Australian Government
Department of Health
Therapeutic Goods Administration

Complying with Wearable Health Device Regulation

Which devices does the TGA regulate and how do they do it?

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TGA Health Safety Regulation

Overview of the TGA

- Part of the Australian Government Department of Health
- Administers the Therapeutic Goods Act 1989
- Main offices in Canberra – satellite offices in Sydney, Melbourne, Adelaide and Brisbane
- Operations cost recovered from industry
- Mission: To safeguard and enhance the health of the Australian community through the effective and timely regulation of therapeutic goods

Purpose built science and engineering building

Overview of the TGA – What we do

- Evaluate therapeutic goods before they are supplied
- Focus on safety, quality and performance
- Monitor products once they are on the market
- Allow for access to unapproved goods in certain circumstances
- Provide input to therapeutic goods standards
- We **do not** make decisions based on value for money or make decisions about which products receive Government subsidy

Who does this work?

Approximately 750 staff made up of:

Biomedical scientists	Engineers	Physiotherapists	Medical officers
Pharmacists	Nurses	Toxicologists	Lawyers
Nutritionists	Dieticians	Scientists	Administrative staff

The legislation

The TGA makes decisions based upon:

- Therapeutic Goods Act 1989
- Therapeutic Goods Regulations 1990
- Therapeutic Good (Medical Devices) Regulations 2002

Wearable medical devices

Available on Australian Government: Federal Register of Legislation website

Legislative instruments

- Therapeutics Goods Orders (TGO)
- Excluded Goods Orders
- Medical Device Standards Orders (MDSO)
- Conformity Assessment Standards Orders (CASO)

Available on Therapeutic Goods Administration website

Is my wearable device regulated by the TGA?

41BD What is a *medical device*

(1) A ***medical device*** is:

(a) any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following:

(i) diagnosis, prevention, monitoring, treatment or alleviation of disease;

(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability;

(iii) investigation, replacement or modification of the anatomy or of a physiological process;

(iv) control of conception;

and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means; or

(aa) any instrument, apparatus, appliance, material or other article specified under subsection (2A); or

(ab) any instrument, apparatus, appliance, material or other article that is included in a class of instruments, apparatus, appliances, materials or other articles specified under subsection (2B); or

(b) an accessory to an instrument, apparatus, appliance, material or other article covered by paragraph (a), (aa) or (ab).

(2) For the purposes of paragraph (1)(a), the purpose for which an instrument, apparatus, appliance, material or other article (the ***main equipment***) is to be used is to be ascertained from the information supplied, by the person under whose name the main equipment is or is to be supplied, on or in any one or more of the following:

(a) the labelling on the main equipment;

(b) the instructions for using the main equipment;

(c) any advertising material relating to the main equipment;

(d) technical documentation describing the mechanism of action of the main equipment.

(2A) The Secretary may, by notice published in the *Gazette* or on the Department's website, specify a particular instrument, apparatus, appliance, material or other article for the purposes of paragraph (1)(aa). The notice is not a legislative instrument.

(2B) The Secretary may, by legislative instrument, specify a particular class of instruments, apparatus, appliances, materials or other articles for the purposes of paragraph (1)(ab).

(3) The Secretary may, by order published in the *Gazette* or on the Department's website, declare that a particular instrument, apparatus, appliance, material or other article, or that a particular class of instruments, apparatus, appliances, materials or other articles, are not, for the purposes of this Act, medical devices.

Is it a medical device as defined by the TG Act?

My tech is a medical device, what now?

Australian regulatory guidelines for medical devices (ARGMD)

- Available on Therapeutic Goods Administration website
- Currently under review

In summary:

- Australian Register of Therapeutic Goods (ARTG)
- Risk based regulation
- Classification
- Essential Principles
- Quality System
- Evidence

Risk based regulation and classification

Higher risk devices receive higher scrutiny

Class I	Class Is and Class Im	Class IIa	Class IIb	Class III and AIMD
The lowest level				The highest level

