Australian Government
Department of Health
Therapeutic Goods Administration

Consultation: Products used for and by people with disabilities

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

September 2019

TGA Health Safety Regulation

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Introduction

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

In 2015, the Report of the Expert Panel Review of Medicines and Medical Devices Regulation (MMDR) made 58 recommendations for reform of the regulatory framework for medicines and medical devices in Australia. The Australian Government Response to the Review of Medicines and Medical Devices Regulation was released in September 2016. The Government accepted 56 MMDR recommendations which addressed matters within the remit of the TGA.

This consultation seeks feedback on the implementation of Recommendations Fourteen (14) and Twenty Three (23).[1] These Recommendations provided that products which might best be regulated under other regulatory frameworks, without undermining public health and safety, should be removed from the auspices of the *Therapeutic Goods Act 1989* (TG Act). It further recommended that the Australian Government undertake a review of the range of products currently classified as Class I medical devices, with a view to reclassifying products as consumer goods in circumstances where the product poses little or no risk to consumers, should it not perform as specified or malfunction, or may be best regulated under Australian consumer law only.

[1] Sansom L, Delaat W, Horvath J. Review of Medicines and Medical Devices Regulation: Recommendations to the Minister for Health on the Regulatory Frameworks for Medicines, Medical Devices, Complementary Medicines and Advertising of Therapeutic Goods, July 2015, pp. 13, 17.

Background

The TGA regulates therapeutic goods in Australia, including medical devices, having regard to the risks and benefits (to the individual or public health) considered in the context of the goods' intended use.

All therapeutic goods carry some level of potential risk, and the TGA applies scientific and clinical expertise to ensure assessments and decisions are based on the balance between the benefits and the risks.

The risk classifications of medical devices take into account factors such as potential harm, level of invasiveness, reliance on power, where in the human body the device is used, terms of use, the end user, etc. Class I are medical devices with the lowest level of risk-classification.[2]

The Government periodically reviews regulatory requirements for therapeutic goods, including low-risk medical devices, to ensure the regulations continue to be appropriate and that the level of regulation for therapeutic goods is commensurate with the potential risk these products pose to public health and safety.

This ensures sustainability of the Australian therapeutic goods regulatory system, appropriateness and robustness of assessments, and timeliness of access to these goods.

Please note

This consultation paper does not consider in vitro diagnostic (IVD) medical devices.

Previous consultation

Following the Australian Government Response to the Review of Medicines and Medical Devices Regulation, in 2017 the TGA consulted on *Options for the future regulation of 'low risk' products*, including Class I medical devices. In response to stakeholder feedback, the Government through the TGA undertook to review Class I medical devices to ensure they meet regulatory requirements, and to establish and work with a Low Risk Devices Working Group.

In October 2018, the TGA facilitated a meeting of a Low Risk Devices Working Group that included representatives from industry, state and territory health departments and other organisations, including the Australian Dental Industry Association, the Optical Distributors and Manufacturers Association, Assistive Technology Suppliers Australasia, Ability Technology and the Medical Technology Association of Australia. The purposes of the Working Group included:

- To provide advice on which products could be excluded from the therapeutic goods regulatory framework, but continue to be subject to Australian Consumer Law
- To assist with guiding principles to clarify the scope of products to be excluded
- To provide advice on which products should be excluded but are not currently excluded.

[2] *Therapeutic Goods Act 1989*, s. 41DB, and *Therapeutic Goods (Medical Devices) Regulations 2002*, Part 3, Div. 3.1, Schedule 2 and Schedule 2A – Classification rules for medical devices (other than an IVD) and IVD medical devices respectively

The Working Group assisted in providing clarifying descriptions of some categories of products currently included in Schedule 1 and Schedule 2 of the Determination. The outputs from that meeting have been incorporated in this consultation paper.

This consultation

The focus of this paper is to obtain feedback 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 regulated as consumer rather than therapeutic goods.

The Government's reforms aim to improve the clarity, appropriateness and operation of regulations governing medical devices. This paper considers the regulatory framework for low-risk medical devices used as assistive technology for people with disability.

Options for regulatory amendments: summary

Aim

Having regard to the Review of Medicines and Medical Devices Review (MMDR) recommendations, amend the *Therapeutic Goods (Excluded Goods) Determination 2018* in order to improve clarity regarding the products intended for people with disabilities that are regulated or not regulated under the TG Act.

Currently, Schedule 1, Item 9 of the Determination provides that the "household and personal aids, or furniture and utensils, for people with disabilities" are not regulated as therapeutic goods. These items, products and equipment that are intended to help adults and children with disabilities in their daily living are broadly known as 'assistive technology'.

Proposal

It is proposed that Schedule 1, Item 9 and, if required, Schedule 2 in the Determination be amended to introduce clarity regarding 'assistive technology' products that are regulated or not regulated by the TGA. Transparency will also be achieved regarding assistive technology products that are medical devices and are regulated under the TG Act.

Your feedback

Are you a consumer, industry stakeholder, healthcare provider, patient, industry representative body, consumer advocacy group or other interested party?

We seek your views on the proposed options for amending Schedule 1, Item 9 and, if required, Schedule 2 of the Determination. Your input will assist us to address any unintended consequences and inform the proposal and implementation of a clearer Determination.

On page 18 there is a list of questions to help you address the proposal in your feedback.

Please refer to page 19 for information on how to submit your feedback to the TGA.

Please note

This consultation closes on **25 October 2019**.

Before providing feedback, it is important to read the explanatory material that follows.

Regulation of therapeutic goods in Australia

The TGA regulates *therapeutic goods* as defined in the TG Act.

Therapeutic goods

Broadly, **therapeutic goods** include:

- Products represented in any way likely to be taken for therapeutic use; or
- For use as an ingredient or component in the manufacture of therapeutic goods; or
- Used as a container or part of a container for therapeutic goods.[3]

Therapeutic goods also **include biologicals and medical devices**, but **do not include** any goods declared not to be therapeutic goods;[4] or goods determined to be **excluded goods**[5].

Therapeutic use includes the use in or in connection with:

Preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury; or

- Influencing, inhibiting or modifying a physiological process; or testing the susceptibility of persons to a disease or ailment; or
- Influencing, controlling or preventing conception; or
- Testing for pregnancy; or
- The replacement or modification of parts of the anatomy in persons.[6]

The TGA does not regulate products that are not therapeutic goods.

Medical devices

Products are regulated as medical devices if they are intended to be used for humans, for one or more of the following:

- diagnosis, prevention, monitoring, treatment or alleviation of disease
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability
- investigation, replacement or modification of the anatomy or of a physiological process or
- control of conception

and the products do not achieve its principal intended action by pharmacological, immunological or metabolic means. Accessories to medical devices are also regulated as medical devices.[7]

Any medical devices (unless exempted) must be included in the Australian Register of Therapeutic Goods (ARTG) prior to being able to be legally imported, exported or supplied in Australia.

