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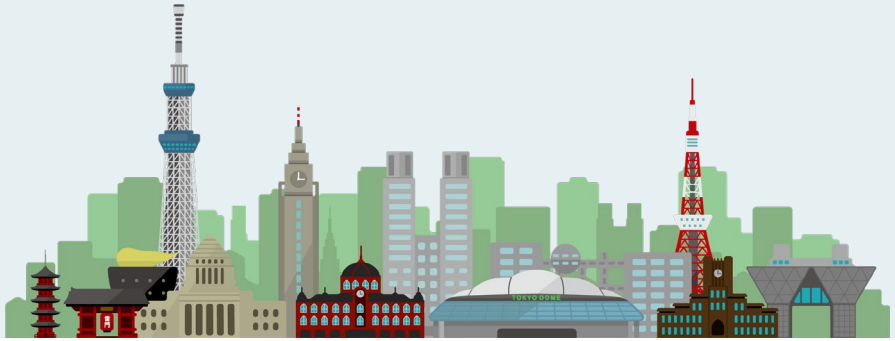

Regulatory update from TGA Australia

Tracey Duffy
First Assistant Secretary
Medical Devices and Product Quality Division
Therapeutic Goods Administration (TGA)
11 March 2025

Adoption of IMDRF guidance

- 16 fully implemented
- 10 partially implemented, reasons include:
  - differences in frameworks (e.g. different definition of software and medical device production system in Australia; some labelling requirements are specific to Australia)
  - no applications received (e.g. Australian Conformity Assessment Bodies)
- 6 not implemented, reasons include:
  - legislation not established or ready (e.g. UDI)
  - changes are subject to consultation (e.g. market authorisation table of contents)

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Unique Device Identifier (UDI) implementation – Update

UDI amendments to the Medical Device Regulations

- Draft Regulations being reviewed by government – expected start Q1/Q2 2025

UDI Guidance

- Final updates following recent industry consultation
- To be released when the Regulations take effect

Australian UDI Database (AusUDID)

- Go-live when the Regulations take effect
- Latest beta version used by sponsors and manufacturers since December 2024

Healthcare adoption

- Engagement with hospitals and healthcare continues but is limited

Electronic IFU for medical devices

- Following public consultation (Apr-Jun 2024) on the availability of IFUs in more flexible formats, the Australian Government has agreed to the preparation of regulatory amendments to effect the following changes:
  - eIFU can be provided with a medical device (in place of a paper IFU)
  - Paper IFU must be available free of charge within a reasonable timeframe when requested
  - Paper IFU must still be provided for single use/disposable consumer products, self-tests and point of care tests, emergency-use consumer devices etc.
  - Manufacturer to determine suitability of eIFU, with appropriate risk assessment, version control, etc.

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Mandatory Reporting of Medical Device Related Adverse Events by Healthcare Facilities

Proposed staged approach to implementation

March 2025 – March 2030

Transition Period	Stage 1	Stage 2	Stage 3
March 2025 – March 2026	**March 2026 – March 2028**	**March 2028 – March 2030**	**March 2030 onwards**
IT system development; stakeholder training and education	Reporting death and serious injury / deterioration related to high-risk medical devices	Reporting death, serious injury / deterioration and near misses for high-risk and medium-risk medical devices	Reporting death, serious injury / deterioration and near misses for all medical devices

Mandatory Reporting of Medical Device Related Adverse Events by Healthcare Facilities

Minimum Data Set

Healthcare facility identifier	Auto-generated (each healthcare facility in Australia has its own unique identifier)
Date/Time of incident	Date is imperative (time would also be beneficial if possible)
Description of incident	Comprehensive narrative (detailed description of medical device related adverse event)
Extent of injury	Death or serious deterioration in health (and nature or description of serious deterioration)
Name or Description of Device	Name and description of the medical device
Device manufacturer	If known. This information will assist the TGA to accurately and definitively identify the device involved, in the first instance (gold standard)

