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Interaction

- Please type in your questions using the Q&A icon at the bottom of the screen

- Feel free to chat to each other during the course of the presentation
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TGA Health Safety Regulation

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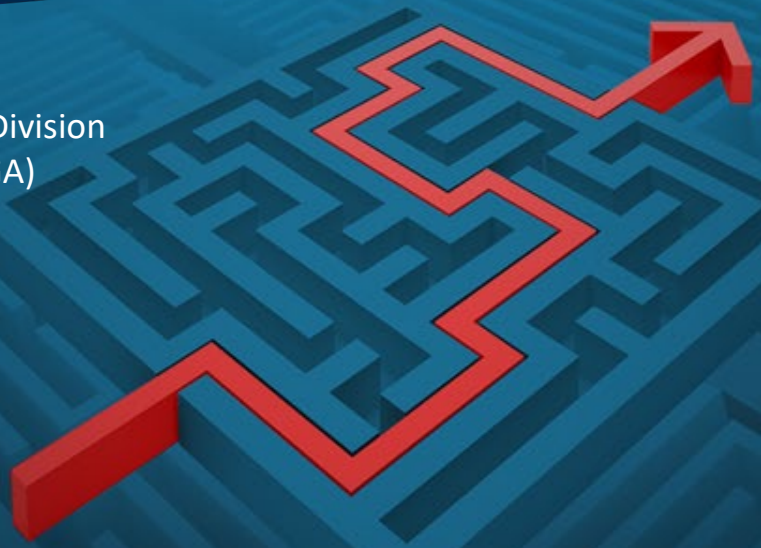
Engaging with the TGA

General regulation overview, software regulation, and useful resources

Xin-Lin Goh and Olivia Reeves
Medical Devices and Product Quality Division
Therapeutic Goods Administration (TGA)

NSW Active MedTech Webinar
8 September 2021



TGA Health Safety Regulation

Presentation Overview

General regulation overview and useful resources

- The Australian Register of Therapeutic Goods
- Definition and classification of medical devices
- Regulatory lifecycle and getting a device to market in Australia
- Evidence requirements for applications
- Assessment process and useful resources

Software regulation

- What’s in and what’s out
- Exclusion vs exemption
- Classification rules and Essential Principles
- Cyber security, artificial intelligence, and advertising

Australian Register of Therapeutic Goods

All therapeutic goods must be entered in the ARTG before they can be supplied in, imported to, or exported from Australia

- Medicines
- Medical Devices
- Biologicals
- Other Therapeutic Goods

What is a medical device?

- A medical device is a product used for:
  - diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease, injury or disability
  - investigation, replacement or modification of the anatomy or of a physiological process
  - support or control of conception
- It does **not** achieve its primary function through pharmacological, immunological or metabolic means.
- It can also be an accessory to a medical device.

Defined in Section 41BD of the Act

What is a kind of medical device?

- Medical devices are included in the ARTG as a '**kind** of medical device'.
- A medical device is taken to be the same kind as another medical device if they have the following characteristics:

For all classes of medical device:

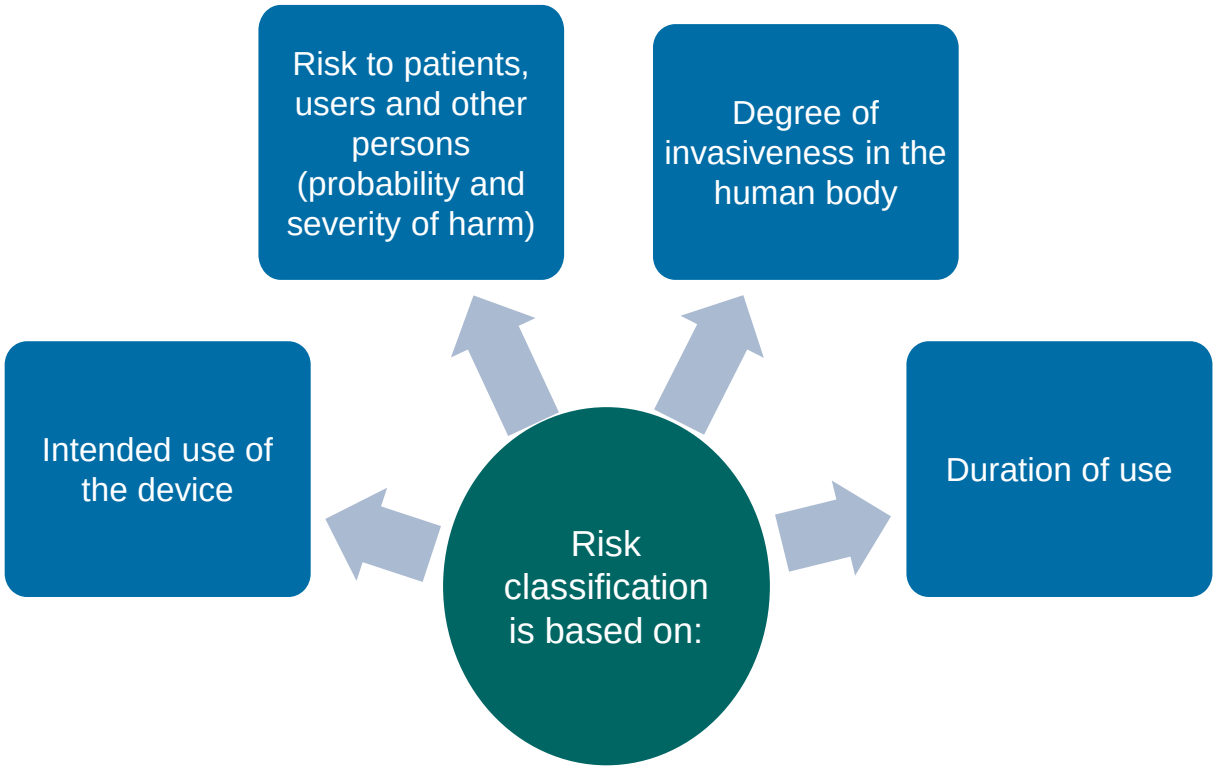
- the same sponsor
- the same manufacturer
- the same classification
- the same Global Medical Device Nomenclature (GMDN) system code

