Proposed changes to the regulation of Exempt Devices and OTGs

Xin-Lin Goh
Director, Devices Reforms Taskforce
Department of Health and Aged Care, TGA

Acknowledgement of Country

I would like to acknowledge the Traditional Owners and Custodians of the lands on which we meet today and pay my respects to Elders past and present.

I would like to extend that acknowledgement and respect to any Aboriginal and Torres Strait Islander peoples here today.

Welcome

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Public Consultation

Please provide feedback

Opened 15 April 2024

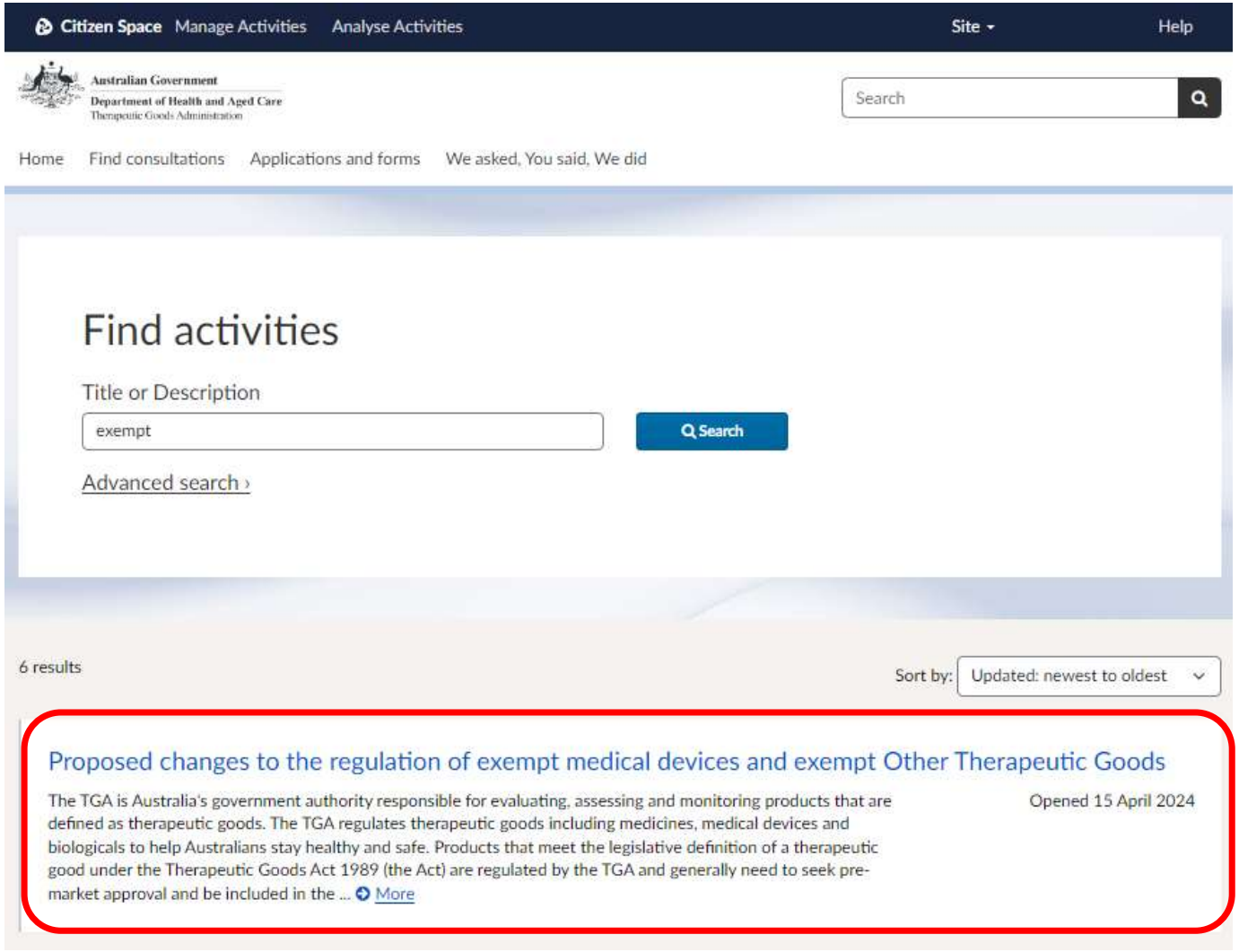
Closes 9 June 2024

Webinars to support consultation

- 8 May 2024
- 10 May 2024

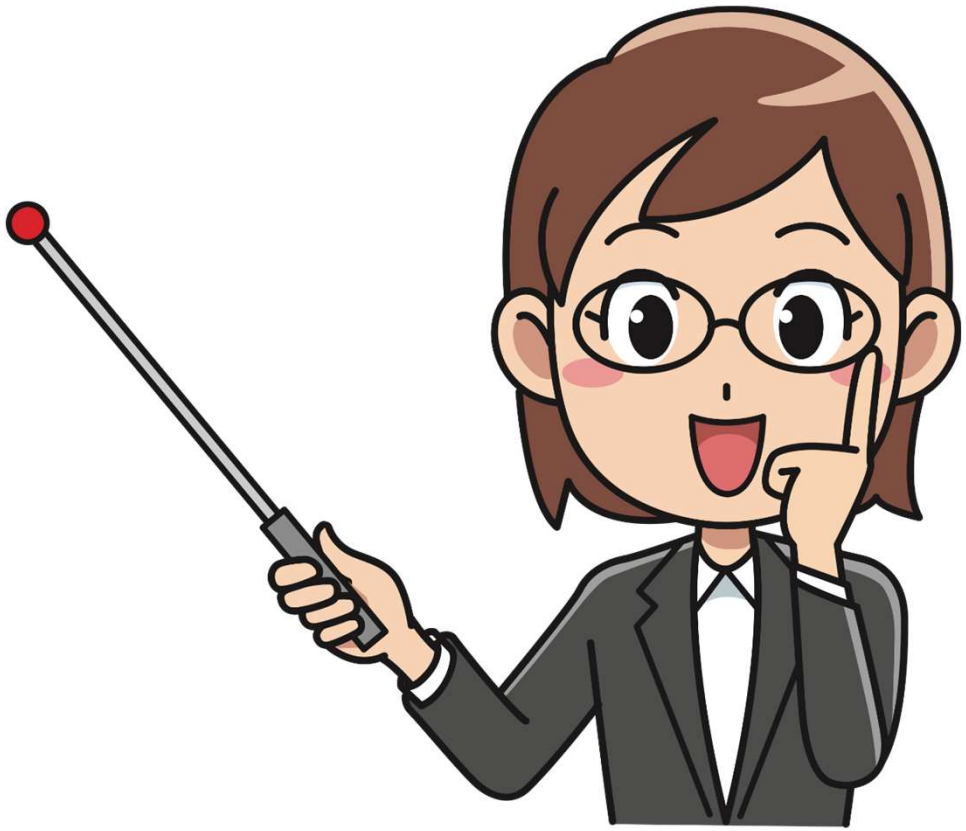
Enquiries

devicereforms@tga.gov.au

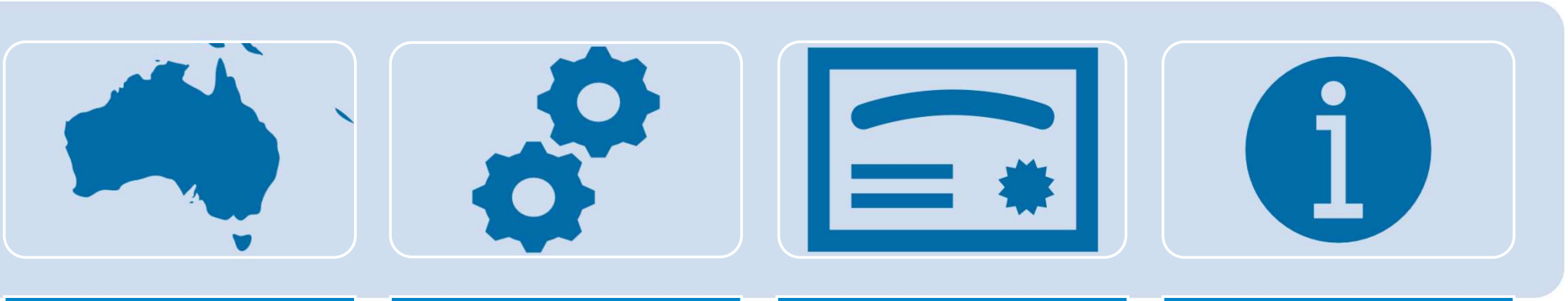


Today's presentation

- Background
  - How are exempt devices and exempt OTGs regulated?
  - The problem
- Public consultation
  - Proposals for change
  - Which exemptions are proposed to be impacted?
  - Which exemptions are not proposed to be impacted?
- We need your feedback
- Resources and contact information
- Questions



Regulation of medical devices and Other Therapeutic Goods (OTGs)



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

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

Sponsors of devices and OTGs 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

Regulation of exempt medical devices and exempt Other Therapeutic Goods (OTGs)

EXEMPT devices and OTGs are not required to be included in the ARTG

EXEMPT devices and OTGs must meet TGA regulatory requirements and comply with advertising requirements.

