Medical Devices Surveillance Branch

Regulatory update

Fiona McCormack
Director, Devices Emerging Technology &

Maria Ong
Director, Devices Vigilance and Monitoring

Medical Devices Surveillance Branch
Department of Health and Aged Care, TGA

Agenda

MDSB who we are

Overview of how TGA regulates SaMD and AIaMD

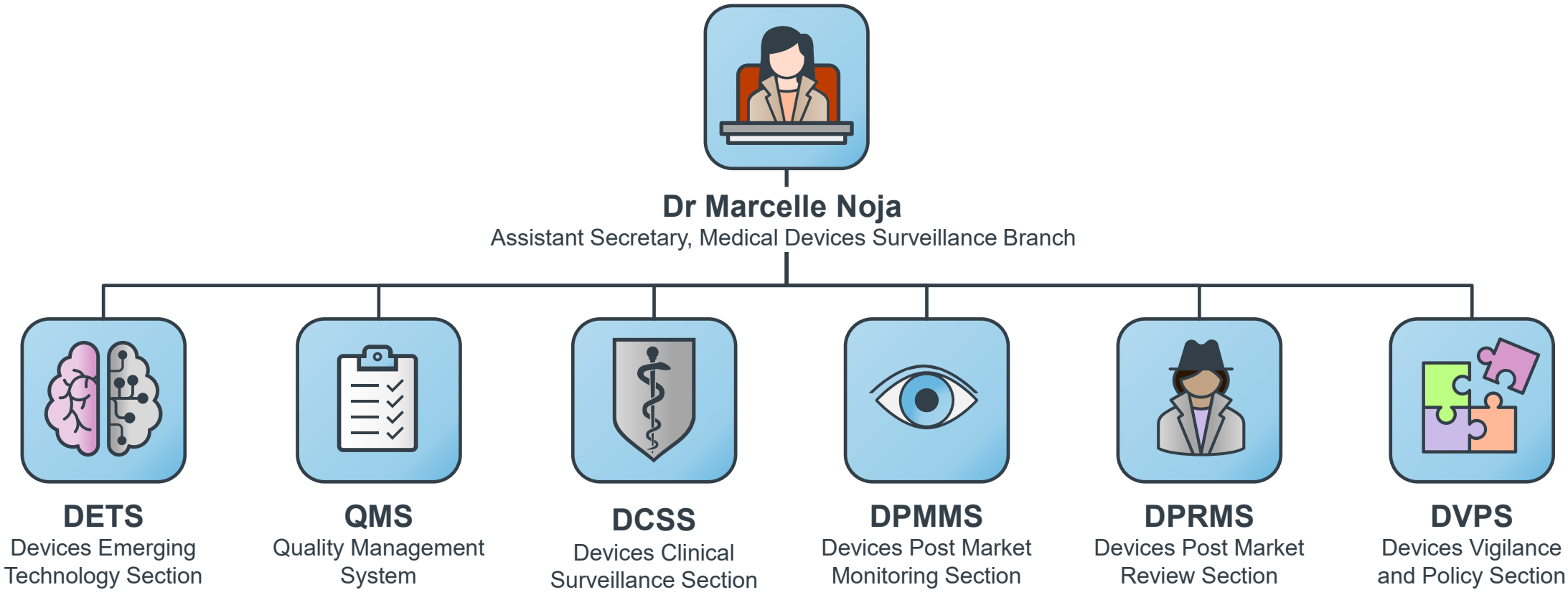
AI Review

Recent activities

Medical Devices Vigilance program

Mandatory Reporting by Healthcare facilities

Medical Devices Surveillance Branch – who we are



Software and AI
Update on recent activities

Overview of how TGA regulates SaMD and AIaMD

AI Review

Recent activities

Is my software a medical device?

Software is a medical device when the manufacturer **intends** for their product to be used for: diagnosis, **prevention, monitoring, prediction, prognosis** or
treatment of a disease, injury or disability.

Software as a medical device (SaMD)…

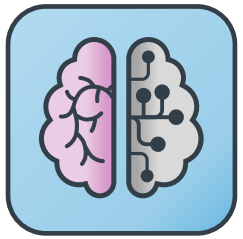
- Depends on the manufacturer's intended purpose
- Is technology agnostic (AI, ML, bioinformatic pipeline, etc)
- Is not based on how it is supplied (online, in hardware, app, cloud-based, etc)

Not all health-related software is a medical device

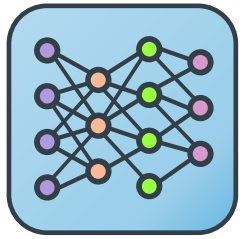
AI is regulated as a subset of medical devices

What is artificial intelligence (AI)?

