The challenges of regulating direct to consumer digital medical devices

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• What are digital medical devices?
• What is the Role of the Regulator?
• What are the Challenges in Applying the Framework to Digital Devices?
• What are Some International Approaches?
• What is the TGA doing?
• Questions
What are digital medical devices?

- Connected medical devices
- Telehealth
- Machine learning and AI
- Mobile health
- Smart medical device
- Phone & tablet apps
- Medical imaging
- Electronic medical or health records
- Medical software
- Sensors and wearables
- Big health data and analytics
- DIY medical devices
Enablers of DTC digital medical devices

- Technology advances (sensor technology/computing platforms)
- Accessibility of solutions and computing platforms (app stores/ smartphones and tablets)
- Uptake of technology by consumers
- Low barriers to entry for industry (programming = manufacturing - no capital investment)
Examples of DTC digital medical devices

- Smartphone Pulse Oximeters
- Smartphone EKG devices
- Smartphone ultrasound devices
- Apps for calculating medicine dosages
- Apps for tracking chronic disease parameters
- Apps for treating behavioural issues
Examples of DTC medical-device-like consumer goods

• Activity trackers
• Sleep monitors
• Heart rate monitors for exercise
• Apps for exercise programs
• Apps for recording dietary intake
• Apps for reducing stress
Benefits of DTC digital medical devices

• Consumers are more engaged with their health
• Chronic disease sufferers can better manage their conditions
• Healthcare providers have access to more patient data
• Bigger data sets for population health
Issues with DTC digital medical devices

Consumer ultrasound: Dangerous & irresponsible?

[Link to the article](https://www.mobihealthnews.com/6594/consumer-ultrasound-dangerous-idiotic-irresponsible)

Consumers warned about accuracy of heart rate apps

- **Date:** May 3, 2017
- **Source:** European Society of Cardiology
- **Summary:** Consumers are being warned about the accuracy of heart rate apps after a study found huge variability between commercially available apps, even those using the same technology.

[Link to the article](https://www.sciencedaily.com/releases/2017/05/170503092146.htm)

Diabetes Management app: Safety advisory – update app to correct programming error

[Link to the article](https://www.medpagetoday.com/Blogs/IltifatHusain/51888)

[Link to the article](https://tga.gov.au)

App Claims to Measure Oxygen Saturation With Only a Smartphone

- **Title:** App Claims to Measure Oxygen Saturation With Only a Smartphone
- **Subtitle:** There are apps making unjustifiable claims, exposing patients to unnecessary risk.
- **Author:** Sulich Misra MD

[Link to the article](https://www.medpagetoday.com/Blogs/IltifatHusain/51888)

[Link to the article](https://www.statnews.com/2019/07/24/fitbit-accuracy-dark-skin/)

[Link to the article](https://www.mobihealthnews.com/6594/consumer-ultrasound-dangerous-idiotic-irresponsible)
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The role of the TGA

• The TGA, part of the Department of Health and Ageing, was established in 1989 as the main Australian Government entity responsible for ensuring that medicines and medical devices used by Australian consumers are evaluated and regulated before they reach the market and monitored once they are in use.

• About the work of the TGA – a risk management approach
  – Australian can expect the medicines and medical devices they use to meet an acceptable level of safety and quality.

• Therapeutic product vigilance
  – The work of the TGA is to ensure that the benefits to consumers outweigh any risks associated with the use of medicines, medical devices and biologicals.
Regulatory requirements for medical devices

- Does it Fit the Definition of a Medical Device?
- Apply the Classification Rules
- Evidence of Quality, Safety and Performance
- Regulatory Review of Evidence (if device is above Class I)
- Manufacturing Certification (if device is above Class I)
- Inclusion in the ARTG
- Post Market Requirements
  - Monitor Post Market Performance
  - Report Problems to the TGA
  - Annual Manufacturing Inspections
What is a medical device?

Defined in s41BD of the *Therapeutic Goods Act 1989*

1 (a) Any instrument, apparatus, appliance, material or other article intended 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.

- Bandages
- Dental implant
- Breast implant
- Glucose monitor
What is a medical device? (continued)

Defined in s41BD of the *Therapeutic Goods Act 1989*

(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.
Risk based classification

Risk classification is based on:

- Intended use of the device
- Potential to harm patients, users and other persons
- Degree of invasiveness in the human body
- Location and duration of use
Regulatory oversight increases with increasing risk category

Regulatory Scrutiny

Class III ✔✔✔✔
Class IIb ✔✔✔
Class IIA ✔✔
Class I ✔

(IVD Device Classes – Class 1 to Class 4)
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
What is clinical evidence for a medical device?

