Australian Government
Department of Health
Therapeutic Goods Administration

# Advice for health procurement teams about therapeutic goods and medical devices

Version 1.0, January 2021

TGA Health Safety Regulation

# Contents

# About this guidance

This guidance is for procurement areas in hospitals, aged care residential facilities and other facilities that procure therapeutic goods. It provides information regarding:

- what is and is not a medical device
- what is an 'exempt' therapeutic good and what is an 'excluded' good
- the Australian Register of Therapeutic Goods (ARTG)
- reporting problems with therapeutic goods.

Only therapeutic goods are required to be entered in the ARTG. Products that are not therapeutic goods **should not** be in the ARTG.

'Exempt' therapeutic goods are **not required** to be entered in the ARTG, but they are subject to other regulatory requirements under the *Therapeutic Goods Act 1989* (the Act) and related legislation (such as compliance with labelling orders, advertising requirements and relevant standards).

'Excluded' goods are goods that have been specifically declared not to be therapeutic goods and therefore should not be entered in the ARTG. 'Excluded' goods are not subject to therapeutic goods regulatory requirements under the Act or related legislation. 'Excluded' goods should not make therapeutic claims. The TGA publishes a number of excluded goods orders, determinations and specifications on its website.

The purpose of this guidance is to assist health procurement areas understand what is and is not a therapeutic good or medical device. This will help to:

- reduce the need for health procurement areas to contact the sponsor, supplier or the TGA to determine if a product involved in a procurement process is a therapeutic good or an 'exempt' therapeutic good or 'excluded' good
- streamline and simplify tender processes
- prevent non-therapeutic goods being included in the ARTG.

# Therapeutic goods regulation

The TGA is responsible for ensuring that therapeutic goods authorised for supply in Australia are safe and fit for their intended purpose. These goods include medicines and medical devices that are relied on every day, such as vitamin tablets, sunscreens and adhesive bandages, as well as those used to treat serious conditions, such as prescription medicines, vaccines, blood products and surgical implants.

## Medical device regulation

The regulation of medical devices includes:

- classifying medical devices based on the level of risk to the user
- assessing compliance with a set of internationally agreed essential principles for their quality, safety and performance
- implementing appropriate regulatory controls for manufacturing medical devices
- including the medical devices in the Australian Register of Therapeutic Goods (ARTG) where appropriate.

Once available for supply, medical devices are subject to post market monitoring by the TGA. This monitoring includes a comprehensive adverse event reporting program.

## The Australian Register of Therapeutic Goods (ARTG)

The ARTG is the reference database of the TGA. It provides information on the majority of therapeutic goods that are supplied in Australia.

In most circumstances, therapeutic goods must be in the ARTG before they can be imported into, manufactured, supplied in, or exported from Australia. When a therapeutic good is included in the ARTG it will be given an ARTG number. This number is unique to that good and is used to identify the good.

'Exempt' therapeutic goods are not required to be in the ARTG and will not have an ARTG number.

In addition, products that are **not** therapeutic goods, including 'excluded' goods, should not be in the ARTG and will not have an ARTG number.

You can search the ARTG for current ARTG entries and download Public Summary documents for each therapeutic good, which include information about the:

- sponsor (supplying company) and manufacturer details
- product type
- functional description
- intended purpose.

## Definition of medical device

Medical devices are broadly defined as products intended by their manufacturer for use in humans in connection with:

- preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury
- influencing inhibiting or modifying a physiological process
- testing the susceptibility of persons to a disease or ailment
- influencing, controlling or preventing conception
- testing for pregnancy.

The TGA has developed the online tool 'Is my product a medical device?' to help identify whether a product is a medical device, other type of therapeutic good or 'excluded' good.

## What is not a medical device

The fact that a product will be used in a hospital, aged care or other facility does not make it a therapeutic good or a medical device.

Some examples of products commonly used in hospitals or aged care facilities that are **not** medical devices include:

- furniture
  - items such as visitor chairs, bedside cabinets and instrument trolleys do not meet the definition of a medical device
- linen
  - items such as bed pillows, sheets, and divider curtains do not meet the definition of a medical device
- laboratory equipment
  - unless intended for use by the manufacturer directly for patient treatment as described in the above definition of a medical device, laboratory equipment is not generally defined as a therapeutic good or medical device.

Items that are not therapeutic goods will not have an ARTG number and should not be included in the ARTG.

## Exempt therapeutic goods

'Exempt' therapeutic goods are therapeutic goods that are exempt from being in the ARTG under the *Therapeutic Goods Regulations 1990* (the Regulations) or the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations). This means they will **not** have an ARTG number.

