Australian Government
Department of Health
Therapeutic Goods Administration

Consultation on Draft Guidance

Assistive Technologies and the *Therapeutic Goods (Excluded Goods) Determination 2021*

Version 1.0, (August) 2021

TGA Health Safety Regulation

About the Therapeutic Goods Administration (TGA)

- The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health, and is responsible for regulating medicines and medical devices.
- The TGA administers the *Therapeutic Goods Act 1989* (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.
- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.
- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. The TGA investigates reports received by it to determine any necessary regulatory action.
- To report a problem with a medicine or medical device, please see the information on the TGA website www.tga.gov.au.

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Introduction

In 2019 the TGA undertook a consultation with a view to amending the Therapeutic Goods (Excluded Goods) Determination 2018 (the Determination) in order to improve clarity regarding which products used for or by people with disabilities are regulated, or not regulated, under the Act.

Previously, Schedule 1, Item 9 of the Determination provided that "household and personal aids, or furniture and utensils, for people with disabilities" were not regulated as therapeutic goods. These items, products and equipment are broadly known as 'assistive technology'.

Assistive technology products are used for or by people with disabilities to assist them with their activities of daily living[1] which are carried out in their daily living environments. Daily living environments may include the home, workplace or other locations where activities of daily living take place. For the purposes of the Determination, and this guidance, health care settings such as aged care homes, group homes and hospitals are not considered to be daily living environments due to the unique nature of these facilities and the requirements for assistive technology products used in them (e.g. different sanitation requirements for products and the types and amounts of use products receive may have an effect on the performance of the product).

Assistive technology supports a person to undertake an activity they may otherwise be unable to perform, or increases the ease and safety with which the activity can be undertaken. Assistive technology can also help in increasing the social or economic independence or participation of a person with a disability.

ISO:9999 Assistive products for persons with disability – Classification and terminology can provide some guidance for manufacturers and sponsors as to what type of products are considered to be assistive technology.

Schedule 1, Item 9 of the Determination has now been repealed and a new item (Schedule 1, Item 2B has been included via the *Therapeutic Goods (Excluded Goods) Amendment (Assistive Technology) Determination 2021 (insert link to web)* to provide that **"assistive technology products"** are excluded goods for the purposes of the Act when they meet certain requirements. This amendment has been made in order to provide greater clarity to stakeholders about which assistive technology products are, and are not, regulated by the TGA.

Purpose and scope of this guidance

The purpose of this guidance is to help manufacturers and sponsors of assistive technology products understand what products may be excluded from regulation by the TGA under Schedule 1, Item 2B of the Determination, and, thus, how to comply with the regulation of these products. This is a guide only, and manufacturers and sponsors are encouraged to familiarise themselves with the legislative and regulatory requirements in Australia. If necessary, we advise manufacturers and sponsors to seek professional advice as it is the responsibility of each manufacturer or sponsor to understand and comply with these requirements.

This document will evolve over time and updates and clarifications will be included as required. Feedback on the guidance is always welcome.

[1] Edemekong PF, Bomgaars DL, Sukumaran S, et al. Activities of Daily Living (ADLs) [Updated 2020 Jun 26]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2020 Jan-. www.ncbi.nlm.nih.gov/books/NBK470404/

Therapeutic Goods (Excluded Goods) Determination 2021

Some products that meet the definition of a therapeutic good may be excluded from the operation of the Act under the *Therapeutic Goods (Excluded Goods) Determination 2018* (the Determination).

Prior to determining that some specified therapeutic goods are to be excluded from the operation of the Act, the TGA must have regard to the following matters, whether:

- It is likely that the specified goods, if not regulated under the Act, might harm the health of members of the public
- It is appropriate in all the circumstances to apply the national system of controls relating to the quality, safety, efficacy, and performance of therapeutic goods established by the Act to regulate the specified goods
- The kinds of risks from the specified goods to which members of the public might be exposed could be more appropriately dealt with under another regulatory scheme
- Any other relevant matters may also be considered.

Schedule 1 of the Determination provides a list of goods specified as excluded goods for the purposes of the Act.

Schedule 2 of the Determination provides a list of goods that are excluded from the operation of the Act when used, advertised, or presented for supply in a particular way specified in that Schedule.

Please note

Excluded goods *are not* therapeutic goods and *are not* regulated by the TGA.

Manufacturers and suppliers of **excluded goods** are still required to **comply with the provisions of any other legislation that relate to the goods**, including state, territory and federal consumer protection laws.

Assistive Technology Products and the Determination

Schedule 1, Item 9 of the Determination has been repealed and Schedule 1, Item 2B included in the Determination in order to provide that certain **"assistive technology products"** [2] are excluded goods for the purposes of the Act.

[2] The TGA has recently undertaken a consultation on software-based medical devices. This consultation contains reference to software products that may be considered "assistive technology." Once the outcome of the software-based medical devices consultation is finalised the Determination may require amendment.

Schedule 1, Item 2B of the Determination reads as follows:

Specified goods	
Column 1 **Item**	**Column 2** **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

Medical devices are classified according to their intended purpose, as specified by the manufacturer. Class I devices are considered to be low-risk and do not require conformity assessment certification before they can be included in the Australian Register of Therapeutic Goods (ARTG). Class IIa and above devices do require conformity assessment certification by the TGA before they are included in the ARTG, and the higher the class of a device, the higher the requirements for the conformity assessment procedures that manufacturers must apply to their device. However, manufacturers and sponsors should also be aware that the existence of a GMDN code which may apply to their product does not automatically make the product a medical device.

Assistive technology products as set out in Schedule 1, Item 2B of the Determination are only those goods that could otherwise be considered to be Class I medical devices if they were not excluded from the operation of the Act by the Determination.