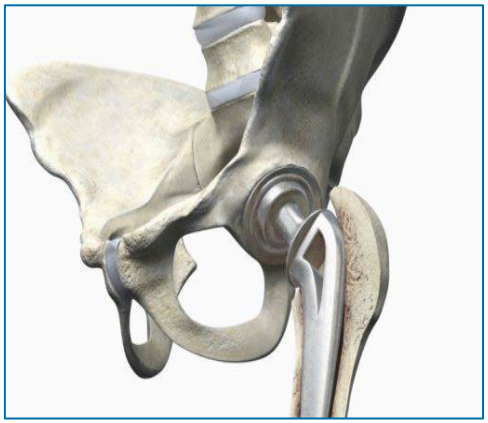
Additionally for Class III and Class AIMD medical devices:

- the same unique product identifier (UPI)

Risk based classification

Device classification is based on consideration of:





Classification of medical devices

Classification	Class I	Class Is and Class Im	Class IIa	Class IIb	Class III and AIMD
Risk	Low risk	Low-Medium risk		Medium-High risk	High risk
Example	Medical gloves	Sterile dressing/ Weighing scale	IV tubing	Electrosurgical electrode	Cardiovascular catheters /implantable pacemaker

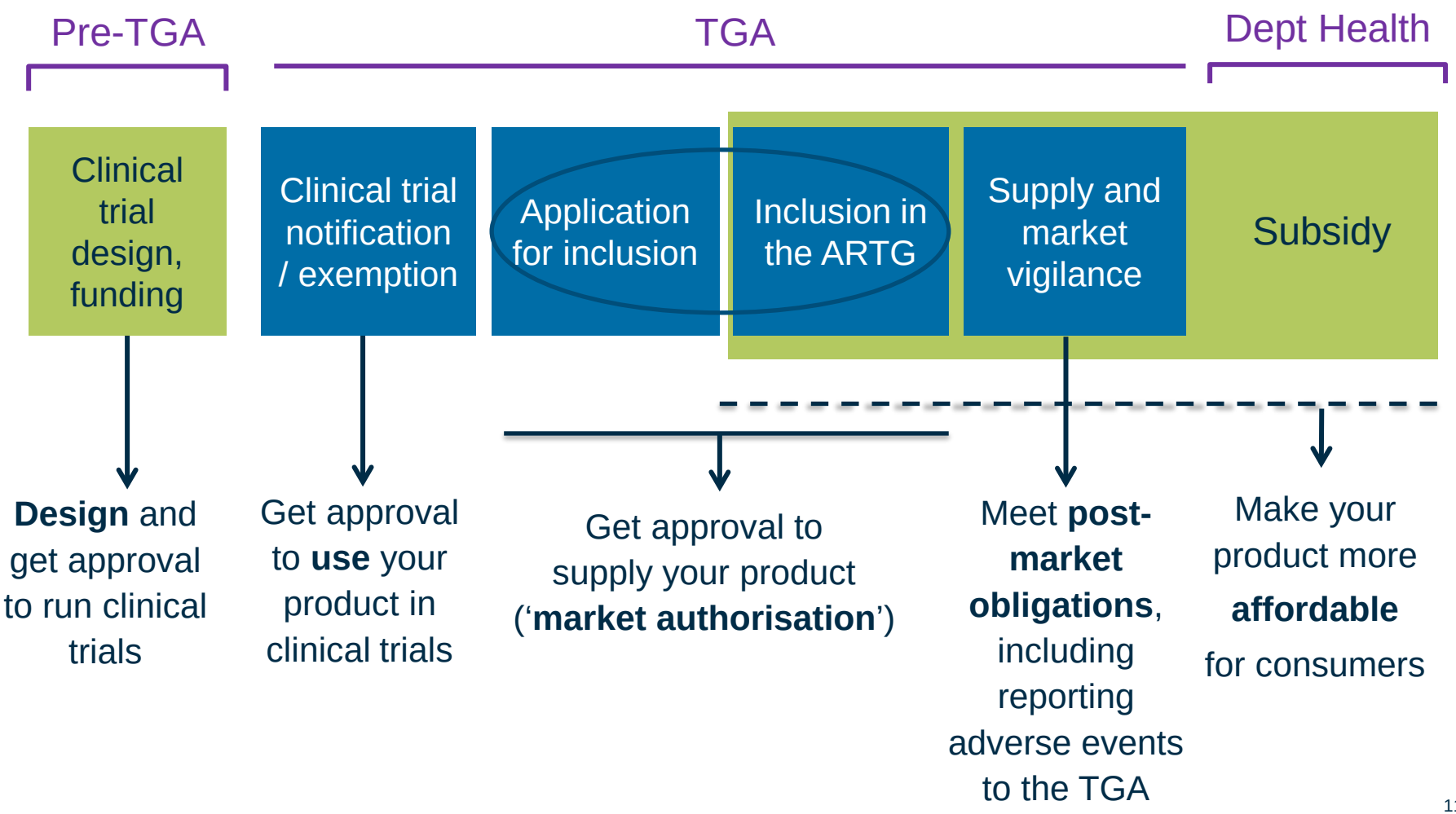
Classification principles and rules are defined in *Therapeutic Goods (Medical Devices) Regulations 2002,* Part 3 Division 3.1 and Schedules 2

