



Australian Government
Department of Health
Therapeutic Goods Administration

Therapeutic Goods Administration

An introduction to regulation of medical devices in Australia

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TGA Health Safety
Regulation

Overview

Introduction

- National regulator of therapeutic goods
- What is classified as Therapeutic good
- Regulatory approach and process



Regulation of medical Devices

- Legislative instruments and legal definition
- Regulatory approach and risk classification
- Special rules for particular devices
- In vitro diagnostic tests
- Regulatory steps and requirements
 - Conformity assessment
 - Essential principles
 - Quality management system
- Regulation of Software based medical device
- Regulatory reforms
- IMDRF and new guidance documents
- Post-market Surveillance
 - Post-market obligations of manufacturers and sponsors
 - Adverse event reporting
 - Regulatory actions
 - Recall action and database

Who regulates therapeutic goods in Australia?

The Therapeutic Goods Administration was established in 1990 to “**safeguard** and **enhance** the health of the Australian community through **effective** and **timely regulation** of therapeutic goods” used in or exported from, Australia

TGA is part of the Health Products Regulation Group (HPRG) in the [Australian Government Department of Health](#)

HPRG includes the [TGA](#) and the [Office of Drug Control](#)

- Every decision the TGA makes is based on the *Therapeutic Goods Act 1989*
- Main offices in Canberra – satellite offices in Sydney, Melbourne, Adelaide and Brisbane
- Operations are primarily cost recovered (98%) industry pays fees for making applications and annual charges for their products



Who works at the TGA?

Approximately 750 staff made up of:

Biomedical
scientists

Engineers

Physiotherapists

Medical officers

Pharmacists

Nurses

Toxicologists

Lawyers

Nutritionists

Dieticians

Scientists

Administrative
staff

Under the *Therapeutic Goods Act 1989*, therapeutic goods are defined as:

Products 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 people to a disease or ailment
- influencing, controlling or preventing conception
- testing for pregnancy
- replacing or modifying parts of the anatomy



All therapeutic goods must be entered in the [ARTG](#) before they can be supplied in, imported to, or exported from Australia

Types of therapeutic goods



Medicines and blood products

- prescription medicines
- over-the-counter medicines
- complementary medicines
- blood, blood components and plasma derivatives



Medical devices

- implants (artificial hips, breast implants)
- in-vitro diagnostics (pregnancy tests, blood glucose monitors)
- low risk medical devices (bandages, tongue depressors, condoms)



Biologicals

- human stem cells
- tissue-based products (skin and bone)
- cell-based products

Regulatory oversight

1

Good Manufacturing Practice or Manufacturing Principles: licensing Australian manufacturers and verifying compliance of overseas manufacturers

2

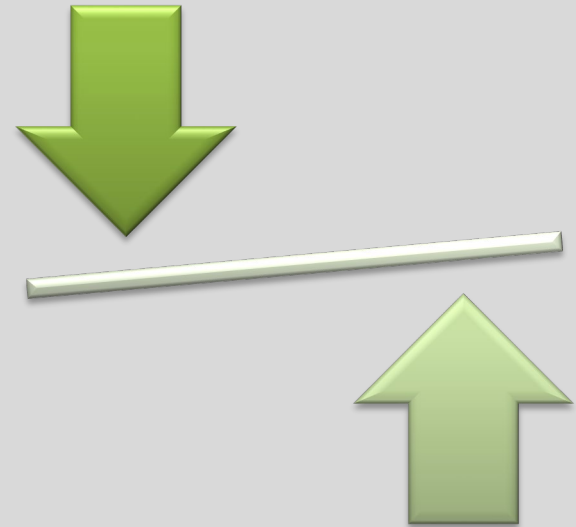
Premarket assessments: assessing therapeutic goods for quality and safety (the extent of the assessment depends on the type of product and level of associated risk), and for higher risk products also for efficacy or performance

3

Postmarket assessments: monitoring of therapeutic goods and enforcement of standards

The benefit versus risk approach

- No therapeutic good is **risk free**
- The work of the TGA is based on **applying scientific and clinical expertise to decision making**
- We ensure that the **benefits outweigh any risks** associated with the use of medicines, medical devices and other therapeutic goods



Premarket assessment

The level of assessment is based on how much risk the product poses

Low risk

Products such as complementary medicines and low risk medical devices are assessed for **quality** and **safety**

