Australian Government
Department of Health
Therapeutic Goods Administration

Consultation: Proposed amendment to the *Therapeutic Goods (Excluded Goods) Determination 2018*

Assistive Technologies

Version 1.0, August 2021

TGA Health Safety Regulation

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Introduction

In 2017, consultation was undertaken on Options for the future regulation of 'low risk' products. As a result a number of changes were progressed across a broad range of low risk products, including the making of the *Therapeutic Goods (Excluded Goods) Determination 2018*. This determination (and its predecessors) provides that "household and personal aids, or furniture and utensils, for people with disabilities" are *excluded goods*, and so regulated as consumer products rather than therapeutic goods.

This exclusion of aids for people with disabilities is now under review, and this consultation provides an exposure draft of the proposed amendment, and related guidance for applicants, for review and comment by stakeholders.

Previous consultation

In late 2019, consultation was undertaken on options for amending the *Therapeutic Goods (Excluded Goods) Determination 2018*, to clarify which products intended for use for, or by, people with disabilities are excluded goods, and so are regulated as consumer goods rather than therapeutic goods.

The aim of the amendment was to improve the clarity, appropriateness, and operation of the regulatory framework for low-risk medical devices used as assistive technology for people with disability. The paper for that consultation outlined the need for change, issues to be considered, and outlined three options:

Option 1: The current text "household and personal aids, or furniture and utensils, for people with disabilities" in Item 9, Schedule 1 in the Determination will be replaced to use the term "assistive technology" with an accompanying definition based on the WHO definition of assistive technology.

This exclusion could:

A extend to all assistive technology (irrespective of the risk of the product), or

B a subset of the World Health Organisation (WHO) definition of assistive technology, limited to low risk products i.e. those which would otherwise be Class I medical devices (without a measuring function or not supplied sterile)

Option 2: The current text "household and personal aids, or furniture and utensils, for people with disabilities" in Item 9, Schedule 1 of the Determination will be replaced with a list of specified products that are determined to be excluded from the therapeutic goods regulation.

A new item will also be added in Schedule 2 that lists specified products that will be determined to be excluded goods when these products are used, advertised or presented for supply in a particular way.

Following consideration of responses to the consultation, and further discussions with a number of stakeholders in the assistive technology sector, a modified version of Option 1B has been progressed. **The intention is to exclude low risk assistive technologies (as outlined in Option 1B) but to modify this to continue to regulate medical devices which, if they malfunction when used as intended, can cause significant injury.**

While all of the products intended to be excluded are classified as low risk (ie they would be Class I if regulated as medical devices), some products have greater risk of significant injury if they malfunction (eg failure of a weight bearing device such as a walking stick or a lifting aid foreseeably results in falls which can cause significant injury or death). This modification aims to address this risk of some products for users (and/or their carers), which was raised as a concern by stakeholders.

Proposed amendment

Schedule 1, Item 9 of the *Therapeutic Goods (Excluded Goods) Determination 2018* currently provides that **"household and personal aids, or furniture and utensils for people with disabilities"** are excluded goods for the purposes of the *Therapeutic Goods Act 1989*.

Under this proposed amendment Item 9 would be deleted and replaced with the following:

Schedule 1:

Specified goods	
Column 1	**Column 2**
Item	**Specified goods**
2B	assistive technology products that are intended by the manufacturer to maintain or improve functional capacity of persons with disability to undertake activities of daily living in settings other than health care settings and: (a) are not IVD medical devices, or medical devices classified under the Medical Devices Regulations as Class IIa or higher; and (b) do not have a measuring function and are intended by the manufacturer to be supplied in a non-sterile state; and (c) would not pose a risk of harm that requires medical attention in circumstances where: (i) the products are used in accordance with the labelling, instructions for use, advertising, or technical documentation describing the mechanism of action of the products; and (ii) there is a malfunction or deterioration in the characteristics or performance of the products

Issues

Scope

As outlined above, the intention for this change is to reclassify low risk assistive technologies as consumer products, but with an exception for products which have a risk of significant injury should they malfunction.

This will mean that many weight bearing products would continue to be regulated as medical devices. Specifically, lower body prostheses (where weight bearing) would continue to be regulated as medical devices, while many upper body prostheses (where not weight bearing) may not. Other items which would continue to be in scope of being regulated as a medical device would include pressure management devices such as anti-oedema stockings or cushions and underlays for tissue integrity.

