Software as a Medical Device

Regulatory insights and Q&A

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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
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 800 staff made up of:**

<table>
<thead>
<tr>
<th>Biomedical scientists</th>
<th>Engineers</th>
<th>Physiotherapists</th>
<th>Medical officers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacists</td>
<td>Nurses</td>
<td>Toxicologists</td>
<td>Lawyers</td>
</tr>
<tr>
<td>Software developers</td>
<td>Dieticians</td>
<td>Scientists</td>
<td>Administrative staff</td>
</tr>
</tbody>
</table>
The legislation

The TGA makes decisions based upon:

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


Legislative instruments

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

Available on www.tga.gov.au

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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.
Higher potential harm, more oversight

High Risk

Class III: ✔✔✔✔
Class IIb: ✔✔✔
Class IIa: ✔✔
Class I: ✔

Low Risk

Regulatory Scrutiny

(IVD Device Classes – Class 1 to Class 4)
All medical devices

Compliance with the essential principles
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 your 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

www.legislation.gov.au
Minimum conformity assessment procedures:

- Declaration of conformity
- Compliance with the essential principles
- Demonstrated using conformity assessment procedures

Class I medical devices

Compliance with the essential principles

Minimum conformity assessment procedures:

- Declaration of conformity
- Oversight of the developer’s Quality Management System
  - Product production and inspection
- Post-market monitoring, reporting and correction
Class Ia & Ibb medical devices

Compliance with the essential principles

Minimum conformity assessment procedures:

Declaration of conformity

Oversight of the developer’s Quality Management System

- Product design
- Product production and inspection
- Packaging and labelling
Class IIa & IIb medical devices

Compliance with the essential principles

Minimum conformity assessment procedures:

- Declaration of conformity
- Oversight of the developer’s Quality Management System
  - Product design
  - Product production and inspection
  - Packaging and labelling
- Post-market monitoring, reporting and correction
- Design examination
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

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Software as a Medical Device (SaMD)

Software that is intended to run on general purpose computing platforms and is also a medical device\(^1\)

- Platforms could include computers, tablets, phones, web browsers
- Examples:
  - Image processing for diagnosis or pathology
  - Software that collects information and makes a clinical decision or referral
  - Apps that calculate drug dose

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1. As defined in 41BD of the *Therapeutic Goods Act 1989*. 
Software as a Medical Device (SaMD)

• Does not include:
  – general health and lifestyle apps (not a MD)
  – software that is part of a medical device (not regulated separately)
  – apps that control a medical device (accessory and MD)
  – apps that rely on hardware in addition to a general purpose computing platform, eg – sensors, to achieve their intended purpose
Proposed New Requirements in Australia

• New rules to **appropriately classify SaMD products according to the potential harm they could cause to patients**

• **Exclude SaMD products from the personal importation provisions** so that SaMD products will be required to be included in the ARTG and have an Australian sponsor

• Ensure the **essential principles for medical devices include clear and transparent requirements for demonstrating the safety and performance of SaMD and other regulated software.**

Therapeutic goods regulation can be difficult to navigate!

- What kind of device **application** do I need to submit?
- My therapeutic good is for a **life-threatening illness** – is there a quicker approval pathway?
- What are the **time frames** for applications?
- Can I **advertise** my product?
- My product has been granted approval **overseas** – is this valid in Australia?
- What are my regulatory **obligations**?
- What **information** do I need to provide to the TGA?
SME Assist

- **Targets** the needs of small to medium enterprises (SMEs), start-ups, researchers and those unfamiliar with therapeutic goods regulation
- **Assists** users with navigating the ‘regulatory maze’
- **We offer:**
  - Guidance articles
  - Interactive decision tools (including ‘What classification is my medical device?’)
  - Educational face-to-face workshops across Australia (including a dedicated medical device focus session)
  - Email and phone support
  - A subscription service to keep up-to-date with news and events

`tga.gov.au/sme-assist`
`sme.assist@tga.gov.au`
`1800 020 653`

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