Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Consultation: Proposed changes to the regulation of assistive technologies

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Introduction

The Australian Government has been undertaking a significant program of reform to the regulation of medical devices in Australia. As part of the Australian Government Department of Health and Aged Care, the Therapeutic Goods Administration (TGA) regulates these products, and is responsible for implementing the Government's reforms.

The TGA has issued this consultation paper as part of the Government's reform program.

This consultation seeks feedback on:

- the current provisions in the *Therapeutic Goods (Excluded Goods) Determination 2018* that "household and personal aids, or furniture and utensils, for people with disabilities" are excluded goods, and so regulated as consumer goods rather than therapeutic goods, and
- feedback on options for change to ensure appropriate oversight of such products (hereafter referred to as *assistive technologies*) by removing the current exclusion and potentially introducing an exemption for some assistive technologies.

Assistive technologies

Assistive technologies are products that are used to maintain or improve an individual's functioning and independence, thereby promoting their well-being. These kinds of products:

- support people to engage in activities they may otherwise be unable to perform,
- improve the ease and safety with which people can undertake certain activities, and
- potentially improve social or economic independence for a person living with a disability.

ISO 9999:2022 Assistive products for persons with disability – Classification and terminology can provide some guidance on the broad range of products that are assistive technologies.

Background

Products that meet the legislative definition of a therapeutic good under the *Therapeutic Goods Act 1989* (the Act) are regulated by the TGA and generally need to be included in the Australian Register of Therapeutic Goods (ARTG) before they can be imported, exported or supplied, unless they are **excluded** from regulation, **exempt** from ARTG inclusion or otherwise approved by the TGA.

Exclusion

An **exclusion** means the products are not regulated as therapeutic goods, and therefore are NOT:

- × subject to regulation by the TGA (provided they are only supplied for the explicit purposes stated in the exclusion)
- × required to meet any of the Australian regulatory requirements for therapeutic goods, including medical devices
- × required to be assessed in any way by the TGA before they are supplied

- × required to be included in the ARTG
- × required to report adverse events to the TGA

Excluded goods remain subject to other regulatory requirements, including consumer protection laws administered by the Australian Competition and Consumer Commission (ACCC), and state or territory consumer protection laws.

Exemption

Exempt medical devices are still regulated by the TGA as medical devices, but they are not required to undergo a pre-market assessment or be included in the ARTG before they are imported, exported or supplied in Australia. Medical devices that are exempt must comply with regulatory requirements including:

- ✓ ensuring the devices meet all relevant Essential Principles, including supplying the devices with adequate labelling and instructions for use
- ✓ ensuring advertising complies with the advertising requirements
- ✓ reporting adverse events

Current arrangements

Under the current provisions in the *Therapeutic Goods (Excluded Goods) Determination 2018* "household and personal aids, or furniture and utensils, for people with disabilities" are excluded. The impact of the exclusion is that these products are currently regulated as consumer goods, not therapeutic goods.

The current approach to the regulation of assistive technologies was established following three public consultations:

1. Options for the future regulation of 'low risk' products (2017): As a result of this consultation 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*.
2. Products used for and by people with disabilities: Options for amendment to the *Therapeutic Goods (Excluded Goods) Determination 2018* (2019): This consultation sought feedback on proposals to amend the Order. Options included specifying the exclusion of all assistive technology products or limiting the exclusion to a specific range of products. Feedback from stakeholders indicated a desire for further clarity on the scope of excluded products, noting the risks associated with some products made them inappropriate candidates for exclusion. Stakeholders also asked for changes to be made in a manner that would future-proof regulation of these kinds of products.
3. In 2021, further consultation on draft guidance Assistive Technologies and the *Therapeutic Goods (Excluded Goods) Determination 2021* was undertaken. Legislative changes were proposed seeking to clarify that "assistive technology products" were excluded goods for the purposes of the Act providing they met certain requirements. The proposed amendments and supporting guidance were designed to provide greater clarity to stakeholders about which assistive technology products were to be regulated by the TGA and those that were not.

The problem

The current exclusion was intended to capture assistive technologies intended for day-to-day activities outside health or residential care settings. It was established at a time when assistive technologies were frequently distributed to consumers through care models where they were often recommended by practitioners through facilities operated by a state or territory government.

Over time there have been changes to the way these products are supplied and used including:

- The scope of products that meet the current exclusion has increased, and changes to technology have altered the risk profile for these kinds of products.
- The assistive technology sector is experiencing a period of strong growth, investment and development resulting in a wide range of new products.
- Reimbursement for the cost of assistive technologies from both private and public funding sources is also on the rise.
- Supply models have moved away from traditional structures involving health practitioners and are increasingly direct to consumer.

Feedback from consumers, the assistive technology sector and relevant bodies who provide reimbursement for these kinds of products indicates:

- assistive technologies continue to evolve to meet consumer need and are becoming more complex
- people are living in the community for longer as they age and increasingly rely on assistive technologies, amongst other interventions, to support activities of daily living
- consumers using assistive technologies are exposed to risk, and the regulatory framework should safeguard against this in a consistent, proportionate manner
- publicly available information about these kinds of products is needed to facilitate reimbursement and post-market monitoring activities
- exclusion of these kinds of products may no longer be appropriate due to their risk profile and the reduction or removal of previous mechanisms for oversight.