TGA maintains **regulatory powers** with respect to exempt products including post-market reviews, recalls and enforcing offence provisions

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

Slide **corrected** on 31 July 2024

Current state – Exempt devices and OTGs

Regulations	Exemption type	Must comply with TGA regulations?	Are sponsors notifying the TGA?	Are sponsors providing reports?	Is product information publicly available?	Must comply with post market obligations?
MD Regs Schedule 4, Part 1, 1.3B	Certain dental and orthopaedic medical devices manufactured by a healthcare professional. E.g. aligners and orthotics.	✓	✗	✗	✗	✓
MD Regs Schedule 4, Part 1, 1.7	Low-volume patient-matched medical devices	✓	✗	✗	✗	✓
MD Regs Schedule 4, Part 2, 2.12	Custom-made medical devices	✓	✓	✓	✗	✓
MD Regs Schedule 4, Part 2, 2.13	Custom-made medical devices manufactured outside Australia	✓	✓	✓	✗	✓
MD Regs Schedule 4, Part 2, 2.15	Certain Clinical Decision Support Software (CDSS)	✓	✓	✗	✗	✓
TG Regs Schedule 5, item 14	Tampons and menstrual cups	✓	✗	✗	✗	✓
TG Regs Schedule 7	Exempt disinfectants	✓	✗	✗	✗	✓

MD Regs refers to the *Therapeutic Goods (Medical Devices) Regulation 2002*
TG Regs refers to the *Therapeutic Goods Regulations 1990*

Non-exhaustive examples of applicable regulations and post market responsibilities

	Included Medical Devices (ARTG)	Exempt devices	Excluded Goods
Regulatory requirements	• EPs and CAPs (in some cases) in the Act and MD Regs • Therapeutic Goods Advertising Code		Not applicable as unregulated by the TGA, but may be subject to regulation by other entities, such as the Australian Competition & Consumer Commission (ACCC)
Post-Market obligations	• Adverse event reporting • Undertaking recall actions • Provision of information • Provision of samples	• Adverse event reporting • Undertaking recall actions	

	Listed OTGs (ARTG)	Exempt OTGs	Excluded Goods
Regulatory requirements	• TGO 104 • Therapeutic Goods Advertising Code • Poisons Standard		Not applicable as unregulated by the TGA, but may be subject to regulation by other entities, such as the Australian Competition & Consumer Commission (ACCC)
Post-Market obligations	• Adverse event reporting • Undertaking recall actions • Provision of information • Provision of samples	• Adverse event reporting • Undertaking recall actions	

Act refers to the *Therapeutic Goods Act 1989*
MD Regs refers to the *Therapeutic Goods (Medical Devices) Regulation 2002*
TG Regs refers to the *Therapeutic Goods Regulations 1990*
TGO104 refers to the *Therapeutic Goods (Standard for Disinfectants and Sanitary Products) (TGO 104) Order 2019*
Poisons Standard refers to the *Therapeutic Goods (Poisons Standard – February 2024) Instrument 2024*

Slide corrected on 31 July 2024

The Problem

1. **Lack of information about exempt devices and OTGs**
   - Sponsors are generally not notifying the TGA of manufacture/supply
   - Presents barriers to TGA post market activities (adverse events, recalls) and educational out-reach activities

2. **Low rates of sponsor awareness and compliance**
   - Exempt ≠ Excluded

3. **Lack of transparency and accountability**
   - Consumers unclear if product meets regulatory requirements
   - TGA does not currently have the authority to request:
     - product samples from sponsors for testing purposes
     - additional information regarding exempt devices and OTGs

The way forward – Proposals for change

1. Require notification of supply to the TGA
   - Platform to allow sponsors to view and update exempt device/OTG information

Sponsor Information
As per the Organisation details form on our website

Device/OTG Information
- Manufacturer name and address (physical)
- Relevant exemption (and conditions)
- Kind of device or OTG
- Product or brand names