AI-based systems are a subset of software that use computer programming to perform tasks that mimic human capabilities, such as understanding language, recognising objects and sounds, learning and problem solving. AI may be further broken down into subsets including:



Machine learning (ML)



Deep learning

Generative AI

Large language models (LLM)

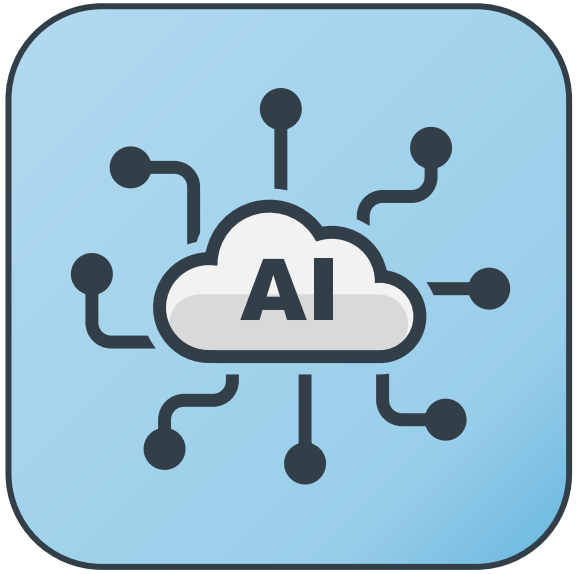
Neural networks

The regulations that apply to software-based medical devices also apply to **all subsets of AI-based software systems** that meet the **definition of a medical device.**

Artificial Intelligence

Clarifying and Strengthening regulations

- Government has initiated a review of artificial intelligence (AI) across the Australian economy
- Multiple agencies will address priority areas, including the Department of Health and Aged Care
- Detailed review of the legislation to identify gaps and opportunities relating to AI
- Targeted stakeholder and public consultation
- Output will include a report to be delivered to government containing the results of our review and options for reform



Regulatory amendments – exempt and excluded

The 2021 regulatory amendments provided for some software-based medical devices (including certain CDSS software) to be **exempt** from ARTG inclusion and **excluded** other software from the TGA's regulatory framework

Exempt

The product **is a medical device** but is only subject to limited regulatory requirements relating to compliance with the Essential Principles, advertising and adverse event reporting. ARTG inclusion of devices is not required

Excluded

The product is **not considered a medical device** and is not regulated by the TGA. Excluded devices must comply with Australian Consumer and Advertising Laws

Excluded software

There are 15 conditional exclusions (in 6 groups) that may capture certain software-based devices:

Consumer health products
(e.g. wellness apps, fitness heart rate monitors, medication reminders)

Digitisation
(e.g. digital versions of paper-based patient surveys)

Population-based analytics
(e.g. research or population-based screening – bowel cancer program)

Digital mental health tools
(e.g. meditation and mindfulness applications, CBT)

Enabling technology
(e.g. telehealth and eScript software)

Laboratory Information Management Systems
(e.g. workflow automation software, pathology reporting)

Exempt CDSS software

There are exemptions for certain CDSS software that are:

- ***intended*** *by its manufacturer 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*
- ***not intended*** *by its manufacturer to directly process or analyse a medical image or signal from another medical device; and*
- ***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.*

Schedule 4 Part 2 Item 2.15 of the Regulations

Not all CDSS software is exempt

Software that does not meet the exemption criteria must be included in the ARTG

These kinds of software include but are not limited to:

- Consumer or patient-facing products
- IVD software or software-related diagnostic products
- Products labelled as CDSS software that:
  - make a diagnosis or treatment decision
  - process signals or medical images from other medical devices, and/or use opaque methods that are not accessible or interpretable by a health professional to enable them to make an informed clinical decision

Clarification of how CDSS software is regulated

Consultation recently undertaken proposes to clarify what CDSS software medical devices are low risk, and the requirements for these devices:

- The introduction of a definition for CDSS software.
- Amending the exemption criteria to improve clarity regarding diagnostic treatment decisions, and to ensure transparency of the product's calculation or logic to enable verification of any recommendations by th health professional.
- The improvement of existing, and development of new, guidance and resources to assist stakeholders with understanding how CDSS softwa regulated