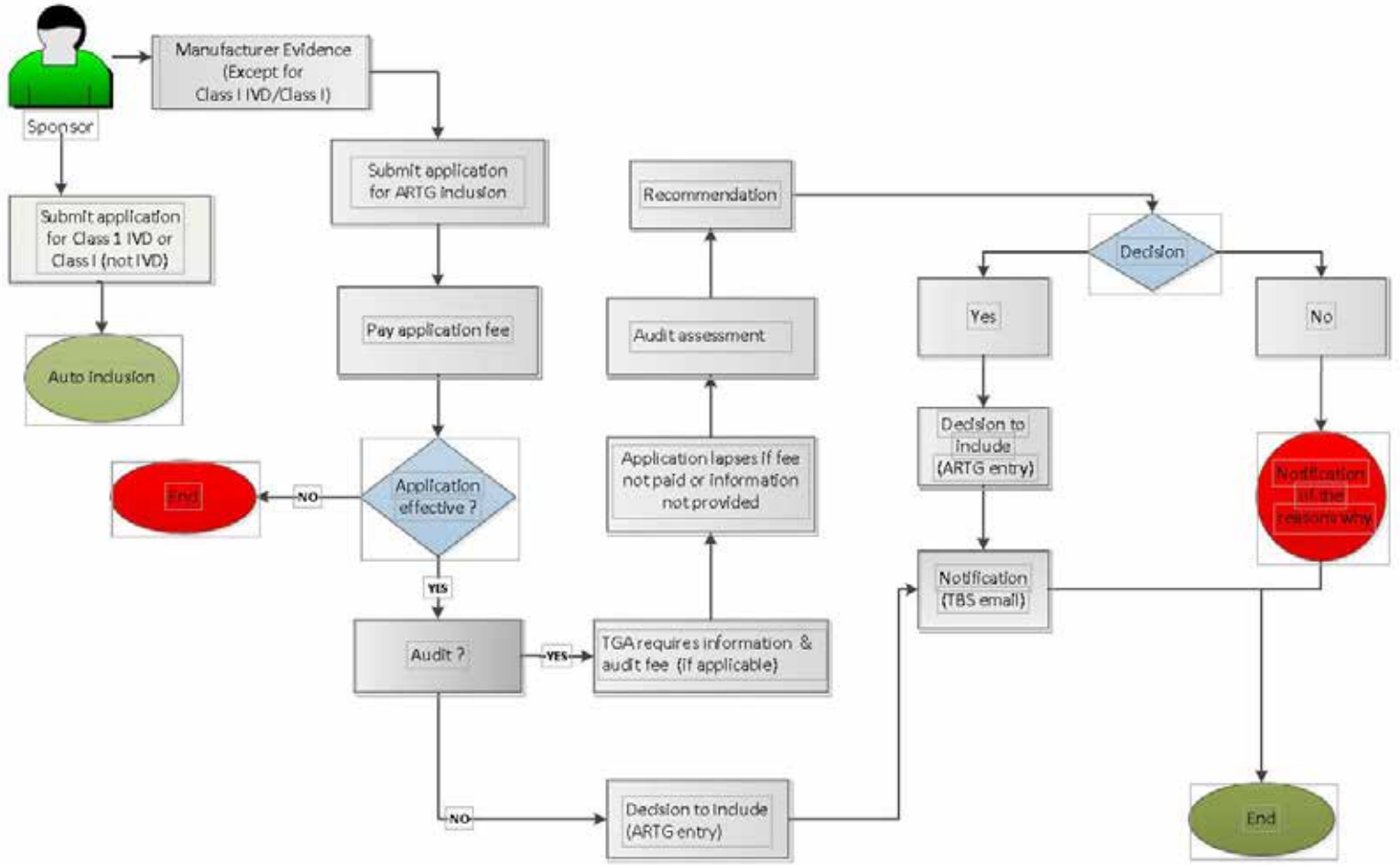
Devices are classified with regard to intended purpose