The TGA website contains a tool which has been developed to help manufacturers and sponsors to determine what class their medical device is. For further detailed information on the classes and regulation of medical devices please refer to the Australian Regulatory Guidelines for Medical Devices on the TGA website.

For the purposes of the Determination and this guidance "harm that requires medical attention" means presentation to a medical practitioner, walk-in clinic, hospital or similar facility for treatment.

Please note that just because a medical device is an assistive technology product does not mean that it is automatically an excluded good. In order to be an excluded good the product must meet all of the requirements as set out in Schedule 1, Item 2B of the Determination.

ISO: 9999 Assistive Products for Persons with Disability – Classification and Terminology

ISO 9999:2018 establishes the classification of and terminology used for assistive products produced or generally available for persons with disabilities. It lists both products intended for use by an individual and those which require the assistance of another person for their operation.

The classification consists of three hierarchical levels, termed classes, subclasses and divisions respectively. Each class, subclass or division consists of a code, a term and if necessary an explanatory note and/or reference to other parts of the classification.

Use of the terminology as set out in the classification helps manufacturers and suppliers of assistive technology products to ensure the language they use is consistent with standard best practice and it is aligned with the terminology used by the National Disability Insurance Agency (NDIA). The use of this terminology will help limit any potential confusion for stakeholders and consumers, and may assist them in navigating NDIA processes.

Risk Management and Assessment

Even if an assistive technology product is classified as an excluded good it is still considered best practice to undertake a risk assessment process for the product throughout its lifecycle. A risk assessment will also assist applicants to assess whether their product does or does not 'pose a risk of harm that requires medical attention'.

A risk management system should identify and manage risk throughout all stages of the product's lifecycle, from concept and development to release and clinical use, and is essential for ensuring optimum product quality and safety. The risk management methodology should assist the manufacturer to identify, analyse, evaluate and control the risks in all phases of a products' lifecycle. A risk management plan should be a living document which is adjusted in light of any relevant new information being uncovered.

The ISO 31000:2018 - Risk management series contains information on risk management systems and can provide guidance to assist manufacturers and suppliers of assistive technology products in developing their own risk management systems.

The stages of a risk management process are:

1. ***Risk analysis***: This is the process whereby the risks identified are comprehended and the level of risk subsequently determined. This analysis should be updated throughout product development and lifecycle, as data are collected and product knowledge increases, to further characterise the risk.

2. ***Risk evaluation:*** Having carried out a risk analysis to determine the nature and level of risk, the evaluation of these risks results in the determination of which risks are acceptable and which require mitigation.

3. ***Risk treatment:*** Following the risk evaluation and the determination of whether the current level of risk is acceptable or unacceptable, those that are deemed unacceptable must undergo risk mitigation. This would involve creating plans for the procedures required to reduce the risk to an acceptable level, implementing and documenting them, and determining the effectiveness of the risk treatment.

4. ***Evaluation of overall residual risk acceptability:*** This involves evaluation of the remaining risk to ensure that it is at an acceptable level.

5. ***Preparing the risk management report:*** After steps 1 – 4 have been completed the procedures and outcomes need to be documented in a risk management report. This report should be reviewed regularly and amended as new risks are identified or current risks are modified, and/ or new treatments implemented.

6. ***Production and post-production information and review:*** At regular intervals the entire risk management process should be systematically reviewed. There should be processes for the collection and review of information that could inform the manufacturer or supplier of risk that may apply at any stage in the lifecycle of the product.

As part of assessing the risk of their product, and as a an aid in determining whether their product is a therapeutic good or is excluded by the Determination, suppliers and manufacturers of assistive technology products may wish to also consider the information about adverse events contained in the Database of Adverse Event Notifications - medical devices (DAEN – medical devices) on the TGA website. The DAEN – medical devices contains information from reports of adverse events that the TGA has received in relation to medical devices used in Australia.

It is likely that if a product type (e.g., shower chair, walking frame) has adverse events associated with it in the DAEN – medical devices which are the result of a malfunction or deterioration in the characteristics or performance of the product it would be considered a medical device and not excluded by the Determination. However, it should be remembered that this is not the sole factor for determining whether an assistive technology product is an excluded good – the product must meet all the criteria as set out in Schedule 1, Item 2B of the Determination.

Examples of Goods Excluded by the Determination

Please note

While these goods have been excluded from regulation by the TGA this does not mean that they do not have risks associated with their use.

Manufacturers and suppliers of **excluded goods** should seek to manage these risks as part of their due diligence in providing products in the Australian marketplace. The risk management framework set out above is intended to provide guidance for manufacturers and suppliers on how this may be achieved.

Examples of goods which are excluded by the Determination are presented below using their *ISO:9999 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

Examples of Goods Not Excluded by the Determination

Examples of goods which are not excluded by the Determination are presented below are presented using their *ISO:9999 Assistive products for persons with disability – Classification and terminology* classification:

Please note

This does not capture goods considered to be personalised (aka custom-made) medical devices.

Further information on the regulation of personalised medical devices, including the new arrangements coming into force on 25 February 2021, can be found at www.tga.gov.au/therapeutic-goods-legislation-amendment-2019-measures-no1-regulations-2019#pmd and www.tga.gov.au/custom-made-medical-devices

04 06 06 – Anti-oedema stockings for arms and legs and other parts of the body

04 33 03 – Seat cushions and underlays for tissue integrity

06 24 03 – Partial foot prostheses

09 12 03 – Commode chairs

12 23 – Powered wheelchairs

12 03 03 – Walking sticks and canes

12 36 – Assistive products for lifting persons

22 06 12 – In-the-ear hearing aids

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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