IMDRF International Medical Device Regulators Forum

Regulatory update from Australia

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Overview

- **An Action Plan for Medical Device**
  - Medical Device Vigilance Program (MDVP)
  - Point-of-Care Manufacturing of medical devices
  - Proposed Application Audit Framework for Medical Devices
  - Mandatory Reporting of adverse events by healthcare facilities
- **TGA Strategic Activities and Transformation**

An Action Plan for Medical Devices

Continues to guide medical device reforms that:

- strengthen our regulatory system
- remains patient focused
- provides greater transparency: and
- increases public confidence in Australia's medical device regulatory system.

Also takes account of international harmonisation efforts.

The three strategies in the Action Plan are:

1. Pre-market medical device reforms - improve how new devices get on the market
2. Post-market medical device reforms - strengthen monitoring and follow-up of devices already in use (focus for 2022-2024)
3. Consumer focused reforms - provide more information to patients about the devices they use

[An Action Plan for Medical Devices | Therapeutic Goods Administration (TGA)]

[Action Plan for Medical Devices - Progress Report Card: December 2022]

The Medical Devices Vigilance Program (MDVP)

The MDVP was developed after receiving public and Government support of the proposal – 2020 *Proposed enhancements to adverse event reporting for medical devices* consultation paper.

The MDVP will complement and enhance existing post-market surveillance activities:

- with an educational self-assessment tool - a resource for sponsors and a screening tool for the TGA
- through desktop audits and on-site inspections that will review and confirm compliance with post-market regulatory requirements.

Medical Device Vigilance Program (MDVP)

- MDVP pilot commenced 14 September 2023
- Sponsors will complete the Sponsor Vigilance Self-Assessment Tool containing 18 questions
- TGA will take a risk based approach to selecting sponsors for the desktop audits and inspections
- On-site inspections, reviewing systems and procedures to demonstrate compliance
- A MDVP Inspection Report will be provided to sponsors summarising findings

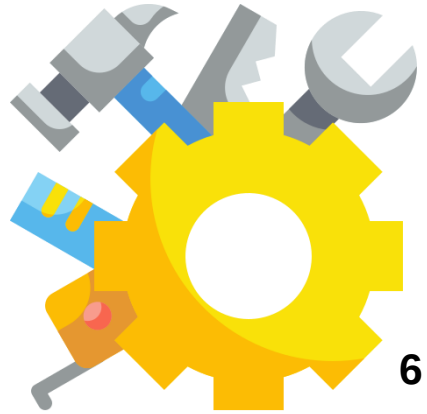
Point of Care Manufacturing of Medical Devices

TGA is focusing on how the Personalised Medical Devices Framework applies to manufacturing at the point-of-care to ensure regulation is appropriate without introducing unnecessary burden for point-of-care facilities.

Four surveys conducted (mid 2023) about point of care manufacturing activities in four sectors:

- Allied health sector
- Dental sector
- Manufacturing hubs at the point-of-care
- Hospital and healthcare facilities

Medical devices manufactured at the point-of-care - Analysis of survey results by sector | Therapeutic Goods Administration (TGA)



