30 March 2016

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

Dear Sir/Madam

Re: Support for Medicines New Zealand's submission to the consultation on Implementation of the Trans-Pacific Partnership Intellectual Property Chapter

Medicines Australia supports Medicines New Zealand's submission to the Ministry of Business, Innovation & Employment (MBIE) targeted consultation on the implementation of the Intellectual Property (IP) chapter of the Trans-Pacific Partnership (TPP). We support the position that the IP chapter may not adequately address areas where the current IP laws of New Zealand are compatible with the obligations in the IP Chapter of the TPP.

Four key implementation issues have been raised by Medicines New Zealand that would benefit from further consultation and discussion:

- Data protection for small molecule and biologic drugs;
- Data protection for new pharmaceutical products other than biologics;
- Effective patent enforcement mechanisms for pharmaceutical products; and
- Appropriate implementation of Patent term extension provision, to compensate for delays in the regulatory access processes

Similar to the Australian experience, we agree with Medicines New Zealand's request that the MBIE provide greater clarity on how the data protection articles (18.51.1 of the agreement) will be implemented to achieve the additional three years' protection. This clarity will encourage greater consistency and transparency in the international business environment within which innovative pharmaceutical companies make their investments.

We support Medicines New Zealand's agreement with the Ministry's proposals to implement patent term extensions, although we are concerned about the potential for 'unreasonable curtailment' of this extension earlier than necessary. There is an opportunity to align patent term extensions with other jurisdictions (such as Australia's five year extension for pharmaceutical products) to incorporate the periods for clinical trials and regulatory approval. We agree that imposing a maximum extension term would be unnecessary and may inadvertently fail to meet the intent of the Article 18.46.

We support Medicines New Zealand's request for further clarity about the proposals, and join Medicines New Zealand in seeking an opportunity to comment prior to an implementation Bill being put forward on these issues. We would welcome the opportunity to discuss further, and please feel free to contact our Director of Policy and Advocacy Elizabeth de Somer. She can be contacted on Redacted s.9(2)(a) OIA 1982

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Respectfully yours,

Wes Cook

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