[3] *Therapeutic Goods Act 1989,* s.3
[4] *Ibid*, s. 7
[5] *Ibid*, s. 7AA
[6] *Ibid*, s.3
[7] *Ibid*, s.41BD

The **purpose for which the product is intended to be used** is ascertained from the **information provided by the manufacturer**, including: labelling, instructions for use, any advertising material, and/or technical documentation describing the mechanism of action of the product.[8]

TGA has separately consulted on the possible amendments to the definitions of a *medical device, accessory, intended purpose*.[9] Changes to these definitions may also impact on whether a particular product is a medical device.

Therapeutic Goods (Excluded Goods) Determination 2018

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

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

- It is likely that the specified goods, if not regulated under the TG 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 TG 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 TG Act.[10]

Schedule 2 of the Determination provides a list of goods that are excluded from the operation of the TG Act when used, advertised, or presented for supply in a particular way specified in that Schedule.[11]

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.

[8] *Therapeutic Goods (Medical Devices) Regulations 2002*, Dictionary (reg. 1.3)
[9] Consultation: Changes to a number of definitions and scope of the medical device regulatory framework in Australia, Appendix A, Table A1, Closed 18 February 2019
[10] *Therapeutic Goods Act 1989*, ss.7AA(1)
[11] *Ibid*, ss.7AA(2)

Excluded Goods Determination

Schedule 1, Item 9 of the Determination provides that **"household and personal aids, or furniture and utensils for people with disabilities"** are excluded goods for the purposes of the TG Act.

As a result of the broad terms of Item 9, there is a lack of clarity which has led to significant confusion. Accordingly, there have been inconsistencies in the regulatory approaches taken by sponsors in relation to their products and variability in the level of compliance. A large proportion of 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 ARTG as medical devices (i.e. as products intended for the alleviation of or for compensation for an injury or disability).

The intended uses, functionalities, configuration and technologies associated with these products vary significantly. Assistive technology may help people who have difficulty with walking, moving, speaking, typing, remembering, seeing and hearing. Different disabilities may require a variety of many different assistive technologies.

Examples of these products include wheelchairs (mechanical, motorised, stairs climbing, etc.), scooters, walkers, crutches, prosthetic and orthotic devices, hearing aids, cognitive aids, voice recognition software and hardware, screen readers, mobility devices that enable people with disability to play sports and be physically active, etc.[12]

Some of these products are technologically simple (e.g. bath/shower bench) while other products may be extremely complicated equipment with modern designs and technologies (e.g. artificial limbs or exoskeletons). Consequently, the risks of potential harm if the products do not comply with safety and performance requirements and do not perform as intended may also vary significantly. The safety of products should also be considered in context of various users of these products.

Options for clarifying the Determination

The Determination must *specify the goods* that are excluded for the purposes of the TG Act.

There is flexibility in relation to how the specified goods can be described in the legislative instrument. Two options for consideration are provided to help decide the best path for clarifying the exclusion of *"household and personal aids, or furniture and utensils, for people with disabilities"*.[13]

To consider which products could be listed in the Determination (and therefore not regulated as therapeutic goods), the TGA must have regard to the level of actual or perceived risks presented by the products to users.

The option chosen should provide sufficient clarity regarding which products intended for people with disabilities are not regulated under the TG Act. The option should also ensure that the specified products pose little or no risk to consumers, should these products not perform as specified, and that removing these products from the auspices of the TG Act will not undermine public health and safety.

[12] US Department of Health and Human Services.
[13] As specified in Item 9, Schedule 1 of the *Therapeutic Goods (Excluded Goods) Determination 2018*.

The following options could be chosen for the clarification of excluded goods currently described as "household and personal aids, or furniture and utensils, for people with disabilities":

1. (a) replacement of Item 9, Schedule 1, with a definition and description of products known as "assistive technology", or

   (b) replacement of Item 9, Schedule 1, with a definition and description of products known as "low risk assistive technology"

Including a list of specific products in:

- Schedule 1, determining specific products to be excluded goods, and/or
- Schedule 2, determining specific products to be excluded goods when these products are used, advertised or presented for supply in a particular way.

Option 1

Proposed action for Option 1

It is proposed that **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)

"Assistive technology" broadly describes products intended to be used by children or adults with a disability. It covers the full range of technological solutions that allow people with a disability to be more independent and connected, and provide opportunities for them to realise their potential as active members in their families, schools, workplaces and communities.[14]

According to the World Health Organization assistive technology is:

> An umbrella term for any device or system that allows individuals to perform tasks they would otherwise be unable to do or increases the ease and safety with which tasks can be performed.[15]

The WHO further provides that assistive devices and technologies are those whose primary purpose is to maintain or improve an individual's functioning and independence to facilitate participation and to enhance overall well-being. They can also help prevent impairments and secondary health conditions. Examples of assistive devices and technologies include

[14] National Disability Insurance Agency, Assistive Technology Strategy, October 2015, p.4
[15] WHO Centre for Health Development, Ageing and Health Technical Report, Volume 5, A glossary of terms for community health care and services for older persons, WHO/WKC/Tech.Ser./04.2, 2004, p.10

wheelchairs, prostheses, hearings aids, visual aids, and specialised computer software and hardware that increase mobility, hearing, vision, or communication capacities.[16]

This paper **does not consider** any products that **are not therapeutic goods**, for example, guide dogs, or noise cancelling headphones (does not have *therapeutic use*), etc.

Also this paper does not discuss regulation of implantable medical devices (which are clearly defined as medical devices in law).

The products vary in levels of complexity and technology, and include any product that is intended by the manufacturer to be used to increase, maintain, or improve different functional capabilities of people with disabilities. Medical devices, including assistive technologies, are regulated based on the risk the product poses to users (whether patients or operators). This is based on issues such as the degree of invasiveness, instructiveness with the body or whether it has an active power source. Class I medical devices are the lowest risk, while Class III and Active Implantable Medical Devices (AIMDs) are the highest risk.

The exclusion of assistive technologies from the operation of the TG Act could be limited to low risk products i.e. those which would otherwise be Class I medical devices (without a measuring function or not supplied sterile) – as per Option 1(b). This would mean higher risk assistive technologies would be subject to the TG Act based on the risk associated with the device as already outlined by the classification rules,[17] irrespective of the complexity of the technology itself. Many "assistive technologies" will be low risk Class I products (e.g. shower chairs or walking frames), noting that some Class I products may involve more complex technology (e.g. motorised wheelchairs). If not drafted to limit the scope to low risk products, the definition of "assistive technology" may also include within the exclusion a range of moderate risk technologies (e.g. hearing aids are typically moderate risk Class IIa devices). However, the definition of "assistive technology" would be drafted to exclude implantable technologies, such as cochlear implants (which tend to 'replace anatomy' rather than 'assist').