Point of Care Manufacturing of Medical Devices

Overview and insights

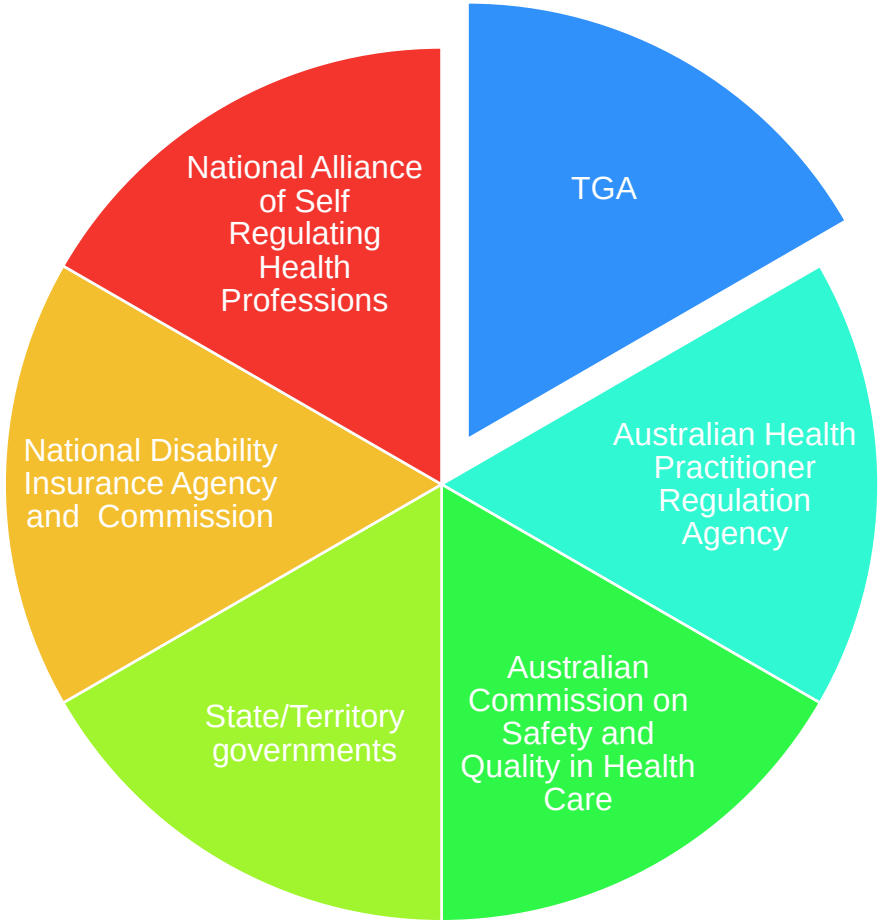
- Many healthcare professionals and practitioners did not realise they are regulated by TGA
- Many are not compliant with existing TGA regulatory requirements
- In many cases manufacturing models differ from mass-production and commercial models
- Increasingly the manufacture of devices is not aligned with the training of the healthcare practitioner/professional
- Requiring many stakeholders in healthcare sectors to comply with current regulatory requirements is likely to disrupt supply and cause impacts on consumers/patients

"Direct communication and engagement between the TGA and State, Health Service and Hospital Governance Teams is required to meet regulatory requirements. There appears to be very limited understanding on what the regulatory obligations are for personalised medical devices produced within public health services."

Point of Care Manufacturing of Medical Devices

National symposium held June 2023

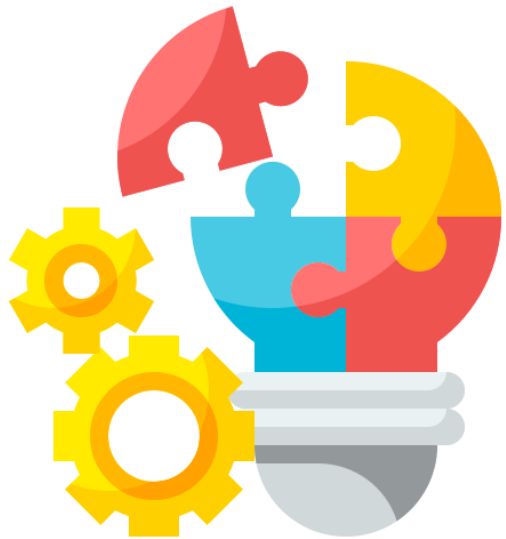
- What devices are made at the point of care?
- Who is making them?
- What are the risks associated with these devices?
- What is the most appropriate way to manage them?
- Who is best placed to regulate?



Point of Care Manufacturing of Medical Devices

The work ahead

- Over-arching steering committee
- Sector-specific working groups
- Mapping existing frameworks
- Identifying gaps
- Changes to frameworks
- Implementation, communication and education



Proposed Application Audit Framework

Before medical devices can be supplied in Australia, an application needs to be submitted to the TGA and approved to include the product in the Australian Register of Therapeutic Goods (ARTG).

We assess the application against the *Therapeutic Goods Act 1989* and the *Therapeutic Goods (Medical Devices) Regulations 2002*. Some applications are audited, which is a more thorough review/assessment.

Currently reviewing the framework for how applications for audit are selected and conducted – due to:

- changes to the EU regulations, including enhanced standards, processes, and clinical evaluation requirements
- regulatory amendments in Australia to enhance recognition of MDR certificates vs MDD certificates
- concerns raised by industry about existing processes, timeframes, and predictability
- a need to flexibly target our premarket assessment resources to areas of risk

Proposed Application Audit Framework

The audit framework needs to allow regulatory effort to be aligned with risk and be streamlined to reduce regulatory burden and cost.