Products NOT requiring notification
- Non-commercial export only products
- Use by non-Australians (e.g. cruise ships, international athletes etc.)
- Personal importation for personal use

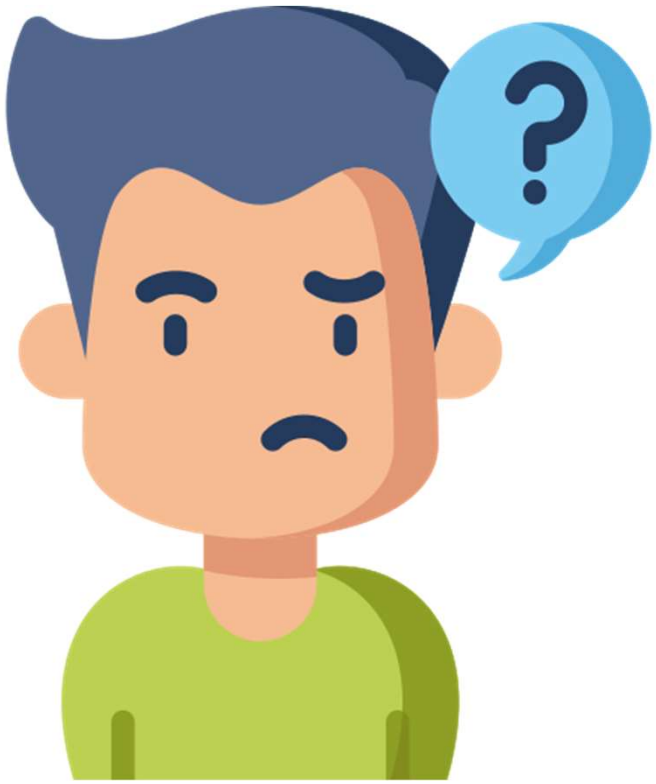
2. Publish information about supply

Published information
- Sponsor name and address (postal)
- For devices, manufacturer name and address (physical)
- Relevant exemption (and conditions)
- Product description or intended purpose
- Kind of device or OTG
- Product or brand names
- Date of notification of supply

Exemptions NOT subject to publication
- Special Access Scheme
- Authorised Prescriber Scheme
- Personal Importation Scheme

3. Provision of information and samples upon request to the TGA
   - Enable TGA post market activities to verify safety, quality and performance

Proposals 1 & 2 - Which exemptions would be affected?



We are proposing to collect and publish information about the supply of these exempt devices and OTGs and their sponsors:

- Custom-made medical devices (made in Australia and overseas)
- Patient-matched medical devices supplied in low volumes
- Exempt dental devices and orthopaedic devices manufactured by a health professional
- Exempt Clinical Decision Support Software (CDSS)
- Tampons and menstrual cups
- Exempt disinfectants

Proposed changes – Exempt devices and OTGs

Slide **amended** on 31 July 2024

Regulations	Exemption type	Must comply with TGA regulations?	Need to notify the TGA?	Is product information publicly available?	Must comply with post market obligations?
MD Regs Schedule 4, Part 1, 1.3B	Certain dental and orthopaedic medical devices manufactured by a healthcare professional. E.g. aligners and orthotics.	✓	✓	✓	✓
MD Regs Schedule 4, Part 1, 1.7	Low-volume patient-matched medical devices	✓	✓	✓	✓
MD Regs Schedule 4, Part 2, 2.12	Custom-made medical devices	✓	✓	✓	✓
MD Regs Schedule 4, Part 2, 2.13	Custom-made medical devices manufactured outside Australia	✓	✓	✓	✓
MD Regs Schedule 4, Part 2, 2.15	Certain Clinical Decision Support Software (CDSS)	✓	✓	✓	✓
TG Regs Schedule 5, item 14	Tampons and menstrual cups	✓	✓	✓	✓
TG Regs Schedule 7	Exempt disinfectants	✓	✓	✓	✓

MD Regs refers to the *Therapeutic Goods (Medical Devices) Regulation 2002*
TG Regs refers to the *Therapeutic Goods Regulations 1990*

Exempt devices that would **NOT** be affected by proposals 1 & 2?