Implications of adopting Option 1(a) – exclusion of "assistive technology"

If **Option 1 (a)** is adopted, the current exclusion in Item 9, Schedule 1 of "household and personal aids, or furniture and utensils, for people with disabilities", would be replaced with a definition describing "assistive technology".

Any item, equipment, software,[18] or products that are used to increase, maintain, or improve different functional capabilities of people with disabilities, irrespective of the risk associated with the product or its complexity or technology, would be excluded from the therapeutic goods regulation by the TGA.

Effectively it will clarify that all these products are excluded from the TG Act. Given the 'assistive technologies' definition is broader than the existing "household and personal aids, or furniture and utensils, for people with disabilities", it is assumed that the changes will exclude some products presently included in the ARTG (e.g. in practice many hearing aids are currently

[16] World Health Organization, Assistive devices and technologies
[17] The classification rules are defined in Schedule 2 of the *Therapeutic Goods (Medical Devices) Regulations 2002*
[18] Note that separate consultation the regulation of software has been undertaken www.tga.gov.au/consultation/consultation-regulation-software-including-software-medical-device-samd

included in the ARTG but would fall within the "assistive technology" definition), but few if any products would newly be brought within the scope of the regulatory framework.

Adopting Option 1(a) will continues the existing broad application of the exclusion of products for people with disabilities, irrespective of the risk associated with the product. This reflects an ongoing perception, not necessarily based in fact, that the risks of goods used for people with disabilities is relatively low, regardless their users, designs and/or technologies.

Basing the exclusion on a definition of "assistive technology" also allows some capacity to deal with newly emerging assistive technology without further regulatory amendment.

Implications of adopting Option 1(b) – exclusion of "low risk assistive technology"

If **Option 1(b)** is adopted, the current exclusion in Item 9, Schedule 1 of "household and personal aids, or furniture and utensils, for people with disabilities", would be replaced with a definition describing "**low risk** assistive technology".

Thus only low risk items, equipment, software, or products that are used to increase, maintain, or improve different functional capabilities of people with disabilities, irrespective of its complexity or technology, would be excluded from the therapeutic goods regulation by the TGA.

This may draw some additional medium or higher risk products into the medical devices regulatory framework, where these are currently excluded as "household and personal aids, or furniture and utensils, for people with disabilities". For example, any sponsors who have not included hearing aids (typically a Class IIa medical device) in the ARTG on the basis that they are a "personal aid for people with disabilities" would need to include these products in the ARTG.

Basing the exclusion on a definition of "low risk assistive technology" also allows some capacity to deal with newly emerging assistive technology without further regulatory amendment.

Option 2

Proposed action for Option 2

It is proposed that:

- **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.

There are many different types of products designed and intended to be used to assist people with disabilities.

Some of these products have a very simple design and construction, while other products use complex modern technologies. Some may only have minor impact if they do not perform as intended or malfunction, while other products, such as for example, those that are intended to bear the weight of a person or apply forces to the body, may pose significant risk.

It should be noted that, in specifying products for inclusion, it is expected that some products which are currently excluded under the existing Determination's broader "household and

personal aids, or furniture and utensils for people with disabilities" exclusion will now need to be included in the ARTG.

Implications of adopting Option 2

If **Option 2** is adopted, **the current Item 9, Schedule 1 will be replaced with a list of specified products** that are determined to be excluded from the therapeutic goods regulation by the TGA.

Also **a new item may be included in Schedule 2 determining that some specified products will be excluded goods when these products are used, advertised or presented for supply in a particular way.**

Any other assistive technology products that meet definition of a medical device will be regulated under the TG Act. This may draw in a series of devices currently excluded, where these are not described in the list at Appendix A.

Appendix A – List of products used by or for adults and children with disabilities has been included on page 20 as a reference tool. Specifically, it provides a list of assistive technologies products with descriptions that currently may be interpreted as the products covered under Item 9, Schedule 1 – "household and personal aids, or furniture and utensils, for people with disabilities". It also seeks the views on the proposed regulatory pathways for these products – whether they should be excluded unconditionally, excluded when used, advertised or presented for supply in a particular way, or regulated as a medical device. The list is not necessarily comprehensive, and feedback is welcome on whether the items listed should or should not be excluded, or other products not listed which should be excluded. Appendix A may assist you in providing your feedback.

Basing the exclusion on a list of technologies provides very clear advice on which products are excluded (in comparison with a definition approach, where there can be differences of interpretation). However, maintenance of the list will require assessment of emerging assistive technology and regulatory amendment if exclusion is appropriate.

What will change for sponsors?

Option 1(a)

If a new assistive technology definition is included in the Determination, there will be no immediate changes for sponsors of existing ARTG entries.[19] This is because the "assistive technology" definition is a little broader than the existing exclusion of "household and personal aids, or furniture and utensils, for people with disabilities". Those sponsors who currently have ARTG entries for the assistive technology products will be required to review their ARTG entries; and if their products are now excluded from being therapeutic goods, request cancellation of the respective ARTG entries. As it is not an offence to have products which are not therapeutic goods included in the ARTG, removal of ARTG no longer required is not urgent. Rather cancellation of no longer necessary ARTG entries will remove obligations from sponsor (to comply with the TG Act and to pay annual fees for those ARTG entries).

Option 1(b)

As for option 1(a), if a new low risk assistive technology definition is included in the Determination, sponsors who currently have ARTG entries for low risk assistive technology

[19] The sponsor is the importer, exporter or Australian manufacturer of the medical device, and is responsible for applying for marketing approval for a medical device.

