Regulatory Update from the Medical Devices Surveillance Branch-Medical Devices Vigilance Program and Mandatory Reporting of Adverse Events by Healthcare Facilities

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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

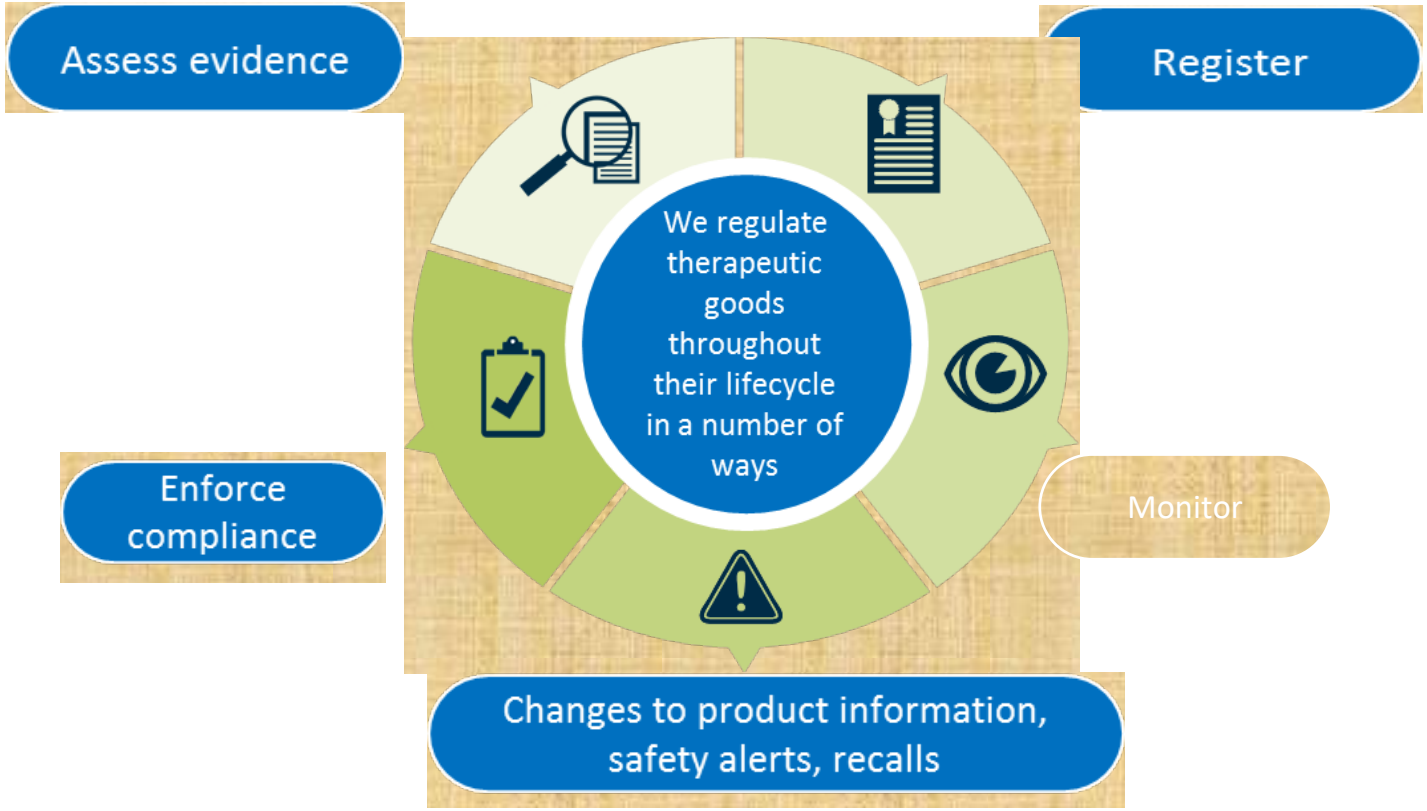
Key projects progressing under Strategy 2 and 3

- 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

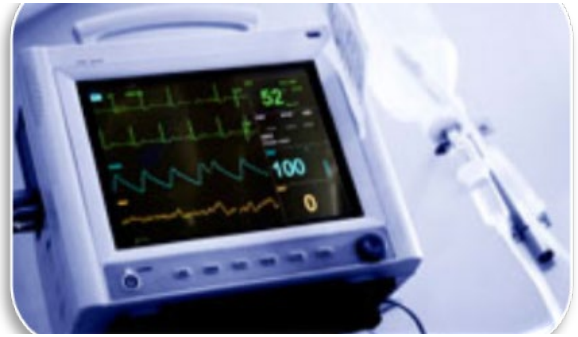
Sponsor responsibility

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

Sponsor – mandatory reporting obligations

- Sponsors must report the details of events associated with their medical device(s) that have resulted, or could have resulted, in serious injury or death
- 41MP & 41MPA refers to reporting information related to malfunction or deterioration in characteristics or performance of a device
- Conditions of inclusion
  - *Therapeutic Goods Act 1989* (41FN(3),(d) and 41MP(2) & 41MPA)
  - *Therapeutic Goods (Medical Devices) Regulations 2002* (Reg 5.7)



It is often difficult to determine whether an adverse event was caused by a medical device.