Upcoming reclassification of Active Implantable Medical Devices (AIMD)

- From 25 November 2021, Active Implantable Medical Devices (AIMD) will be required to be reclassified from Class AIMD to Class III.
- Examples
  - implantable cardiac pacemakers
  - cochlear implants
- Transition period
  - For existing devices, notify the TGA by 25 May 2022, and submit and Class III application before 1 November 2024

https://www.tga.gov.au/resource/reclassification-active-implantable-medical-devices-aimd

Therapeutic good development lifecycle



How does a Medical Device get to the Australian Market?

A sponsor makes an application to include a device on the Australian Register of Therapeutic Goods (ARTG) so that it can be legally supplied in Australia

The applicant must have information available to demonstrate the **quality**, **safety** and **performance** of the medical device

The device must demonstrate compliance with regulations, such as appropriate Quality Management System (QMS), risk management and post market surveillance procedures.

General regulatory requirements

Conformity Assessment

QMS (Manufacturer)

Could include:

- Overview of manufacturing stages
- Quality manual
- Purchasing requirements/supplier control
- Process validations and Change Controls
- Procedures for post-market monitoring system

Product Assessment

Could include:

- Device Description and History
- Essential Principles Checklist
- Risk Analysis and Control Summary (e.g. ISO 14971)
- Design and Manufacturing Information
- Clinical Evidence Report
- Performance Evaluation
- Product Validation and Verification
- Stability
- Information to be Supplied with the Medical Device

Essential 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
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

Evidence requirements by Classification - Examples

Classification	Examples of regulatory evidence required (non-exhaustive list)*
Class I	Manufacturer's self-declaration of compliance with Essential Principles
Class I sterile Class I measuring	• TGA Production Quality Assurance • MDSAP • EU MDD Annex II.3
Class IIa	• TGA Production Quality Assurance • MDSAP **+ Japan Pre-market certificate** • MDSAP **+ US FDA 510(k)** • EU MDD Annex II.3
Class IIb	• TGA Full Quality Assurance • TGA Production Quality Assurance **+ Type Examination** • MDSAP + Japan Pre-market certificate • MDSAP + US FDA 510(k) • EU MDD Annex II.3
Class III / AIMD **	• TGA Full Quality Assurance **+ Design Examination** • TGA Production Quality Assurance + Type Examination • MDSAP **+ Japan Pre-market approval certificate** • MDSAP **+ US FDA PMA** • EU MDD Annex II.3 **+ Design Examination**