We are not proposing any changes to these exempt devices:

Medical Device Regulations	Exemption type
Schedule 4 (Part 1, 1.1)	Personal importation scheme
Schedule 4 (Part 1, 1.1A)	Therapeutic vaping devices or accessories, therapeutic cannabis vaping devices or accessories, imported into Australia by a person (the first person) on board a ship or aircraft
Schedule 4 (Part 1, 1.2)	Export only devices
Schedule 4 (Part 1, 1.3)	Samples of devices for particular uses like demonstration, audit, assessment, etc
Schedule 4 (Part 1, 1.3A)	Oxygen administration hood for use in hyperbaric chamber for hyperbaric oxygen therapy
Schedule 4 (Part 1, 1.4)	Medical devices imported only to be exported again
Schedule 4 (Part 2, 2.1)	Special Access Scheme
Schedule 4 (Part 2, 2.2)	Importing devices for auditing purposes
Schedule 4 (Part 2, 2.3)	Clinical trial notification scheme for conducting clinical trials using “unapproved” goods
Schedule 4 (Part 2, 2.4)	Device imported into Australia by group member participating in national/international sporting event
Schedule 4 (Part 2, 2.5)	Device imported into Australia by group member of military forces of another country who are visiting Australia for military training
Schedule 4 (Part 2, 2.6)	Device imported into Australia by a medical practitioner or a member of a medical team (being 1 or more persons under the professional supervision of a medical practitioner)
Schedule 4 (Part 2, 2.7)	Device imported into Australia by visiting group member on official business of Head of State or Head of Government of a foreign country and senior Government officials of that country

Exempt devices that would **NOT** be affected by proposals 1 & 2?

We are not proposing any changes to these exempt devices:

Medical Device Regulations	Exemption type
Schedule 4 (Part 2, 2.8)	Medical device that is part of the medical supplies of a ship (including a yacht or other marine vessel) or aircraft visiting Australia
Schedule 4 (Part 2, 2.9)	System or procedure packs for the national stockpile (for devices imported, supplied or manufactured on or before 31 December 2010)
Schedule 4 (Part, 2.10)	Medical device that is a Class 1, Class 2 or Class 3 in-house IVD medical device
Schedule 4 (Part 2, 2.10A)	Medical device that is a Class 4 in-house IVD medical device and that is intended by its manufacturer to be used to detect the presence of, or exposure to, transmissible agents in blood, stool or other specimens from a person's body in order to assess the suitability of the person to be a donor of human stool for use in the manufacture of a faecal microbiota transplant product
Schedule 4 (Part 2, 2.11)	Unused emergency medical devices directed to be exported by the Secretary
Schedule 4 (Part 2, 2.14)	Transitioning patient-matched medical devices
Schedule 4 (Part 2, 2.16)	Surgical loan kits
Schedule 4 (Part 2, 2.17)	Therapeutic vaping device or accessories
Schedule 4 (Part 2, 2.18)	Medical device imported into Australia which is a component or article imported for use in the manufacture of a therapeutic vaping device or accessory

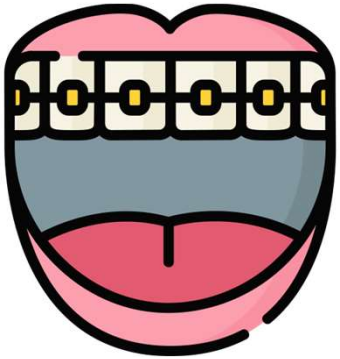
Exempt dental and orthopaedic devices manufactured by health professionals

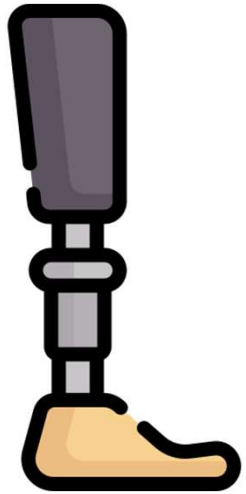
These devices are exempt from ARTG inclusion where they are:

- non-implantable dental devices, or externally applied orthopaedic devices
- manufactured in Australia by a health professional, or a trained person working to instructions received from a health professional, and
- made from starting materials and components included in the ARTG.

Currently health professionals are not required to notify the TGA when they supply devices under this exemption.

Proposed changes: TGA is proposing to introduce requirements for sponsors to provide notification of supply and to publish information about the manufacturer, sponsor and products being supplied.





Patient-matched medical devices supplied in low volumes

Patient-matched medical devices are exempt from ARTG inclusion where they are supplied in low volumes.

- Sponsors who supply **5 or less** of a kind of patient-matched medical device **per financial year** do NOT need to include these devices in the ARTG.