'Exempt' therapeutic goods must still comply with post market obligations set out in the *Therapeutic Goods Act 1989* (the Act), the Regulations and the MD Regulations. This includes complying with the therapeutic goods advertising requirements, reporting adverse events and conducting recalls according to the Regulations and the Uniform Recall Procedure for Therapeutic Goods (URPTG).

For further information on 'exempt' therapeutic goods, refer to:

- Schedules 5 and 5A of the *Therapeutic Goods Regulations 1990*
- Schedule 4 of the *Therapeutic Goods (Medical Devices) Regulations 2002*
- Guidance on regulation of sterilants and disinfectants in Australia

Unapproved medical devices may be supplied in limited circumstances, such as through the Special Access Scheme or Authorised Prescriber arrangements.

## Excluded goods

'Excluded' goods are products that have been specifically declared not to be therapeutic goods by an Order of the Secretary of the Australian Government Department of Health and are therefore not subject to any requirements of the Act.

These products will **not** have an ARTG number and should **not** be required to have one.

As 'excluded' goods are not regulated by the TGA, the TGA cannot take action on reports of adverse events or issue recalls for these products.

For more information, refer to:

- Therapeutic Goods (Excluded Goods) Determination 2018
- Therapeutic Goods (Declared Goods) Order 2019
- Excluded goods orders, determinations and specifications

**COVID-19 related exclusions**

Due to the COVID-19 emergency, a number of temporary exclusions have also been put in place. These include exclusions for COVID-19 tests, hand sanitisers, personal protective equipment for supply to the national stockpile, and ventilators.

Information about the TGA's response to the COVID-19 emergency is on the TGA website at Coronavirus (COVID-19): Information on medicines and medical devices.

# Recommendations when procuring medical devices

When procuring medical devices in Australia, we recommended you confirm with the sponsor of the goods that the product is either included in the ARTG, or is an 'exempt' medical device or an 'excluded' product and therefore does not have an ARTG number.

You can search the ARTG for all therapeutic goods currently included in the register. This information includes the sponsor and manufacturer details, formulation details (if relevant), and intended use of the goods. Information that is not included on the publicly available ARTG summary may be commercial-in-confidence and, for this reason, the TGA does not release information relating to products in the ARTG without consulting the relevant parties it belongs to first.

The only ***regulatory*** requirements that procurement departments should request from medical devices sponsors are:

- the ARTG number

OR

- confirmation (including relevant evidence where appropriate) that the product is an 'exempt' medical device or an 'excluded' good (and therefore not a therapeutic good).

If you would like more information about a product, you can contact the sponsor who is identified in the ARTG certificate, or the supplier of the good if this differs from the sponsor, or apply to have the information released under Freedom of Information.

## Exempt devices and excluded goods do not need ARTG numbers

'Exempt' medical devices and 'excluded' goods will **not** have ARTG numbers, as these products are not required to be included in the ARTG. These goods **do not** need to have an ARTG number before they can be procured by an organisation.

In addition, non-therapeutic goods, such as bedside cabinets or bed linen (as listed above), **do not** need to have an ARTG number before they can be procured by an organisation.

## How to find out more

Please contact devices@health.gov.au if you require assistance about the Excluded Goods Determinations, 'exempt' therapeutic goods or about whether a sponsor/supplier has an ARTG number. You may also wish to subscribe to the TGA News and Updates feeds or visit the TGA website for further information.

# Reporting problems and adverse events

To report a problem, adverse event or suspected adverse event experienced with a medical device, please refer to our Medical device incident reporting & investigation scheme (IRIS) for details on where to send an adverse event report or contact IRIS@health.gov.au.

# Recalls of therapeutic goods

Information about recall actions for therapeutic goods is available in the System for Australian Recall Actions (SARA) database. The SARA database holds information on recall actions undertaken in Australia since 1 July 2012.

SARA is searchable for recalls, product defect corrections, hazard alerts (for implanted medical devices and biologicals) and product defect alerts. Recall actions are included in SARA 2 days (excluding weekends) after a decision to commence the recall action has been made between the responsible entity (sponsor/supplier/importer) and the TGA. This allows time for the responsible entity to distribute the recall communication.

In certain circumstances, notices are also published on the alerts page of the TGA website. For example, consumer-level recall actions and recall actions involving implantable medical devices.

If you require further information about Australian recall actions, contact recalls@health.gov.au.

# Version history

| Version | Description of change | Author | Effective date |
|---|---|---|---|
| V1.0 | Original publication | Devices Business Support Section / Medical Devices Authorisation Branch and Regulatory Guidance Team | January 2021 |

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Reference/Publication #