High risk

Products such as prescription medicines are assessed for **quality**, **safety** and **efficacy**

High risk medical devices are assessed for **quality**, **safety** and **performance**

For both categories there are manufacturing standards that must be met

Postmarket activities

Monitoring/Alerts

- **Monitors claims** made in advertisements for therapeutic goods and issues fines and sanctions if they can not be supported
- **Issues alerts**

Databases

- **Records** reports of **adverse events** by consumers, health professionals and industry
- **Records recall actions**

Manufacturing

- **Further inspections of manufacturers** of therapeutic goods



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The regulation of medical devices in Australia

Legislation & legislative instruments

Acts & regulations

- [Therapeutic Goods Act 1989](#)
- [Therapeutic Goods Regulations 1990](#)
- [Therapeutic Goods \(Medical Devices\) Regulations 2002](#)
- [Therapeutic Goods \(Charges\) Act 1989](#)
- [Therapeutic Goods \(Charges\) Regulations 2018](#)

Legislative instruments

- [Authorisations](#)
- [Excluded goods orders, determinations and specifications](#)
- [Groups orders](#)
- [Instruments](#)

Legislative instruments

- [Listing notices](#)
- [Manufacturing principles & guidelines](#)
- [Medical devices notices & standards orders](#)
- [Orders that goods are therapeutic goods](#)
- [Pharmacopoeias](#)
- [Product information](#)
- [Single therapeutic goods orders](#)
- [Special access scheme rules](#)
- [Specifications](#)
- [Therapeutic goods advertising code](#)
- [Therapeutic goods determinations](#)
- [Therapeutic goods orders](#)



What is a medical device?

The TGA defines a medical device as an instrument apparatus, appliance, material or other article intended to be used for human beings for:

- diagnosis, prevention, monitoring, treatment or alleviation of disease, injury or disability
- investigation, replacement or modification of the anatomy or of a physiological process
- control of conception
- in vitro examination of a human specimen for a medical purpose

Defined in Section 41BD of the *Therapeutic Goods Act 1989*



Dressings



Dental implant



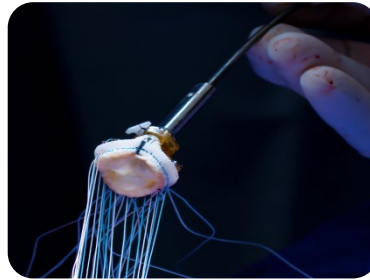
Breast implant



Glucose monitor



Comparing medicines and medical devices



A medical device does not achieve its **principal intended action** by pharmacological, immunological or metabolic means like a medicine or a vaccine

