Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Consultation: Proposed changes to the regulation of exempt medical devices and exempt Other Therapeutic Goods

Version 1.0, April 2024

Confidentiality
All submissions received will be placed on the TGA's Internet site, unless marked confidential. Any confidential material contained within your submission should be provided under a separate cover and clearly marked "IN CONFIDENCE". Reasons for a claim to confidentiality must be included in the space provided on the TGA submission form. For submission made by individuals, all personal details, other than your name, will be removed from your submission before it is published on the TGA's Internet site. In addition, a list of parties making submissions will be published. If you do not wish to be identified with your submission you must specifically request this in the space provided on the submission form.

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Introduction

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

This consultation seeks feedback on potential changes to the regulation of medical devices exempt under Schedule 4 of the *Therapeutic Goods (Medical Devices) Regulations 2002* and all "other therapeutic goods" (OTGs) exempt under Schedule 5 or Schedule 5A of the *Therapeutic Goods Regulations 1990* to:

- Address emerging issues associated with these kinds of exemptions; and
- Ensure regulation of these kinds of products remains fit-for-purpose.

Background

The TGA is Australia's government authority responsible for evaluating, assessing and monitoring products that are defined as therapeutic goods. The TGA regulates therapeutic goods including medicines, medical devices and biologicals to help Australians stay healthy and safe.

Products that meet the legislative definition of a therapeutic good under the *Therapeutic Goods Act 1989* (the Act) are regulated by the TGA and generally need to seek pre-market approval and be included in the Australian Register of Therapeutic Goods (ARTG) before they can be imported, exported or supplied. If the therapeutic good is a medical device, an application for inclusion in the ARTG must be supported by manufacturer's evidence. Manufacturer's evidence consists of documents, including certification from independent bodies, demonstrating that the medical device is safe and fit for its intended purpose.

Exempt medical devices and exempt OTGs

In some circumstances it is not practical to require pre-market approval by the TGA and/or ARTG inclusion for a therapeutic good or there are existing risk mitigating strategies in place. Exemption allows these kinds of products to be continually supplied without seeking pre-market approval by the TGA or inclusion in the ARTG. In the case of devices and OTGs, circumstances where an exemption may be given include:

- Where there are already suitable frameworks for the regulation of a product in place to manage risks associated with the manufacture of a product, such as where a device is manufactured as a component of clinical practice.
- Where a device is not freely available on the market, such as for use in a clinical trial or for use by a visiting sporting team.
- Where a device is subject to a transition period due to the introduction of new regulatory requirements, such as patient-matched medical devices that were previously custom-made and are now transitioning to inclusion in the ARTG.

While exempt products are not required to be included in the ARTG, they are not excluded from regulation and must generally still meet all regulatory obligations under the *Therapeutic Goods Act 1989*, including:

- Ensuring the device(s) meets all relevant Essential Principles, including supplying the devices with adequate labelling and Instructions For Use.

- Applying appropriate conformity assessment procedures to the device at all times.
- Ensuring advertising complies with the advertising requirements.
- Reporting adverse events where required (noting there are some circumstances where reporting an adverse event is not required).

The TGA maintains a number of relevant regulatory powers with respect to exempt products including the capacity to:

- Undertake post-market review to ensure they meet all relevant regulatory requirements.
- Require exempt devices and OTGs to comply with the Advertising Code.
- Conduct a recall activity in relation to the products, including issuing a hazard alert if there is a problem with the product.

Exemptions can only be granted in circumstances where certain conditions are met. Examples include:

- Where a notification of manufacture/supply has been provided to the TGA (eg: custom-made medical devices).
- Where devices are supplied in low volumes (eg: patient-matched medical devices).
- Where a device is only for use on an individual or an immediate family member (eg: personal importation).
- Clinical decision support software that meet specific criteria.

The problem

Recent work undertaken to refine the regulation of medical devices in Australia has led to an increase in the use of exemptions to remove barriers to supply where appropriate. These changes have highlighted regulatory issues and risks associated with the use of exemptions. Feedback from external stakeholders indicates in many cases the current arrangements for exempt medical devices and OTGs are not fit-for-purpose, and a review is required to ensure appropriate regulation for these kinds of products.

Issues with the current use of exemptions for medical devices and OTGs include:

- **Lack of information** about exempt products. Where sponsors are not required to notify the TGA about the manufacture and/or supply of these kinds of products, an inability to determine the supplier of exempt products is a barrier to post-market activities, delaying responses to adverse events and recall activities. These delays represent a risk to consumer/patient health and safety.
- **Expenditure** on regulating exempt devices and exempt OTGs is continuing to rise as the number of exemptions increases. Without cost-recovery measures for the regulation of a widening scope of sponsors and products, pressure on available resources for post-market and reform work will continue to rise.
- In a number of instances, the sponsors of exempt products have assumed "exempt" means "excluded" from all regulation by the TGA. Consequently, there are **low rates of awareness and compliance** with regulatory requirements associated with some exempt products. Lack of available information identifying these sponsors further limits TGA's ability to contact them for the purposes of education and communication.