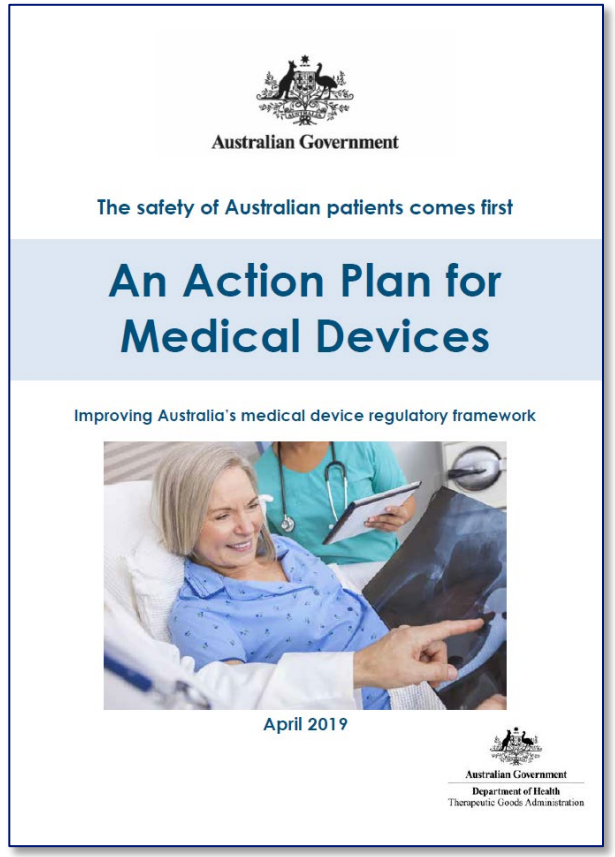
Proposed clarification of how CDSS software is regulated – see TGA website: https://www.tga.gov.au/resources/consultation/consultation-clarification-how-clinical-decision-support-system-cdss-software-regulated

For further information, contact digital.devices@tga.cov.au

SaMD IT project for capture and display functionality

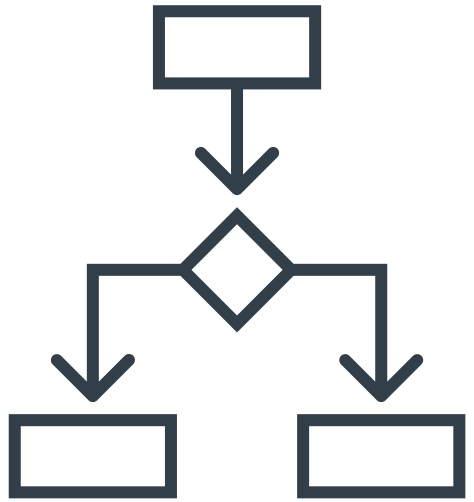
The ability to identify medical devices

- Need for improved systems for identification of medical devices, for users, their families and health care professionals
- TGA has undertaken to provide more transparency about software-based devices, including AI-enabled devices
- Government policy approval obtained in 2022 to make changes to IT functionality, for both stand-alone software (SaMD) and software incorporated in devices



SaMD IT project for capture and display functionality

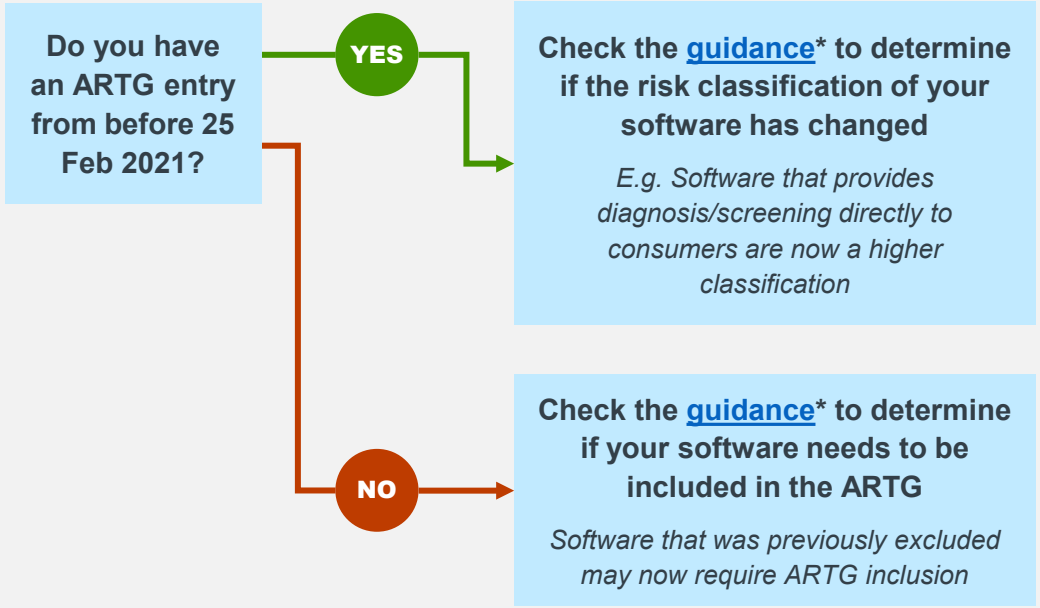
- IT changes are progressing to include the ability to collect software related information at the time of application for inclusion in the ARTG
- Development allows for a staged roll-out
- Includes identification of SaMD, Medical Devices that incorporate software, artificial intelligence (AI) or machine learning, cloud-based components
- Timing and additional features, including collection of more detailed software-related information, and providing options for information to be searchable in the ARTG public summary is subject to further consultation and related regulatory changes