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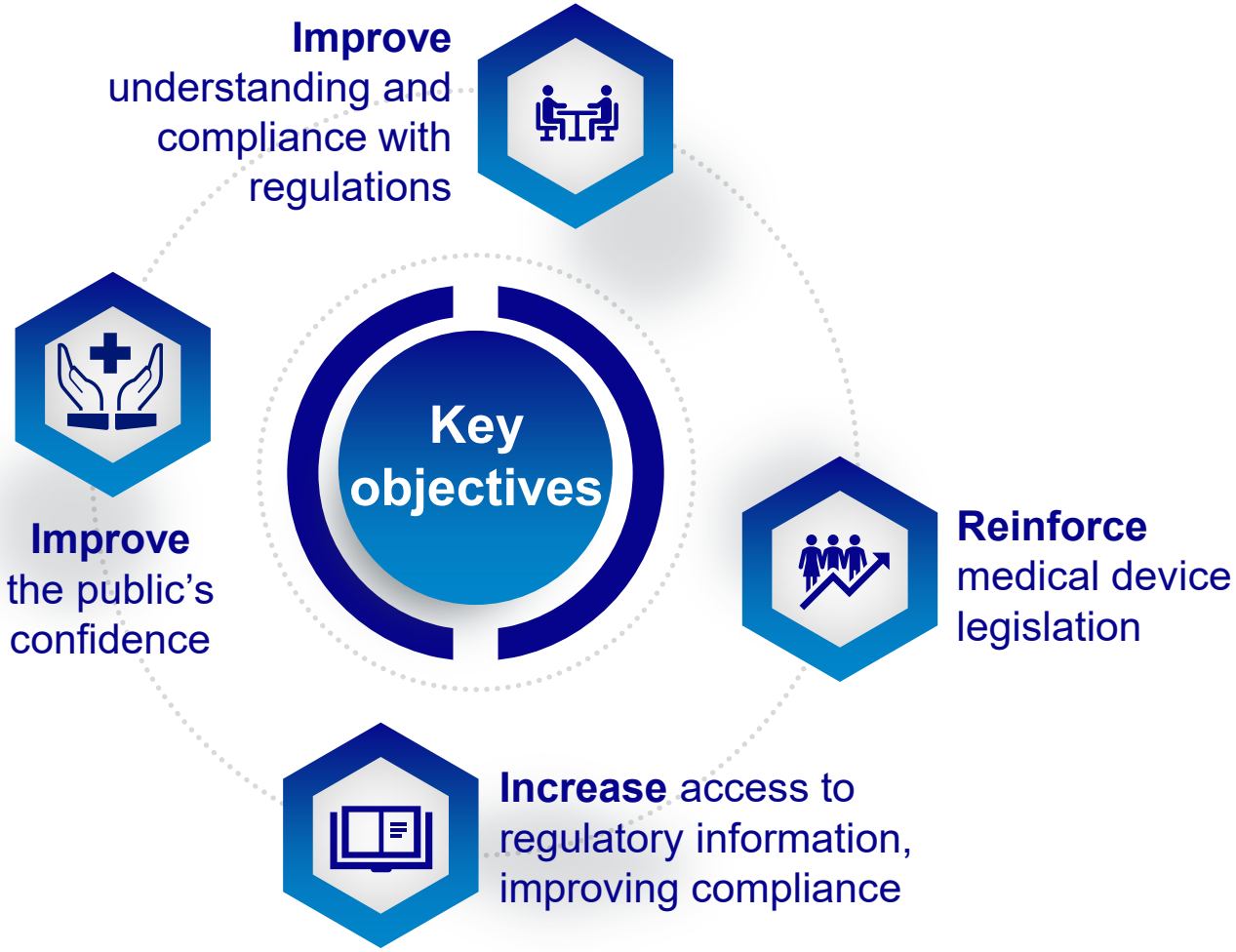
Medical Device Vigilance Program (MDVP)

Complements and enhances existing post-market surveillance activities, through:

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



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Medical Device Vigilance Program (MDVP)

2023

Sep 2023
Start of Pilot educational webinar

Seek volunteer sponsors

Nov – Dec 2023
Sponsor Vigilance Self-Assessment Tool

Gather information on sponsors' understanding and compliance to regulations

Nov – Dec 2023
Review SAT responses and regulatory information

Risk assessment and selection of sponsors to progress to next stage

2024

Jan – Jun 2024
Desktop audits and requests for information

Review sponsors' documents and records

July – Jan 2025
On-site inspections and inspection plans

Conduct on-site inspections, inspection reports and close-outs

2025

Jan – Mar 2025
MDVP review and evaluation

Identify areas for modification and improvement of the MDVP

Early/mid 2025
Government consideration

Advice to government

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Medical Device Vigilance Program (MDVP)