1. ***Scope:*** The continuing regulation of products which have a risk of significant injury should they malfunction means that come categories of assistive technology product will be regulated as medical devices. In addition to weight bearing and pressure management devices, are there other categories which may continue to be regulated as medical devices and what are the associated risks?
2. ***Practicality:*** Does the proposed scope for assistive technology exclusion work in practice?
   - Are there products which would be excluded but should continue to be regulated as medical devices?
   - Are there products which would continue to be regulated as medical devices which would be better treated as consumer products?

Clarity

An additional aim for this change is to provide clarity on which products are and are not regulated as medical devices.

As currently drafted the new provision:

- exempts assistive technology
  - The definition of assistive technology is reasonably well developed, based on the World Health Organisation (WHO) definition, and supported by ISO 9999:2018 Assistive Products for Persons With Disability – Classification and Terminology.
- limits the exemption to Class I (low risk) medical devices based on existing classification rules
  - The existing classification rules for Class I (not supplied sterile or with a measuring function) have been in operation since the current regulatory framework commenced in 2002, and so are well established The classification rules are also reasonably internationally consistent, being based on the Global Harmonisation Task Force framework (now the International Medical Device Regulators Forum, or IMDRF, framework).

- restricts the exemption to products which **do not** pose a risk of harm that requires medical attention in circumstances if it malfunctioned when used as intended
  - The objective is to limit the risk of injury to more than relatively trivial harms (ie requiring a band aid) but not requiring catastrophic harms (eg hospitalisation or death). The provision is drafted based on the need for medical attention; potentially providing a practical and easily understood risk threshold.

This exemption has been developed in consultation with some key stakeholders, and has proved difficult to convey as simply as possible while reflecting the intention. A primary reason for this further consultation is to ensure the exemption is clear and will work in practise.

3. ***Clarity:*** Is the proposed text of the exemption sufficiently clear for stakeholders? If not, do you have suggestions on how it might be better framed or worded?

Transitional arrangements

The interpretation of the existing exemption for "household and personal aids, or furniture and utensils for people with disabilities" is broadly framed, and this lack of clarity has led to confusion. There have been inconsistencies in the regulatory approaches taken by sponsors in relation to their products and variability in the level of compliance. Many suppliers have interpreted Item 9 to mean that assistive technology products are excluded goods (i.e. are not regulated by the TGA), while other suppliers have been including their products in the Australian Register of Therapeutic Goods (ARTG) as medical devices (i.e. as products intended for the alleviation of or for compensation for an injury or disability).

Implementing this new exemption will require movement of products into and off the ARTG:

- Sponsors who currently have ARTG entries for low risk assistive technology products will be asked to review their ARTG entries, and any excluded goods entries will be cancelled either by the sponsor, or the TGA, following consultation with the sponsor.
- Some sponsors may not currently have ARTG entries for their moderate or higher risk products, or low risk products with a risk of harm that requires medical attention. Those importing, exporting or supplying assistive technologies will need to check whether their products are covered by the new "low risk assistive technology" definition in the Determination, and include those products as medical devices in the ARTG. Transitional arrangements for sponsors impacted if a change to the Determination is made are discussed on the following page.

The number of moderate or higher risk products which may need new ARTG inclusions under this proposal is expected to be small, as it appears to have been assumed by potential applicants that the existing definition of "household and personal aids, or furniture and utensils, for people with disabilities" is for low-risk products.

For low risk products the expectation is that there will be more products to be cancelled from the ARTG than to be newly included, as the "low risk assistive technology" definition would appear broader then the existing "personal and house-hold aids" definition. Feedback on whether this expectation is true would be useful, as would feedback on any sectors which might be especially impacted by this change.

4. ***Products coming into the ARTG:*** Do you anticipate the need for products to be newly included in the ARTG? Can you provide examples of those products, the scope of changes you expect, etc? Are these higher risks medical devices, or additional low risk (but potentially harmful) products?
5. ***Products cancelled from the ARTG:*** Do you anticipate cancellations of ARTG entries for existing assistive technologies to be required? Can you provide examples of those products, the scope of changes you expect, etc?

At this stage the intention is that the amended Determination will take effect in **12 months** after it is made. This will provide time for the change to be communicated to, and consideration by, affected sponsors, and to make any applications required. The TGA will provide support and focus on sponsors coming into compliance with the new arrangement, rather than punishing non-compliance where stakeholders are unaware of the changes and/or need time to adjust to the new requirements.

