grant delays will help reduce uncertainties for inventors and encourage more innovative activity in New Zealand, including the filing of more patent applications by innovative pharmaceutical companies in New Zealand.
9	**Do you think that there should be a limit on the maximum length of extension available for grant delays? If so, what should it be?**
	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 is both unnecessary and could undermine the intent of Article 18.46 to compensate a patent owner for certain patent office delays. As noted in the chart under Paragraph 61 of the Document, "[m]ost patent applications are determined within 18 months of the request for examination" in New Zealand, and thus would be unlikely to qualify for an extension. However, 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.
10	**Do you consider that third parties should be able to oppose decisions to extend patents on the ground of unreasonable delays in grant?**
	We do not believe that third parties should be able to oppose decisions to extend patents on the ground of unreasonable delays in grant. First, Article 18.46 of the TPP provides clear direction as to how TPP signatory countries are to address patent term adjustment for patent office delays. Moreover, from a practical perspective, as explained in Paragraph 67 of the Document, the Commissioner of Patents has very little discretion in deciding whether a patent is eligible for an extension, especially given that the eligibility decision made by applying the rules set forth in the Document would be purely ministerial. It is not clear what value a third party could bring to the ministerial eligibility decision process. Further, if the process were to be made adversarial, this approach would impose a costly administrative burden on the Commissioner of Patents.
Patent term extension for pharmaceuticals	
11	**Do you agree with the proposed definition of "unreasonable curtailment" for pharmaceutical patent term extensions? If not, what other definition should be used?**
	We disagree with the proposal that any delays not directly attributable to 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 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.

12	**Do you agree that the definition of "unreasonable curtailment" should apply different time periods for small molecule pharmaceuticals and biologics? If so, what could these time periods be? If you consider that only one time period should apply to both, what should this be?**

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 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.

We propose that there should be only one time period that applies to both small molecule pharmaceuticals and biologics, and that time period should be one year between the date the application for marketing approval was made and the date approval was granted. We understand that Medsafe aims to complete its initial evaluation within 200 calendar days of receipt of the application even though the total time taken to reach a final decision can vary.

Therefore, we believe one year strikes the right balance taking into consideration Medsafe's evaluation timeline.

13	**Do you agree with the proposed method of calculating the length of extensions for pharmaceutical patents?**
	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.
14	**The proposed method of calculating extensions for pharmaceutical patents includes a maximum extension of two years. Do you agree with this? If not, what do you think the maximum extension should be?**
	We do not agree that a maximum extension of two years is appropriate because it could fail to compensate the patent owners for effective patent term lost due to the marketing approval process. In addition, as noted earlier, we strongly recommend that the proposed method of calculating the length of extensions for pharmaceutical patents take into consideration the clinical "testing phase" of the regulatory review period. We do not support a maximum length of extension; however, if there is a need for a maximum length, we propose a maximum length or cap for the patent term extension to be five years, which is the same maximum length of patent term extension for pharmaceuticals in Australia, United States Singapore, and Japan.
15	**Do you agree or disagree that only patents for pharmaceutical substances *per se* and for biologics should be eligible for extension? Why?**
	We disagree that only patents for pharmaceutical substances *per se* and for biologics should

	be eligible for extension. When considering subject matter restrictions on eligibility for extension, we urge the Ministry 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 limitation set forth in Paragraph 88 of the Document is 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, footnote 10 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 regions. 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.
16	**Do you think the Australian definition of "pharmaceutical substance" should be adopted? Why / why not?**
	We have no objection to the adoption of the Australian definition of "pharmaceutical substance." As drafted, we understand the proposed definition to encompass various forms of novel chemical and biological products.
17	**Do you agree that patent rights during the extended term should be limited in the manner proposed?**
	We disagree with the proposal that patent rights during the extended term should be limited

	in the manner proposed in Paragraphs 93-94. 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, consistent with our response to Q.15 above, 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 Ministry 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.
18	**Do you agree that third parties should be able to oppose decisions to extend patents for pharmaceuticals through the Commissioner of Patents? Why / why not?**
	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. 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.
Performers' rights	
19	**Do you agree that a performer's moral rights should apply to both the aural and visual aspects of their live performance and of any communication of the live performance to the public? Why / why not?**
	N/A
20	**Should performers' moral rights apply to the communication or distribution of any recording (i.e. both sound recordings and films) made from their performances, rather than just sound recordings as required by WPPT? Why / why not?**
	N/A
21	**Do you agree or disagree with any of the exceptions or limitations proposed for a**

	performer's right to be identified? Why?
	N/A
22	**Are there any other exceptions or limitations to a performer's right to be identified that should be included in the Copyright Act? If so, can you please explain why they would be necessary.**
	N/A
23	**Do you agree or disagree with providing for any of the exceptions or limitations proposed for a performer's right to object to derogatory treatment? Why?**
24	**Are there any other exceptions or limitations to a performer's right to object to derogatory treatment that should be included in the Copyright Act? If so, please explain why they would be necessary.**
	N/A
25	**Should the new property rights for performers be extended to apply to the recording of visual performances in films? Why / why not? (Please set out the likely impacts on performers and producers, and any others involved in the creation, use or consumption of films.)**
	N/A
26	**Do you agree or disagree with any of the exceptions or limitations proposed above? Why?**
	N/A
27	**Are there any other exceptions or limitations to the new performers' property rights that should be included in the Copyright Act? If so, can you please explain why they would be necessary.**
	N/A
28	**Do you agree or disagree with any of the proposals above? Why?**
	N/A
29	**Are there any other amendments that need to be made to the Copyright Act, and in particular to Part 9, to clarify the new performers' property rights? If so, can you please explain why they would be necessary.**
	N/A
Border protection measures	
30	**Do agree that Article 4 of European Union Council Regulation (EC) No 3295/94 is an appropriate model for implementing *ex officio* powers into the border protection measures set out in the Copyright Act 1994 and Trade Marks Act 2001? If not, please explain why not and outline an alternative approach to implementing *ex officio* powers.**

	N/A
31	**Do you agree that the detention period of three business days following notification to the rights holder is appropriate? Can you outline the impact on both the right holders and any importer/exporter where you consider the period should be shorter or longer than three business days?**
	N/A

Other comments