Many patients require medical devices

Reported knee procedures and hip procedures in Australia

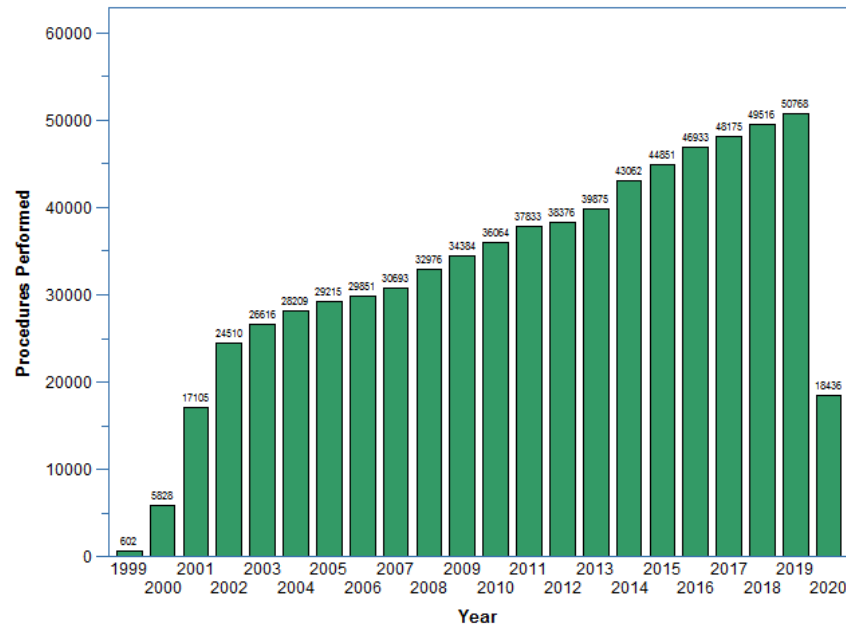
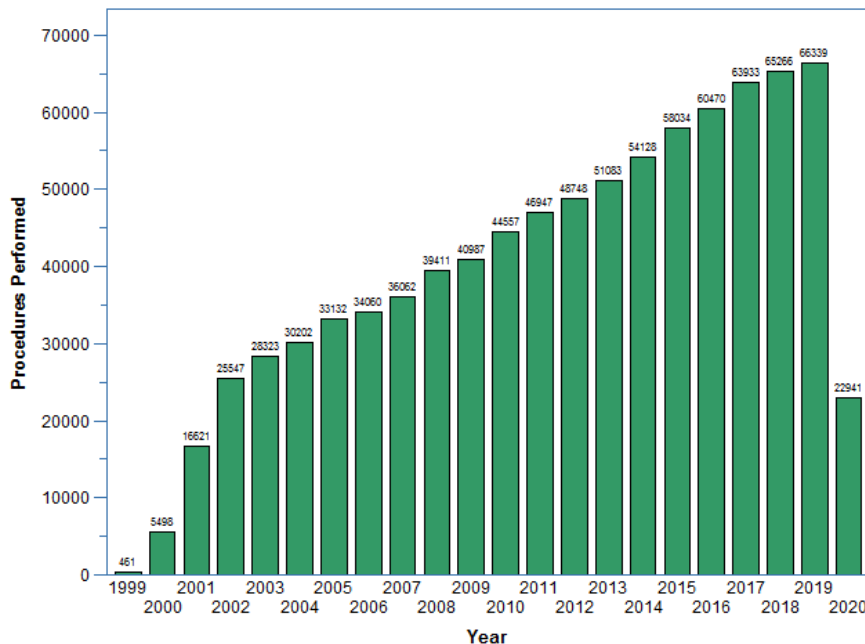
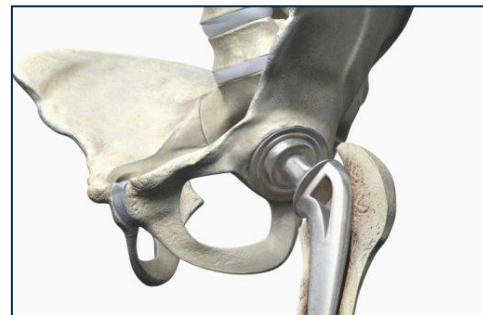
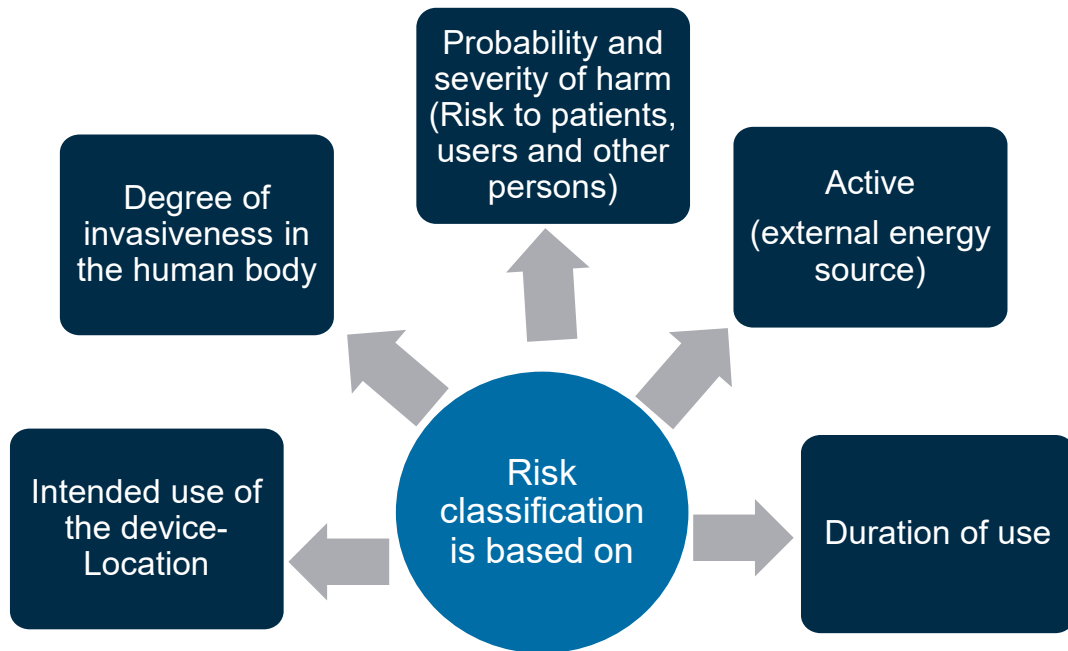


Photo: National Joint Replacement Registry *partial data for 2020

Tens of thousands of hip and knee procedures are performed every year. Ongoing safety and performance monitoring is important to ensure public safety after the device is made available on the market.