Regulatory changes to software based medical devices

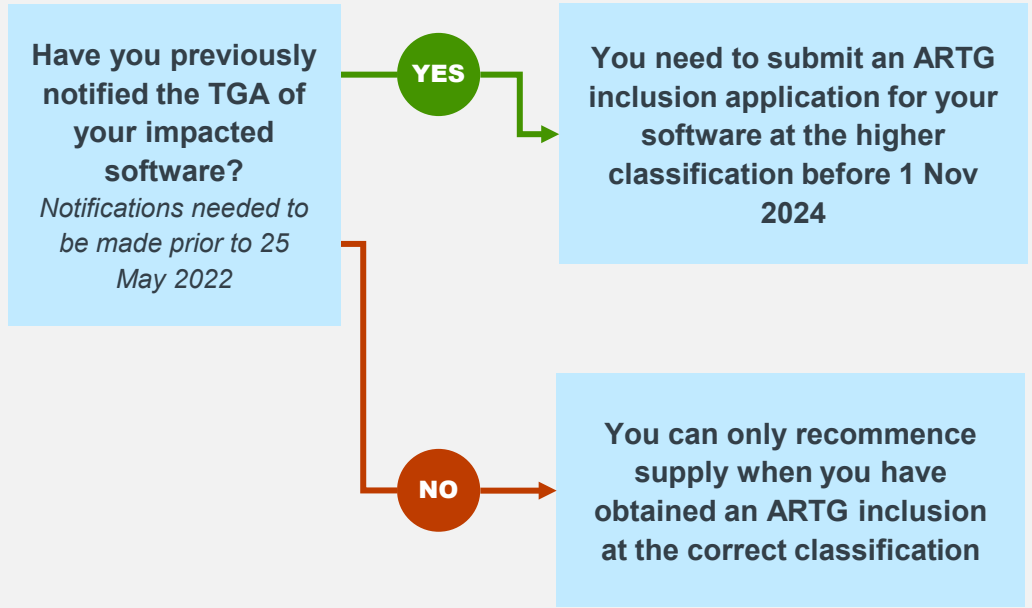
Regulatory changes to software based devices took effect from 25 February 2021. New classification rules for software were introduced and some now have a higher risk classification. Sponsors will need to take action to continue supply in Australia.

Am I **impacted**?



My software **is impacted**

What do I need to do?



Further questions?
Contact the TGA at digital.devices@health.gov.au

*Guidance: https://www.tga.gov.au/resources/resource/guidance/regulatory-changes-software-based-medical-devices

Medical Device Supply Disruption program

- Disruptions to supply may occur for a variety of reasons
    - shortage of raw material or supply chain disruptions, discontinuations, and unexpected surge in demand
- Dedicated team established in Aug 2023 to monitor, manage and follow up signals of national supply disruptions.
- The priority and urgency of a supply disruption signal is assessed by:
    - Contacting the sponsor to confirm the signal and to obtain an estimate of the impact and anticipated duration.
    - Seeking information about alternative devices and their availability.
    - Communicating with jurisdictions to assess the impact to clinical services and patients.
- Supply disruptions limited to local regions are managed by the impacted jurisdiction or private health facility.
- Sponsors can assist in shortages by maintain updated stock and supply info with their suppliers, and voluntarily reporting disruptions and discontinuations to the TGA, and providing updates to customers

Vigilance Program and Mandatory Reporting of Adverse Events by Healthcare Facilities

Maria Ong
Director, Devices Vigilance and Policy Section
Medical Devices Surveillance Branch
Department of Health and Aged Care, TGA

Action Plan for Medical Devices

1. Improve how new devices get on the market in Australia
2. Strengthen monitoring and follow up of devices already in use
3. Provide more information to patients about the devices they use