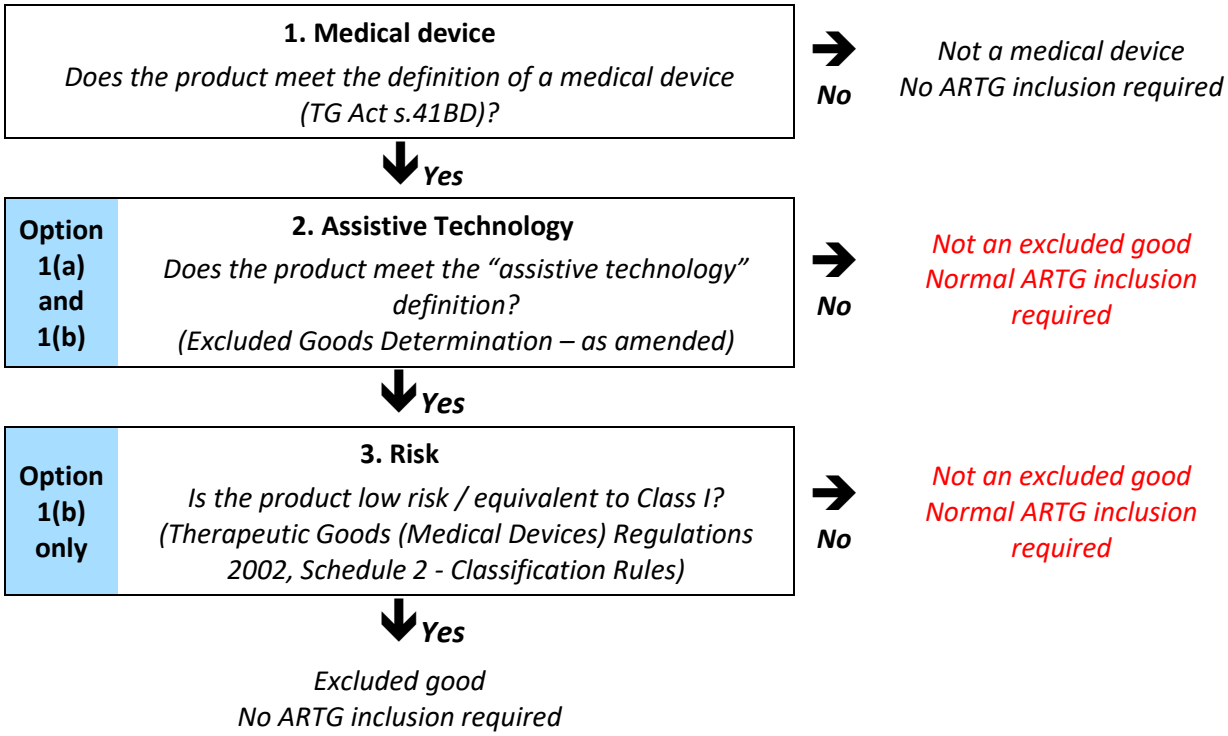
products will be required to review their ARTG entries, and cancel any entries for excluded goods.

Some **sponsors may not currently have ARTG entries for their (moderate or higher risk) products**. They will need to check whether their products are covered by the new "assistive technology" definition in the Determination.

If their products are excluded goods in line with the "assistive technology" definition, sponsors will not be required to do anything.

If their products are not covered in the Determination, such as where they are moderate or higher risk products, sponsors will be required to submit applications seeking pre-market approvals (ARTG inclusion) for their medical devices. An application must be made in accordance with the normal classification rule and respective requirements that apply to the device in accordance with the medical device regulatory framework.[20]

The following diagram outlines the process for reviewing products to see if ARTG inclusion is required:



The number of moderate or higher risk products which may need new ARTG inclusions under Option 1(b) is expected to be small, as it appears to have been generally 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. This is despite the existing arrangements not being limited to low risk products. Feedback from stakeholders on this would be appreciated.

[20] *Therapeutic Goods Act 1989*, s. 41DB; *Therapeutic Goods (Medical Devices) Regulations 2002*, Part 3, Div. 3.1. Schedule 2 and Schedule 2A; Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2018 (F2018L01410).

Option 2

If the Determination takes effect with the revised Schedule 1 and/or Schedule 2:

Sponsors of existing Class I ARTG entries for assistive technologies will need to review their products against the revised Determination:

There will be no immediate changes for sponsors who have ARTG entries for those products that are not determined as excluded goods.

Where a product has been clarified as an excluded good, the sponsor may need to cancel their ARTG entry (if all products in the ARTG are now excluded goods).

Sponsors that do not currently have ARTG entries for their products will need to check whether their products are specified in the Determination (in either Schedule 1 or Schedule).

If their products are specified as excluded goods, sponsors will not be required to do anything.

If their products are not specified in the Determination, sponsors will be required to submit applications seeking pre-market approvals (ARTG inclusion) for their medical devices. An application must be made in accordance with the classification rule and respective requirements that apply to the device in accordance with the medical device regulatory framework.[21]

Transitional arrangements

Option 1(a)

We propose that the amended Determination will take effect on the date when the Determination is made. This is based on the assumption that few if any products will newly require inclusion in the ARTG, and so there is little risk of the change resulting in sponsors being non-compliant (because they are required to include a device in the ARTG but have not done so).

This change will require removal of unnecessary ARTG entries. However, this can be done over time as having an unnecessary entry is not an offence under the TG Act.

The TGA would undertake a communication campaign with sponsors to educate them about the changes, and encourage removal of unnecessary ARTG entries, and may then undertake regulatory action to remove unnecessary entries where sponsors fail to do so (using normal proposal to cancel and cancellation powers under Part 4-6 Division 2 the TGA Act).

Option 1(b) or Option 2

If proposed amendments are consistent with Option 1(a) or Option 2, we propose that the amended Determination will take effect in **12 months** after it is made. This is based on the assumption that some products **will** newly be required to be included in the ARTG.

When the amended Determination takes effect, sponsors will be required to submit applications seeking pre-market approvals (ARTG inclusion) for any medical devices that are no longer covered in the Determination as excluded goods. An application must be made in accordance

[21] *Therapeutic Goods Act 1989*, s. 41DB; *Therapeutic Goods (Medical Devices) Regulations 2002*, Part 3, Div. 3.1. Schedule 2 and Schedule 2A; Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2018 (F2018L01410).

with the classification rule and respective requirements that apply to the device in accordance with the medical device regulatory framework.[22]

The TGA would undertake a communication campaign with sponsors to educate them about the changes, and encourage inclusion of products newly regulated, and removal of any unnecessary ARTG entries. The TGA may then undertake regulatory action to remove unnecessary entries where sponsors fail to do so (using normal proposal to cancel and cancellation powers under Part 4-6 Division 2 the TGA Act).

Fees and charges

The usual application and audit assessment fees (where applicable) will apply for applications for inclusion in the ARTG.[23] The usual annual charges will apply following inclusion of a medical device in ARTG.

Engagement

Wherever practicable, the TGA will:

- Liaise with the healthcare sector, patient associations and industry peak bodies to inform and raise awareness about this proposal; and
- Provide relevant material on the TGA website.

Feedback notes

It is important to note that while we plan to take your feedback on the intent of the proposed amendments into account as much as practicable, the Australian legislative instruments are structured in a particular way and there are certain requirements in the legal terminology. Therefore, we acknowledge that legislation cannot always be successfully replicated based on the stakeholders' feedback.

[22] *Therapeutic Goods Act 1989*, s. 41DB; *Therapeutic Goods (Medical Devices) Regulations 2002*, Part 3, Div. 3.1. Schedule 2 and Schedule 2A; Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2018 (F2018L01410).
[23] Fees and charges for medical devices are outlined on the TGA website at: https://www.tga.gov.au/schedule-fees-and-charges

What we invite you to do

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

Questions

1. 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"?
- If 'yes', do you have a proposed definition or consideration to be given when preparing the definition?
- 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?
- 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.)?

