Submission in response to:

TGA

Consultation:

Products used for and by people with disabilities

Options for amendment to the Therapeutic Goods (Excluded Goods) Determination 2018

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Introduction

Assistive Technology Suppliers Australia (ATSA) welcomes the opportunity to respond to this Consultation by the TGA.

ATSA is a national organisation representing assistive technology and home modification (ATHM) suppliers, including manufacturers, importers, distributors, retailers, tradespeople and technicians. Our 140 members comprise businesses and not-for-profit organisations and range from small family owned concerns to multinational organisations throughout Australia. It is estimated that, excluding ATHM for communication and sensory disabilities, approximately 80% of the ATHM in Australia passes through the hands of ATSA members.

Executive Summary

The ATSA membership do not support wholesale removal of the listing of assistive technology (AT) as Class 1 medical devices on the Australian Register of Therapeutic Goods (ARTG).

ATSA is of the view protections should be strengthen not diluted, to protect for the persons with a disability. Regulation under the TGA provides a frame that aims to minimise the risk of harm, it instils "good work practises", it is not just focused on the post event, rather it has the framework to minimise risk premarket. This strengthens quality standards that protect the venerable persons in our society. The TGA systems are "fit for purpose" for medical devices. The TGA context includes a strong, rigorous, recall framework that is designed for prompt and effect responses for when things go wrong.

In 2002 the Therapeutic Goods Act 1989 was amended to introduce the current medical devices regulatory framework and the Therapeutic Goods (Medical Devices) Regulations 2002 were put in place. Most of the exemptions of the previous Regulations were removed, and after a transition period which ended in October 2007, all medical devices were to be included on the Register. The manufacturer must be able to demonstrate the devices complied with the Essential Principles (of safety and performance) described in Schedule 1 of the 2002 Regulations.

This introduction of formal regulation and oversight, and the need for a manufacturer, through their Australian sponsor, to be able to demonstrate their products are in compliance with the Essential Principles (of safety and performance) has had the effect of 'tidying up' the market. Facilitating the exit of poorly manufactured products with dubious safety records to have for the most part left the market.

Removing these products outside the jurisdiction of the TGA will take away the *"fit for purpose"* safety device management model and will once again open the market to inferior and potentially unsafe products. The fact is, the ACCC/Fair Trading model is designed for "any sold item/service" in the community, not medical devices.

> *We sight the Takata airbag, issue where a lethal product is in the market yet the ACCC has had difficulty in the removal of the effected product from Australian roads. ATSA suggests that this would not be the case for TGA monitored medical devices, as it has in place the appropriate legislative authority/mechanisms to deal with life threatening devices. This is due to their understanding of clinical risk, call to action mechanisms that is supported with pre market protections that minimise the risk in the first place combined with a stronger recall legislative framework of products from the market.*

Neither public interest or public health and safety can be undermined. Therefore, the AT industry supports regulation under the TGA, ensuring only quality products with a high degree of safety are prescribed and supplied into the Australian market.

However, ATSA recognises the need to exempt some products that are inadvertently 'captured' by the regulations, that do not require the TGA oversight, such as items that pose low to no risk to the user, e.g. special cutlery, plates or some non-weight bearing devices. Identified exemptions should be clearly listed and not covered by broad descriptions that could be misinterpreted. Applications for an "Excluded Goods Order" must follow a procedure that includes consultation with the industry to determine the level of risk of harm for the device in question, prior to applying the "Excluded Goods Order", for that device.

ATSA can only support the adoption of Option Two

All AT is designed to provide a solution to a medical condition/need; hence the term of medical devices is applied to AT. For this reason, all AT must be considered that it may pose a risk to the health and welfare of the user and must be regulated under the TGA unless a valid reason can be given to provide an Excluded Medical Goods Order.

To apply a blanket definition strategy risks compromising the regulatory system and allow for the perpetuation of the current issue that this discussion paper is endeavouring to address, i.e. misinterpretation of wording. For this reason, neither of the Option 1 choices provide valid solutions, but potentially perpetuate the current issue.

When a product solution is identified/created it is a combination of the purpose and the design, not the naming convention of the device itself. Therefore, it is the solution i.e. the end device is what needs to be reviewed, not via a naming convention of the device that provides the bases of exemption or inclusion on the ARTG.

Option 2 provides the ability to manage the situation as case by case by review and determine the most suitable exemption or inclusion on the ARTG. The review process must include, users, industry with the TGA in the determination of the risk and what protections may need to be applied, i.e. list on the ARTG or not.

Feedback to TGA listed Questions Option 1

ATSA does not support these options and has already commented its held concerns of these options.

Feedback to TGA listed Questions 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?

Yes. This is a great concern for ATSA as interpretation has shifted over time dependant on an individual view of the situation.

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.

Assuming the design of the device is not weight bearing, adhered/attached to the skin/mouth/ear/eye then the following could be considered as an "Exempted Medical Device":

- *Communication Devices*
- *Visual Aids*
- *Therapeutic use – daily activities*

The remainder of the list should remain as regulated devices on the ARTG, plus any of the suggested Exempted Medical Devices design that is weight bearing, adhered/held on the skin/mouth/ear/eye from Communication Devices, Visual Aids and Therapeutic use – daily activities groups.

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.

ATSA is not aware of any other possible exclusions.

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 model will follow the existing model of listing AT as a Medical device on the ARTG.

The advantage is there would be clarity on what medical device/s are an "Exempted Medical Device".

The only risk is how to promote and educate the method/process that triggers an application for an Exempted Medical Device. Plus, there is a need to ensure it does not become a complex process.

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

This is difficult to determine as the mixed interpretation of the definition of excluded goods, Item 9, Schedule 1 will have likely created a range of items with unknown numbers that could be affected.

This circumstance will need to recognise as a change to conditions, i.e. the new clear definition will create the need for inclusion onto the ARTG.

An incentive will be required along with a "period of time" to comply. Due to the cost to register it will have an impact, therefore an amnesty should be considered along with a "free period" to register, to get these devices listed onto the ARTG.

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

The design of the device is not weight bearing, adhered/attached to the skin/mouth/ear/eye then the following could be considered as an "Exempted Medical Device"

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?

ATSA is not aware of any.

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

Transition plan and fee relief to register a medical device on the ARTG

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?

Fee relief period to encourage sign up.