Inclusion in the ARTG

Evidence requirements

**Class I:**
Self-assessment and declaration

**Class Is, Im, Ila:**
Manufacturing certification including technical file review

**Class IIb:**
Manufacturing certification including technical file review
Mandatory application audit for some Class IIb devices

**Class III:**
Manufacturing certification
Device design examination certification
Mandatory application audit
Postmarket obligations

For higher risk devices: AIMD, Class III or implantable Class IIb device
Annual reports to the TGA required

Monitoring of product performance
Adverse event reporting to the TGA

Environmental scanning
Review of medical & scientific literature, regulatory news, media and other sources
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Is it regulated as a medical device?

A product is regulated by the TGA when it meets the definition of a medical device. *That is, when the legal manufacturer intends for the product to be used for:*

- diagnosis,
- prevention,
- monitoring,
- treatment, or
- alleviation, of disease, injury or disability

Software is regulated by the TGA…
- When it is part of a hardware medical device or medical device system
- When it controls a medical device
- When it meets the definition of a medical device.
Software as a Medical Device (SaMD)

Software that is intended to run on general purpose computing platforms and is also a medical device¹

- 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

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 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, e.g., sensors, to achieve their intended purpose
Current classification rules for software

4.1 Active medical devices - general
An active medical device is classified as Class I, unless the device is classified at a higher level under another clause in this Part or in Part 2, 3 or 5.

Regulation 3.3

(5) If a medical device is driven, or influenced, by an item of software, the software has the same classification as the medical device.

Most software is Class I under the current rules
Challenges for regulating DTC digital devices

- Gaps in the current framework
- Interpretation of ‘intended purpose’ to determine regulatory status
- “Off-label use” of medical-device-like consumer goods
- Consumer expectation for medical device = consumer good
- New industry players unfamiliar with medical device regulation
- Variable levels of consumer health literacy
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International digital device regulation
International digital device regulation

Recent Regulatory Reforms

• Europe
  – Higher Classification for Software that provides information for clinical decision making,
  – New general safety and performance requirements for software

• FDA
  – New medical device definition with details for software
  – Premarket assessment and certification of manufacturers for software products

• Australia
  – Recent consultation for regulatory reforms for software
New requirements in Europe

• The EU MDR 2017/745 has introduced the following new classifications for software:
  • Software that provides information to be used in making decisions for diagnosis or treatment is:
    – Class III if the decisions have an impact that may cause death or an irreversible deterioration of a person’s state of health
    – Class IIb if the decisions have an impact that may cause a serious deterioration of a person’s state of health or a surgical intervention
    – Class IIa in any other case

NOTE: The EU already has an additional classification rule applicable to software compared with Australia:

Rule 16 (MDD 93/42/EEC)
Devices specifically intended for recording of X-ray diagnostic images are in Class IIa.
New requirements in the USA

(1) The term device, as defined in section 201(h), shall not include a software function that is intended—

(A) for administrative support of a health care facility, including the processing and maintenance of financial records, claims or billing information, appointment schedules, business analytics, information about patient populations, admissions, practice and inventory management, analysis of historical claims data to predict future utilization or cost-effectiveness, determination of health benefit eligibility, population health management, and laboratory workflow;

(B) for maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition;

(C) to serve as electronic patient records, including patient-provided information, to the extent that such records are intended to transfer, store, convert formats, or display the equivalent of a paper medical chart, so long as—

(i) such records were created, stored, transferred, or reviewed by health care professionals, or by individuals working under supervision of such professionals;

(ii) such records are part of health information technology that is certified under section 3001(c)(5) of the Public Health Service Act; and

(iii) such function is not intended to interpret or analyze patient records, including medical image data, for the purpose of the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition;

(D) for transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results, findings by a health care professional with respect to such data and results, general information about such findings, and general background information about such laboratory test or other device, unless such function is intended to interpret or analyze clinical laboratory test or other device data, results, and findings...
New requirements in the USA

Digital Health Software Precertification (Pre-Cert) Program

The Software Precertification Pilot Program (Pre-Cert)’s version 1.0 working model explains how the FDA has reimagined its way of regulating digital health products and details the proposed key components of the Pre-Cert pilot program.

https://www.fda.gov/medicaldevices/digitalhealth/digitalhealthprecertprogram/default.htm#program
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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.**

Consultation on software reforms

- Consultation 14 February to 31 March 2019
- 41 Submissions, broad support for the proposals
- Revised proposals based on feedback
- Stakeholder workshop 24 June 2019 for additional feedback

Next steps

- Policy approval
- Drafting, approval and publication of regulations
- Identify carve outs for certain software categories
- Stakeholder engagement and education
- Regulatory guidance for new legislation
Website references and contacts


Regulation of Software as a Medical Device (SaMD): https://www.tga.gov.au/regulation-software-medical-device

Premarket medical device enquiries: devices@tga.gov.au

The TGA’s Digital Devices team: digital.devices@tga.gov.au
• Questions