As for many medical devices, there can be tensions around the boundaries of regulation of assistive technology, where products are not essentially medical in nature but do meet the definition of a medical device (i.e. under the *Therapeutic Goods Act 1989* s.41DB ("treatment, alleviation of or compensation for an injury or disability" – s.41BD included below). The proposed changes would shift some of these boundary issues, but it is likely that tension would continue to exist around the edges of the regulatory framework, on whether a particular assistive technology meets the definition of a medical device. The TGA is also conscious that the therapeutic goods regulatory framework is a medicalised model for assistive technologies, and this can be in tension with the social model of disability.

This consultation

A review of the current arrangements for assistive technology devices, and a holistic approach to their future regulation, is required to ensure regulation:

- remains fit-for-purpose
- aligns with the objectives of the *Therapeutic Goods Act 1989* and the Australian Government approach to regulation more broadly
- adequately addresses the risks associated with these kinds of products thereby ensuring patient health and safety is maintained.

We are proposing to:

- remove the exclusion for "household and personal aids, or furniture and utensils, for people with disabilities" from the *Therapeutic Goods (Excluded Goods) Determination 2018*
- introduce exemptions for assistive technologies in some circumstances.

These changes would seek to ensure regulation is appropriate for the current products available in the market, and for the expected continuation in the development and diversity of assistive technology products. The broader impacts of these changes would also seek to ensure that:

- assistive technology devices are regulated appropriately for the risks they pose
- stakeholders, including both consumers and those who provide reimbursement for devices supplied to consumers, can easily identify assistive technology devices that are meeting Australia's regulatory requirements.

The regulation of assistive technologies has possible implications for a range of other government programs. This paper has been discussed with relevant industry peak bodies and other government agencies including the aged care program within the Department of Health and Ageing, the National Disability Insurance Agency, the Department of Social Services, the Department of Veterans Affairs and the Australian Competition and Consumer Commission. Feedback from all stakeholders on these impacts would also be useful.

Proposed solutions and options for change

Based on feedback and information from both internal and external stakeholders, we have reviewed the current regulation of assistive technologies. The consultation process has occurred over several years and the following options are offered for your consideration:

1. Remove the exclusion for "household and personal aids, or furniture and utensils, for people with disabilities" from the *Therapeutic Goods (Excluded Goods) Determination 2018.*
2. If the exclusion is removed, introduce exemptions for certain assistive technology devices in accordance with the options proposed in this public consultation.

Proposal 1. Remove the current exclusion

Removing the current exclusion will mean that all "household and personal aids, or furniture and utensils, for people with disabilities" that meet the definition of a medical device under section 41BD of the Act, will need to meet medical device regulatory requirements. An extract of section 41BD appears in the box below. A full version of the Act can be accessed online.

41BD What is a *medical device*

(1) A ***medical device*** is:

(a) any instrument, apparatus, appliance, software, implant, reagent, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following:

(i) diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease;

(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability;

(iii) investigation, replacement or modification of the anatomy or of a physiological or pathological process or state;

(iv) control or support of conception;

(v) in vitro examination of a specimen derived from the human body for a specific medical purpose;

and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means…

Examples of the kinds of products that are currently excluded which may become subject to regulation by the TGA if the exclusion is removed and they are presented in a manner that meets the definition of a medical device is presented below using the *ISO 9999:2022 Assistive products for persons with disability – Classification and terminology* classification:

- 04 48 12 – Finger and hand exercise devices
- 05 03 – Assistive products for communication therapy and communication training
- 06 30 03 – Wigs
- 09 09 – Assistive products for dressing and undressing
- 15 03 – Assistive products for preparing food and drink
- 18 12 15 – Bedding
- 22 03 09 – Magnifier glasses, lenses and lens systems for magnification
- 24 18 27 – Arm supports to permit manual activities

If the exclusion is removed, regulatory requirements that would apply include:

- Ensuring the devices meet all relevant Essential Principles, including supplying the devices with adequate labelling and instructions for use
- Ensuring advertising complies with the advertising requirements
- Including the device in the ARTG before it is imported, exported or supplied
- Reporting adverse events

The impact of removing the exclusion and requiring these kinds of devices to be included in the ARTG would mean:

- stakeholders would be able to access readily available information about devices that meet current regulatory requirements
- manufacturers of these devices would be required to have appropriate documentation ensuring these devices meet Australian regulatory requirements
- sponsors of these kinds of devices would be required to include these kinds of devices in the ARTG before they import, export or supply the device.

While ensuring these kinds of devices are appropriately regulated and improving access to information about these kinds of devices may benefit a range of stakeholders, there are costs associated with:

- procuring documentation demonstrating compliance with regulatory requirements
- applying for a medical device to be included in the ARTG
- maintaining an inclusion in the ARTG.