Currently sponsors are not required to notify the TGA when they supply devices under this exemption.

Proposed changes: TGA is proposing to introduce requirements for sponsors to provide notification of supply and to publish information about the manufacturer, sponsor and products being supplied.

Custom-made medical devices manufactured in Australia or overseas

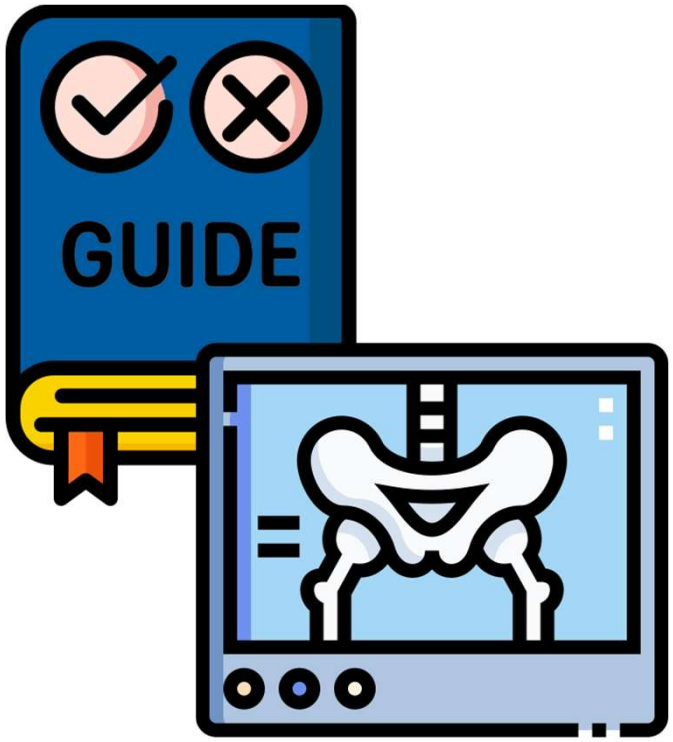
All custom-made medical devices are exempt from ARTG inclusion.

Currently sponsors are required to:

- notify the TGA within two months of supply
- provide annual reports of supply numbers

Proposed changes: TGA is proposing to introduce requirements to publish information about the manufacturer, sponsor and products being supplied under this exemption.

Exempt Clinical Decision Support System (CDSS) software



CDSS are only exempt if they are:

1) intended to be for the sole purpose of providing or supporting a recommendation to a health professional about preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons; and

2) not intended by its manufacturer to directly process or analyse a medical image or signal from another medical device; and

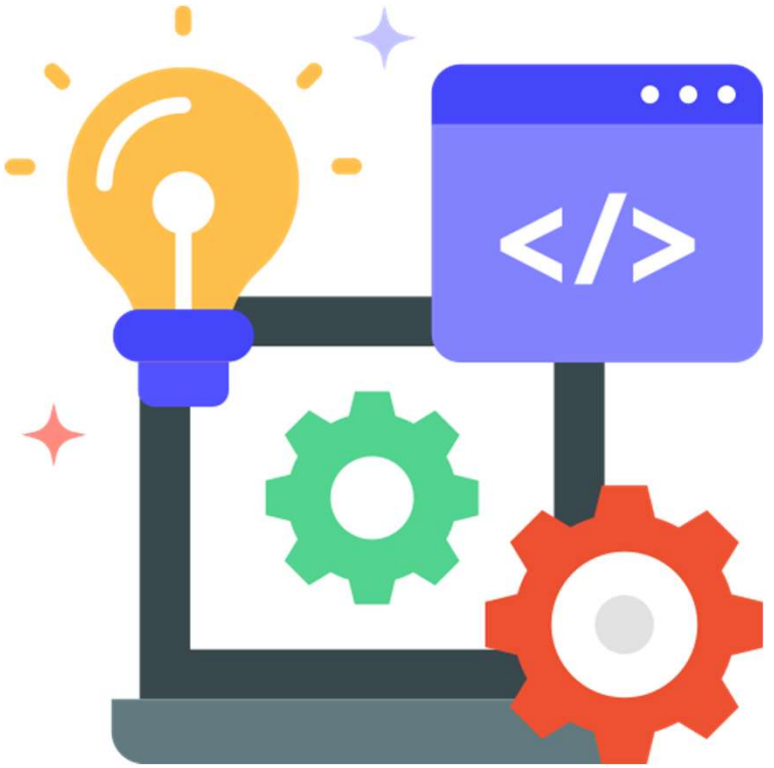
3) not intended by its manufacturer to replace the clinical judgement of a health professional in relation to making a clinical diagnosis or decision about the treatment of patients