Benefit versus risk approach

The level of regulation is based on consideration of:



Risk classification rules – medical devices

Lower
risk

Medical device classification

Example

- | | |
|----------------------------------------------|------------------------------------|
| • Class I | • Urine collection bottles |
| • Class Is (intended to be supplied sterile) | • Sterile adhesive dressing strips |
| • Class Im (with measuring function) | • Clinical thermometer |
| • Class IIa | • X-ray films |
| • Class IIb | • Blood bags |
| • Class III | • Biological heart valves |
| • AIMD (active implantable medical device) | • Implantable pacemakers |

Higher
risk



Special rules for particular kinds of medical devices

The *Therapeutic Goods (Medical Devices) Regulations 2002* includes special provisions for devices that incorporate a medicine with an ancillary action

Part 5 in schedule 2-

5.1 Medical devices incorporating a medicine

(1) This clause applies to a medical device of any kind that incorporates, or is intended to incorporate, as an integral part, a substance that:

- a) if used separately, would be a medicine; and
- (b) is liable to act on a patient's body with action ancillary to that of the device.

(2) The device is classified as Class III.

(3) For the purposes of this clause, any stable derivative of human blood or human plasma is considered to be a medicine

For example, Pacemaker leads coated with anti-inflammatories would still be regulated as Medical devices, based on the principal intended action of the pacemaker and ancillary action of the anti-inflammatory.

In vitro diagnostic tests

An in vitro diagnostic medical device (IVD) is

- a reagent, calibrator, control material, kit, specimen receptacle, software, instrument, apparatus, equipment or system, whether used alone or in combination with other diagnostic goods for *in vitro* use
- intended by the manufacturer to be used *in vitro* for the examination of specimens derived from the human body, solely or principally for the purpose of giving information about a physiological or pathological state, a congenital abnormality or to determine safety and compatibility with a potential recipient, or to monitor therapeutic measures.



Pregnancy
test kits



Blood
glucose
meters




Blood
screening
tests

Examples of IVDs



Risk classification rules - IVDs

 Lower risk	IVD classification	Example
	Class 1 IVD or Class 1 in-house IVD: no public health risk or low personal risk	Glucose meter
	Class 2 IVD or Class 2 in-house IVD: low public health risk or moderate personal risk	Pregnancy and fertility self-testing kits
	Class 3 IVD or Class 3 in-house IVD: moderate public health risk or high personal risk	Tests to detect a sexually transmitted disease- Viral load and genotyping assays for HIV and Hepatitis C
	Class 4 IVD or Class 4 in-house IVD: high public health risk	All tests used by the Australian Red Cross Blood Service for the testing of blood


Regulation of PPE and COVID-19 - Face masks

- A face mask meets the definition of a medical device and is required to be included in the ARTG, **if** the manufacturer's labelling, advertising, or documentation claim that it is:
 - to be used for the prevention of the transmission of disease between people, or
 - intended for therapeutic use such as for surgical, clinical, medical use, or use in other health services.(as per, item 1 of Schedule 1 to the [*Therapeutic Goods \(Medical Devices - Specified Articles\) Instrument 2020*](#))
- Non-sterile face masks defined as medical devices are regulated as Class I - low risk device, however, there are some requirements for the performance and the quality of the face masks. Further information can be found here: [Evidence requirements for face masks that are medical devices](#)

The following resources provide an overview of the regulatory requirements for face masks in Australia:

- [Face masks and respirators that are regulated by the TGA](#)
- [Regulation of Personal Protective Equipment and COVID-19](#)

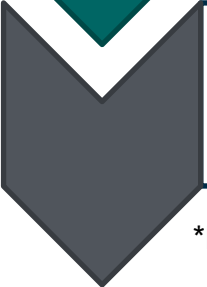
How does a medical device get to market?



