



Australian Government
Department of Health
Therapeutic Goods Administration

Regulation of software as medical devices

When is software a medical device?

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TGA Health Safety
Regulation

Overview

- What is a 'medical device'?
 - Definition and regulation but not classification
- Software as a Medical Device (SaMD)
 - IMDRF working group update (NOT a regulation framework)
- Post-market perspectives
 - Issues and challenges of software
- Q&A
 - Time permitting...

Medical device definition

Under the *Therapeutic Goods Act 1989*, section 41BD states:

(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 (cont...)

What's the intended purpose?

Under the *Therapeutic Goods Act 1989*, Section 41BD (2) states the intended purpose:

- is to be derived from labelling, instructions, advertising material and technical documentation, provided by the Legal Manufacturer
- NOTE:
 - The Secretary may declare particular things, devices, classes, types, or articles to be Medical Devices or NOT!
 - Such a declaration under this section does not stop articles from being therapeutic goods
 - Such a declaration takes effect on the day on which the declaration is published – unless specified

When software becomes a medical device...

Software becomes a medical device when it meets the definition of a medical device

That is, when the legal manufacturer intends* for the software to be used in:

- diagnosis;
- prevention;
- monitoring;
- treatment; or
- alleviation; of disease

*The intention is ascertained from statements made by the Manufacturer in the labelling, instructions, advertising material or any other documentation provided with or about the software.

Types of software regulated by TGA

- Software used in manufacturing
- Software for maintaining QMS
- Software systems and toolsets
- Software with a therapeutic purpose
 - Firmware/embedded software in:
 - monitors, defibrillators, pumps
 - in vitro diagnostic devices
 - implantable devices (Pacemakers etc.)
 - Traditional applications
 - Central station on a PC
 - Standalone software
 - Ships on a disk only
 - Apps
 - Downloaded from the store

Generally NOT regulated:

- No therapeutic purpose
 - (not itself, nor part of, a device)
- HIS, LIMS, PACS...
 - Info storage and retrieval only with no “device” functions/features

Possible room for doubt:

- Configuration/setup software
- Service tools
- “Measurement” displays (graphs etc.)

How is software regulated by TGA?

- The TGA regulates medical device software used for therapeutic purposes under the **medical devices** regulatory framework (if they meet the definition)
 - Mobile apps would be considered within this framework
 - Standalone software would also be considered within this framework
- Regulation is risk based, and depends on the **intended purpose**
- Manufacturers of medical device software products (other than Class 1 – lowest risk) to obtain [Conformity Assessment](#) certification
- All medical devices are expected to meet the [Essential Principles](#) for safety and performance
- For further information, please refer to Section 13 in Part 2 of the [Australian Regulatory Guidelines for Medical Devices \(ARGMD\)](#)



SaMD Quality Management Principles : A grouping of QMS activities from a Software perspective

- **A governance structure** provides leadership, accountability and an organization with adequate resources that assures the safety, effectiveness and performance of SaMD;
- **SaMD lifecycle processes** -- A scalable set of quality processes that apply commonly across lifecycle activities;
- **A set of key lifecycle activities** that is scalable for the type of SaMD, the size of the organization takes into account important elements required for assuring the safety, effectiveness and performance of SaMD.



- Leadership and organizational support provides a **foundation** for SaMD lifecycle processes
- SaMD lifecycle processes **support and apply across** the SaMD lifecycle activities.



SaMD – translating QMS to software terms

- Converging on a common terminology and understanding of Quality Management System (QMS) principles
- Terminology common in the software industry is used in the document to illustrate how typical software-engineering activities translate to equivalent activities in a medical device QMS

Software industry	Medical device
Software requirements	Product requirements
Testing	Verification and Validation (V&V)
Configuration management	Identification and traceability

IMDRF – SaMD comments open...

- **SaMD: Application of Quality Management System**
- A proposed document has been released by the International Medical Device Regulators Forum (IMDRF) Software as a Medical Device Working Group for public comments
- [IMDRF Consultation](#)
- Document link: [Software as a Medical Device \(SaMD\): Application of Quality Management System - PDF \(270kb\)](#)
- [IMDRF comments template](#)
- **This consultation will close on Monday 1 June 2015**

Post-market – some general issues

- **Feature creep** - crossing the definitional line, one feature at a time
- E.g. a BSL tracking app:
 - Record BSL (rev 1.0)
 - Graph BSL (rev 1.3)
 - Trend BSL (rev 2.3)
 - Alert BSL (rev 2.7)
- **Blind to the Regs** – not being aware of building a regulated medical device
 - Home tinkerers
 - An “obvious” extension of an existing product – remote view
- **Feature obfuscation** – deliberate “de-emphasising” of features to down-classify a device – practiced in USA
- **Media and public interest** – matching the promise to reality
 - mHealth market to reach **\$26 billion** by 2017 (was just \$700 million in 2011!)

Post-market incidents and complaints

- Learning to recognise reportable incidents is a big challenge – users may think...
 - Software issues are managed by a “reboot” so no report is needed... wrong.
 - Software issues are misidentified as “user issues” so no report needed... wrong.
- Software issues most evident immediately after an update/upgrade
- Upward trends (relating to quality) are reportable
- Capturing and tracking incidents and complaints – a big challenge
- Linking incidents to risk management – closing the feedback loop
- TGA’s Recognise, Retain, and Report campaign

Post-market regulatory actions

Challenges

- Safety related updates under Universal Recall Procedure for Therapeutic Goods (URPTG) – not widely known in Software industry
- Software expected to follow IEC 62304 – recognised as state-of-the-art – linked to Essential Principles
- Proliferation of “manufacturers” with limited or no medical domain knowledge
- Software recalls – fixed by the time its reported

Benefits

- Software recalls – fixed “overnight”, everywhere, globally...
- Feedback in stores for possible complaint records
- Some ecosystems (e.g. Apple) can “force” updates or disabling of features and apps

Summary

- What is a 'medical device'?
 - Something that meets the definition in the Act
- Software as a Medical Device (SaMD)
 - If it looks like a duck...
 - IMDRF paper open for comment
- Post-market perspectives
 - Tracking and reporting incidents
 - Updates aligned to correct regulatory pathway
- Q&A

Q&A?



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