- Identification of exempt devices and OTGs that are complying with current regulatory requirements is difficult for stakeholders including members of the public and other government providers who use TGA approval as a basis for reimbursement. Healthcare providers, members of industry and consumers have all expressed a **desire for increased transparency and accountability** of exempt products.
- Recent changes to the medical device regulatory framework mean supply of medical devices from smaller manufacturers, particularly in healthcare sectors, is likely to become constrained in the coming years as the cost of including devices in the ARTG becomes prohibitive. The **use of exemptions to provide a pathway for the manufacture and supply of devices in these sectors is therefore likely to increase**, compounding the existing issues.

Proposals

Based on feedback and information from stakeholders, we have identified three key proposals for change:

1. Require notification of supply
2. Publish information about supply
3. Provision of information and samples

Introducing mechanisms and infrastructure to allow the collection and publication of information relating to exempt medical devices / OTGs are proposed to streamline existing regulation and future-proof the framework for the regulation of these kinds of products.

In addition to introducing mechanisms and infrastructure under these proposals to support the future use of exemptions, we are also proposing to apply these options to existing exemptions in some instances. A summary of exemptions impacted by the proposals is included for your convenience at Appendix A – Proposed changes to exemptions for medical devices and OTGs.

Proposal 1. Require notification of supply to the TGA

Currently notification of manufacture and/or supply is only required for a small number of exempt medical devices/OTGs. The method used to collect this information, and the kind of information collected, also varies.

We are proposing to:

- Introduce consistent collection of notification data through a uniform platform that will allow sponsors to view and update information about their exempt products.
- Require notification of supply to the TGA for exempt medical devices/OTGs that can be sold to, or used on, members of the Australian public.

What information would be required in the notification?

We are proposing to require information about both the sponsor and their exempt devices/OTGs. This information would include:

- Sponsor information: the same details are currently collected using the Organisation details form on our website
  - Sponsor name
  - Contact name

  - Business address (physical)
  - Postal address
- Exempt device/OTG information:
  - Manufacturer's name
  - Manufacturer's address (physical)
  - Relevant exemption (and conditions)
  - Kind of device/OTG
  - Product/brand name(s)

Products that will not require notification

We are not proposing to change the notification requirements for exempt goods where they are:

- not intended for supply on the Australian market; and/or
- only intended to be supplied to, or used by, a person who is aware that the device has not been subject to TGA pre-market assessment/audit.

Products that would not require a notification of supply to the TGA include:

- Devices that are intended for non-commercial export only (i.e. export for charitable purposes).
- Exemptions intended to allow non-Australians to use unapproved medical devices (such as visiting international athletes or international military forces, and visiting cruise ships).
- Personal importation for personal use.

A summary of exemptions that will not be impacted by the proposals is included for your convenience at Appendix B – Exemptions for medical devices and OTGs with no proposed changes

Proposal 1 – Questions

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. Publish information about supply

Currently, information about exempt devices and exempt OTGs that have provided notification to the TGA is not made publicly available. Stakeholders including consumers and healthcare providers have expressed a desire for increased transparency and accountability for exempt devices and exempt OTGs through the publication of information, including the capability to identify the sponsor of a product and the specific exemption a device is supplied under. Healthcare providers have indicated they need this information to treat patients and ensure that they are using legally supplied medical devices and OTGs that can confirm their safety and performance.

Sponsors of exempt goods have also expressed a desire for this information to be made public:

- to demonstrate to consumers and healthcare providers that they are aware of, and compliant with, their regulatory obligations;
- to preserve information on the public record even after a business or clinic winds up or closes; and
- to assist with self-regulation by providing stakeholders with the ability to identify and report non-compliant sponsors.

We are proposing to introduce regulatory changes that will allow the publication of certain information about specific exempt medical devices/ OTGs where they are required to notify the TGA of supply. These changes would apply to any devices or OTGs required to submit a notification under the changes outlined in Option 1.

A summary of exemptions impacted by the proposals is included for your convenience at Appendix A – Proposed changes to exemptions for medical devices and OTGs.

What information would be published?

We are proposing to publish similar information to the information currently available in a public summary for a medical device included in the ARTG, and information that would allow stakeholders to identify the exemption a product is supplied under.