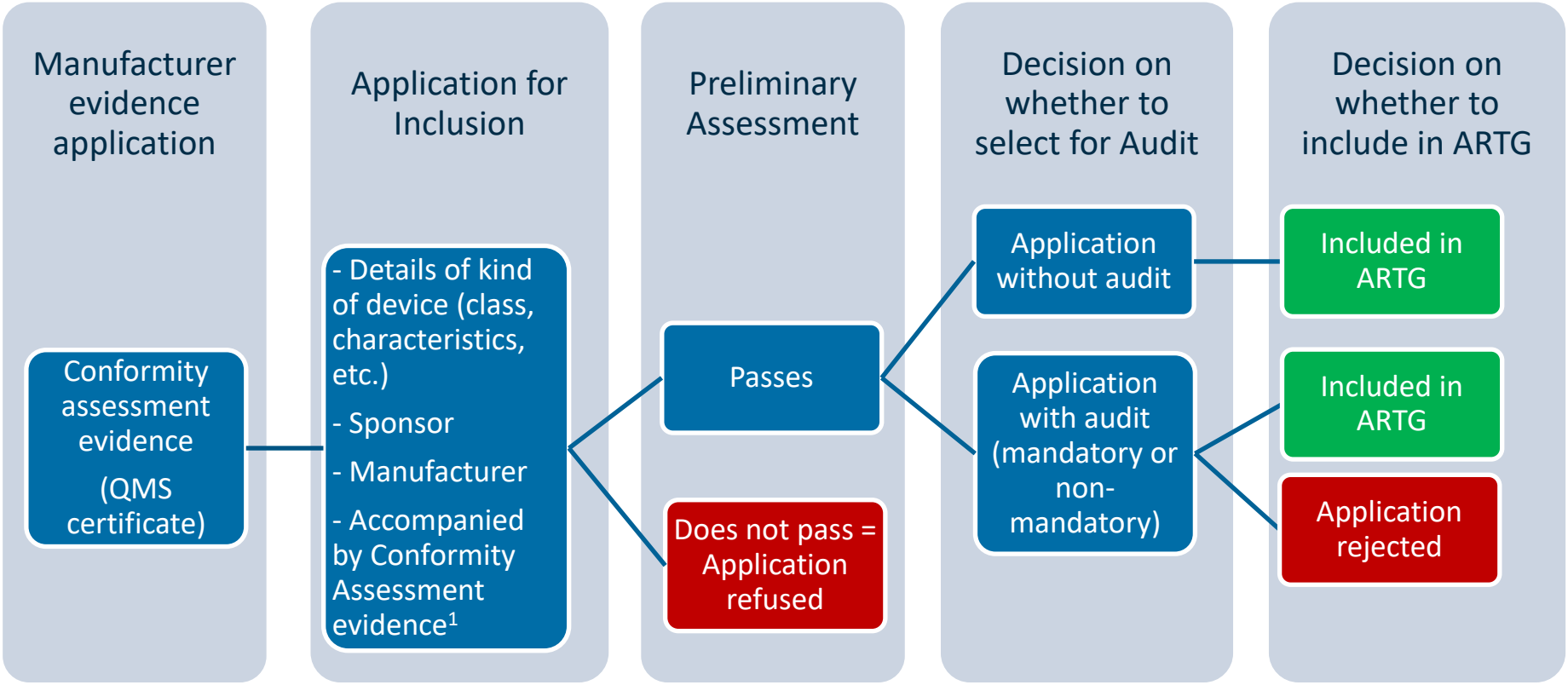
* For a full list, see *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2018*

** For specified medical devices containing non-viable animal origin tissues, tissues or cells or substances of microbial or recombinant origin, stable derivatives of human blood or plasma, or incorporating medicine, TGA or EU certificates are required.

Supply of medical devices in Australia

- Majority of devices are supplied in Australia under EC certification.
- Certifications from Comparable Overseas Regulators was introduced in 2018 (USA, Canada, Japan, MDSAP)
- TGA issued conformity assessment certification was previously mandatory for certain high risk devices

Medical Device assessment process



[1] Therapeutic Goods (Medical Devices – Information that Must Accompany Application for Inclusion) Determination 2018
[2] Mandatory audit applies to some categories of medical devices

Level 1 vs Level 2 audits

Level 1 Audit

- Clarification of classification
- Conformity assessment procedures – certification and declaration of conformity
- Essential Principle 13 – information provided with the device

Level 2 Audit

- As above
- Clinical evidence
- Risk management report
- Efficacy and performance data for medical devices that are intended for disinfecting another medical devices
- Audit reports from Notified Bodies

Lodging an application

- Applications for inclusion in the ARTG are submitted via the TGA Business Services (TBS) online services website (https://www.tga.gov.au/tga-business-services).
- A Sponsor must first obtain a Client ID and access to the TBS website. A Sponsor can apply for a Client ID by submitting the "Organisation details form". The following web page provides guidance on Client ID - https://www.tga.gov.au/tga-business-services-getting-started-tga
- Two stage process to include devices in the ARTG
  - Step 1 - Submission of Manufacturer's Evidence
  - Step 2 - Submission of inclusion application
- For comprehensive guidance, see www.tga.gov.au/publication/medical-device-inclusion-process
- Medical Device Information Unit – 1800 141 144 (free call) or devices@health.gov.au

Priority Applicant Determination

- Priority applicant for
  - TGA Conformity Assessment Certification, OR
  - Application for inclusion in the ARTG
- Enables ‘front-of-queue’ priority
- **Must meet <u>all three</u> criteria**
  1. Life-threatening or seriously debilitating condition
  2. Unmet need/ significant improvement
  3. Major clinical advantage / public health benefit

Pre-submission meetings

- Purpose
  - Obtain a common understanding of the therapeutic good
    - What supporting documentation is needed
    - Any issues to resolve before submitting applications
  - Non-binding guidance or feedback on the strength of the proposed application.