- Causality of the event does not need to be established at the time of reporting
- When in doubt it is better to report than not to report

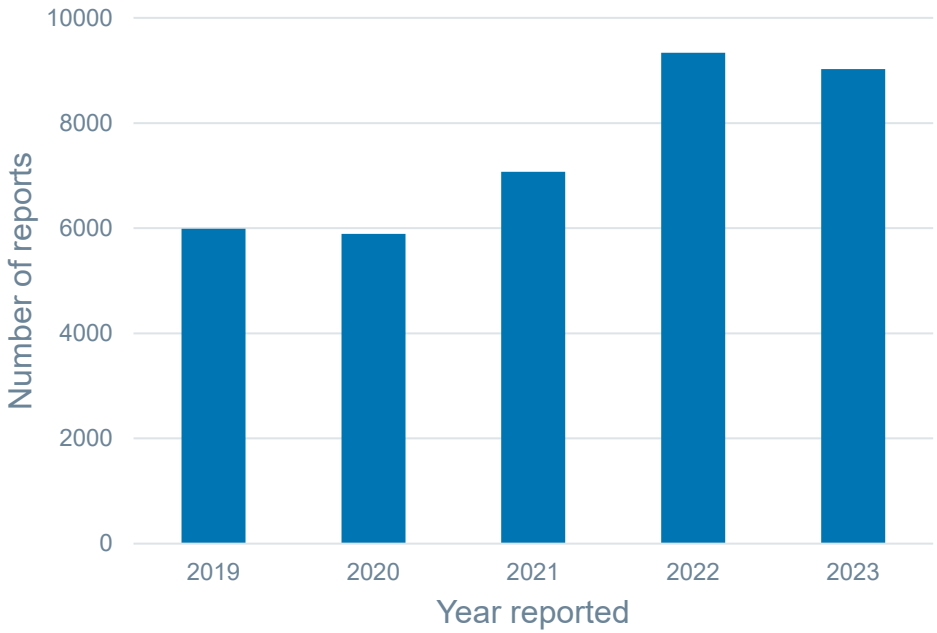
Examples of TGA post-market activities

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.

Future of 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

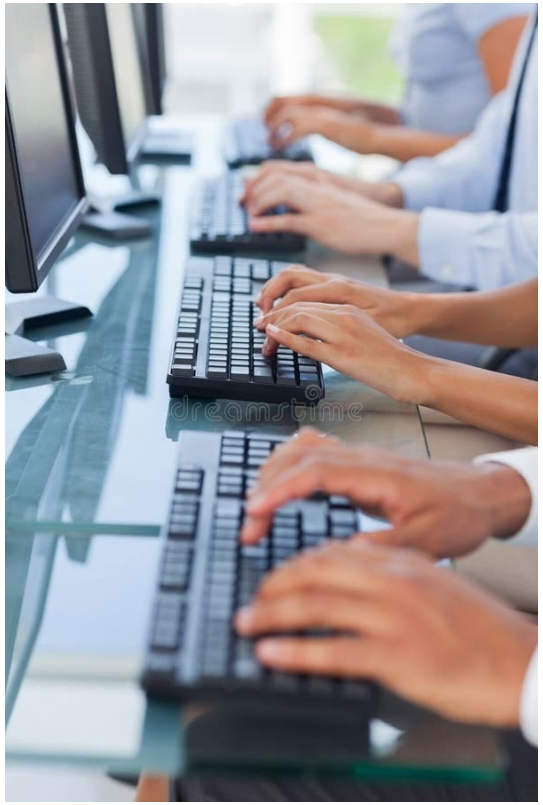
Desktop audits – high level observations (Feb-Apr 2024)

- 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
- Some written agreements appear to lack detail on Australian regulatory requirements, missing or have significant gaps e.g. adverse events and recalls

MDVP Findings to Date

Desktop audits continued (Feb-Apr 2024)

- Potential lack of understanding / experience of ***new sponsors*** regarding Australian regulatory requirements
- Impact of organisational change regarding documentation, roles and responsibilities
- Not reporting adverse events per Australian requirements
- Records anomalies – ARTG, written agreements, e.g. addresses



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

Prior to 21 March 2023

Obligation for sponsors, manufacturers; voluntary for healthcare facilities

June – Sep 2023

Stakeholder roundtables

Sep 2023 – June 2024

Establish interjurisdictional steering committee

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

Jul 2024

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

22 March 2025

Regulations - obligation for sponsors, manufacturers and healthcare facilities

Therapeutic Goods Administration (TGA)

Exhibition booth **No.1**

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