Exempt Clinical Decision Support Software (CDSS)

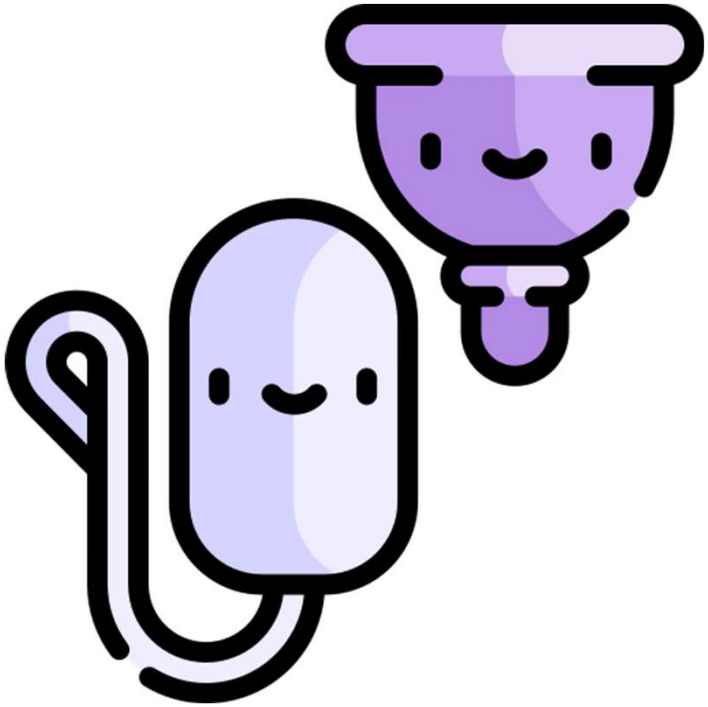
Exempt CDSS is not required to be included in the ARTG and does not need pre-market approval from the TGA.

Currently, sponsors must notify the TGA of supply of exempt CDSS devices.

Proposed changes: Information in notifications submitted for exempt CDSS are proposed to be published.



Tampons and menstrual cups



- All tampons and menstrual cups are exempt from ARTG inclusion
- Tampons and menstrual cups must comply with Therapeutic Goods Orders TGO 103 and TGO 99, respectively
- Currently sponsors are not required to notify the TGA when they supply these products.

Proposed changes: TGA is proposing to introduce requirements for sponsors to provide notification of supply and to publish information about the sponsor and products being supplied.

Exempt Disinfectants

- Hospital grade and household or commercial grade disinfectants that do NOT make **specific claims** are exempt if they are:
  - Not intended for use internally or on skin
  - Not intended for use on a medical device
  - Intended for use on inanimate objects such as hard and soft surfaces (for example curtains, floors, bench tops, lounge furniture and carpets)
- Currently sponsors are not required to notify the TGA when they supply exempt disinfectants.

Proposed changes: TGA is proposing to introduce requirements for sponsors to provide notification of supply and to publish information about the sponsor and products being supplied.

Claims of virucidal, sporicidal, tuberculocidal, fungicidal or other biocidal activity are known as ***specific claims***

Proposal 1 - We want your feedback

We want your feedback on:

Providing notifications to the TGA

1. Do you broadly agree that notifications to the TGA should be required for exempt devices and OTGs?
2. Why or why not?
3. Which existing exemptions should require a notification to be sent to the TGA?
4. Do you broadly agree with the information we're proposing to collect about the sponsor of an exempt device/OTG?
5. Why or why not?
6. Do you agree with the information we're proposing to collect about exempt devices/OTGs?
7. Why or why not?
8. Do you currently manufacture or supply any exempt devices/OTGs?
9. What kinds of exempt device/OTGs do you currently supply?

Proposal 2 - We want your feedback

We want your feedback on:

Publishing information from notifications

1. Do you broadly agree that information about exempt devices/OTGs that are required to notify the TGA of supply should be made publicly available?
2. Why / why not?
3. For which exemptions should information be made publicly available?
4. What information about exempt devices/OTGs should be publicly available?
5. Are there any exemptions for a device or an OTG where information should not be made publicly available?
6. Why / why not?