Formal transitional arrangements would also be put in place. For example, changes to reclassify a range of medical devices allows time for manufacturers to seek additional certification and sponsors of existing products additional time to apply to reclassify the affected ARTG entries. Formal transitional arrangements are not proposed for:

- Changes for products moving out of the ARTG are straight forward, and have minimal cost. A request to cancel is simple form, submitted without any TGA fees, and will save the sponsor their ongoing annual charge for the entry.
- Changes requiring new entries in the ARTG are for products not currently regulated. Transitional provisions (beyond the proposed 12 month delay in the amended Determination coming into effect) would be based on sponsors of impacted products notifying the TGA within a specified timeframe. We need to ensure those eligible for any transitional arrangements are aware of the change and the requirement to notify us.

Given these impacts are broad, the 12 month transitional period for changes coming into effect is proposed.

6. ***Educative approach:*** Does the approach to the transition seem reasonable? Is 12 months an appropriate timeframe for managing the transition?
7. ***Transition arrangements:*** Are any additional transitional arrangements required? If so, what are the issues to be addressed by such arrangements? Are some sectors likely to be more impacted than others?

Personalised medical devices

Regulatory changes are also in progress for personalised medical devices. Many devices which were previously regulated as custom-made devices (which are exempt from the requirement for inclusion in the ARTG) will now be regulated as patient matched medical devices and will require inclusion in the ARTG.

The personalised medical device changes do have transitional arrangements for existing devices. This transition requires existing suppliers to notify the TGA before 25 August 2021 that they have products impacted by the change and will need to submit applications to include any such devices before 1 November 2024.

It is intended that this change to exclude low risk assistive technologies will be in place prior to 25 August 2021. This should avoid previously custom-made low risk assistive technology devices needing to be included under the personalised medical devices changes, only to then be excluded under the proposed change to exclude low risk assistive technologies.

However, if you manufacture or supply custom-made low risk assistive technology medical devices, we advise that you to notify the TGA of your existing supply. This will ensure you are covered by the personalised medical device transition arrangements, even if this is not needed in the longer term, and there is no fee to make such a notification.

Guidance

Guidance to support this change has been drafted, and is included on the consultation page.

Any feedback on this guidance would be most appreciated. This might include examples to explain the exclusion, or perhaps suggestions for case studies which stakeholders might find helpful.

In addition, any other feedback you would like to offer on this proposed change would be very welcome.

8. Do you have any feedback on the draft guidance document?
9. Do you have any other feedback on the proposed exclusion of low risk assistive technologies from the therapeutic goods regulatory framework?

What we invite you to do

In your submission, we ask you to consider the questions outlined above and gathered below, and provide comments related to any other matter outlined in this consultation paper.

CONSULTATION QUESTIONS (as listed above)

Scope

1. ***Scope:*** The continuing regulation of products which have a risk of significant injury should they malfunction means that come categories of assistive technology product will be regulated as medical devices. In addition to weight bearing and pressure management devices, are there other categories which may continue to be regulated as medical devices and what are the associated risks?
2. ***Practicality:*** Does the proposed scope for assistive technology exclusion work in practice?
   - Are there products which would be excluded which should continue to be regulated?
   - Are there products which would continue to be regulated which would be better treated as consumer products?

Clarity

3. ***Clarity:*** Is the proposed text of the exemption sufficiently clear for stakeholders? If not, do you have suggestions on how it might be better framed or worded?

Transitional arrangements

4. ***Products coming into the ARTG:*** Do you anticipate the need for products to be newly included in the ARTG? Can you provide examples of those products, the scope of changes you expect, etc? Are these higher risks medical devices, or additional low risk (but potentially harmful) products?
5. ***Products cancelled from the ARTG:*** Do you anticipate cancellations of ARTG entries for existing assistive technologies to be required? Can you provide examples of those products, the scope of changes you expect, etc?
6. ***Education and communication:*** Does the approach to the transition seem reasonable? Is 12 months an appropriate timeframe for managing the transition?
7. ***Transition arrangements:*** Are any additional transitional arrangements required for this change? If so, what are the issues to be addressed by such arrangements? Are some sectors likely to be more impacted than others?

Guidance

8. Do you have any feedback on the draft guidance document?
9. Do you have any other feedback on the proposed exclusion of low risk assistive technologies from the therapeutic goods regulatory framework?

How to submit

We invite you to complete our online survey for this consultations, addressing the questions posed in this paper, at the Department of Health's consultation hub (consultations.health.gov.au).

You can also submit feedback, whether this addresses the consultation questions, broader comments or both, directly to the TGA by email at: LowRiskDevices@health.gov.au. If emailing your submission, **please ensure your submission is accompanied by a completed cover sheet** (template available on the consultation landing page).

This consultation closes on **1 October 2021**.

Enquiries

If you have any questions relating to this consultation or submissions please direct them to: LowRiskDevices@health.gov.au.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Section/Office	August 2021

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
www.tga.gov.au

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