New Zealand Medical Association
Te Hauora mō ngā Iwi Katoa

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By email: opp@pharmac.govt.nz

PHARMAC's implementation of TPP provisions and other amendments to application processes

Dear Sarita

The New Zealand Medical Association (NZMA) wishes to provide feedback on the above consultation. The NZMA is New Zealand's largest medical organisation, with more than 5,500 members from all areas of medicine. The NZMA aims to provide leadership of the medical profession, and to promote professional unity and values, and the health of all New Zealanders. Our submission has been informed by feedback from our Advisory Councils and Board.

1. We note that PHARMAC is proposing the following main changes to comply with TPP obligations and improve existing application processes:

- Establish a separate TPP track for eligible applications. This would set a timeframe of 36 months for a final determination and create an internal review process for decisions not to list applications.
- Establish an open track for all other applications.
- Develop an online product application assessment record that would continuously publish information for all new applications.
- Add a 'decline as proposed' decision type to complement the existing 'decline' decision type.

2. The NZMA has previously outlined its concerns regarding the potential impact of the TPP on access to medicines.[1] We are pleased that the proposals in the current consultation document do not appear to change the fundamentals of the PHARMAC model.

[1] NZMA Submission on International treaty examination of the Trans-Pacific Partnership Agreement (TPPA), March 2016, Available from https://www.nzma.org.nz/__data/assets/pdf_file/0011/48944/NZMA-Submission-on-Examination-of-the-TPPA.pdf

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3. We are generally comfortable with the proposed creation of a separate TPP track for eligible applications and the 36-month timeframe it would entail. We note that this timeframe only commences from the point of submission of a duly formulated application. Applicants can engage with PHARMAC before making an application. We understand that the proposed TPP track does not preclude the usual style of free negotiation that occurs before, during or after completion of the application process. Nor does it diminish the competitive environment that PHARMAC currently uses to achieve the best value for money. We also understand that the proposals allow PHARMAC to extend the standard timeframe in some situations (eg, where additional clinical advice is needed).

4. If PHARMAC determines not to list a new medicine that is the subject of a TPP track application, we note that it will make available an internal review process that the supplier may choose to invoke. We understand there are limitations to the scope of this review. For example, reviews will not allow applicants to query the prioritisation of one application over another. We are generally comfortable with the proposed internal review process and believe that the limitations to the scope of reviews will preclude vexatious reviews by applicants.

5. We have some concerns that the requirement to meet a timeframe for applications under the TPP track (but not the open track) may result in applications under the former taking precedence over applications under the latter. There have been suggestions that the same timeframe should apply for both tracks in order to create a level playing field for all applicants and to avoid queue jumping in order to comply with TPP obligations.

6. We note that page 3 of the consultation states that "a number of PHARMAC's activities are not subject to TPP, including: funding decisions for medical devices; funding decisions for medicines that are purchased directly by the Government (eg, hospital cancer treatments)". We do not believe that this is strictly correct. While these activities are not subject to the provisions in the **Transparency Annex**, our understanding is that they **are** still subject to the TPP's **general provisions**, including the potential for investor-state dispute settlement provisions. We request that PHARMAC clarify this issue.

7. We welcome the proposed development of a new Product Application Assessment Record that would be publically available regardless of which track an application was filed on. We also welcome the proposed addition of a new decision category 'decline as proposed'. This category would make it clearer that the application, rather than the pharmaceutical itself, was declined.

We hope that our feedback has been helpful and look forward to learning the outcome of this consultation.

Yours sincerely

Dr Stephen Child
NZMA Chair