The manufacturer must apply a Conformity Assessment* procedure to establish evidence of conformity with the Essential Principles* and maintain a Quality Management System*



A sponsor makes an application to include a device on the Australian Register of Therapeutic Goods (ARTG) so that it can be legally supplied in Australia



The applicant must have information available to demonstrate the **quality**, **safety** and **performance** of the medical device

*More information about what this means is provided later in the presentation

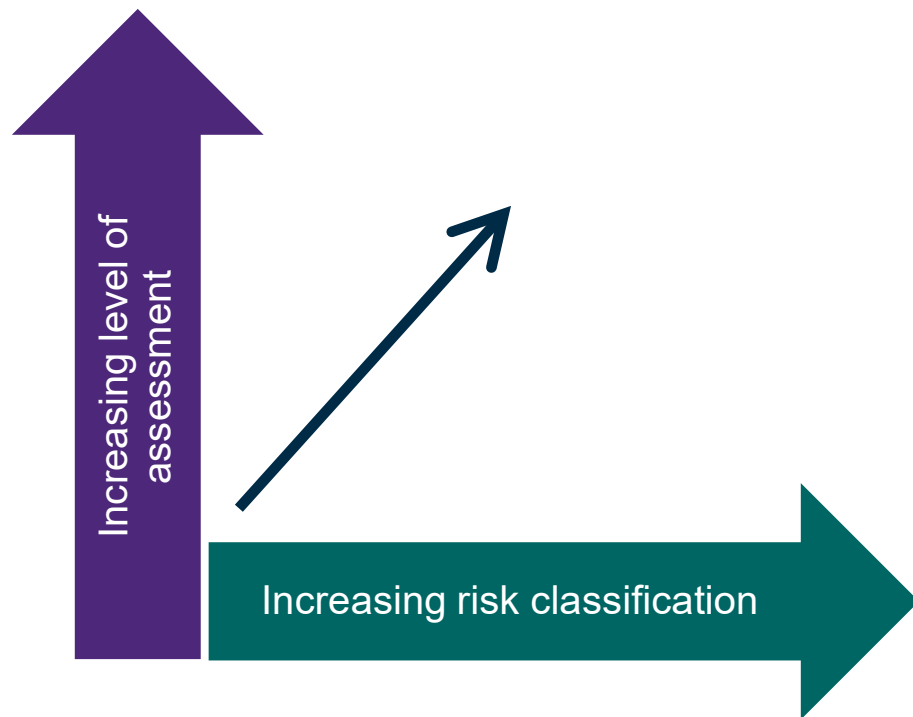


Medical devices can not be tested like medicines in a traditional clinical trial

Information on their performance and safety is important prior to market authorisation

Most new devices are improvements of older versions based on data collected from real life use

Conformity assessment



Conformity assessments are obligations on a manufacturer!

They are used to ensure the essential principles and other regulatory requirements are met.

The procedure for demonstrating this varies depending on the classification of the device.

Generally, the conformity assessment procedure is more rigorous the higher the risk class

Essential principles that govern devices

General principles

- Use of medical device should not compromise health and safety
- Design and construction should conform to safety principles
- Suitability for intended purpose
- Long-term safety
- Medical device should not be adversely affected by transport or storage
- Benefits to outweigh any side effects
- Information to be provided with the product
- Clinical evidence requirements



See the following slide for an example





Assessing benefits versus known side effects

Left ventricular assist device

Complex medical devices used to assist with the ventricular flow of blood to the body in patients with significant heart failure

Associated with a number of known complications due to their mechanical complexity and the patient groups in which they are used

Clinical evidence generated by the manufacturer could demonstrate that the benefits outweigh the side effects of the device by offering significant improvements in quality of life for users



Essential principles that govern devices

Principles about design and construction

- Chemical, physical and biological properties
- Infection and microbial contamination
- Construction and environmental properties
- Medical devices with a measuring function
- Protection against radiation
- Medical devices connected to or equipped with an energy source
- Information to be provided with medical devices
- Clinical evidence



See the following slide for an example

Devices and energy sources



ECG patient monitor

Interprets the electrical activity of the heart using electrodes attached to the surface of the skin

Manufacturer must design and produce the device in a way that ensures that when the device is used correctly under normal conditions there is protection against faults

For example, patients and users are protected against the risk of accidental electric shock





Quality management system (QMS)

A QMS is used for managing the product lifecycle, including **quality**, **safety** and **performance/efficacy**. Comprised of-

- people;
- processes and procedures;
- facility(ies);
- tools (including IT systems); and equipment

Manufacturers can choose a system that works for business- helps them meet regulatory requirements

Key standard for medical devices QMS-

- ISO 13485 - *Medical devices- Quality management systems - Requirements for regulatory purposes*- based on ISO 9001.