This includes:

- Sponsor name
- Sponsor's address (postal)
- Manufacturer name
- Manufacturer's address (physical)
- Relevant exemption (and conditions)
- Product description/intended purpose
- Product/brand name
- Date of notification of supply

Products that will not be subject to publication

The proposed changes will generally only apply to exempt goods that are required to make a notification (as proposed in Proposal 1). We are not proposing to publish information about exempt goods that are not required to submit a notification to the TGA or to publish information where an individual's private information could be made available.

Exemptions that **will not be subject to publication** include:

- Special Access Scheme
- Authorised Prescriber Scheme
- Personal Importation Scheme.

A summary of exemptions that will not be impacted by this proposal is included for your convenience at Appendix B – Exemptions for medical devices and OTGs with no proposed changes

Proposal 2 – Questions

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. Provision of information and samples to the TGA upon request

Under the current framework, sponsors of medical devices that require inclusion in the ARTG have automatic conditions that are applicable to their ARTG entry. Automatic conditions include the requirement for sponsors to provide information and samples of the medical device to the TGA upon request. At the moment, the TGA:

- Can only request particular information, or information under particular circumstances, for exempt devices and OTGs; and
- For most exempt devices and OTGs, the TGA does not currently have the authority to require sponsors to provide samples to the TGA upon request.

These arrangements are challenging as:

- sponsors are unclear what information the TGA is able to request and under what circumstances; and

- the TGA is currently unable to obtain samples from sponsors when required to conduct post market activities (including testing) in relation to the safety, quality and performance of these exempt medical devices.

We are proposing 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* be required to provide information and a reasonable number of samples to the TGA upon request.

Proposal 3 – Questions

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?

Consultation – What we invite you to do

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

How to respond

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

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

You can:

- submit your views by clicking the link below – this will step you through our questions https://consultations.tga.gov.au/tga/proposed-changes-to-exempt-devices-and-otgs

OR

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

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

Privacy and your personal information

We collect your personal information in this submission in order to:

- Contact you if we need to seek clarification of issues raised in your submission or to check whether you consent to certain information that you have provided being made publicly available; and
- Help provide context about your submission (e.g., to determine whether you are an individual or a director of a company or representing an interest group).

We may disclose your name, work title, company, and submission on the Internet (i.e. make this information publicly available) with your consent. You may specify whether there is anything in your submission which you would prefer to not be published online (e.g. names, email addresses, proprietary information) by:

- Providing an additional, redacted copy of your submission; or
- Providing details of content not to be published e.g. “Do not publish pages 3-5”, “Please redact contact details”; or
- Identifying any text within your submission to remain confidential by having it clearly marked 'IN CONFIDENCE' and highlighted in grey.

Please do not include personal information about other individuals in the body of your submission. Personal information in this context means information or an opinion about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion. The TGA will not publish personal information about you/others without your/their consent unless authorised or required by law.

Response timeframe

- This paper opened on **15 April 2024**.
- Interested parties should respond by midnight on **9 June 2024**. Please note that late submissions after this date may not be considered.
- Following consideration of submissions, summaries of this discussion will be published to the Consultation Hub web page.

ENQUIRIES

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

What happens next?

This consultation is seeking your feedback on the introduction of new measures to collect and publish information about exempt devices/OTGs. Further, targeted consultation may be undertaken with specific cohorts to assess the specific impact of any changes that are made as a result of this consultation.

Appendix A – Proposed changes for exempt medical devices/OTGs

Exemption	Comments
Medical Device Regulations (Schedule 4, Part 1, 1.3B) Certain dental and orthopaedic medical devices manufactured by a healthcare professional. Examples include personalised non-implantable dental devices and non-implantable orthopaedic devices such as aligners and orthotics, respectively.	Currently healthcare professionals are not required to notify the TGA when they supply devices under this exemption. ***We are proposing to commence collection and publication of information about the sponsors of these exempt devices and the devices they are supplying.***
Medical Device Regulations (Schedule 4, Part 1, 1.7) Low-volume patient-matched medical devices	Currently manufacturers and suppliers of low volume patient-matched devices are not required to notify the TGA of supply or provide an annual report. ***We are proposing to commence collection and publication of information about the sponsors of these exempt devices and the devices they are manufacturing.***
Medical Device Regulations (Schedule 4, Part 2, 2.12) Custom-made medical devices	Notification is currently required, but this information is not made publicly available. ***We are proposing to publish information about the sponsors of custom-made medical devices and the kind of devices they are supplying.***
Medical Device Regulations (Schedule 4, Part 2, 2.13) Custom-made medical devices manufactured outside Australia	Notification is currently required, but not made publicly available. ***We are proposing to publish information about the sponsors of custom-made medical devices and the kind of devices they are supplying.***