Please note:

- we provide advice to clarify any issues you have relating to existing studies or the proposed data package
- we do **not** address issues that require evaluation of data
- we do **not** generally give advice on developing a data package or the number of studies required to support an application

https://www.tga.gov.au/publication/pre-submission-meetings-tga

PriorityDevices@health.gov.au

Assistance and further resources

- Medical devices information unit
  - Email devices@tga.gov.au
  - Phone 1800 141 144
  - Inclusion process www.tga.gov.au/publication/medical-device-inclusion-process
- Pre-submission meetings
  - https://www.tga.gov.au/publication/pre-submission-meetings-tga
- Priority Applicant determination
  - https://www.tga.gov.au/form/application-priority-applicant-determination-medical-devices
- Unapproved products
  - https://www.tga.gov.au/accessing-unapproved-products

Regulation of medical device software

When is software a medical device?

Software is a medical device when the manufacturer *intends* for its product to be used for:

- diagnosis
- prevention
- monitoring
- prognosis & prediction
- treatment
- alleviation

…of disease, injury or disability

It's not based on…

- what colour it is
- what shape it is
- whether or not it looks good
- what it is called
- whether it is novel or not
- what technology is used
- how it is supplied (online, in hardware, through the sneaker net, …)

Intended purpose is critical…

What is ‘intended purpose’?

It’s not necessarily what your device *can* do…

It is how your product is marketed, or what claims are made.

Example

An infrared thermometer marketed to measure human body temperature for clinical purposes.

Versus

An infrared thermometer marketed to measure the temperature of cooked meat.

Who is the manufacturer?

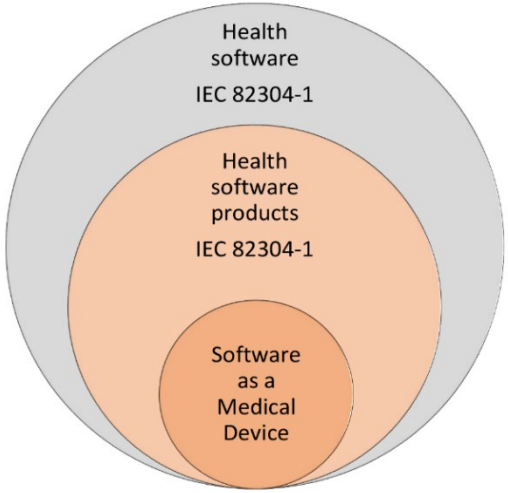
It's not necessarily who makes the device.

It's who has their name on the label or the name under which the product is supplied

Example

A service provider wants to publish some software under their name, but outsource design and development of the software to a third party developer. In this case, the service provider maintains responsibility for these aspects, and publishes the software under their name. This makes the service provider the manufacturer.

Not all health software is a medical device



Most health software is not a medical device and is not regulated by the TGA.

Carve-out mechanisms: Exclusion vs Exemption

Exclusion	Exemption
means that the devices are completely unregulated by TGA	means that TGA retains some oversight for advertising, adverse events and notification Registration of the devices is not required.

Carve-out mechanisms: Exclusion vs Exemption

- **Excluded products** are not subject to any TGA oversight
- **Exempt products** are
  - Not required to be in the ARTG
  - Do not have pre-market evaluation by the TGA
  - Must meet the relevant essential principles for safety and performance
  - Must report adverse events to the TGA
  - Are subject to recalls or hazard alerts in the event of a problem
  - Are subject to the Therapeutic Goods Advertising Code