Medical Device manufacturers

Manufacturers of medical devices are required to:

- put in place a business system for managing safety, performance, and quality according to a total product lifecycle model;
- generate and maintain evidence that the devices produced by the system meet the Essential Principles of Safety and Performance;
- manage changes to their devices over time;
- obtain appropriate certification in support of the above;
- provide information and evidence of certification to sponsors;
- monitor and respond to safety and performance issues during the entire supply period.

Some record-keeping requirements extend beyond the end of supply.



Medical Device- sponsors

The sponsor's responsibilities include the following activities:

- obtain information from the manufacturer when requested by the TGA
- submit the evidence to support the device to the TGA
- apply to include the medical device in the ARTG
- pay the fee
- provide documentation relating to the medical device to the TGA
- deliver samples of the medical device to the TGA
- allow a person authorised by the TGA to enter and inspect any premises, including outside Australia, where the devices are manufactured
- post-market responsibilities

Regulatory activities



Review of technical and clinical information to ensure that compliance with the essential principles and conformity assessment procedures is demonstrated



Testing to confirm compliance with the essential principles- as required



Inspection of manufacturing site, process, manufacturer or sponsor's records - as required



Trend analysis and reporting to sponsors



Review / investigations of adverse event reports



Consultation with expert advisory committees



Informing consumers and health professionals of issues



Regulation of medical software and mobile medical 'apps'

Software is becoming increasingly important in medical devices; its rapid evolution presents new and complex challenges for the regulatory agencies

A software product is considered a medical device if it fits the definition in s41BD of the *Therapeutic Goods Act 1989*.

Examples of Software as a Medical Device (SaMD):

- Analysers used for pathology/detection of disease, Patient monitors, Pacemakers, Infusion pumps.
- Smart phone apps that measure blood glucose levels and patient body temperature, X-ray image-processing software, Diagnostic software. Such software may be used with or in devices such as: Computers, Mobile phones, Tablets.

However, a mobile phone, computer or tablet not intended by its manufacturer to be used for therapeutic purposes would not meet the definition of a medical device.



How is medical device software classified?

- Medical device software
 - intended to control a device, or influence the functions of a device will generally fall into the same classification as that device.
 - intended as an accessory to a medical device is classified separately from the device with which it is used.
- Regulation is risk-based.
- Therapeutic goods legislation requires manufacturers of medical device software products (other than Class 1 - the lowest risk classification) to obtain Conformity Assessment certification
- Software that meet the definition of a medical device must conform to the Essential Principles for safety and performance.
- SaMD products must be included on the ARTG before they are supplied in Australia.



Australia's regulatory model for Software based medical device

Based on certification of *manufacturers* and their business systems, rather than of individual devices, similar approach is used in the European Union, Singapore, Japan, Canada.

Obligations placed on manufacture

- certified to manufacture medical devices within approved categories (e.g., MRI image diagnostic software).
- must meet specified regulatory requirements, assess their compliance and be able to demonstrate- if/as required.
- Can either self certify or must obtain certification from an independent body (third-party certification).

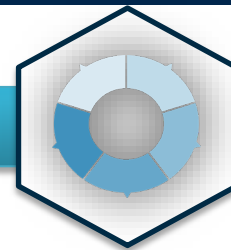
Degree of regulatory oversight varies according to the manufacturer's intended purpose for the device

- Manufacturers of Class III devices must also have the design (or type) of their devices examined by a third party.
- Australia accepts TGA certificates (and licences) and also some *comparable overseas regulators*, including regulatory agencies in EU, Health Canada, US, and Japan.
- TGA certification is mandatory for certain types of medical devices (those containing animal, biological, microbial, medicinal, or recombinant-DNA origin; and all Class 4 IVDs).

Inspections of software manufacturers



Inspection considerations



The manufacturer is expected to:

- **design** for safety and performance
- **develop** for quality, robustness, resilience, and predictability
- **monitor, report, and improve**
- using appropriate, sufficient, robust, and defensible tools, approaches, and methods.