Option 1(b)

- Do you agree rather than excluding all assistive technologies, the exclusion should be limited to only low risk assistance technologies?
- If 'yes', do you have a proposed definition or consideration to be given when preparing the definition?
- 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?
- 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.)?
- 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?

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?
- 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.

- 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.
- 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.)?
- 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?

All Options

- Do you have any other options to clarify the meaning of Item 9, Schedule 1 of the Determination?
- 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?
- Are there any further issues and questions we should consider when implementing this change (including areas that can/should be clarified in our guidance)?
- 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?

How to submit

Complete the online consultation submission form to upload your submission in either pdf or word format.

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

This consultation closes on **25 October 2019**.

Enquiries

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

Appendix A – List of certain products used by or for adults and children with disabilities

Table A – seeking stakeholders feedback and views on regulatory pathways for specified devices used for people with disabilities.

Instructions for Table A:

The 1st and 2nd columns in the table provide the product group titles and their descriptions and intended purposes.

The 3rd column has been included to obtain stakeholders' views on whether the specified products should be entered in either Schedule 1 (products to be excluded unconditionally) or Schedule 2 (products to be excluded goods when these products are used, advertised or presented for supply in a particular way), or whether the product should be regulated as a medical device under the TG Act.

The 4th column seeks the reasons for the proposed regulatory pathway.

Therapeutic good	Description	Choose: 1. Exclude unconditionally 2. Exclude when used, advertised or presented in a particular way 3. Regulate as a medical device	Reasons
Communication devices			
Non-powered communication system	A non-powered communication system is a mechanical device that is used to assist a patient in communicating when physical impairment prevents writing, telephone use, reading, or talking. Examples of non-powered communications systems include an alphabet board and a page turner.		
Powered communication system	A powered communication system is an AC- or battery-powered device that is used to transmit or receive information. It is used by persons unable to use normal communication methods because of physical impairment. Examples of powered communication systems include: a specialised typewriter, a reading machine, and a video picture and word screen.		

Therapeutic good	Description	Choose: 1. Exclude unconditionally 2. Exclude when used, advertised or presented in a particular way 3. Regulate as a medical device	Reasons
Powered environmental control system	A powered environmental control system is an AC- or battery-powered device that is used by a patient to operate an environmental control function. Examples include: to control room temperature, to answer a doorbell or telephone, or to sound an alarm for assistance.		
Voice synthesiser / digitiser	An assistive device designed to deliver voice output based either in the reproduction of previously-recorded natural speech and/or on an electronic synthesised voice following a pre-established set of pronunciation rules. It typically consists of an electronic unit with a keyboard and screen; the keyboard may include letters, symbols, or both. The device is often customised to meet the user's needs and is mostly used by patients with disabilities that partially or totally impair voice capabilities, including chronic progressive diseases.		
Foreign-language assistive training device	A device designed to be used by a person with a disability for voice and speech training when learning a foreign language.		
Assistive acoustical orientation device	A battery-powered device designed to be used by a person with a visual impairment that electronically produces a sound or a voice message to help them orientate. It is commonly known as a sound beacon.		
Training aid, communication, speaking	A technical aid designed to assist a disabled or infirm person in training and developing communication techniques which involve the use of voice and speech, particularly in relation to the production and awareness of sounds. Aids for training spoken language, S-, F- and Sch-indicators and acoustic spectral analysers are included.		

Therapeutic good	Description	Choose: 1. Exclude unconditionally 2. Exclude when used, advertised or presented in a particular way 3. Regulate as a medical device	Reasons
Hearing aid			
Hearing aid, air-conduction, receiver-in-canal	A battery-powered acoustic device intended to compensate for impaired hearing by transmitting amplified sound waves to the eardrum through air. It consists of a microphone and an amplifier in a case behind-the-ear (BTE) connected, via a wire, to a receiver (speaker) in the ear canal [receiver-in-canal (RIC)]; this separation reduces acoustic feedback. The microphone receives sound waves and converts them into electrical signals which are increased by the amplifier and sent as sound waves, by the speaker, to the eardrum. The device is used for mild to profound hearing loss; most types are programmable to enable computerised adjustments for a patient's hearing loss and related factors.		
Hearing aid neck induction loop, active	A portable, battery-powered device worn around the neck intended to receive sound from an audio source [e.g., mp3 player] via a wire (e.g., 3.5mm Jack plug) and transfer it via an audio frequency magnetic field to a hearing aid with an induction coil (i.e., bypassing the hearing aids microphone) when it is switched to the "T" or “M”’ position, in order for the hearing aid user to hear (e.g., music) more clearly. It typically consists of an input cable leading to a small active amplifier with a wire loop worn around the neck.		

Therapeutic good	Description	Choose: 1. Exclude unconditionally 2. Exclude when used, advertised or presented in a particular way 3. Regulate as a medical device	Reasons
Hearing aid enhanced audio attachment	A passive device intended to enable a wired audio transmission from a multimedia device (e.g., computer, phone, mp3 player) to a behind-the-ear (BTE) hearing aid, to enhance the sound quality received by the wearer of the hearing aid. Also known as an audioshoe, it consists of a hearing aid attachment which attaches/plugs directly into the hearing aid, making an electrical connection [e.g., direct audio input (DAI)], to receive power from and transmit the signal to the active hearing aid. A wire is used to connect the device to the multimedia device.		
Hearing aid remote control	A battery-powered device designed to be operated by the wearer of a hearing aid to enable discreet wireless (remote) adjustments to the hearing aid (e.g., volume and program changes). It is designed to be conveniently portable (e.g., carried in a pocket, handbag, or attached to a key ring).		
Visual aid			
Visual orientation material	A device used by a person with a disability who has an impaired sense of orientation to supply information on orientation through sight. This is typically used in their surroundings, e.g. at home, work, and in the normal daily life of society.		
Ophthalmic prism reader	An ophthalmic prism reader is a device intended for use by a patient who is in a supine position to change the angle of print to aid reading.		
Low-vision magnifier	A low-vision magnifier is a device that consists of a magnifying lens intended for use by a patient who has impaired vision. The device may be held in the hand or attached to spectacles.		

Therapeutic good	Description	Choose: 1. Exclude unconditionally 2. Exclude when used, advertised or presented in a particular way 3. Regulate as a medical device	Reasons
Ptosis crutch	A ptosis crutch is a device intended to be mounted on the spectacles of a patient who has ptosis (drooping of the upper eyelid as a result of faulty development or paralysis) to hold the upper eyelid open.		
Ophthalmic bar reader	An ophthalmic bar reader is a device that consists of a magnifying lens intended for use by a patient who has impaired vision. The device is placed directly onto reading material to magnify print.		
Assistive talking reading material	A digital medium which presents the content of written publications, e.g., books, in spoken form for the user to comprehend. It is particularly used by a person with a disability and/or a vision impairment or other debilitating condition.		
Closed-circuit television reading system	A closed-circuit television reading system is a device that consists of a lens, video camera, and video monitor that is intended for use by a patient who has subnormal vision to magnify reading material.		
Magnifying spectacles	Magnifying spectacles are devices that consist of spectacle frames with convex lenses intended to be worn by a patient who has impaired vision to enlarge images.		
Spectacle frame	A spectacle frame is a device made of metal or plastic intended to hold prescription spectacle lenses worn by a patient to correct refractive errors.		
Prescription spectacle lens	A prescription spectacle lens is a glass or plastic device that is a lens intended to be worn by a patient in a spectacle frame to provide refractive corrections in accordance with a prescription for the patient. The device may be modified to protect the eyes from bright sunlight (i.e., prescription sunglasses). Prescription sunglass lenses may be reflective, tinted, polarizing, or photosensitised.		

Therapeutic good	Description	Choose: 1. Exclude unconditionally 2. Exclude when used, advertised or presented in a particular way 3. Regulate as a medical device	Reasons
Low-vision telescope	A low-vision telescope is a device that consists of an arrangement of lenses or mirrors intended for use by a patient who has impaired vision to increase the apparent size of objects. This generic type of device includes handheld or spectacle telescopes.		
Electronic vision aid	An electronic vision aid is an AC-powered or battery-powered device that consists of an electronic sensor/transducer intended for use by a patient who has impaired vision or blindness to translate visual images of objects into tactile or auditory signals.		
Oral electronic vision aid	An oral electronic vision aid is a battery-powered prescription device that contains an electrode stimulation array to generate electrotactile stimulation patterns that are derived from digital object images captured by a camera. It is intended to aid profoundly blind patients in orientation, mobility, and object recognition as an adjunctive device to other assistive methods such as a white cane or a guide dog.		
Image intensification vision aid	An image intensification vision aid is a battery-powered device intended for use by a patient who has limited dark adaptation or impaired vision to amplify ambient light.		
Artificial eye	An artificial eye is a device resembling the anterior portion of the eye, usually made of glass or plastic, intended to be inserted in a patient's eye socket anterior to an orbital implant, or the eviscerated eyeball, for cosmetic purposes. The device is not intended to be implanted.		

Therapeutic good	Description	Choose: 1. Exclude unconditionally 2. Exclude when used, advertised or presented in a particular way 3. Regulate as a medical device	Reasons
Scleral shell	A scleral shell is a device made of glass or plastic that is intended to be inserted for short time periods over the cornea and proximal-cornea sclera for cosmetic or reconstructive purposes. An artificial eye is usually painted on the device. The device is not intended to be implanted.		
Prosthetic and orthotic devices			
Accessory	A prosthetic and orthotic accessory is a device intended to support, protect, or aid in the use of a cast, orthosis (brace), or prosthesis. Examples of prosthetic and orthotic accessories include: A pelvic support band and belt, a cast shoe, a cast bandage, a limb cover, a prosthesis alignment device, a postsurgical pylon, a transverse rotator, and a temporary training splint.		
External limb orthotic component	An external limb orthotic component is a device intended for use in conjunction with an orthosis (brace) to increase the function of the orthosis for a patient's particular needs. Examples of external limb orthotic components include: A brace-setting twister and an external brace stirrup.		
External limb prosthetic component	An external limb prosthetic component is a device that, when put together with other appropriate components, constitutes a total prosthesis. Examples of external limb prosthetic components include: Ankle, foot, hip, knee, and socket components; mechanical or powered hand, hook, wrist unit, elbow joint, and shoulder joint components; and cable and prosthesis suction valves.		

Therapeutic good	Description	Choose: 1. Exclude unconditionally 2. Exclude when used, advertised or presented in a particular way 3. Regulate as a medical device	Reasons
Upper extremity prosthesis including a simultaneously powered elbow and/or shoulder with greater than two simultaneous powered degrees of freedom and controlled by non-implanted electrical components	A upper extremity prosthesis including a simultaneously powered elbow and/or shoulder with greater than two simultaneous powered degrees of freedom and controlled by non-implanted electrical components, is a device intended to replace a partially or fully amputated or congenitally absent upper extremity. It uses electronic inputs (other than simple, manually controlled electrical components such as switches) to provide greater than two independent and simultaneously powered degrees of freedom and includes a simultaneously powered elbow and/or shoulder. Prosthetic arm components that are intended to be used as a system with other arm components must include all degrees of freedom of the total upper extremity prosthesis system.		
Limb orthosis	A limb orthosis (brace) is a device that is worn on the upper or lower extremities to support, to correct, or to prevent deformities or to align body structures for functional improvement. Examples of limb orthoses include: A whole limb and joint brace, a hand splint, an elastic stocking, a knee cage, and a corrective shoe.		
Truncal orthosis	A truncal orthosis is a device intended to support or to immobilise fractures, strains, or sprains of the neck or trunk of the body. Examples are: Abdominal, cervical, cervical-thoracic, lumbar, lumbo-sacral, rib fracture, sacroiliac, and thoracic orthoses and clavicle splints.		

Therapeutic good	Description	Choose: 1. Exclude unconditionally 2. Exclude when used, advertised or presented in a particular way 3. Regulate as a medical device	Reasons
External assembled lower limb prosthesis	External assembled lower limb prosthesis is a preassembled external artificial limb for the lower extremity. Examples are: Knee/shank/ankle/foot assembly and thigh/knee/shank/ankle/foot assembly.		
Arm sling	An arm sling is a device intended to immobilise the arm, by means of a fabric band suspended from around the neck.		
Congenital hip dislocation abduction splint	A congenital hip dislocation abduction splint is a device intended to stabilise the hips of a young child with dislocated hips in an abducted position (away from the midline).		
Denis Brown splint	A Denis Brown splint is a device intended to immobilise the foot. It is used on young children with tibial torsion (excessive rotation of the lower leg) or club foot.		
Powered wheeled stretcher	A powered wheeled stretcher is a battery-powered table with wheels that is intended for use by patients who are unable to propel themselves independently and who must maintain a prone or supine position for prolonged periods because of skin ulcers or contractures (muscle contractions).		
Chairs and tables			
Mechanical chair	A mechanical chair is a manually operated device intended to assist a disabled person in performing an activity that the person would otherwise find difficult to do or be unable to do. Examples of mechanical chairs include: A chair with an elevating seat used to raise a person from a sitting position to a standing position and a chair with casters used by a person to move from one place to another while sitting.		

Therapeutic good	Description	Choose: 1. Exclude unconditionally 2. Exclude when used, advertised or presented in a particular way 3. Regulate as a medical device	Reasons
Electric positioning chair	An electric positioning chair is a device with a motorised positioning control that can be adjusted to various positions. The device is used to provide stability for patients with athetosis (involuntary spasms) and to alter postural positions.		
Flotation cushion	A flotation cushion is a device made of plastic, rubber, or other type of covering, that is filled with water, air, gel, mud, or any other substance allowing a flotation media, used on a seat to lessen the likelihood of skin ulcers.		
Mechanical table	A mechanical table is a device that has a flat surface that can be inclined or adjusted to various positions. It is used by patients with circulatory, neurological, or musculoskeletal conditions to increase tolerance to an upright or standing position.		
Powered table	A powered table is a device that is an electrically operated flat surface table that can be adjusted to various positions. It is used by patients with circulatory, neurological, or musculoskeletal conditions to increase tolerance to an upright or standing position.		
Robotic equipment			
Powered lower extremity exoskeleton	A powered lower extremity exoskeleton is a device that is composed of an external, powered, motorised orthosis that is placed over a person's paralysed or weakened limbs, allowing the person to stand, walk, turn, etc.		

Therapeutic good	Description	Choose: 1. Exclude unconditionally 2. Exclude when used, advertised or presented in a particular way 3. Regulate as a medical device	Reasons
Walking aid			
Cane	A cane is a device intended to provide minimal weight support while walking. Examples of canes include: A standard cane, a forearm cane, and a cane with a tripod, quad, or retractable stud on the ground end.		
Crutch	A crutch is a device intended for use by disabled persons to provide minimal to moderate weight support while walking.		
Cane, crutch, and walker tips and pads	Cane, crutch, and walker tips and pads are rubber (or rubber substitute) device accessories that are applied to the ground end of mobility aids to prevent skidding or that are applied to the body contact area of the device for comfort or as an aid in using an ambulatory assist device.		
Mechanical walker	A mechanical walker is a four-legged device with a metal frame intended to provide moderate weight support while walking. It is used by disabled persons who lack strength, good balance, or endurance.		
Wheelchairs and three or four wheeled vehicles			
Motorised three-wheeled vehicle	A motorised three-wheeled vehicle is a gasoline-fuelled or battery-powered device that is used for outside transportation by disabled persons.		
Mechanical wheelchair	A mechanical wheelchair is a manually operated device with wheels that is intended to provide mobility to persons restricted to a sitting position.		
Powered wheelchair	A powered wheelchair is a battery-operated device with wheels that is intended to provide mobility to persons restricted to a sitting position.		

Therapeutic good	Description	Choose: 1. Exclude unconditionally 2. Exclude when used, advertised or presented in a particular way 3. Regulate as a medical device	Reasons
Special grade wheelchair	A special grade wheelchair is a device with wheels that is intended to provide mobility to persons restricted to a sitting position. It is intended to be used in all environments for long-term use, e.g., for paraplegics, quadraplegics, and amputees.		
Stair-climbing wheelchair	A stair-climbing wheelchair is a device with wheels that is intended to provide mobility to persons restricted to a sitting position. The device is intended to climb stairs.		
Stand-up wheelchair	A stand-up wheelchair is a device with wheels that is intended to provide mobility to persons restricted to a sitting position. The device incorporates an external manually controlled mechanical system that is intended to raise a paraplegic to an upright position by means of an elevating seat.		
Wheelchair accessory	A wheelchair accessory is a device that is sold separately from a wheelchair and is intended to meet the specific needs of a patient who uses a wheelchair. Examples of wheelchair accessories include but are not limited to the following: armboard, lapboard, pusher cuff, crutch and cane holder, overhead suspension sling, head and trunk support, and blanket and leg rest strap.		
Wheelchair component	A wheelchair component is a device that is generally sold as an integral part of a wheelchair, but may also be sold separately as a replacement part. Examples of wheelchair components are: Armrest, narrowing attachment, belt, extension brake, curb climber, cushion, antitip device, footrest, handrim, hill holder, leg rest, heel loops, and toe loops.		
Wheelchair elevator	A permanently mounted wheelchair platform lift is a motorised vertical or inclined platform lift device permanently installed in one location that is intended for use in mitigating mobility impairment caused by injury or		

Therapeutic good	Description	Choose: 1. Exclude unconditionally 2. Exclude when used, advertised or presented in a particular way 3. Regulate as a medical device	Reasons
	other disease by providing a guided platform to move a person from one level to another, with or without a wheelchair.		
Wheelchair platform scale	A wheelchair platform scale is a device with a base designed to accommodate a wheelchair. It is intended to weigh a person who is confined to a wheelchair.		
Therapeutic use –daily activities			
Daily activity assist device	A daily activity assist device is a modified adaptor or utensil (e.g., a dressing, grooming, recreational activity, transfer, eating, or homemaking aid) that is intended to assist a patient to perform a specific function.		
Powered patient transport	A powered patient stairway chair lift is a motorised lift equipped with a seat and permanently mounted in one location that is intended for use in mitigating mobility impairment caused by injury or other disease by moving a person up and down a stairway.		
Therapeutic use – beds			
Air-fluidised bed	An air-fluidised bed is a device employing the circulation of filtered air through ceramic spherules (small, round ceramic objects) that is intended to treat or prevent bedsores, to treat severe or extensive burns, or to aid circulation.		

Therapeutic good	Description	Choose: 1. Exclude unconditionally 2. Exclude when used, advertised or presented in a particular way 3. Regulate as a medical device	Reasons
Powered flotation therapy bed	A powered flotation therapy bed is a device that is equipped with a mattress that contains a large volume of constantly moving water, air, mud, or sand. It is intended to treat or prevent a patient's bedsores, to treat severe or extensive burns, or to aid circulation. The mattress may be electrically heated.		
Manual patient rotation bed	A manual patient rotation bed is a device that turns a patient who is restricted to a reclining position. It is intended to treat or prevent bedsores, to treat severe and extensive burns, or to aid circulation.		
Powered patient rotation bed	A powered patient rotation bed is a device that turns a patient who is restricted to a reclining position. It is intended to treat or prevent bedsores, to treat severe and extensive burns, urinary tract blockage, and to aid circulation.		
Therapeutic use – bath and steam cabinets			
Moist steam cabinet	A moist steam cabinet is a device that delivers a flow of heated, moisturised air to a patient in an enclosed unit. It is used to treat arthritis and fibrosis (a formation of fibrosis tissue) and to increase local blood flow.		
Non-powered sitz bath	A non-powered sitz bath is a device that consists of a tub to be filled with water for use in external hydrotherapy to relieve pain or pruritus and to accelerate the healing of inflamed or traumatised tissues of the perianal and perineal areas.		

