Future regulation of assistive technologies

Rachel Croome
Director
Devices Engagement Section
Medical Devices Authorisations Branch
Therapeutic Goods Administration

Amy Soebagyo
Assistant Director
Devices Engagement Section
Medical Devices Authorisations Branch
Therapeutic Goods Administration

Acknowledgement of Country

In the spirit of reconciliation, the Department of Health and Aged Care acknowledges the Traditional Custodians of country throughout Australia and their connections to land, sea and community.

We pay our respect to their Elders past and present and extend that respect to all Aboriginal and Torres Strait Islander peoples today

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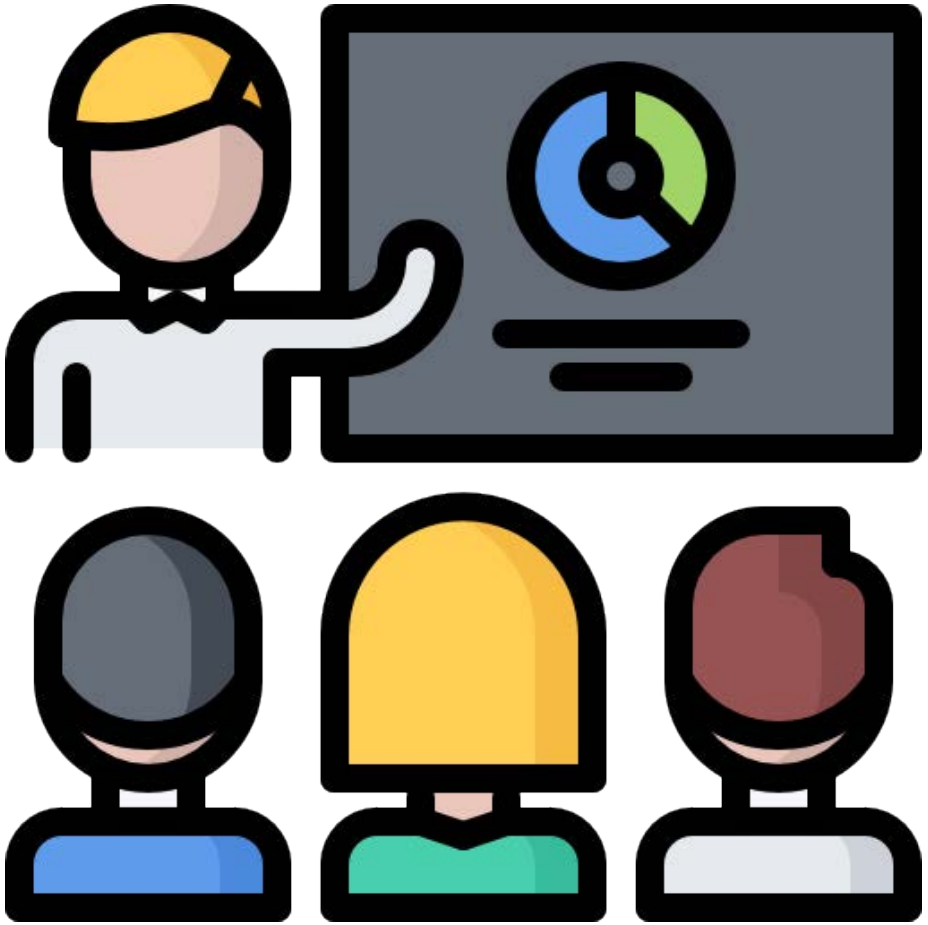
Today’s presentation

- Introduction – How did we get here?
- Proposal 1
  Remove exclusion
- Proposal 2
  Exemption for some assistive technologies
- Boundaries
  Social versus medical approach to disability
- Next steps
- Resources and contacts
- Questions



Introduction

Medical device regulation

Therapeutic Goods Administration regulates the import, export and supply of therapeutic goods, including medical devices

Medical devices must be included in the Australian Register of Therapeutic Goods (ARTG), unless they are **EXEMPT**

Sponsors of devices included in the ARTG must hold and be able to provide manufacturer's evidence to demonstrate safety and performance

Sponsors must provide the TGA with information and product samples upon request and meet all regulatory requirements

Introduction

Classification of assistive technologies

Class	Risk	Examples
Class I	Low risk	Wheely walker, shower chair, compression garment
Class I sterile	Low to medium risk	Sterile urinary collection leg bag, sterile wound dressings
Class I measuring	Low to medium risk	Medicine cup, scales (including seated, bed, wheelchair), clinical ruler, atomiser
Class IIa	Low to medium risk	Hearing aid, electric nasal aspirator, ambulation exosketon, CPAP
Class IIb	Medium to high risk	Oxygen concentrator, haemodialysis unit, infusion pump
Class III	High risk	Implantable deep brain stimulator, cochlear implant

In vitro diagnostic devices (IVDs) are also medical devices (Classes 1 to 4).
These may also be assistive technologies used for or by people with disabilities

Introduction

Medical device regulation

Many assistive technologies are Class I (low risk)