Some relevant standards- **ISO 13485; ISO/IEC/IEEE 29148; IEC 62304; IEC 82304; and IEC/TR 80002-1 and 80002-2.**



Medical devices reforms

To enhance the safety, performance and quality of medical devices in Australia and focus on patient safety

An Action Plan grouped under three strategies

Strategy 1: Improve how new devices get on the market

Strategy 2: Strengthen monitoring and follow-up of devices already in use

Strategy 3: Provide more information to patients about the devices they use

<https://www.tga.gov.au/medical-devices-reforms-action-plan-medical-devices>

Regulatory changes to support the reforms are ongoing

<https://www.tga.gov.au/medical-device-reforms-regulatory-changes>

Recent reforms- Software as a Medical Device (SaMD)

25 February 2021 onwards the following changes have been implemented to the regulation of software-based medical devices, including software that functions as a medical device in its own right, with a transition period ending 1 November 2024.

- New classification rules
- Update to Essential Principles-
 - EP 12.1 amended to clarify the requirements for- cyber security, management of data and information; requirements relating to development, production, and maintenance.
 - EP 13.2(3) amended to allow information to be provided electronically.
 - New EP 13B introduced requiring the current version and build number for the software to be made accessible and identifiable to users of software-based medical devices. This information must be in English, however may also be displayed in other languages.
- Certain software-based medical devices carved-out (through either an exemption or exclusion) from the scope of TGA regulation



Medical devices reforms: Personalised medical devices (PMD)

- Prior to 25 February 2021, most PMD met the definition of 'custom-made' and were exempt from TGA approval and ARTG registration before import, export or supply (other regulatory obligations applied).
- New technology such as 3D-printing allowed more complex and, in some cases, higher-risk medical devices to be personalised and supplied under the custom-made medical device exemption

In liaison with other global regulators, TGA developed a new regulatory framework for PMD, which came into effect on 25 February 2021, and includes:

- new definitions for personalised medical devices
- changes to the conditions of exemption
- new requirements for inclusion of Medical Device Production System (MDPS) in the ARTG.

Guidance for industry- A guidance document for the new regulatory framework for PMD is available at: [Personalised medical devices \(including 3D-printed devices\)](#).



The International Medical Device Regulators Forum (IMDRF)

Australia's medical devices regulatory framework is based on a globally recognised model of medical device manufacturer certification.

IMDRF-

- Australia Founder member – 2011
- Works to accelerate international medical device regulatory harmonisation and convergence.
- Current work items include focused working groups on SaMD, Personalized Medical Devices (PMD), Artificial intelligence medical devices and others
- Technical documents published on <http://www.imdrf.org/documents/documents.asp#technical>





New Guidance documents

Guidance on reclassification of certain devices (non IVD):

The following guidance documents have been published on 12 May 2021:

- [Reclassification of active medical devices for therapy with a diagnostic function](#)
- [Reclassification of devices that administer medicines or biologicals by inhalation](#)
- [Reclassification of active implantable medical devices \(AIMD\)](#)

Other guidance documents are in development and will be published when available

More details on reforms at www.tga.gov.au/medical-devices-reforms

Further information

Medical device regulation basics

<http://www.tga.gov.au/medical-devices-regulation-basics>

Regulation of Software as a Medical Device (SaMD):

<https://www.tga.gov.au/regulation-software-medical-device>

General medical device enquiries- Medical Devices Information

Unit devices@tga.gov.au or 1800 141 144

The TGA's Digital Devices team- digital.devices@tga.gov.au

More details on reforms at www.tga.gov.au/medical-devices-reforms

[Australian regulatory guidelines for medical devices \(ARGMD\) | Therapeutic Goods Administration \(TGA\)](#)

- provides information on the import into, export from and supply of medical devices within Australia.
- Explains the legislative requirements that govern medical devices.

Regulatory Assistance Support

info@tga.gov.au

1800 020 653



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Postmarket Surveillance- Medical Devices



Post-market obligations

- Getting a device on the market is just the beginning.
- Post-market performance is monitored for trends or issues not previously known.
- Devices are subject to conditions of inclusion such as annual reports for higher classes of device.
- Devices can be subjected to post market review or investigations at any time.