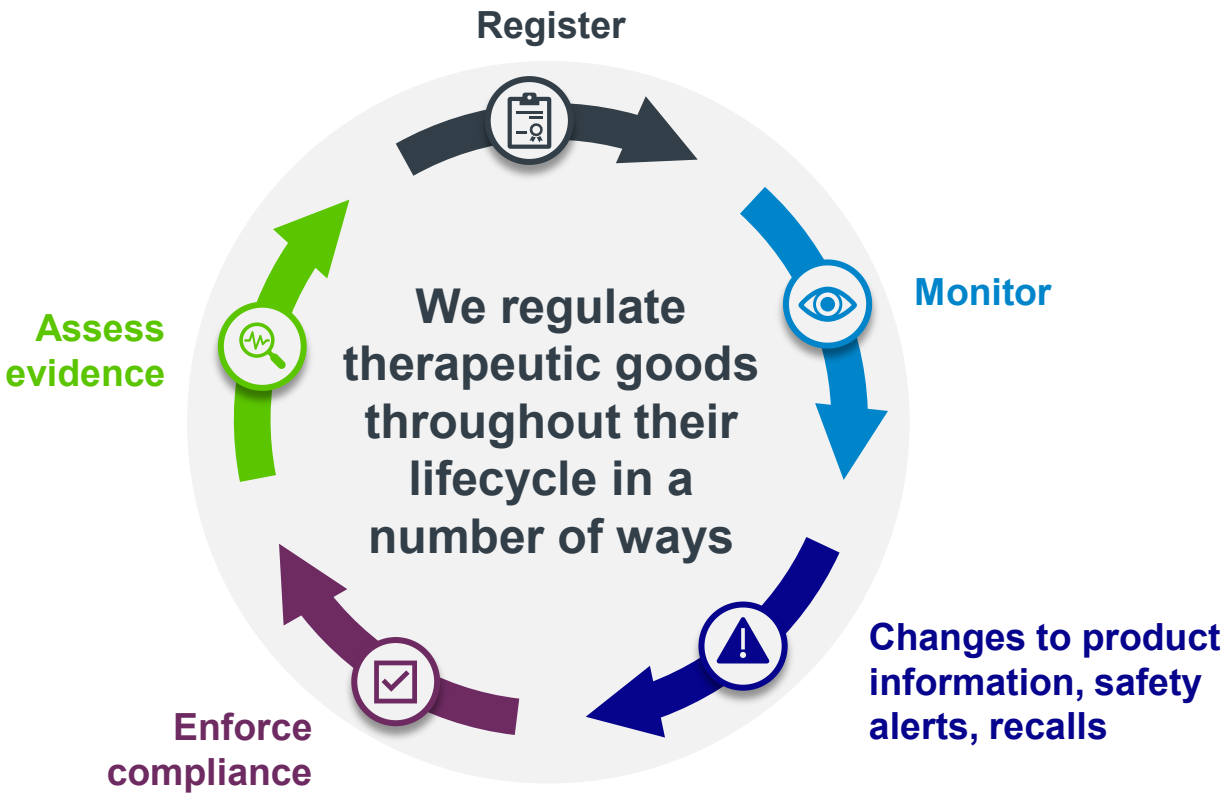
Key projects progressing under Strategy 2 and 3

- Medical Devices Vigilance Program (MDVP)
- Mandatory reporting of medical device adverse events by healthcare facilities
- Consumer engagement on regulatory reforms

What is an ‘adverse event’?

- An event that resulted in serious injury, illness or death to patient, healthcare worker or other person
- A medical device adverse event is an event associated (caused or partially attributable) with the use (or misuse) of a medical device
- Faults that may affect the quality, timeliness and cost-effectiveness such as, problems with getting the device to operate, repeated repairs, device design and difficulty of use