More information

More information about how medical devices are regulated, including how to check the classification of your device and submit an application for inclusion of a device in the ARTG can be found in the TGA's Medical device inclusion process guidance.

More information about the fees and charges associated with medical devices can be found in the TGA's Summary of fees and charges to applications submitted to the TGA.

Remove exclusion – Questions

1. Do you broadly agree that the current exclusion for "household and personal aids, or furniture and utensils, for people with disabilities" should be removed?
2. Why or why not?
3. What would be the financial impact for you if the TGA removed the current exclusion for "household and personal aids, or furniture and utensils, for people with disabilities"? If possible, please provide a breakdown of the impacts (cost, time, types and estimated numbers of impacted products). *This information will be used to quantify the financial impact to all affected stakeholders.*
4. What period would be needed for your organisation to implement the proposed changes? *This information will be used to inform any transitional arrangements.*

Proposal 2. Introduce exemptions for some assistive technologies

One option for reducing the regulatory burden (including financial costs) for manufacturers and sponsors of assistive technology devices is to **exempt** them from inclusion in the ARTG. Exemptions are used to reduce regulatory burdens, particularly where:

- a device is manufactured in circumstances where another regulatory framework is already in place to manage risks associated with the device
- the supply of devices may be restricted if an exemption is not introduced (e.g. supply is not for a commercial purpose)
- the evidence needed to support an ARTG inclusion is not available (e.g. clinical trials)
- a device is transitioning to ARTG inclusion (patient-matched, reclassification etc).

More information

If exemptions are offered for assistive technology devices, they would potentially be offered under the options proposed in the *Proposed changes to the regulation of exempt medical devices and exempt Other Therapeutic Goods* consultation. These options include:

a. Collecting information about exempt assistive technology devices

b. Publishing information about exempt assistive technology devices

c. Introducing cost recovery measures that align with TGA expenditure on regulation of exempt assistive technology devices

Possible exemption/s – Questions

5. Are there assistive technology devices that should be granted an exemption in order to reduce regulatory burden for manufacturers and/or sponsors?
6. Why or why not? If you are in favour of granting an exemption, please provide the explicit conditions under which an exemption should be granted and explain why an exemption is warranted.
7. Do you agree that information about exempt assistive technology devices should be collected?
8. Why or why not? If there are reimbursement programs or schemes that could use information about exempt assistive technology devices, please indicate here the names of those programs/schemes and the department/body/agency/entity administering them.
9. Do you agree that information about exempt assistive technology devices should be made public through a register?
10. Why or why not?
11. If a registry of exempt assistive technology devices is established, should information be arranged by kind of assistive technology device or by manufacturer/provider/sponsor?
12. Why or why not?
13. Do you agree that cost recovery measures should be introduced to recover TGA expenditure associated with the regulation of assistive technology devices?

14. Why or why not?

Boundaries

Examination of the broad range of assistive technology products illustrates that, while many assistive technology products are appropriately regulated as therapeutic goods, many others are not medical in nature.

It is possible for some assistive technologies which do not meet the medical device definition (s.41BD, extract at page 8) to meet the broader definition of a 'therapeutic good' and 'therapeutic use' under s.3 of the *Therapeutic Goods Act 1989*.

Therapeutic goods means goods:

(a) that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be:

(i) for therapeutic use…

Therapeutic use is defined as for use in or in connection with:

(a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons; or

(b) influencing, inhibiting or modifying a physiological process in persons; or

(c) testing the susceptibility of persons to a disease or ailment; or

(d) influencing, controlling or preventing conception in persons; or

(e) testing for pregnancy in persons; or

(f) the replacement or modification of parts of the anatomy in persons.

This paper does not include a proposal on assistive technologies which sit outside the therapeutic goods regulatory framework. The possible tension between medical and social models of disability in the context of assistive technologies is also acknowledged. The TGA invites commentary on this issue from interested stakeholders.

Boundaries – Questions

15. Do you have feedback or comments, both generally or for specific products, on assistive technologies which are appropriate for medical device regulation, and those 'boundary' products which should not be medicalised as therapeutic goods?

Consultation – What we invite you to do

We invite comments on issues with current regulation of assistive technologies and the proposed options for improvement. We are seeking your feedback on the suitability and potential impact that any proposed changes to the regulations will have on you or your organisation.

How to respond

We have posed questions within this discussion paper to help guide your feedback. You can also give us any additional comments and attach a separate response document if you wish.

You do not have to answer all the questions and none are compulsory.

You can

- submit your views by clicking the link below – this will step you through our questions https://consultations.tga.gov.au/tga/consultation-future-regulation-of-assistive-techno

OR

- download the full discussion paper and upload your own response document on the final page of the link above.

You can also submit your feedback directly to the TGA by email at: devicereforms@tga.gov.au If you do so, **please ensure your submission is accompanied by a cover sheet**.

This consultation closes on 14 October 2024.

Enquiries

If you have any questions relating to submissions please direct them to: devicereforms@tga.gov.au

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