Class 1	Class 2	Class 3	Class 4
The lowest level			The highest level

IVD are classified with regard to the risk to public health

Therapeutic Goods (Medical Device) regulations 2002, Schedule 2

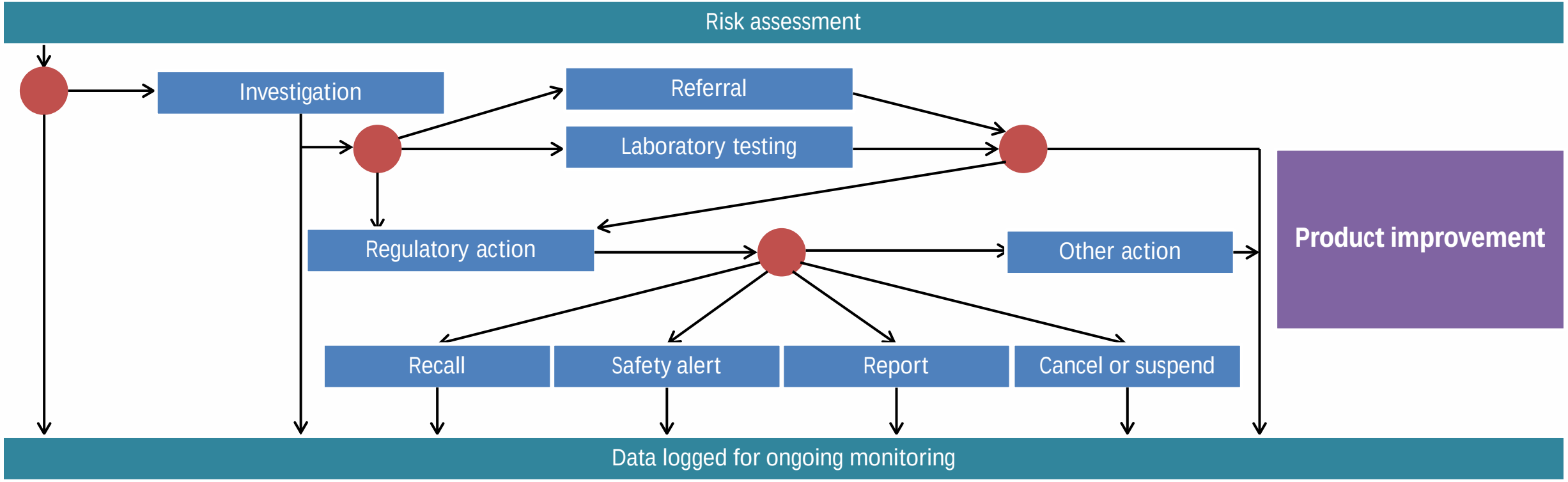
Inclusion on the ARTG



My device is included in the ARTG, am I done?

Incident Report Investigation Scheme (IRIS)

- Sponsor must report the details of events associated with their devices that have, or could have resulted in serious injury or death – TG (MD) Regs 2002



Other considerations

TGA can approve the supply of unregistered therapeutic goods

- Authorised prescribers
- Special access scheme
- Clinical trials
- Personal importation
- See Therapeutic Goods Administration website

There are penalties for (TG Act 1989, Part 4-11):

- Supplying a medical device that does not comply with the Essential Principles
- Not applying conformity assessment procedures
- Supplying a medical device that is not included in the register

There are advertising and labelling requirements (TG Act 1989, Chapter 5)

The Essential Principles

Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 1

- A legislated requirement for medical devices (TG Act 1989, Section 41CA)
- Used in pre-market evaluations
- Used in post market monitoring
- Standards may or may not be sufficient to demonstrate compliance

TGA assessors will assess your device against the Essential Principles

You should assess your device against the Essential Principles

You should consider the Essential Principles at every stage of you medical device's life

The Essential Principles

Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 1

General principles

1. Use of medical devices not to compromise health and safety
2. Design and construction of medical devices to conform to safety principles
3. Medical devices to be suitable for intended purpose
4. Long-term safety
5. Medical devices not to be adversely affected by transport or storage
6. Benefits of medical devices to outweigh any side effects

Principles about design and construction

7. Chemical, physical and biological properties
8. Infection and microbial contamination
9. Construction and environmental properties
10. Medical devices with a measuring function
11. Protection against radiation
12. Medical devices connected to or equipped with an energy source
13. Information to be provided with medical devices
14. Clinical evidence
15. Principles applying to IVD medical devices only

Austrailan Government: Federal Register of Legislation website

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