Regulating throughout the lifecycle



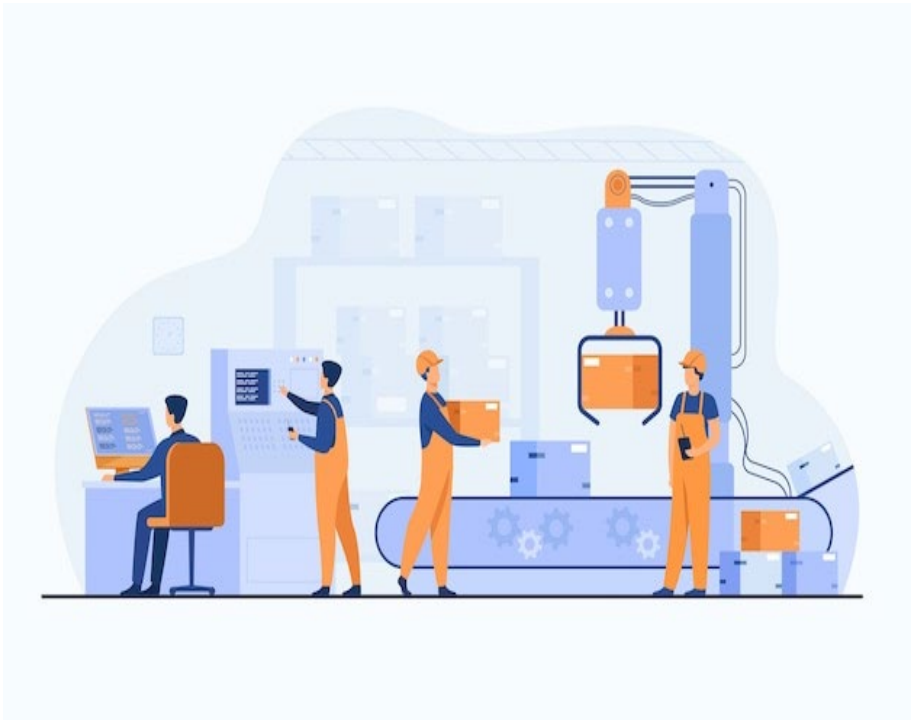
Post-Market Obligations

- Post-market performance is monitored for trends or issues not previously known
- Medical devices are subject to conditions of inclusion
- Medical devices can be subjected to post-market review or investigations at any time
- Summary available on the TGA website

Manufacturer responsibility

Manufacturer - the person who is responsible for the design, production, packaging and labelling of the device before it is supplied under the person's name

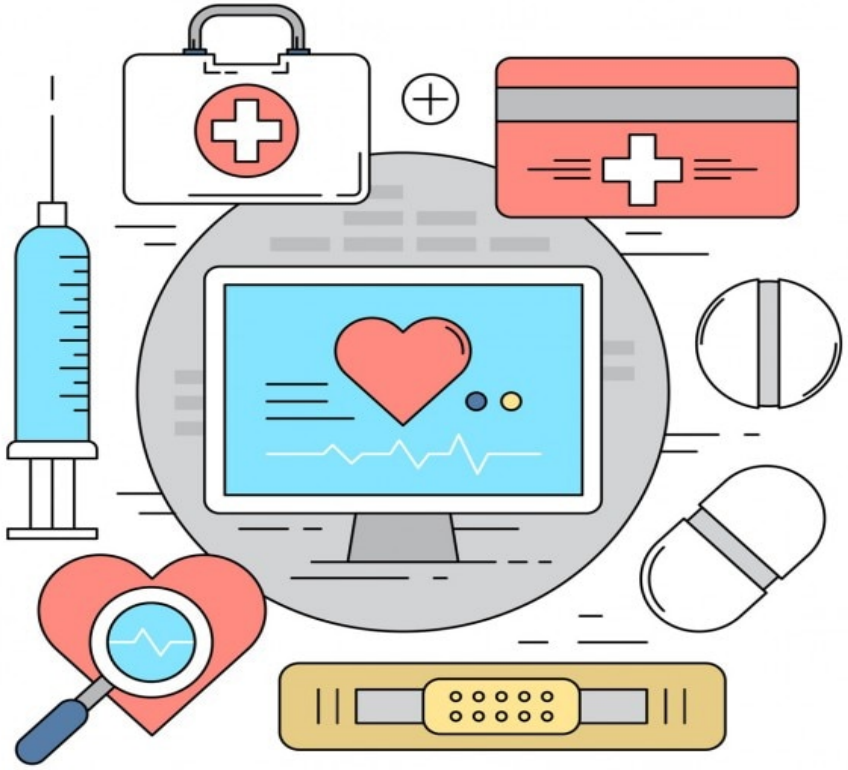
- Allow entry and inspections of premises
- Demonstrate compliance with essential principles
- Demonstrate and maintain compliance with conformity assessment procedures (CAP)
- Notify TGA of substantial changes in design, production or changes to CAP
- Maintain records of complaints, adverse event records and post-market action
- Undertake investigations and implement actions based on post-market experience, including recalls



Sponsor responsibility

Sponsor - person who arranges for import, export and supply of therapeutic goods in Australia

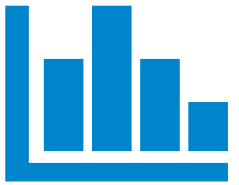
- TGA's point of contact for regulation, legal entity for post-market action
- Arrange for import/ export/ supply of goods in Australia
- Have written agreement with manufacturer to obtain information when requested by the TGA
- Deliver samples upon request
- Facilitate Australian recall actions
- Comply with the Therapeutic Goods Advertising Code
- Pay annual charges