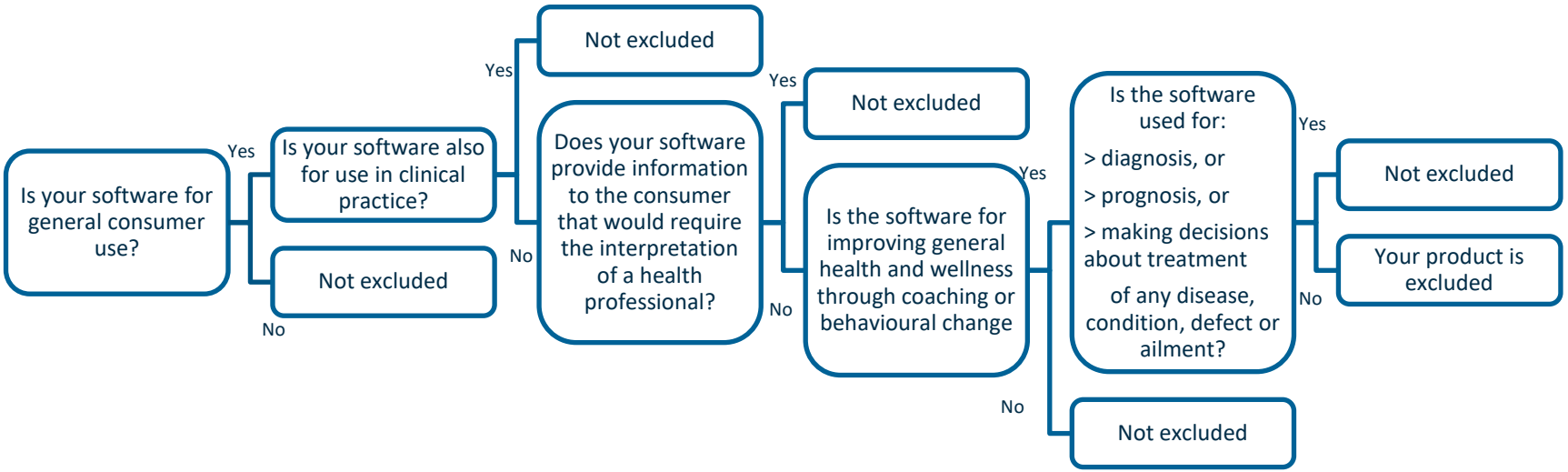
Excluded software

15 conditional exclusions including:

- **Consumer** health products - prevention, management and follow up devices that do not provide specific treatment or treatment suggestions
- **Digital mental health tools**
- **Enabling** technology - for telehealth, remote diagnosis, healthcare or dispensing
- **Digitisation** - of paper based or other published clinical rules or data including simple calculators and Electronic Medical Records
- **Analytics** - population based
- **Laboratory Information Management Systems**

Excluded – software

Exclusions are conditional, e.g.:



Examples of excluded software:

A 'sun smart' app that gives user alerts for UV protection to minimise skin cancer risk.

Examples of software that is not excluded:

A smartphone app intended to provide a direction to adjust the dosage of a prescribed medication.

Clinical decision support software

Exemption for clinical decision support software that is:

a) intended to be for the sole purpose of providing or supporting a recommendation to a health professional about preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons; and

b) not intended by its manufacturer to directly process or analyse a medical image or signal from another medical device; and

c) not intended by its manufacturer to replace the clinical judgement of a health professional in relation to making a clinical diagnosis or decision about the treatment of patients

Clinical decision support software

Exempt clinical decision support software (CDSS) is not required to be approved by the TGA and included in the ARTG.

Sponsors/suppliers **must** notify the TGA of their exempt CDSS devices using the Notification form: Clinical decision support software exemption.

Exempted CDSS devices must clearly reference the basis of the recommendations, so that the information can be independently reviewed by the user.

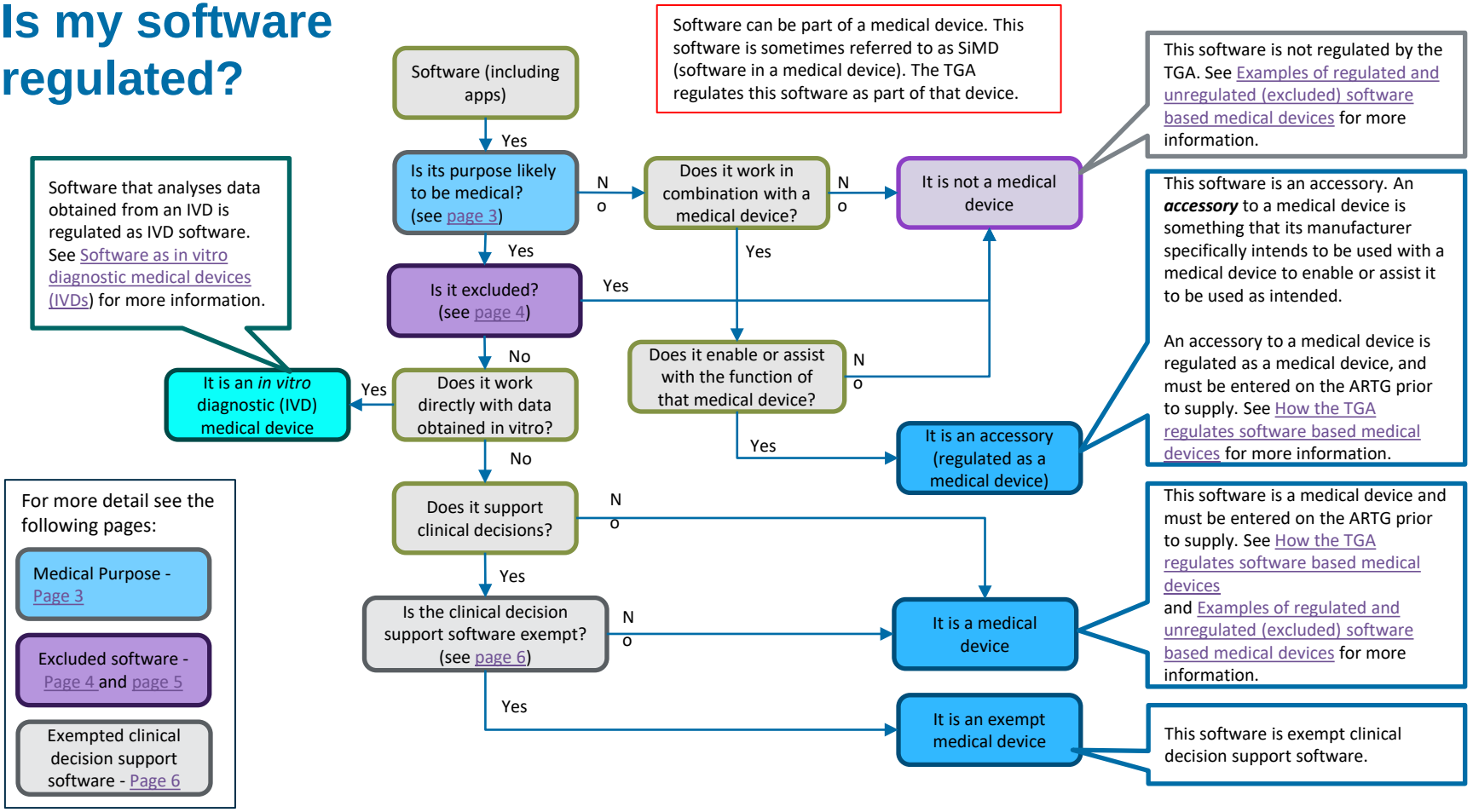
Is my product regulated by TGA?

