Therapeutic Goods Amendment (2016 Measures No. 1) Bill 2016

MTAA Submission - March 2017

MTAA Medical Technology ASSOCIATION OF AUSTRALIA

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1. Executive Summary

The Medical Technology Association of Australia (MTAA) is the national association representing 71 manufacturers and suppliers of medical technology used in the diagnosis, prevention, treatment and management of disease and disability. The MTAA works with all stakeholders to ensure the benefits of innovative and reliable medical technology are delivered effectively to provide better health outcomes to the Australian community. Over 80% of MTAA members are small-medium enterprises (SMEs) (less than 200 employees) and only around 15% are subsidiaries of large multinational companies.

On 10 February 2017 the MTAA received an invitation from the Community Affairs Legislation Committee to provide a written submission on the Therapeutic Goods Amendment (2016 Measures No. 1) Bill 2016 which can be accessed at: http://www.aph.gov.au/Parliamentary_Business/Bills_Legislation/Bills_Search_Results/Result?bId=r5786

The MTAA would like to thank the Community Affairs Legislation Committee for the opportunity to provide feedback on the proposed changes to the Therapeutic Goods Act 1989. The MTAA supports the overarching intentions of the proposed amendment to implement key recommendations of the Expert Panel Review of Medicines and Medical Devices Regulations relevant to medical devices (recommendations 15, 24 and 27), and streamline the structure of statutory advisory committees for medical devices. However, certain proposed changes outlined in the Therapeutic Goods Amendment (2016 Measures No. 1) Bill 2016, require further discussion and clarification as detailed in this submission.

The table below summarises our recommendations.

1. Recommendation: Regulations will need to clearly define 'novel device'
The Bill does not include a definition of what constitutes a 'novel device' qualifying for the expedited approval pathway. This does not appear to require an amendment to the Bill however the MTAA would like to ask the Committee to recommend to Government that 'novel device' be clearly defined in the medical devices regulations. The MTAA provided specific feedback on the matter during the recent TGA Consultation: *Accelerated assessment of medical devices – Priority Review pathway, Implementation* (closed 11 January 2017).

2. Recommendation: The TGA will have to adequately resource the Priority Pathway
This does not require an amendment to the legislation but is a recommendation that we would like the Committee to make to Government. The TGA needs to adequately resource the Priority Review pathway so that routine applications which form the vast majority of regulatory submissions are not delayed.

3. Recommendation: TGA review timelines, including for clinical reviews, need to meet KPIs in line with international benchmarks
This does not require an amendment to the legislation but is a recommendation that we would like the Committee to make to government. Novel medical technologies are certain to require clinical reviews, hence in order to ensure that the new expedited approval pathway can meet its intended goal of facilitating patient access to novel therapies it will be necessary to improve timelines of the TGA clinical review. The MTAA would like to ask the Committee to recommend to Government that KPIs are set for TGA review timelines, in line with international benchmarks and as recommended in the Expert Panel Review.

4. Recommendation: Third party Conformity Assessment Bodies (CABs) designated in Australia must be subject to the same level of scrutiny as the TGA's conformity assessment function
This does not appear to require an amendment to the Bill however the MTAA would like to ask the Committee

to recommend to Government that the designation criteria for local CABs be clearly defined in the medical devices regulations. To ensure protection of patient safety it is essential that third party CABs designated in Australia meet the same standards and be subjected to the same level of scrutiny as the TGA Medical Devices & Product Quality section. Transparency is essential to ensure community's confidence in the local conformity assessment process for medical devices.

5. Recommendation: The Australian designation authority will have to be totally separate from TGA's conformity assessment function
The MTAA would like to ask the Committee to recommend that the Bill be amended or perhaps regulations made to prevent the Secretary from delegating CAB designation to the TGA. If the Secretary delegates the designation of third party Australian CABs to the TGA this will potentially create a conflict of interest whereby the TGA is tasked to audit and designate its own competition.

To ensure compliance with the Commonwealth's competitive neutrality requirements, the designation authority will have to be totally separate from TGA's conformity assessment function. The cost of designating third party CABs should be recovered from the CABs seeking designation in Australia. The MTAA provided specific feedback on the matter during the recent TGA Consultation: *Designation of Australian conformity assessment bodies for medical devices, Implementation* (closed 11 January 2017).

6. Recommendation: Post-market surveillance requirements in Australia should align with current international best practice
This does not require an amendment to the legislation but is a recommendation that we would like the Committee to make to Government. Strengthening of post-market activity should utilise established methods for post-market monitoring that are currently in use internationally such as post-market clinical follow-up (PMCF) studies and clinical quality registries as appropriate.

2. New pathways for approval of 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.

The MTAA has been supportive of introducing an expedited approval pathway to accelerate the development, assessment and review process for novel medical devices using priority review (recommendation 15, pathway 3). This new pathway, which allows innovative therapeutic goods to be fast-tracked by regulators, has been available in the U.S. for some time. In the U.S., it is called the Expedited Access PMA or shortly EAP (PMA stands for Premarket Approval).

The U.S. EAP pathway applies to novel medical devices that demonstrate the potential to address unmet medical needs for life-threatening or irreversibly debilitating diseases or conditions. The advantage of the EAP pathway is that the FDA engages with an innovator company early on in the development stage and provides interactive advice throughout the process. This significantly reduces the time to market and saves costs by avoiding mistakes and multiple loops with the regulator.

To ensure that a similar expedited approval pathway is successful in Australia, the definition of what constitutes a "novel device" will need to be set out in the regulations to clearly identify which applications qualify for a priority review. Without clear criteria, sponsors would potentially be tempted to use the priority review indiscriminately to place their applications at the beginning of the review queue, defeating the purpose of having a separate expedited approval pathway.