Proposal 3 - Which exemptions would be affected?

We are proposing to introduce requirements for sponsors of these exempt devices and OTGs to provide information and a reasonable number of samples to the TGA upon request:

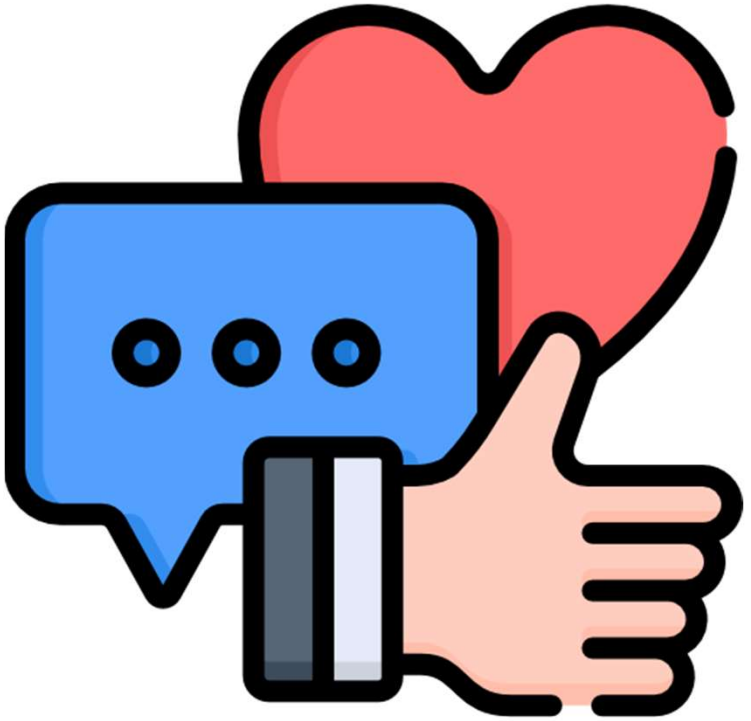
- all medical devices that are exempt under Schedule 4 to the Therapeutic Goods (Medical Devices) Regulations 2002
- all OTGs that are exempt under Schedule 5 or Schedule 5A to the Therapeutic Goods Regulations 1990

Proposal 3 - We want your feedback

We want your feedback on:

Providing information and samples to the TGA upon request

1. Do you broadly agree that sponsors of medical devices exempt under Schedule 4 of the *Therapeutic Goods (Medical Devices) Regulations 2002* and all OTGs exempt under Schedule 5 or Schedule 5A of the *Therapeutic Goods Regulations 1990* should be required to provide a reasonable number of samples to the TGA upon request?
2. Why / Why not?
3. Do you broadly agree that sponsors of medical devices exempt under Schedule 4 of the *Therapeutic Goods (Medical Devices) Regulations 2002* and all OTGs exempt under Schedule 5 or Schedule 5A of the *Therapeutic Goods Regulations 1990* should be required to provide information about their products to the TGA upon request?
4. Why / Why not?



Have your say – public consultation details

Public Consultation paper survey link

- https://consultations.tga.gov.au/tga/proposed-changes-to-exempt-devices-and-otgs/

Consultation closes 9 June 2024

Enquiries for the project team

devicereforms@health.gov.au

Website and link references

Personalised medical devices (including 3D-printed devices)	https://www.tga.gov.au/resources/resource/guidance/personalised-medical-devices-including-3d-printed-devices
Refinements to the Personalised medical Device framework	https://www.tga.gov.au/resources/resource/guidance/refinements-personalised-medical-device-framework
Exemption for certain clinical decision support software - Guidance on the Exemption Criteria	https://www.tga.gov.au/resources/resource/guidance/exemption-certain-clinical-decision-support-software
Guidance on the regulation of exempt disinfectants in Australia	https://www.tga.gov.au/resources/resource/guidance/guidance-regulation-exempt-disinfectants-australia
Disinfectant Claim Guide: specific claims and non-specific claims	https://www.tga.gov.au/resources/resource/guidance/disinfectant-claim-guide-specific-claims-and-non-specific-claims
Tampons and menstrual cups	https://www.tga.gov.au/how-we-regulate/supply-therapeutic-good/supply-other-therapeutic-goods/tampons-and-menstrual-cups

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Anonymous or Open responses welcome

Contact us

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devicereforms@health.gov.au

Questions?

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Q&A Panellists

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