TGA Consultation
Accelerated assessment of medical devices – Priority Review pathway

MTAA submission – December 2016
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1. Executive Summary

The Medical Technology Association of Australia (MTAA) welcomes the opportunity to comment on the TGA consultation: *Accelerated assessment of medical devices - Priority Review pathway – Implementation* which was opened on November 16, 2016. We would like to commend the TGA for providing clarity and focus on matters related to implementing an accelerated assessment pathway for medical devices (Priority Review), in response to Recommendations 15 and 19 of the March 2015 report of the Medicine and Medical Devices Review (MDDR).

The MTAA supports the option of introducing a Priority Review pathway to expedite the development, assessment and review process for novel medical devices.

The MTAA is committed to ensure that the benefits of modern, innovative and reliable medical technology are delivered effectively to provide better health outcomes to the Australian community.

2. MTAA recommendations

**Recommendation 1**

The MTAA supports the introduction of a Priority Review that aligns with the FDA Expedited Access Pathway (EAP) which places an application for a novel device at the beginning of the review queue and receives additional review resources, as needed.

However, the TGA must resource the Priority Review pathway adequately so that routine applications are not delayed. Novel medical technologies are certain to require a clinical review, which is currently causing significant delays with Level 2 audits.

**Recommendation 2**

The MTAA agrees with the criteria to restrict acceptance for Priority Review.

Please clarify the intended approach in situations where a novel device is approved via FDA EAP first, then the applicant wishes to submit a Priority Review in Australia; would the TGA still consider the device “novel” even if it is already approved in another established market?

Also, please confirm whether Australian designated CABs (if they exist) will also be able to assess novel devices using the Priority Review pathway.

One MTAA member estimates that the likelihood of making an application for a medical device using the Priority Review pathway is one every two years.

**Recommendation 3**

The MTAA agrees with the proposed sponsor alert timeframes. The timeframes for the Priority Review pathway should be binding for the TGA/ Australian designated CAB, with a refund of a percentage of the fees if the device has not been reviewed within the mandatory timeframe.

The Priority Review status should not be revoked without adequate prior notification. Please clarify whether the existing practice of a 20 working day timeframe for reply to requests for information specifically excludes the 10 day grace period within which the response must be received.

**Recommendation 4**

The MTAA supports the proposal to publish the Priority Review applications that have been approved, but we do not support the proposal to publish the applications for Priority Review that have been declined.

The MTAA does not support the proposal to publish medical device product information for consumers as this is not a requirement for other devices.
Recommendation 5

The MTAA proposes yearly reviews of the Priority Review KPIs such as TGA processing timelines. Depending on the volume of Priority Reviews processed, the frequency may be changed as appropriate.