The proposed new application audit framework aims to:

- enable a more responsive, risk-based approach to selecting applications for audit, based on post-market signals, regulatory reforms, and regulatory intelligence
- provide more predictability and transparency regarding types of applications likely to be selected for audit, their focus and expected timeframes
- appropriately target regulatory effort
- analyse trends and enable findings to inform advice to industry about the quality of applications and continuous improvement of the audit framework.

Mandatory Reporting of medical device adverse events by healthcare facilities

The *Therapeutic Goods Act 1989* was amended in March 2023 making **it mandatory for Australian** public and private hospitals and any other **health facilities** (prescribed by regulations) to **report medical device related adverse events** to the TGA.

Regulations to support implementation due by **March 2025**.

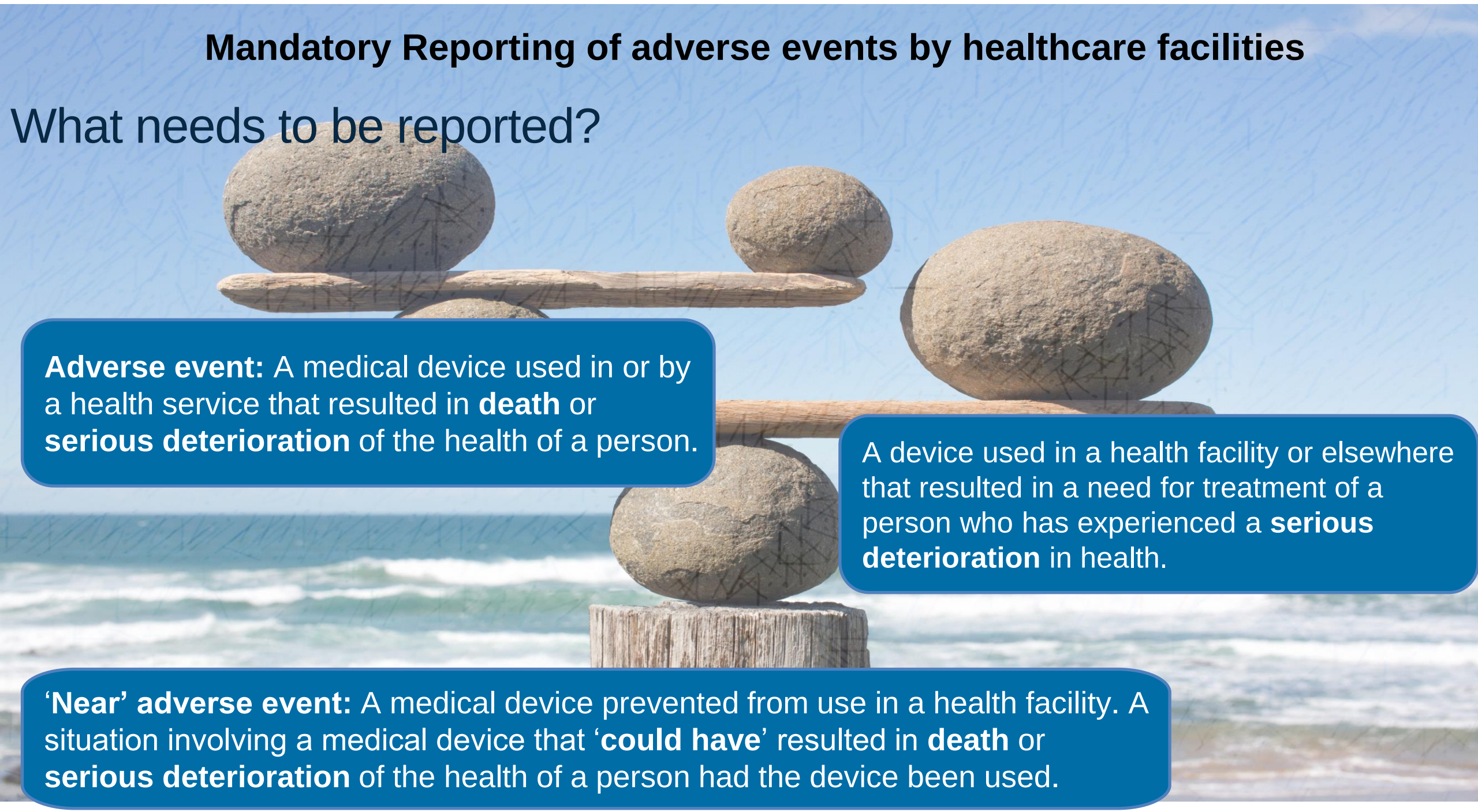
In parallel, the Australian Commission on Safety and Quality in Health Care will update the National Safety and Quality Health Service Standards to include mandatory reporting of medical device adverse events to the TGA.