Most medical devices requiring regulatory approval are equivalent to or represent incremental improvements of existing devices, hence one would expect that only very few applications would qualify for the priority review. The TGA will have to adequately resource the priority review pathway so that routine applications which form the vast majority of regulatory submissions are not delayed. Furthermore, novel medical technologies are certain to require clinical reviews, hence in order to ensure that the new expedited approval pathway can meet its intended goal of facilitating patient access to novel therapies it will be necessary to improve timelines of the TGA clinical review.

3. Enabling Australian 'notified bodies' to undertake conformity assessment of medical devices

Currently, the majority of medical devices distributed in Australia are imported and come with a European CE Marking approval. CE-marked high-risk devices must in addition pass a mandatory Level 2 audit by the TGA before being included in the Australian Register of Therapeutic Goods or ARTG. Certain high-risk devices - containing medicines or tissues of animal, biological or microbial origin - must undergo a full conformity assessment by the TGA regardless whether they already have approval from a European Notified Body, the U.S. FDA or any other reputable overseas regulatory agency. Until now the TGA has been the only Conformity Assessment Body (CAB) authorised to issue conformity certificates in Australia.

The MTAA has been supportive of allowing alternative CABs to operate in Australia. This change in legislation will allow Australian MedTech companies to choose a CAB that has been designated locally to issue conformity certificates required before including medical devices in the ARTG (recommendation 15, pathway 1B).

Designated Australian CABs should be allowed to issue conformity certificates for all types of medical devices for which they have demonstrated capability, including for "very high risk" devices (containing medicines or tissues of animal, biological or microbial origin) and for "novel" medical devices under the priority review pathway.

The same designation criteria and auditing regime should be applied to all CABs operating in Australia – including TGA's CAB function - to ensure a level playing field and comparable level of competency. If the Secretary delegates the designation of alternative Australian CABs to the TGA this will potentially create a conflict of interest whereby the TGA is tasked to audit and designate its own competition. To ensure compliance with the Commonwealth's competitive neutrality requirements, the designation authority will have to be totally separate from TGA's CAB function.

4. Enabling health practitioners to supply certain therapeutic goods not on the Register to patients under a notification scheme

The MTAA supports this change because it streamlines the Special Access Scheme (SAS) process for Category B patients (these are patients other than seriously ill Category A patients). Instead of submitting an SAS Category B form to obtain TGA approval for each individual use of an unapproved device, healthcare practitioners will only require to notify such a use to the TGA (recommendation 24).

Therapeutic goods qualifying for this SAS path are likely to be products with a history of safe use in comparable overseas countries, but which for commercial reasons have not been included in the ARTG.

According to the TGA, from around 20,000 SAS Category B applications that the TGA receives in a year only 0.3% of them are rejected. Application processing requires a high administrative burden for applicants, with paperwork required to be sent to, and followed up with, the TGA and may involve extensive liaison and consultation with health practitioners to ensure sufficient information is available for an approval decision to be made. The low percentage of rejections has led to the conclusion that a significant number of therapeutic goods currently used under the SAS Category B do not appear to pose an issue for public health and safety, hence it makes sense to simplify the process for SAS Category B applications.

However, replacing pre-approval with notification should not be used to bypass the requirement for medical devices (and other therapeutic goods) to be included on the ARTG. Otherwise this penalises companies who go down the path of inclusion. TGA states that "unapproved goods should only be accessed in exceptional circumstances where goods on the ARTG are not clinically suitable for a patient" but it is important for this process to be clearly defined.

5. Strengthening Post-Marketing Activity

The MTAA position has been that the balance of premarket assessment and post-market monitoring should be tipped more in favour of post-market, so as to not delay patient access to new and improved medical devices while ensuring devices are safe and effective. The lifecycle of medical devices is significantly shorter than that of medicines, hence long and overly burdensome premarket processes, such as large amount of premarket clinical trials data, would not be appropriate for devices.

Changes introduced by this Bill specify requirements around the "more comprehensive post-market monitoring scheme" recommended by the Medicines and Medical Devices Review (recommendation 27). They include:
record-keeping obligations (to be detailed in the regulations);

- increased powers for 'authorised persons' (e.g. TGA medical officers) to inspect and make copies of any records kept in compliance with record-keeping obligations;
- increased powers for the Secretary to require the person responsible for undertaking a recall to provide more information about the recalled goods and the circumstances of the recall; and
- a requirement to provide public notifications about recalls.

The MTAA does not have any objections against these changes introduced by the Bill. The MTAA recommends using established methods for post-market monitoring that are currently in use internationally such as post-market clinical follow-up (PMCF) studies and clinical quality registries as appropriate.

6. Amendments to TGA statutory advisory committees

The MTAA supports rationalising the number of advisory committees from nine to five, and in particular the consolidation of the Advisory Committee on the Safety of Medical Devices (ACSMD) functions into the existing Advisory Committee on Medical Devices (ACMD).

The MTAA recognises the important role of the ACMD to provide independent medical and scientific advice to the Minister and the TGA on the safety, performance and manufacturing of medical devices supplied in Australia including issues relating to pre-market conformity assessment and post-market monitoring. Therefore we have previously submitted that decisions made by the ACMD should be transparent and based on widely recognised standards, guidelines and principles rather than personal opinions. We also raised concerns around appropriately resourcing the ACMD so as to not adversely impact timeliness of decisions.

7. Other amendments

Other changes contained in the TG Amendment cover administrative aspects such as cancellation of approval in the event of sponsor providing false or misleading information, payment of annual fees and conditions of inclusion in the ARTG.

The MTAA does not have any objections against these changes introduced by the Bill.