You need to consider the following.

- Is it a medical device (according to the definition)?
- Does it meet any of the exclusions?

If it is a medical device, determine if it is exempt clinical decision support software

Is my software regulated?

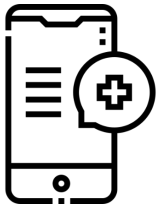


Classification rules

- **Are there any physical interactions with the patient/user?**
  - Is your software stand-alone or does it use hardware?
  - Is it invasive?
  - Does it use energy outside the visible spectrum?

- **What is the intended purpose?**
  - Diagnosis/screening
  - Monitoring
  - Informing or delivering therapy



Classification rules

Software that **provide information for diagnosing or screening** a disease or condition and that is intended to:

- **Software itself makes a diagnosis or screens for a disease or condition**
- **Or Does it provide information to a clinician for them to make a diagnosis (lower classification)**

Classification depends on:

- Risk to public health (high moderate, none)
- Seriousness of the disease or condition
- Where the disease or condition may lead to death or severe deterioration in a short timeframe

Classification rules

Software that **monitors the state or progression of a disease or condition** where:

- **It could indicate a person is in danger**
- **It could indicate a risk to public health**

Classification depends on:

- risk to public health (high, moderate, none)
- whether the person could be in immediate danger or danger that is not immediate

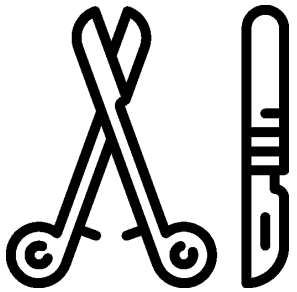
Classification rules

Software that **specifies or recommends a treatment or intervention** where:

- **The treatment or intervention is specified by the software**
  (e.g. – the patient will inject the amount of insulin calculated)
- **Recommend a treatment or intervention for a clinician to decide and administer**

Classification depends on whether the treatment or intervention, or its absence:

- could result in death or severe debilitation
- could be otherwise harmful
- is unlikely to cause harm
- poses a risk to public health (high, moderate, none)

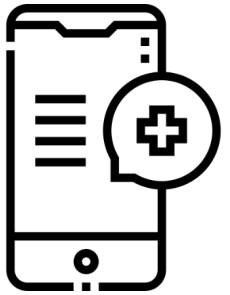


Classification rules

Software that **provides therapy through the provision of information**:

Classification depends on:

- The risk of harm to a person
- The seriousness of the harm



Essential Principles

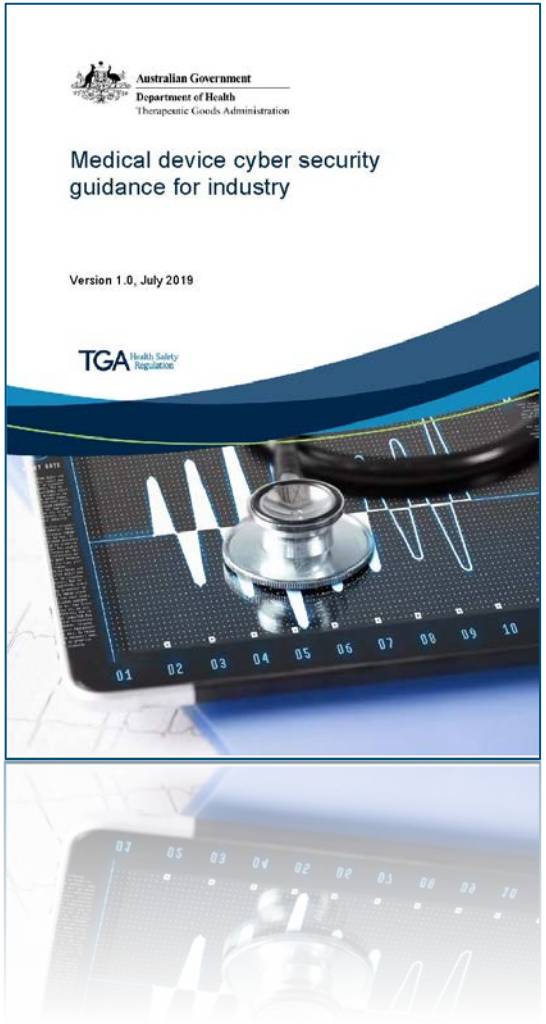
Changes to Essential Principles:

- **EP 12.1** amended to clarify the requirements for:
  - cyber security
  - the management of data and information (including privacy)
  - requirements relating to development, production, and maintenance.
  - platform requirements
- **EP 13.2(3)** amended to allow information to be provided electronically.
- New **EP 13B** introduced requiring the current version and build number for the software to be made accessible and identifiable to users of software-based medical devices. This information must be in English, however may also be displayed in other languages.

Cyber security

Regulatory guidance

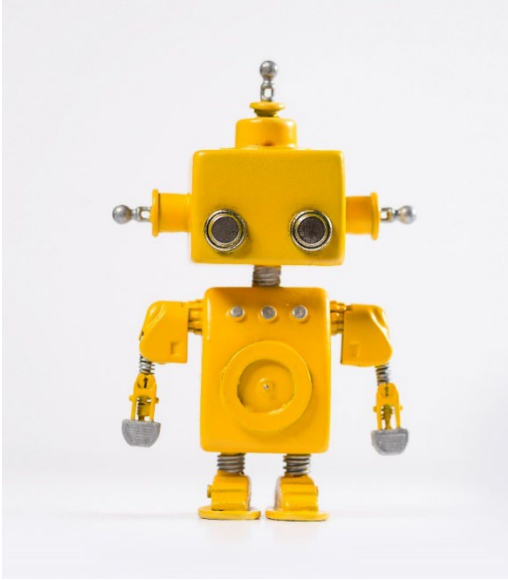
- https://www.tga.gov.au/sites/default/files/medical-device-cyber-security-guidance-industry.pdf
- Total product life cycle
- Applying the Essential Principles
- Relevant standards
- Strategies for risk management
- Design and testing considerations
- Supply chain and platform security
- Post market monitoring, response and change control



AI in medical devices

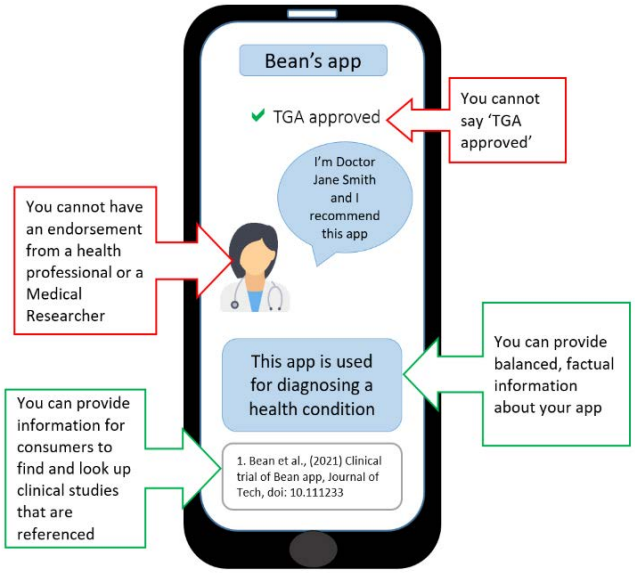
- If a product uses AI (or not) does not affect whether it would be considered a medical device – it depends on what the AI is doing (same for risk classification)

- **It is important for supporting evidence:**
  - Use standards appropriate to technology
  - How have you ensured that the product is fit for purpose, effective and safe?



Advertising medical devices

- Different requirements for advertising to consumers and health professionals
- **What can't be said in consumer ads:**
  - You cannot say "TGA approved"
  - You cannot have endorsements or testimonials from a health professional or medical researcher
  - You cannot make unsubstantiated claims about your software
  - You cannot make claims that are beyond the scope of the software



Questions

Australian Government

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Questions

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Contact

- devices@health.gov.au
- 1800 141 144
- tga.gov.au/medical-devices-ivds

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Upcoming Events

- 22 Sept – **Growing the Active MedTech Industry** by MTP Connect
- 13 Oct -- **Hazards Analysis** by Genesys
- 27 October – **Materials Selection and Manfuacturing** by Romar Engineering
- 10 Nov -- **SAMD** with TGA & CSIRO
- 24 Nov – **Cybersecurity** with CSIRO
- **Special: MTP Connect is subsidising an ISO 13485 educational over 4 days for just $440. See their events page**

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