Exemption	Comments
Medical Device Regulations (Schedule 4, Part 2, 2.14) Transitioning patient-matched medical devices	While there may be a public interest in publishing this information, it is not likely to be a feasible undertaking within the time frames associated with this consultation. ***We are not proposing to publish information about patient-matched medical devices that are transitioning to ARTG inclusion.***
Medical Device Regulations (Schedule 4, Part 2, 2.15) Clinical decision support software	Information about these devices is already collected by TGA. ***We are proposing to publish information about the sponsors of custom-made medical devices and the kind of devices they are supplying.***
Regulations (Schedule 5, item 14) Tampons	Currently sponsors are not required to notify the TGA when they supply exempt OTGs. ***We are proposing to commence collection and publication of information about the sponsors of these exempt OTGs and the specific products they are supplying.***
Regulations (Schedule 5, item 14) Menstrual cups	
Regulations (Schedule 7) Exempt disinfectants	

Further, we are proposing that sponsors of all medical devices that are exempt under Schedule 4 to the *Therapeutic Goods (Medical Devices) Regulations 2002* and all OTGs that are exempt under Schedule 5 or Schedule 5A to the *Therapeutic Goods Regulations 1990* should be required to provide a reasonable number of samples of the medical device or OTG to the TGA upon request.

Appendix B – Exempt medical devices/OTGs with no proposed changes

Exemption	Comments
Schedule 4 (Part 1, 1.1) Personal importation scheme	This exemption is designed to allow consumers to import unapproved medical devices for personal use or for use by a direct family member. Information is not currently collected about devices imported under this scheme.
Schedule 4 (Part 1, 1.2) Devices exported for non-commercial reasons – such as devices exported for personal use or charitable purposes	Designed to allow devices to be exported for non-commercial purposes including for charitable purposes and for personal use of devices overseas.
Schedule 4 (Part 1, 1.3) Samples of devices for particular uses like demonstration, audit, assessment, etc	Allows devices to be imported to meet TGA requirements for audit, etc
Schedule 4 (Part 1, 1.3A) Oxygen administration hood for use in a hyperbaric chamber for hyperbaric oxygen therapy	This was a limited exemption to address a supply issue and is not broadly applicable (there is one supplier affected).
Schedule 4 (Part 1, 1.4) Medical devices imported only to be exported again	
Schedule 4 (Part 1, 1.5) Vaping device	Exemption managed by Prescription Medicines Authorisation

Exemption	Comments
Schedule 4 (Part 1, 1.6) Vaping systems or procedure packs	Exemption managed by Prescription Medicines Authorisation, and Poisons Schedule controls are also in operation
Schedule 4 (Part 2, 2.1) Special Access Scheme	Information is currently collected by TGA through a web-based portal but is not made publicly available. ***We are not proposing to publish the information collected.***
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	The TGA charges fees and collects information on clinical trial notifications through TBS. The general public and volunteers can view clinical trial details recorded in public registries. Clinical trials in Australia are required to be included in a public online registry such as ClinicalTrials.gov or Australian Clinical Trials.
Schedule 4 (Part 2, 2.4) Medical device that is imported into Australia by a member of a group of persons who are visiting Australia to participate in a national or international sporting event	

Exemption	Comments
Schedule 4 (Part 2, 2.5) Medical device that is imported into Australia by a member of a group of persons, being members of the military forces of another country who are visiting Australia for military training	
Schedule 4 (Part 2, 2.6) Medical device that is 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) Medical device that is imported into Australia by a member of a group of persons, being a group that includes a person who is the Head of State or Head of Government of a foreign country and senior Government officials of that country, who are visiting Australia on official business	
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)	

Exemption	Comments
System or procedure packs for the national stockpile (for devices imported, supplied or manufactured on or before 31 December 2010)	
Medical Device Regulations (Schedule 4, Part, 2.10) Medical device that is a Class 1, Class 2 or Class 3 in-house IVD medical device	Notification to TGA of in-house IVDs is currently required under the conformity assessment procedures for these devices, and laboratories must pay a scheduled notification fee. ***Publication of information about in-house IVDs is not proposed, as these devices are not available to the public or health providers to purchase.***
Medical Device Regulations (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	This is a temporary exemption of up to four years, to allow laboratories to work with the TGA to establish processes that allow adequate data to be generated which supports their performance as Class 4 in-house IVDs, and subsequently, inclusion in the ARTG. Notification to TGA of Class 4 in-house IVDs used in FMT donor screening is currently required under the conformity assessment procedures for these devices. ***Publication of information about in-house IVDs is not proposed as these devices are not available to the public or health providers to purchase.***
Schedule 4 (Part 2, 2.11)	

Exemption	Comments
Unused emergency medical devices directed to be exported by the Secretary	
Schedule 4 (Part 2, 2.11A) Vaping products	
Schedule 4 (Part 2, 2.16) Surgical loan kits	Medical devices in a surgical loan kit are in the ARTG.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Devices Emerging Technology	March 2024

Therapeutic Goods Administration

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