- Manufacturer's evidence is self-certified by the manufacturer with a Declaration of Conformity (DoC)

All higher risk medical devices require third party certification, either by TGA or a comparable overseas regulator

- Class I sterile, Class I measuring, Class IIa, Class IIb and Class III (including Active Implantable Medical Devices or AIMDs)
- Manufacturer's evidence of appropriate Quality Management System
- Design or type examination for each Class III medical device

All medical devices must comply with the Essential Principles and have an appropriate conformity assessment procedure

Introduction

International regulation of low-risk assistive technologies

- Europe
  - Class I self-certified (Declaration of Conformity) and affix CE mark
  - Register on EUDAMED (notification with verification)
- USA
  - FDA has ’exempted almost all class I devices’ so premarket approval not required
- Singapore
  - Class I exempt from product registration – no notification requirements
- Brazil
  - Class 1 and 2 devices (broadly equivalent to Class I and IIa) have a notification requirement, but no other pre-market approval

Introduction

How assistive technologies are currently regulated

Generally assistive technologies meet the definition of a medical device:

"alleviate or compensate for an injury or disability"

Regulated by TGA :

inclusion in the Australian Register of Therapeutic Goods (ARTG) before import, export or supply

meet premarket and ongoing regulatory requirements

Unless meets **EXCLUSION**:

"household and personal aids, or furniture and utensils, for people with disabilities"

Not regulated by TGA :

No regulatory requirements

Other regimes may apply, such as Australian Consumer Law

Introduction

The problem

Current exclusion aims to exclude products intended

for use outside health or residential care settings

- distinction increasingly unclear
- changes in supply and use of products
- changes in sectors being supplied

Broader issues around medical versus social model of disability

Introduction

Previous consultation

2017: Options for the future regulation of 'low risk' products
Considered **exclusion** of a broad range of low-risk products

2019: Products used for and by people with disabilities: Options for amendment to the *Therapeutic Goods (Excluded Goods) Determination 2018*
Considered update to **exclusion** of all assistive technologies, or all low-risk technologies

2021: Assistive Technologies and the *Therapeutic Goods (Excluded Goods) Determination 2021*
Follow on from 2019 consultation, proposing definition and guidance for exclusion of assistive technologies in daily living settings

2024: Proposed changes to the regulation of exempt medical devices and exempt other therapeutic goods
Outlined possible changes for regulation of exempt products

Proposal 1. Remove current exclusion

Effect of removing exclusion

Any assistive technology meeting the definition of a medical device regulated by the TGA:

- inclusion in the ARTG before import, export or supply
  - Class I application fee of $602 for each ‘kind of medical device based on self-certification by manufacturer, plus annual charge of $111
  - Higher costs and need for third party certification for higher classifications
- meet premarket and ongoing regulatory requirements, including
  - Essential Principles and have appropriate conformity assessment procedure
  - compliance with conditions of inclusion (general or additional)
  - report adverse events
  - recall actions where required
  - compliance with Therapeutic Goods Advertising Code

Strong presumption of at least some exemption (under Proposal 2)

Proposal 1. Remove current exclusion

Examples and issues

Unclear how many products would be impacted - no information on currently excluded products

- Can you identify products which are not currently included in the ARTG?

Product	ARTG entry required?	Comments
Slide Sheets	Very likely (unless specific intention only for household use)	Would typically include intended use in multiple settings including healthcare
Shower chairs/stools	Likely (unless specific intention only for household use)	Would typically include intended use in multiple settings including healthcare
Non-powered wheelchairs	Likely No if presented for individual (ie personal) use	Typically includes intended use in healthcare settings Custom configured wheelchairs could be seen as ‘personal’ use aids

Proposal 1. Remove current exclusion

Examples and issues

Product	ARTG entry required?	Comments
Furniture	Maybe (where has therapeutic use and not restricted to household use)	Use in healthcare does not make furniture a medical device eg visitor chair, bedside table
Utensils	Likely not	Exclusion of ‘utensils… for people with disabilities’ reasonably clear
Post operative shoes	Maybe	May be presented as a personal use item ie sized and supplied to a single patient for individual use
Heat and cold packs	Maybe (due to medical device definition rather than exclusion)	May be presented as not meeting the definition of medical devices (ie for comfort or warmth – not for therapeutic use)

Proposal 1. Remove current exclusion

Implications

- greater access to information about devices that meet current regulatory requirements
- manufacturers required to have appropriate evidence of meeting safety, quality and performance requirements
- greater clarity on what products need to be included in the ARTG

Costs

- meeting regulatory obligations, including documentation of compliance
- costs of inclusion – application and annual charges
- delay to market and potential loss of products from market and/or increased costs to consumers

Proposal 1. Remove current exclusion

Consultation 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?

