MEDICAL ONCOLOGY GROUP OF AUSTRALIA INCORPORATED

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Submission to the Therapeutic Goods Administration Consultation: Accelerated assessment of medical devices – Priority Review Pathway Implementation Version 1.0, November 2016

From
The Medical Oncology Group of Australia
[redacted]

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INTRODUCTION: I am making this submission on behalf of The Medical Oncology Group of Australia Incorporated (MOGA), the peak professional group for medical oncologists and medical oncology in Australia. MOGA welcomed the 2015 Recommendations that arose from the Review of Medicines and Medical Devices Regulation (MMDR) aimed at streamlining the Therapeutic Goods Administration's (TGA) registration processes and improving access to new medicines and medical devices. This included expedited pathways for the registration of new medicines and devices that addressed unmet clinical need in specific circumstances. Pathways entry to be based on transparent eligibility criteria consistent with those adopted by comparable overseas regulators. The Association is conversant with the expedited assessment processes managed by international regulators such as the European Medicines Agency, the US Food and Drug Administration and Health Canada. We have also supported the introduction of similar assessment processes in Australia. The Association also supports the introduction of further mechanisms to expedite and streamline assessment within the TGA including pre-submission meetings; the provision of guidance documentation; and, European Union conformity assessment. MOGA welcomes the TGA's advice regarding the implementation of a Priority Review accelerated assessment pathway is in response to Recommendations 15 and 19 of the 2015 MMDR report to provide "timely access to devices that are safe, high quality and fit for purpose" via "multiple pathways to seek approval for the inclusion of other classes of medical device in the ARTG".

PRIORITY REVIEW PATHWAY FOR MEDICAL DEVICES: The Association presents the following responses in relation to the consultation paper and the specific consultation queries:

Current environment

- **Are there any other environmental issues that would inform or benefit the development of this proposal?** It is noted that consultation document cites industry development and public health issues amongst some of the key environmental issues underpinning the TGA's approach to the introduction of priority review process. Other issues to be considered is the need for Australia to ensure clinicians and their patients have access to the latest treatment options in keeping with international best practice, in a rapidly evolving professional and increasingly costly environment.
- **Are there other issues to be considered in developing this proposal?** The Association is of view that the financial and infrastructure implications as well as constraints are important considerations for the implementation and continuity of this new pathway given the small size of the Australian marketplace and in some instances the relatively small patient cohorts that may be involved.

Principles and criteria

MOGA supports the TGA approach to implementing the recommendations from the MMDR which aim to reduce process duplication and the Priority Review pathways recommended for both medicines and medical devices: with "a common suite of principles" to apply, and the eligibility criteria for Priority Review to be "aligned to the extent appropriate given the differences between medicines and medical devices".

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Are the criteria appropriate to restrict acceptance for Priority Review to the truly new and novel devices for patients in immediate need? Noting that acceptance of a large number of applications would undermine the viability of Priority Review. It is noted that the proposed criteria for designation of medical device Priority Review (for conformity assessment and for inclusion on the ARTG), were developed with consideration of the US FDA's criteria; and applications are required to meet all the following criteria: "…intended for the prevention, diagnosis or treatment of a life threatening or seriously debilitating disease or condition; …addresses an unmet clinical need in Australian patients; and meets at least one of the following:….a breakthrough technology with evidence of a major clinical advantage over existing technology, ….the device offers a major clinical advantage over existing alternatives included in the ARTG, OR In the case of in vitro devices …, early availability…..will result in a major public health benefit." MOGA is of the view that these criteria are appropriate to restrict acceptance.

- **Do the proposed criteria cover all issues which should be considered in assessing a medical device for Priority Review designation?** Yes.
- **What is your estimated likelihood of making an application for a medical device to have Priority Review designation?** Nil. Not applicable

Implementation of Priority Review

- **Is the proposed sponsor alert timeframe adequate for industry?** The submission of the sponsor alert within the timeframe of a minimum of four (4) weeks prior to the planned application for Priority Review is adequate.
- **Decisions will need to be made promptly, within six (6) weeks. Large submissions will undermine this, as will applications that are incomplete in meeting the criteria. Will applicants be able to present a succinct and compelling argument for Priority Review designation, independent of the full application process?** This timeframe is reasonable but may be challenging for industry above all in relation to major submissions.
- **In the proposed implementation it is expected that sponsors on receipt of designation advice will promptly submit their full application for conformity assessment or inclusion. Is this a reasonable expectation?** This is a reasonable explanation but will depend on the device being considered and the available evidence.
- **It is proposed that priority review status will be revoked if timeframes for reply to request for information are not met. Is the existing practice of a twenty (20) working day timeframe appropriate?** Yes.
- **Is the proposed approach to publication of Priority Review applications and decisions appropriate?** Yes
- **Is the proposal to publish medical device product information for consumers supported, and what extent of detail would consumers seek**? Yes. It is recommended that comprehensive product information be published for each device.
- **Is the Priority Review pathway for designated applications adequately detailed? If not, which areas are unclear or require more detail?** Yes.

TGA operational impacts

Are there any gaps in the proposed implementation plan? It is unclear how the timing and the related fee requirements for the legislative and regulatory amendments required to enable regulations to establish the Priority Review pathway, will impact on the implementation and application process. The proposal also does not address the issue of any co-dependent technologies, tests and medicines that may relate to a medical device for which a Priority Review designation is sought. MOGA also recommends the development of transparent exit criteria for instances where it may no longer be appropriate for a medical device to retain its Priority Review designation and that this could occur at any time during the approval process. We also recommend that an exit strategy and management process should be developed. As a key stakeholder organisation MOGA would like to be consulted on these developments above all in relation to the clinical care and management of oncology patients Eg., in cases where clinical practice and the evidence no longer align or a medical device has been rejected for an accelerated assessment process by a comparable overseas regulator and the decision is deemed applicable within the Australian context.

- **What aspects of the proposed implementation would you suggest for inclusion in a post-implementation review**

It is recommended the post implementation include a comprehensive costs benefits analysis including patient/cohort uptake and outcome data. MOGA believes that the post-implementation review process will play an important role in the implementation and continued application of the priority pathway (eg., to establish if eligibility and exit criteria are fit-for-purpose in the interests of public health). However, this would also require regular review, monitoring and reporting of each decision's efficacy in light of emerging Australian clinical practice, research and trials data, post implementation and on an ongoing basis.

- **What timeframe would you suggest for the review – 1 year, 2 years or 3 years after commencement?**

In light of the Australian regulatory context it is difficult to accurately anticipate the volume of Priority Review pathway applications that will be received it is recommended that the review be undertaken 1 year after commencement in the first instance.