Examples of TGA post-market activities

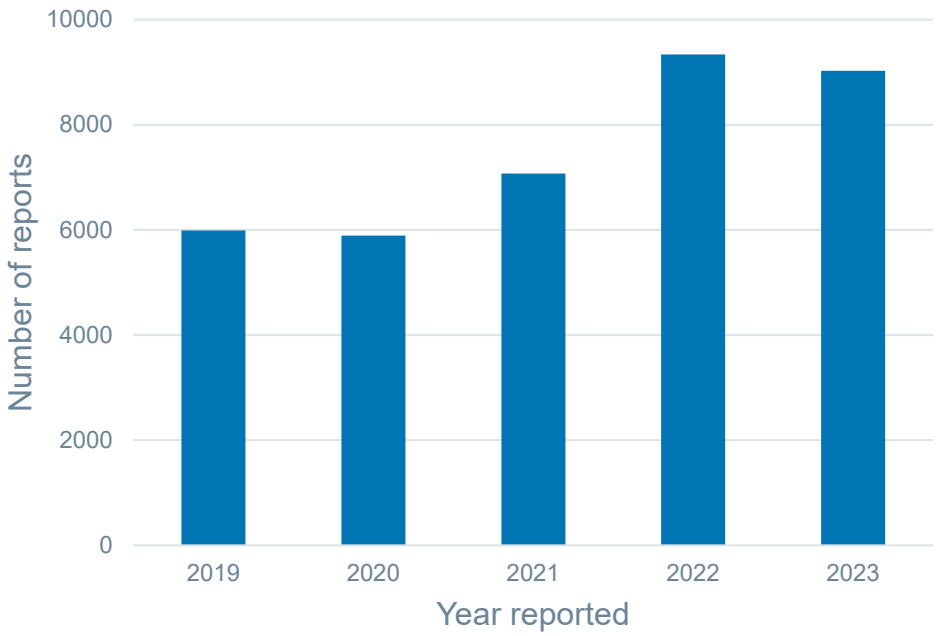
The TGA has a variety of processes for managing ongoing compliance

- Device incident reports
- Product investigations or post-market review
- Desktop and/ or on-site inspections
- Review annual reports (Class IIb implantable, Class III and Class 4 IVD)
- Impose / vary additional conditions of inclusion
- Consent to supply products that don't meet Essential Principles
- Recall actions
- Ongoing surveillance and exchange of information with other agencies, international regulators / notified bodies.



Adverse event surveillance

- The TGA received ~300 reports annually when first implemented market surveillance activities, now >9,000 reports per year
- Additional sources from state and territory mandatory reporting
- How do we effectively manage risk to patients and users in the face of increased reporting?
  - data analytics and trending
  - analysis of adverse event outcome experience
  - focused risk assessment on specific report source or risk criteria
  - focus on non-compliance (e.g. lack of reports)
  - decreased manual risk assessment and increased investigation



Medical Devices Vigilance Program (MDVP)

- Enables proactive post-market vigilance of medical devices
- Will complement and support recent regulatory changes that enabled the acceptance of marketing approvals and certificates from comparable overseas regulators as evidence
- Will complement and enhance existing post-market surveillance activities

MDVP Pilot Timeline

Pilot Commence - education webinar

Sponsor Vigilance Self-Assessment Tool

Review SAT responses and regulatory information

Desktop audits – requests for information

On-site inspections – inspection plans

MDVP review and evaluation

Government approval

September 2023	Nov – Dec 2023	Nov – Dec 2023	Jan – April 2024	Jun – Nov 2024	Nov 2024	Dec 2024
Seek volunteer sponsors	Gather information on sponsors' understanding and compliance to regulations	Risk assessment and selection of sponsors to progress to next stage	Review sponsors' documents and records	Conduct on-site inspections, inspection reports and close-outs	Identify areas for modification and improvement of the MDVP	Advice to government on transitioning to a permanent and mandatory program

MDVP Findings to Date

Desktop audits, on-site inspections and feedback from participants

Feedback from participants (Self-Assessment Tool & Requests for Information)

- Require longer time-period for completion & return of requests for information to TGA

Desktop audits – high level observations (Feb-Apr 2024)

- Majority of sponsors have documented procedures in place covering regulatory requirements, processes, roles and responsibilities
- Majority of sponsors have written agreements with legal manufactures in place
- Some local sponsor procedures lack detail on Australian regulatory requirements e.g. Adverse event reporting to TGA, new sponsors
- Some written agreements appear to lack detail on Australian regulatory requirements, missing or have significant gaps e.g. adverse events and recalls

MDVP Next steps....