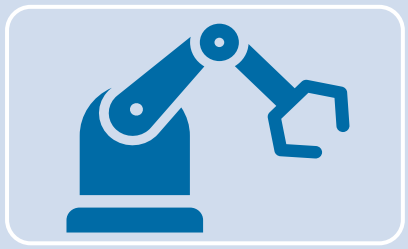
3. What would be the financial impact for you if the TGA removed the current exclusion for “household and personal aids, or furniture and utensils, for people with disabilities”? If possible, please provide a breakdown of the impacts (cost, time, types and estimated numbers of impacted products). This 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. Assistive technology exemption/s

Exempt versus excluded medical devices

Exempt Medical Devices



not required to be included in the ARTG

must meet TGA regulatory requirements and comply with advertising requirements

TGA regulation including post-market reviews, recalls and enforcing offence provisions

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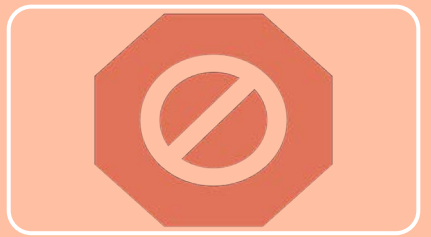
Excluded



EXCLUDED goods do not need to meet any regulatory requirements set by the TGA

Proposal 2. Assistive technology exemption/s

Rationale for exemption

Reduces the regulatory burden (including financial costs) for manufacturers and sponsors of assistive technology devices, 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 or at commercial quantities)
- 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).

Proposal 2. Assistive technology exemption/s

Possible exemptions

Consider:

- what is appropriate based on risk, access, cost, etc
- scope of possible exemptions
  - broad eg all Class I assistive technology medical devices
  - targeted eg categories within ISO 9999:2022
    eg assistive products for eating and drinking (15 09) broadly,
    versus enteral feeding systems (15 09 30)
- impacts across systems eg NDIS and state/territory disability programs, aged care, DVA
- 'add ons' for exempt medical devices
  - notifications, publishing of notifications, information and samples
  - as outlined in previous consultation paper Proposed changes to the regulation of exempt medical devices and exempt Other Therapeutic Goods

Note: products in some categories in ISO 9999 would generally not meet the medical device definition (*Therapeutic Goods Act 1989* s.41BD)

Proposal 2. Assistive technology exemption/s

Example exemptions

Exempt all Class I assistive technologies

- Items listed in ISO 9999:2022
- Would need tweaking to remove medical devices which are not solely assistive technologies eg stethoscopes

Exempt targeted categories within ISO 9999:2022

- Focus could be super low risk (not weight bearing, low technology devices etc)
- Focus could be boundary products eg utensils (may or may not meet medical device definition based on manufacturer’s intended purpose)

Proposal 2. Assistive technology exemption/s

Consultation 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.

Proposal 2. Assistive technology exemption/s

Consultation questions

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?

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Boundaries

Consultation question

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?

Contact us

Email

devicereforms@health.gov.au

Medical Devices Information Team

Ph: 1800 141 144

devices@tga.gov.au

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Next steps

Have your say

Consultation closes 13 October 2024

Assistive technology consultation page

Consultation: Future regulation of assistive technologies - Therapeutic Goods Administration - Citizen Space (tga.gov.au)

Consultation paper link

Consultation: (tga.gov.au)

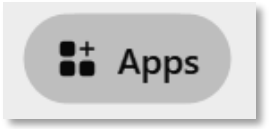
Enquiries for the project team

devicereforms@health.gov.au

or via the Health switchboard on 02 6289 1555 or free call on 1800 020 103

How did we go?

Take a moment to complete our survey



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Information and resources

Therapeutic Goods Act 1989 s.41BD:	https://www.legislation.gov.au/C2004A03952/2024-07-01/2024-07-01/text/original/epub/OEBPS/document_2/document_2.html#_Toc171325498
Therapeutic Goods (Excluded Goods) Determination 2018, Schedule 1 Item 9	https://www.tga.gov.au/resources/consultation/consultation-products-used-and-people-disabilities Assistive Technologies and the *Therapeutic Goods (Excluded Goods) Determination 2021:*
Options for the future regulation of 'low risk' products:	https://www.tga.gov.au/resources/consultation/consultation-products-used-and-people-disabilities Assistive Technologies and the *Therapeutic Goods (Excluded Goods) Determination 2021:*
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Assistive Technologies and the Therapeutic Goods (Excluded Goods) Determination 2021:	https://consultations.tga.gov.au/tga/assistive-technologies-amendment-exposure-draft/supporting_documents/CONSULTATION_Guidance Assistive technologies.pdf
Proposed changes to the regulation of exempt medical devices and exempt other therapeutic goods:	https://consultations.tga.gov.au/tga/proposed-changes-to-exempt-devices-and-otgs/supporting_documents/Exempt devices consultation.pdf
Consultation paper	https://consultations.tga.gov.au/tga/consultation-future-regulation-of-assistive-techno/supporting_documents/TGA%20Public%20Consultation%20%20Future%20regulation%20of%20assistive%20technologies%2022%20July%202024.pdf

Questions?

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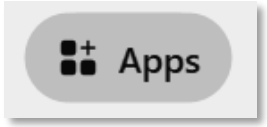

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