Why the change? Lack of reports impacting surveillance capability

- metal hip prosthesis
- breast implants
- trans-vaginal mesh implants

Mandatory Reporting of adverse events by healthcare facilities

What needs to be reported?



Adverse event: A medical device used in or by a health service that resulted in **death** or **serious deterioration** of the health of a person.

A device used in a health facility or elsewhere that resulted in a need for treatment of a person who has experienced a **serious deterioration** in health.

‘**Near’ adverse event:** A medical device prevented from use in a health facility. A situation involving a medical device that ‘**could have**’ resulted in **death** or **serious deterioration** of the health of a person had the device been used.

Mandatory Reporting of adverse events by health care facilities

Next steps

- **Complete discussions with hospital stakeholders**
- **Consolidation of information and follow-up**
- **Develop proposed Implementation Strategy & Options**
- **Undertake Regulatory impact analysis**
- **Consult on Regulatory amendments**
- **Identify IT solutions and data transfer processes to support implementation**
- **Draft Guidance & other resources**

TGA Strategic Activities

Strategic priorities

A focus on four strategic priorities to foster international partnerships:

- Global policy alignment
- Pre-market global collaboration
- Post-market global monitoring
- Regional regulatory capabilities

Activities for this include:

- Continued engagement, domestically and internationally
  - to build flexible and robust regulatory evaluation processes to ensure rapid access for Australian patients and healthcare professionals without compromising our regulatory standards
- Working with National Regulatory Authorities within the Pacific and South East Asia
  - to strengthen regulatory systems, for faster access to products for communicable diseases and reducing supply of products that are of poor quality or present health risks.

TGA Transformation

- The Transformation Program's purpose is to reduce the regulatory burden to make it easier and simpler to do business with the TGA. Examples:
  - Modernise the TGA website to make it easier to access regulatory information
  - Single portal for all interactions and business with the TGA with new authentication processes
  - Future improvements to the Australian Register of Therapeutic Goods (ARTG) search experience and data quality - remediating errors and establishing long term improvements.

- Medical Device IT specific projects
  - Enhance Australian Unique Device Identification Database (AusUDID) to provide storage and online access options for Patient Information Leaflets (PILs), and Electronic Instructions for Use (eIFU)
  - Enhance Clinical Trials Notification form to improve data collection to allow better oversight, improved monitoring to ensure of the safety of medical device clinical trials without adding regulatory burden.

Personalized Medical Devices (PMD) Working Group Update

Publications

- Definitions for Personalized Medical Devices (IMDRF/PMD WG/ N49) *Published November 2018*
- Personalized Medical Devices – Production V&V (IMDRF/PMD WG/ N74) *Published April 2023*
- Personalized Medical Devices – Regulatory Pathways (IMDRF/PMD WG/ N58) *Published September 2023*

Personalized Medical Devices (PMD) Working Group Update

PMD Production Verification & Validation (N74)

- Document published 11 April 2023
- Builds on the definitions and concepts in N49 Definitions of Personalized Medical Devices and N58 Personalized Medical Devices – Regulatory Pathways
- Technical guidance on verification and validation aspects of

  - specified design envelope (patient-matched medical devices)

  - medical device production systems

PMD Regulatory Pathways (N58) – Revisions

- Scope of N58 revisions include:
  - revising the MDPS definition and framework to better represent real world applications, and facilitate its adoption
  - expanding the scope of Appendix 2 to incorporate a broad range of devices, not limited to PMDs
- Feedback from public consultation (Sept – Nov 2022) considered in developing the revised N58
- Revisions approved for publication by the MC, published in September 2023

Opportunities and Challenges

- Developing timely and fit-for-purpose recommendations to address risks introduced by new and emerging technologies in PMDs
- Consistent interpretation and understanding of the document by all stakeholders
- WG intends to:
  - promote IMDRF PMD documents and educate stakeholders
  - develop training/guidance materials for stakeholders in line with N76 recommendations
  - monitor implementation and collect feedback
- Inviting stakeholders to provide suggestions on developing effective training and guidance materials to ensure consistent interpretation of the documents


Thank you