QEII/ Medical Aids Subsidy Scheme

Therapeutic Goods Administration

Consultation: Products used for and by people with disabilities – Options for amendment to the Therapeutic Goods (Excluded Goods) Determination 2018

This is a joint submission from the Medical Aids Subsidy Scheme (MASS) and Rehabilitation Engineering Centre (REC), two departments within Queensland Health. The Medical Aids Subsidy Scheme have provided a large range of Assistive Technology through several funding initiatives across both the disability and aged care sectors. REC designs and manufactures custom assistive technology for persons with disabilities. Both departments are seen as specialists in Assistive Technology (AT) with expertise in reviewing AT and investigating product failures.

Response Summary

The low risk working group raised a request for the TGA to look at the data on the medical devices being referred to under the excluded goods determination; looking closely at reasons why Class I medical devices were stopped or queried at pre-market surveillance and the percentage of recalls or product corrections issued in these categories. While this data has not been made available for this consultation, it is important to review this information as it has the potential to provide evidence in guiding the best path forward.

Additionally, the group raised the relevance of using and aligning terminology and classifications of therapeutic goods with ISO 9999 *Assistive products for persons with disability – classification and terminology*. The goods specified in *Appendix A - List of certain products used by or for adults and children with disabilities* do not have descriptions that align with this standard. It is recommended that the GMDN categories are re-classified to align with this standard.

The overall success of this significant change to the excluded goods determination and the way assistive technology is imported into the country is reliant on clear definitions, in particular the terms *assistive technology*, *disability* and *low risk*. Different registration requirements for products used in various settings or for different client groups may increase ambiguity.

The response to the questions below is based on the following assumption: pre market surveillance has not prevented any Class I products coming to market. Hence, class I medical devices (considered Assistive Technology) could be clearly defined as excluded under the Determination.

Questions

Option 1(a)

- *Do you agree that the exclusion in the Determination currently described as "household and personal aids, or furniture and utensils, for people with disabilities" should be replaced with a definition and description of products known as "assistive technology"?*

The current definition is extremely outdated. The proposed definition would need to provide clarity to assist in identifying what AT would still be included under the scope of TGA and therefore require registration as a therapeutic good.

- *If 'yes', do you have a proposed definition or consideration to be given when preparing the definition?*

  A clear definition of what is considered AT within the scope of TGA and the determination is critical. WHO defines AT as an umbrella term and therefore it is designed to be a very broad definition. The WHO definition should be used as a starting point but would need to be further defined to provide clarity for which products are excluded.

  Additionally, *disability* needs to be appropriately defined if this term is going to stay within the definition. Assistive Technology used for the *alleviation of a defect or injury* is still defined as a medical device, however this could refer to the same device.

  To remove ambiguity, reference to precedence needs to be clearly defined. It is understood that products on the excluded goods determination can still fit into the TGA medical device definition. However, this is not clearly communicated within the determination. It would be extremely confusing for all relevant stakeholders if the same product would require registration depending on the intended user.

- *Do you consider that the real or perceived risks of harm associated with the use of all specified therapeutic goods coming within the definition of assistive technology are insignificant?*

  No, the risks can still be significant. Queensland Health have identified and reported to the TGA several real and perceived risks of harm, these have included a number of near miss incidents which could have resulted in significant injuries to the user of the product. These examples could be identified internally within TGA data, however if further information is required it could be requested by TGA and provided by Queensland Health.

  While the risks are likely no greater than some mainstream devices, people using these medical devices are at greater risk due to lack of sensation, reduced function and compromised health. There is a perceived implied safety factor of medical devices which are regulated by the TGA, the removal of these from registration may result in significant consequences to the industry. Examples include pressure injuries and skin tears that may result in significant secondary injuries. (e.g. A skin tear obtained from a sharp edge on a wheelchair or walking frame, leading to an unresolved infection, leading to an amputation)

- *What impacts—including any that are unintended—do you anticipate this change may have for yourself and other stakeholders (such as consumers, healthcare professionals, health organisations, industry etc.)?*

  This broad definition and removal of a number of medical devices could see changes to government/hospital funding and procurement if poorly informed or understood. Clear communication to highlight that AT included on the determination doesn't mean the device isn't considered a medical device and hence is still alleviating a defect or injury.

  As a government funding body, we regularly encounter misunderstanding that ARTG registration requires the product to be mechanically tested to the relevant Australian or International Standards, this is commonly not the case with Class I devices. While the registration asks for the sponsor to provide what testing has been completed, it is not mandatory to gain ARTG registration. This implied safety factor of the currently regulatory pathway could see the quality of the products being imported and supplied to the market reduced.