Pilot Evaluation – early key findings

- Need for greater education for sponsors to improve their understanding of the post-market requirements of having medical devices active in the ARTG
- Sponsors demonstrated willingness to engage with TGA on feedback and to improve their practices and processes
- Positive use of post-market surveillance data

Next steps

- Complete outstanding MDVP pilot inspection reports
- Gather feedback from participating sponsors of the pilot
- Conduct a review of the pilot and complete an evaluation report
- The outcomes and findings, accompanied by the sponsors' feedback, will dictate the options for a vigilance program

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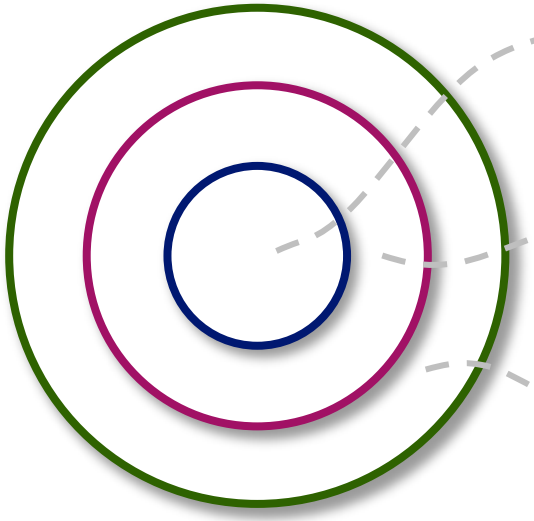
AI regulation – TGA legislative review

How prepared are we for the rising use of AI?

- How well does our framework align with the intent of the proposed guardrails?
- What changes, if any, do we need to make to our framework to ensure the safe and responsible use of AI models and systems in our regulated environment?



1. AI in or as a therapeutic good
2. AI applied within regulatory processes
3. AI in our regulated environment more broadly

Targeted stakeholder consultation — Complete

Public consultation — Closed 20 Oct

Report to government — Delivered Dec 2025

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AI regulation – TGA consultation themes

Potential changes to the Act

Definitions and language updated to clarify responsibility and appropriately capture activities that are now performed by systems

Transparency

A broad term which means different things to different people.

Understanding occurs across a spectrum and transparency will need a multi-faceted approach

Potential changes to medical device regulation

Our technology-agnostic framework is largely fit for purpose. Minor amendments may be needed to ensure risks associated with AI are mitigated

Guidance, education, information and communication

What information do people need?

Where do they need to be able to find it?

International alignment and harmonisation

Our framework harmonises with other jurisdictions as much as possible.

Is our approach appropriate?

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AI regulation – Outcomes

Five strategic priority areas emerging from the AI Review

Priority Area 1 **Supporting stakeholders**	Providing clear information and guidance explaining regulatory requirements to support compliance.	• Multiple channels for communication • Targeted support for specific sectors
Priority Area 2 **Robust regulation**	Refining regulation to ensure risks associated with therapeutic goods continue to be appropriately mitigated throughout their lifecycle	• Medical Devices Regulations 2002 • Excluded Goods Determination 2018 • Pharmaceutical Inspection Co-operation Scheme (PIC/S)
Priority Area 3 **Reinforce roles & responsibilities**	Ensuring language in our legislative framework (the Act) captures responsibility appropriately	• Mapping emerging terminology to existing definitions • Introducing new definitions where needed
Priority Area 4 **Improve transparency of AI use**	Facilitating access to information and support for stakeholders to understand how AI is used in the goods they access and how it is regulated.	• Explore levers for improving transparency of AI use
Priority Area 5 **Conducting compliance**	Pragmatic and timely compliance activities to ensure the policy outcomes	• Ongoing compliance

Boundary and Combination Products

Following public consultation (Jun-Aug 2024) on the regulatory category of certain boundary products, the Australian Government has agreed to the preparation of regulatory amendments:

Product	Regulatory category	Transition period for affected ARTG entries
• head and body lice products • moisturisers and emollients • toothpastes and dentifrices	Exempt	5 years
• products that achieve their principal intended action through pharmacological or chemical means	Medicines	5 years
• products used for sanitising or disinfecting a medical device • weight loss products with physical mode of action that expand in the stomach	Medical device	5 years

Ongoing challenge – regulation and classification of pre-filled saline flush syringes and vascular access device (VAD) locking solutions

Other Medical Device Reforms – in flight!