Therapeutic good	Description	Choose: 1. Exclude unconditionally 2. Exclude when used, advertised or presented in a particular way 3. Regulate as a medical device	Reasons
Therapeutic use – exercise equipment			
Exercise component	An exercise component is a device that is used in conjunction with other forms of exercise and that is intended to redevelop muscles or restore motion to joints or for use as an adjunct treatment for obesity. Examples include weights, dumbbells, straps, and adaptive hand mitts.		
Measuring exercise equipment	Measuring exercise equipment consists of manual devices intended to redevelop muscles or restore motion to joints or for use as an adjunct treatment for obesity. These devices also include instrumentation, such as the pulse rate monitor, that provide information used for physical evaluation and physical planning purposes. Examples include a therapeutic exercise bicycle with measuring instrumentation, a manually propelled treadmill with measuring instrumentation, and a rowing machine with measuring instrumentation.		
Non-measuring exercise equipment	Non-measuring exercise equipment consists of devices intended to redevelop muscles or restore motion to joints or for use as an adjunct treatment for obesity. Examples include a prone scooter board, parallel bars, a mechanical treadmill, an exercise table, and a manually propelled exercise bicycle.		
Powered exercise equipment	Powered exercise equipment consists of powered devices intended to redevelop muscles or restore motion to joints or for use as an adjunct treatment for obesity. Examples include a powered treadmill, a powered bicycle, and powered parallel bars.		

Therapeutic good	Description	Choose: 1. Exclude unconditionally 2. Exclude when used, advertised or presented in a particular way 3. Regulate as a medical device	Reasons
Powered finger exerciser	A powered finger exerciser is a device intended to increase flexion and the extension range of motion of the joints of the second to the fifth fingers of the hand.		
Powered external limb overload warning device	A powered external limb overload warning device is a device intended to warn a patient of an overload or an underload in the amount of pressure placed on a leg.		
Therapeutic use – massage and pressure equipment			
Powered inflatable tube massager	A powered inflatable tube massager is a powered device intended to relieve minor muscle aches and pains and to increase circulation. It simulates kneading and stroking of tissues with the hands by use of an inflatable pressure cuff.		
Therapeutic massager	A therapeutic massager is an electrically powered device intended to relieve minor muscle aches and pains.		
Non-powered lower extremity pressure wrap	A non-powered lower extremity pressure wrap is a device that applies mechanical pressure by wrapping around the lower extremity, such as the leg or foot, and is intended for primary Restless Leg Syndrome.		
Pressure-applying device	A pressure-applying device is a device intended to apply continuous pressure to the paravertebral tissues for muscular relaxation and neuro-inhibition. It consists of a table with an adjustable overhead weight that, in place of the therapist's hands, presses on the back of a prone patient.		
Powered muscle stimulator	A powered muscle stimulator is an electrically powered device that repeatedly contracts muscles by passing electrical currents through electrodes contacting the affected body area.		

Therapeutic good	Description	Choose: 1. Exclude unconditionally 2. Exclude when used, advertised or presented in a particular way 3. Regulate as a medical device	Reasons
Multi-function physical therapy table	A multi-function physical therapy table is a device that consists of a motorised table equipped to provide patients with heat, traction, and muscle relaxation therapy.		
Power traction equipment	Powered traction equipment consists of powered devices intended for use in conjunction with traction accessories, such as belts and harnesses, to exert therapeutic pulling forces on the patient's body.		
Traction accessory	A traction accessory is a non-powered accessory device intended to be used with powered traction equipment to aid in exerting therapeutic pulling forces on the patient's body. This generic type of device includes the pulley, strap, head halter, and pelvic belt.		
Therapeutic vibrator	A therapeutic vibrator is an electrically powered device that incorporates various kinds of pads and that is held in the hand or attached to the hand or to a table. It is intended for various uses, such as relaxing muscles and relieving minor aches and pains.		
Therapeutic use – hot and cold therapy			
Cold pack	A cold pack is a device that consists of a compact fabric envelope containing a specially hydrated pliable silicate gel capable of forming to the contour of the body and that provides cold therapy for body surfaces.		
Hot or cold disposable pack	A hot or cold disposable pack is a device that consists of a sealed plastic bag incorporating chemicals that, upon activation, provides hot or cold therapy for body surfaces.		

Therapeutic good	Description	Choose: 1. Exclude unconditionally 2. Exclude when used, advertised or presented in a particular way 3. Regulate as a medical device	Reasons
Water circulating hot or cold pack	A water circulating hot or cold pack is a device that operates by pumping heated or chilled water through a plastic bag and that provides hot or cold therapy for body surfaces.		
Moist heat pack	A moist heat pack is a device that consists of silica gel in a fabric container used to retain an elevated temperature and that provides moist heat therapy for body surfaces.		
Powered heating pad	A powered heating pad is an electrical device that provides dry heat therapy for body surfaces. It is capable of maintaining an elevated temperature during use.		
Daily living aid			
Personal hygiene aid, toileting, seat, raised, loose	A technical aid designed to assist a disabled or infirm person in attending to their own personal hygiene requirements during a visit to the toilet. It is a raised toilet seat which is placed directly on the toilet bowl, and which is used to increase the height of the sitting position. This raised toilet seat can easily be removed.		
Patient lifting system toilet seat	A lifting device designed to be used with a patient lifting system to provide support for an incapacitated or disabled patient who is being transferred and lifted into position to use the toilet. It is a toilet seat-like device upon which the person to be lifted sits and is secured to during the lifting process and while using the toilet.		

Therapeutic good	Description	Choose: 1. Exclude unconditionally 2. Exclude when used, advertised or presented in a particular way 3. Regulate as a medical device	Reasons
Stand-up toilet seat	An electrically-powered seat designed to be attached to a standard or assistive toilet and intended to lower a person with a disability to a conventional sitting level for toileting, and to raise them for easy standing after toileting. The device operates through a built-in lifting/lowering mechanism.		
Shower head adjustment adaptor	A device designed to be used by a person with a disability to assist them to adjust the position (height and angle) of the shower head when they are taking a shower.		
Chair, bath/shower	A device designed to be sat upon by a person who is bathing, showering, or using some washing facility where there is a need to sit. The sitting requirement can be, e.g. because the person is disabled or infirm, or because it is part of medical treatment.		
Fixed-rail armrest	A wall and/or floor fixed-rail system designed to provide arm support for a disabled person to facilitate their movement/mobility. It is permanently-fixed to the wall and/or floor at strategic points in a building or in the home.		
Eating/drinking aid, cutlery	A technical aid designed to be used by a disabled or infirm person when eating in order to cut food, or on/in/through which food is moved from a container into the person's mouth.		

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Therapeutic Goods Administration, Medical Devices Branch	September 2019

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