  Additionally, it is unclear if this excluded goods determination would impact the GST exemption currently in place and the flow on financial implications.

Option 1(b)

- *Do you agree rather than excluding all assistive technologies, the exclusion should be limited to only low risk assistance technologies?*

  Yes, this appears to be a workable solution. However, it would be beneficial for the appropriate existing data of pre-market surveillance, recalls and reported incidents of these devices currently included on the ARTG to be reviewed to support this decision.

  Clarification around the risk assessment criteria would be beneficial to improve clarity of TGA's definition of a low risk medical device.

- *If 'yes', do you have a proposed definition or consideration to be given when preparing the definition?*

  Same as points under Option 1(a) apply.

- *Do you consider that the real or perceived risks of harm associated with the use of all specified therapeutic goods coming within the definition of low risk assistive technology are insignificant?*

  Same as points under Option 1(a) apply.

- *What impacts—including any that are unintended—do you anticipate this change may have for yourself and other stakeholders (such as consumers, healthcare professionals, health organisations, industry etc.)?*

  Same as points under Option 1(a) apply.

- *What products are excluded under currently arrangements, but would no longer be excluded under the "low risk assistive technology" definition, and so require inclusion in the ARTG?*

  Unable to identify any that are within our area of knowledge.

Option 2

- *Do you agree that the definition "household and personal aids, or furniture and utensils, for people with disabilities" should be replaced with a list of specified products determining these products to be excluded goods and of another list in Schedule 2 determining the products to be excluded goods when these products are used, advertised or presented for supply in a particular way?*

  A list would remove ambiguity and allow government, healthcare professionals and consumers the ability to require ARTG registration before purchasing devices with suppliers/industry. However, if this option is endorsed, the GMDN categories should be re-classified to align with the terms and definitions of ISO 9999 to increase consistency and improve clarity. This option would require a significant amount of maintenance and regular revisions to reduce its overall impact and it is unclear that the benefits would outweigh the cons. It is suggested that a well-defined option 1 (b) would be a more appropriate method to define Item 9.

- *If 'yes', could you specify which products provided in Appendix A should be excluded (unconditionally or where they are used, advertised or presented for supply in a particular way), and which should be regulated as medical devices? Please provide your reasons for the suggestions having regard to the real or perceived risks associated with the use of the specified products.*

  Excluded devices when advertised or presented in a particular way seems detrimental to the proposal and confusing for a number of stakeholders. For this reason, if this option is endorsed, it is recommended products fall into either option 1 or 3 within the table.

- *Do you know other therapeutic goods intended for people with disabilities that should be excluded via the Determination (whether excluded unconditionally or where they are used, advertised or presented for supply in a particular way)? If yes, please provide description of the product group, and the reasons why.*

  Not applicable.

- *What impacts—including any that are unintended—do you anticipate this change may have for yourself and other stakeholders (such as consumers, healthcare professionals, health organisations, industry etc.)?*

  Not applicable.

- *What products are excluded under currently arrangements, but would no longer be excluded under the list of specific products, and so require inclusion in the ARTG?*

  Not applicable.

All Options

- *Do you have any other options to clarify the meaning of Item 9, Schedule 1 of the Determination?*

  Nil.

- *Do you think the description(s) of any other items currently included in Schedule 1 or Schedule 2 of the Determination should be clarified, and if yes, why?*

  Yes, Item 10 has mattress overlays listed, is this to include pressure relieving mattresses that are an overlay? In the context of the sentence it implies it is not a pressure relieving overlay mattress, however it is ambiguous.

- *Are there any further issues and questions we should consider when implementing this change (including areas that can/should be clarified in our guidance)?*

  It is important that all stakeholders are informed of the impacts of these products no longer falling under the TGA and some examples of the differences between Australian Consumer Law and TGA are clearly documented. Additionally, the changes in the pathway for reporting product failures or concerns should be clearly documented. Guidance for purchasing organisations, including hospitals, should provide information of when ARTG numbers are required and when they are no longer required for purchasing of a medical device under the Therapeutic Goods (Excluded Goods) Determination 2018.

- *Do you have any comments regarding the transitional arrangements proposed in this paper? This includes comments on the quantum of products which may shift into or out of the regulatory framework under each option, and any advice on costs and benefits to the sector in these changes?*

  Currently, if the ARTG process is followed correctly, it means that there is one Australian sponsor of a medical device and this person's details are listed on the ARTG listing. With the removal of a large percentage of the 28,000 odd products listed would see products being able to be imported by multiple avenues with reduced oversight. This could see a difficulty in tracking down the relevant industry person responsible for the product.