The role of the TGA in digital health

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TGA Webinar
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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

Upcoming TGA events and presentations: http://www.tga.gov.au/events-training
March Webinar

How the TGA regulates software, including apps

Thursday, 7 March 2019 @ 12:30 pm

Registration will open shortly, refer to our events and training page located on the TGA website.
What is digital health?

The Australian Digital Health Agency says:

“Digital health is about electronically connecting up the points of care so that health information can be shared securely.”

“Genomics, precision medicine, AI-based decision support, and epidemiological applications of “big data” are just some of the other aspects of digital health.”

“Smart medical devices that incorporate digital health technologies to enable new and better ways of monitoring health and delivering care.”

What is digital health?

The FDA says:

“The broad scope of digital health includes categories such as mobile health (mHealth), health information technology (IT), wearable devices, telehealth and telemedicine, and personalized medicine.”

What is digital health?

Wikipedia says:

Digital health "involves the use of information and communication technologies to help address the health problems and challenges faced by patients. These technologies include both hardware and software solutions and services, including telemedicine, web-based analysis, email, mobile phones and applications, text messages, wearable devices, and clinic or remote monitoring sensors.

Generally, digital health is concerned about the development of interconnected health systems to improve the use of computational technologies, smart devices, computational analysis techniques and communication media to aid healthcare professionals and patients manage illnesses and health risks, as well as promote health and wellbeing." 

What is digital health?

- Sensors and wearables
- Machine learning and AI
- Quantified self
- Mobile health
- Phone and tablet apps
- Connected medical devices
- Telehealth

- Electronic medical or health records
- Medical software
- Medical imaging
- Big health data and analytics
- Personal genomics
- DIY medical devices
- Smart medical device
Are any of these regulated by the TGA?

- Sensors and wearables
- Machine learning and AI
- Quantified self
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- Telehealth

- Electronic medical or health records
- Medical software
- Medical imaging
- Big health data and analytics
- Personal genomics
- DIY medical devices
- Smart medical device
Are any of these medical devices?

- Sensors and wearables
- Machine learning and AI
- Quantified self
- Mobile health
- Phone and tablet apps
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Are any of these medical devices?

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.
Where are the challenges?

Medical Devices:

- Sensors and wearables
- Machine learning and AI
- Quantified self
- Mobile health
- Phone and tablet apps
- Connected medical devices
- Telehealth

- Electronic medical or health records
- Medical software
- Medical imaging
- Big health data and analytics
- Personal genomics
- DIY medical devices
- Smart medical device
Where are the challenges?

- Software as a Medical Device (SaMD)
- Security of connected medical devices
- Distributed and backyard manufacturers
- Empowered/participating patients/consumers
- Medical devices that include machine learning or artificial intelligence
What have we done?

Regulated

International Medical Device Regulator’s Forum (IMDRF)

• SaMD working group
  – SaMD – Key Definitions (2013)
  – SaMD – Possible framework for Risk Categorisation (2014)
  – SaMD – Application of QMS (2015)
  – SaMD – Clinical evaluation (2017)

CSIRO research and consultation on SaMD & cybersecurity
What are we doing?

- Public comment on cybersecurity guidance
- IMDRF Cybersecurity working group
- Changes to regulation (adoption, harmonisation)
- Public consultation on regulatory changes
- Produce SaMD guidance documents
- Stakeholder engagement and collaboration
- Capability development
Future challenges

Artificial intelligence and machine learning

- Software that changes itself
- Devices that learn from their decisions
- Centralised devices (cloud)
Registration questions

Thank you

• Helps speakers prepare

• Identifies gaps and informs future activities
Answers to registration questions

• Does the TGA regulate products for mental health?
  – Yes
  β See the definition of a medical device (slide 5) regarding which ones.

• Does this relate to products used in the pharmaceuticals sector?
  – Yes
  β If they meet the definition of a medical device (e.g. dose calculators).
Answers to registration questions

• How does the TGA view the interaction between digital health, digital medical devices, software, and cybersecurity?

• What role does the TGA have with regard to the regulation of mobile health apps?

• Will any categories of digital health be exempted from regulation?

In short, have a look at the legislated definition of a medical device (slide 5).

• If the product is a medical device, the TGA regulates it.

• For more about apps: https://www.tga.gov.au/regulation-software-medical-device

• Current processes are the same as for other medical devices and IVDs.

• Cybersecurity is one risk associated with medical devices, like other risks it is required to be minimised.
Answers to registration questions

- Is the TGA building a separate regulatory scheme for digital health?
  - No

  - The TGA’s regulation of these products is, and will continue, under the existing framework.
  - However, the current framework is under review with regard to whether amendments are needed to appropriately capture some emerging digital health technologies.
  - Some other agencies are considering how to manage products that are not medical devices or IVDs.
Answers to registration questions

- Any tips for sponsors, manufacturers, importers, exporters, or developers?
- When will guidance be provided or updated?

- If your product is a medical devices or IVD, it is regulated as such.
  - The same requirements and processes apply as for other medical devices.
- The framework is under review, and there is a program of consultation and engagement activities for 2019.
  - The goal is to provide new and updated guidance.
  - Please talk to us, respond to consultations and tell us which activities help you.
Answers to registration questions

• How do I report in a Clinical Trial Notification (CTN)?
  – Software is covered under medical devices.
  – For information about how software is regulated as a medical device see:
Answers to registration questions

- Does the TGA take pre-submission meetings on digital health products?
  - Yes

Answers to registration questions

- Will the TGA harmonise with, or recognise approval from other jurisdictions?

Bigger than today’s topic. In summary:

- We seek international harmonisation where possible.

- We are a founder and active member of the International Medical Device Regulators Forum (IMDRF).

- The TGA has recently released guidance on using evidence from overseas regulators:  

- Some products are regulated differently in Australia because our legislation is written to address the risks to Australian patients and consumers.
Answers to registration questions

• Can data collected by digital devices be used as evidence?
  – Yes

  - This is an important advantage of digital medical devices.
  - Feeds into the evidence dossier.
  - Can also be used for post-market monitoring.
Question time
For more on TGA visit…

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