On-site Inspections (July-Nov 2024)

- Desktop audit outcome letters
- Sponsors to be contacted to discuss logistics and expectations
- Confirmation letter – confirming inspection details
- MDVP - Inspection preparation
- Sponsors – 4-6 weeks lead time prior to inspection
- Conduct on-site inspection
- Inspection Report
- Inspection follow-up (sponsor Response and Corrective Action Plan to address any deficiencies)
- Inspection Close-out

Mandatory reporting of medical device adverse events by healthcare facilities – background

- Senate Inquiry into the number of women in Australia who have had transvaginal mesh implants and related matters
- TGA consultation paper- Majority of respondents expressed broad support
- Reform activity aimed at improving patient safety through data driven signal detection
- Amendments to the *Therapeutic Goods Act 1989*- royal assent on 21 March 2023
- *Currently*: TGA consulting the jurisdiction, regulation impact analysis and IT options

What to report?

1. An incident that lead to the death of a patient or user
2. An incident that lead to serious injury or deterioration of health
3. The use of the device could have resulted in serious injury or death (near misses)
4. An incident that resulted in treatment or surgery that could be related to a medical device

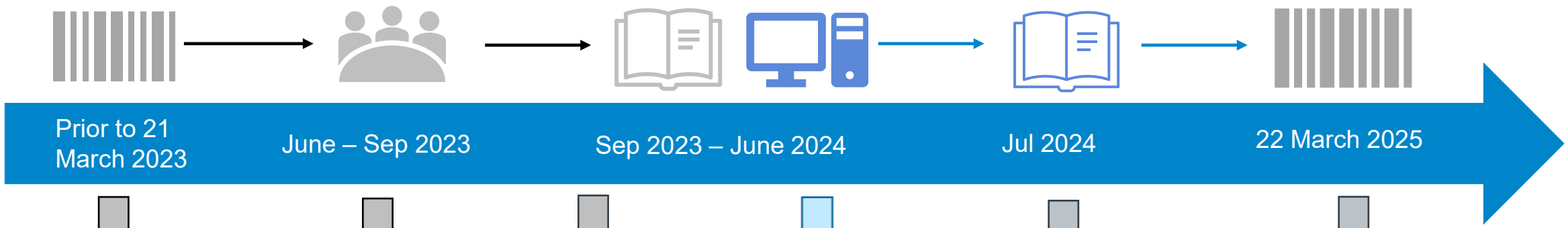
Who needs to report?

The CEO or equivalent officers of hospitals and healthcare facilities to report serious adverse events to the TGA

The exemption to this rule is if they have already reported the adverse event to one of the following:

- the CEO of the Commission
- the head of a state or territory department responsible for health-related matters or
- any other person prescribed in the regulations.

Mandatory Reporting Timeline



Obligation for sponsors, manufacturers; voluntary for healthcare facilities

Stakeholder roundtables

Establish interjurisdictional steering committee

Interjurisdictional consultations, analyse regulatory impacts and commence work on IT options

Commence amendments to regulations, develop standards, education/ communication material

Regulations - obligation for sponsors, manufacturers and healthcare facilities

Website and link references

Clinical trials	https://www.tga.gov.au/clinical-trials
Clinical trials handbook	https://www.tga.gov.au/resource/australian-clinical-trial-handbook
Role of the sponsor	https://www.tga.gov.au/role-sponsor
Priority determination for prescription medicines	https://www.tga.gov.au/publication/priority-determination-eligibility-criteria
Provisional approval for prescription medicines	https://www.tga.gov.au/provisional-approval-pathway-prescription-medicines
ARTG	https://www.tga.gov.au/australian-register-therapeutic-goods
How we regulate medicines	https://www.tga.gov.au/how-we-regulate-medicines
Compliance management	https://www.tga.gov.au/hubs/compliance-and-enforcement/compliance-management
TGA guidelines email list	https://www.tga.gov.au/tga-guidelines-email-list
TGA business services	https://www.tga.gov.au/tga-business-services
Schedule of fees and charges	https://www.tga.gov.au/schedule-fees-and-charges

Questions?

www.tga.gov.au

Therapeutic Goods Administration (TGA)

Exhibition booth **No.1**

Want to chat with me further? Come visit us.

2024 ARCS ANNUAL CONFERENCE

Stay connected

Subscribe to updates

Social media

LinkedIn

X (Twitter)

YouTube

Instagram

Facebook

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration