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Therapeutic Goods Administration
136 Narrabundah Lane,
Symonston, Canberra
ACT 2609

Via email: LowRiskDevices@health.gov.au

25 October 2019

To whom it may concern,

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

Thank you for the opportunity to provides comments in response to the Therapeutic Goods Administration (TGA) options paper on products used for and by people with disabilities.

Engineers Australia is the peak body of the engineering profession. We are a professional association with about 100,000 individual members. Established in 1919, Engineers Australia is a not-for-profit organisation, constituted by Royal Charter to advance the science and practice of engineering for the benefit of the community.

This submission has been developed in consultation with the organisation's National Committee on Rehabilitation Engineering (NCRE), which is an endorsed specialist group within the Biomedical College of Engineers Australia. It represents the profession of Rehabilitation Engineers, who are specialists in Assistive Technology and who work directly and collaboratively with clients to improve health, wellbeing and community engagement.

Engineers Australia believes it would be helpful for existing Australian Register of Therapeutic Goods (ARTG) registered Class I medical devices data is appropriately reviewed to assist in making informed decisions in regard to Item 9 of the excluded goods determination.

Engineers Australia recognises the significant amount of work in the development of ISO 9999 *Assistive products for persons with disability – classification and terminology*, an international standard for the classification and terminology relevant to Assistive Technology. It seems timely as part of this process for the Global Medical Device Nomenclature (GMDN) categories to be re classified to align with this standard.

We see the overall success of this significant change to the regulatory oversight of Assistive Technology within Australia as a significant risk for the sector. Key factors to reduce the negative impacts of this change include clear definitions of the relevant terms within the TGA domain and clear communication to all stakeholders providing relevant guidance on the impacts of this change.

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Appendix A to this letter is Engineers Australia's response to specific questions of the TGA paper. The responses are 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.

To discuss the contents of this submission further, please contact Andrew Dakin, Engineers Australia's Learned Society Advisor to the National Committee on Rehabilitation Engineering (NCRE), on (02) 6270 6117 or ADakin@engineersaustralia.org.au.

Yours faithfully,

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Appendix A: Specific Question Responses

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"?

Yes, determining a framework which clarifies which products would be exempt and which are not would be very important to success of any of the proposed options.

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

A clear definition of what is considered assistive technology (AT) within the scope of TGA and the determination is critical. The World Health Organisation (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, 'disabilities' 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 be required to be registered 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. While a significant amount of AT has extremely low risk there are many products, falling within a broad definition of AT, that can present significant risk to health and safety if inappropriately used or in the event of failure.

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 an implied safety factor of devices for which consequence could be significant if false claims are made at point of sale. 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.)?

There is concern that products which are eligible for exemption could then be advertised as having therapeutic benefits that were not validated or accurate. An example would be pressure care cushions. Fraudulent claims of a product providing 'excellent pressure care' could lead to serious health implications for the unaware consumer.

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

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, with an accurate and detailed definition. 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 push back ARTG registration before purchasing devices with suppliers/industry. However, the necessary level of market vigilance and response needed to make this an effective strategy is unlikely to be met.

It is suggested that a well-defined option 1 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.

Nil.

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.)?

Nil.

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?

Nil.

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.

As a National Committee of Rehabilitation Engineers who have a number of members with strong links within the relevant Australian Standards Committee, 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.