Medical Device Reform	Status
Clinical Decision Support System (CDSS)	Australian Government agreed to the preparation of regulatory amendments to refine exemption requirements
Exempt medical devices	Conducting sector specific stakeholder workshops
Assistive technologies	Review consultation submissions
SOPPs (Surgical Loan Kits)	Finalise and publish SLK guidance
Combination products	Continue internal review of processes
Conformity Assessment Procedures	Preparing public consultation paper
Essential Principles	Review consultation submissions
Personalised medical devices / POC	Continue engagement with sector working groups on regulatory options
Application review audit framework	Finalising dynamic risk factors framework to provide greater transparency and predictability
In-house IVD arrangements	Review to commence shortly
IVD definitions and classifications	Public consultation to be released Feb/Mar 2025

Recent regulatory changes

IVD medical devices supported by EU IVDD

Transition timelines for acceptability of certification issued under European IVD Directives for new applications for inclusion are now aligned with those under European IVD Regulations. More information is available here.

New reliance pathways

Classification	Pathway
Class III	MDSAP Certification + USFDA 510(K) clearance
Class IIa	MDSAP Certification + evidence of exemption from USFDA 510(K) regulation

Recent and current public consultations

Consultation Topic	Consultation Intent	Dates
Assistive Technologies	Review the regulatory requirements for assistive technologies including the current exclusions and exemptions	Closed 31 Oct 2024
Essential Principles	Changes that may be required to the Essential Principles to align with the EU, where appropriate.	Closed 13 Nov 2024
UDI	Review of draft guidance - Complying with the Unique Device Identification regulations for medical devices	Closed 15 Jan 2025
Application Audit Framework	Review of Risk Factors Guidance and Case Management Guidance documents	Closed 17 Feb 2025
IVD definitions and classifications	Review Australia's alignment with the EU classification system and definitions for IVD medical devices.	Feb/Mar 2025

Upcoming public consultations

Consultation Topic	Consultation Intent
Conformity Assessment Procedures	Review the Australian Conformity Assessment Procedures including where appropriate, alignment with the EU.
Exempt Devices and OTGs	Consultation #2 on proposed regulatory changes for exempt medical devices and OTGs
In-house IVDs	Review of In-House IVD arrangements
Patient-matched medical devices (PMMD)	Proposed refinements to the current arrangements for the regulation of personalised medical devices framework, specifically for PMMD, including those manufactured at the point-of-care and personalised medical device production systems.
Disinfectants	Review and refine the current framework for therapeutic disinfectant goods and to align more closely with international risk classifications
Adverse event exemption rules	Follow up consultation on implementation options
Medical device vigilance program	Consultation on next steps, including broader implementation, following pilot program
Clinical trials	Pending review of additional requirements implemented in 2024, we may propose further refinements to the current arrangements for the clinical trials requirements
Software and Artificial Intelligence (AI)	Proposed refinements to the current arrangements for the regulation of software and AI.

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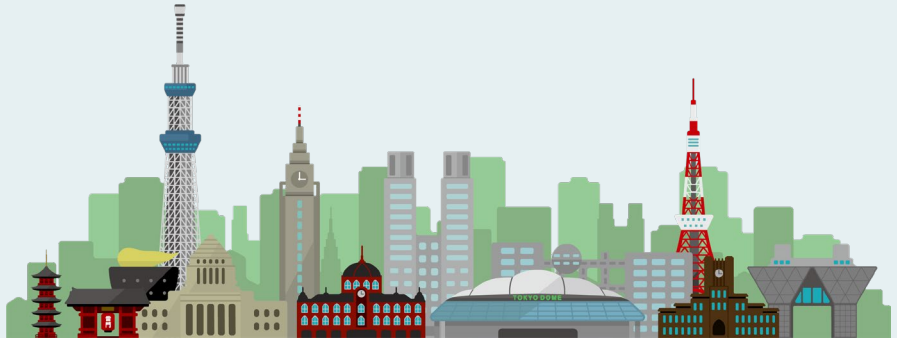

Thank you / Questions

Therapeutic Goods Administration
Australia