Post-market responsibilities: Manufacturer

- Maintain appropriate records
 - ongoing compliance with the essential principles
 - review and updates to conformity assessment procedure, including quality management system
 - current conformity assessment certification (or other comparable overseas regulator approval)
- Adverse event reporting
 - must report the details of events associated with their device(s) that have resulted, or could have resulted, in serious injury or death
- Ongoing systematic review of information gained after the device was supplied in Australia
 - information from various sources – consumer, health profession, academic, scientific
 - overseas actions (recalls, suspensions, cancellations, etc)



Post-market responsibilities: Sponsor

- Sponsors must report the details of events associated with their device(s) that have resulted, or could have resulted, in serious injury or death- as per conditions of inclusion set out in the Therapeutic Goods (Medical Devices) Regulations (2002)
- Sponsors are required to submit three **annual reports** to the TGA following a new inclusion of a high risk medical devices, such as AIMD, Class III, Implantable Class IIb, Class 4 IVDs
- Sponsors are required to maintain distribution records and annually, provide the number of devices supplied, complaint and adverse event data.
- Annual reporting ensures that
 - high risk devices new to the Australian market are continuing to meet the Essential Principles for safety and performance, and
 - the sponsor and manufacturer's post-market surveillance system is functioning sufficiently to detect any issues as early as possible.



What is an adverse event

An event that resulted in, or could have resulted in (had effective intervention not taken place) serious injury, illness or death to patient, healthcare worker or other person.

A medical device adverse event is an event associated (caused or partially attributable) with the use (or misuse) of a medical device.

Faults that may affect the quality, timeliness and cost-effectiveness such as, problems with getting the device to operate, repeated repairs, device design and difficulty of use.



The TGA has authority to:

- Ask questions of sponsors and manufacturers
 - There are penalties for providing false and misleading information and not providing all information in the time frame specified
- Ask for samples of the medical device
- Seize products and inspect premises
- Cancel/suspend products from supply
 - Immediate if there is a potential risk of death or serious injury
 - Failure to respond to a letter requiring information
 - Not reporting an adverse event
 - Safety or performance is unacceptable
- Mandate a recall of a therapeutic product
- Issue infringement notices





Recall actions

To resolve a problem with a therapeutic good already supplied in the market when there are issues or deficiencies in relation to safety, quality, efficacy (performance) or presentation. There are four distinct recall actions:

- **Recall-** to remove therapeutic goods permanently from the market or from use when there are deficiencies or potential deficiencies in safety, quality, efficacy, performance or presentation.
- **Product defect correction-** includes repair, modification, adjustment or re-labelling of therapeutic goods, corrections to expiry date, updates or changes to any accessories, operating instructions or software.
- **Hazard alert** (implanted medical devices and biologicals)- these cannot be recalled
- **Product defect alert-** for critical therapeutic goods for which there is no alternative product or for which a recall action will result in interruption of patient treatment or a medicine shortage

TGAUPDATE

Alerts & recalls



1 April 2019

Mylanta Antacid Double
Strength Oral Liquid 500 mL
Product defect correction -
potential for soft lumps in the
liquid



Case study – one report can make a difference

Report that an epidural catheter, which is normally clear, was yellow when removed from the packaging for use.

Upon testing, the yellow catheter was found to be cytotoxic. New, clear catheters (of the same brand) were also found to be cytotoxic.

Further analysis found a plasticiser used to soften the catheter, n-butyl benzene sulfonamide, is a neurotoxin. The manufacturer had been using it for 30 years with no reports of related adverse events.

The catheter was reformulated worldwide due to the TGA's discovery.



Recall database

- The System for Australian Recall Actions (SARA) provides access to a searchable database for therapeutic good recall action notifications including recalls, product defect alerts and hazard alerts.
- Recall actions are included into the SARA two days (excluding weekends) after the decision between the responsible entity and the TGA, to commence the recall action. This allows time for the responsible entity (sponsor/supplier/importer) to distribute the recall communication.
- In certain circumstances (e.g. consumer level recall actions and recall actions involving implantable medical devices), notices are also published on the alerts page.

Search recall actions

The System for Australian Recall Actions (SARA) provides access to information about recall actions that have been undertaken in Australia since 1 July 2012.



- [System for Australian Recall Actions \(SARA\)](#)
- [SARA: Questions and answers](#)



**Subscribe to the TGA
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stay
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Receive information on:

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- Recall actions
- Medicines Safety Update
- Medical Devices Safety Update
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- Publications
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Thank you

**Please feel free to email your questions to
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