IMDRF International Medical Device Regulators Forum

HSA Health Sciences Authority 25 YEARS AND BEYOND

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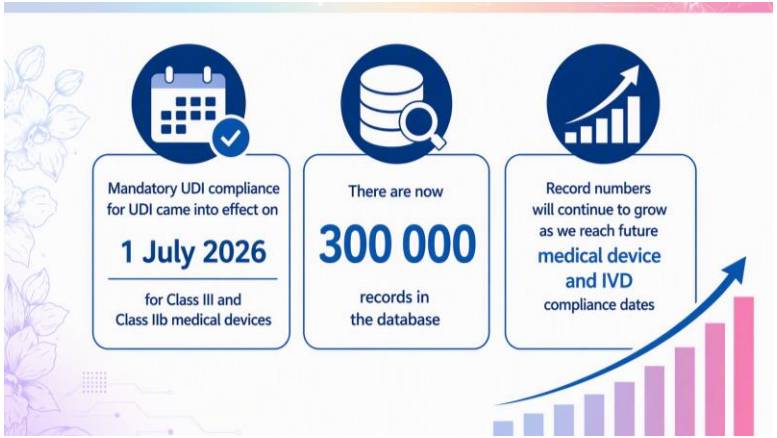
Jurisdictional Update – Australia

Tracey Duffy

First Assistant Secretary, Medical Devices and Product Quality Division

Therapeutic Goods Administration, Australia

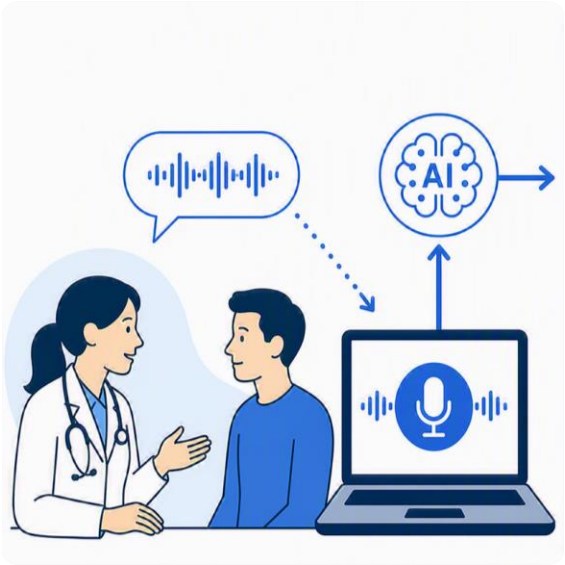
UDI adoption in Australian healthcare



TGA approach

- ✓ **Educate** about UDI key concepts
- ✓ **Motivate** by sharing the benefits and supporting the case for change
- ✓ **Ideate** through input into future state process design

Review of digital scribes



Review:	Started August 2025, ongoing
Goals:	Are scribes medical devices? Education & compliance
Findings:	Many scribes recommend diagnosis or treatment Rely on clinicians to verify outputs Wide non-compliance : no digital scribes included in the ARTG
Next steps:	Clarify regulatory boundary with developers and users Bring products in clinical use into compliance Overcome barriers to compliance while mitigating risks

Review of digital mental health tools

Digital mental health tools

- Includes digital services, web-based tools, apps that support mental health
- Generally used for screening, diagnosis or providing therapy and are therefore medical devices
- **However - 'Excluded'** from TGA regulation if:
  - based on established clinical practice guidelines
  - that are referenced and displayed in a reviewable manner

Work to date

Review of exclusion due to changes in the risk landscape

- Surveys, market research, stakeholder engagement and meetings with a dedicated expert group
- **Finding**: exclusion may no longer be appropriate to protect patient safety

Next steps

- Public consultation on future of exclusion

Mandatory Reporting of adverse events by health facilities

Strengthening reporting to improve patient safety across Australia

Started 21 March 2026

Stage 1 requires all hospitals to report deaths, serious injuries or deteriorations linked to high-risk medical devices (Class III & IVDs)

Growing awareness

~200 reports received per month, with steady growth in awareness across hospital networks

New reporting system

New ASDER system accepts hospital reports online

Expanding requirements

Reporting requirements expand in 2028-2030 to include more device classifications and event types

Nationwide

99% of health facilities registered with TGA, with reporting processes in place across the country

Building a reporting culture

Ongoing communication and education are driving a culture of quality reporting and continuous improvement

Pathways for innovative medical devices

Considering options to improve the regulatory pathway for **innovative medical devices**

1. **Priority review pathway** – Expanding eligibility or support for applicants
2. **Regulatory engagement** – Improving pre-submission meetings and engagement
3. **Provisional approval** – Proposed new pathway for time-limited approval for innovative devices addressing unmet need supported by preliminary data, with subsequent evidence obligations
4. **Existing mechanisms** – Seeking feedback on other existing mechanisms, including reliance pathways, Special Access Schemes, clinical trials, and conditions of approval.

Broad stakeholder feedback is sought to inform potential regulatory reforms.

The TGA is also considering similar models from international regulators.

Strengthening preparedness for medical device shortages

Australian Supply disruptions or shortages

- New pathway enables **temporary** importation and/or supply of specific overseas medical devices and IVDs across **all device classes**.
- The pathway is only available where **approved devices** are unavailable or in critical shortage.
- To date, 2 applications have been approved under this pathway.

Work to date

- Digital reporting tools and guidance have been implemented to:
  - strengthen surveillance and support early identification
  - assess and manage supply disruptions.
- The Australian Critical Medical Devices Framework was established to:
  - identify critical devices
  - monitor supply risks
  - support preparedness for future disruptions.

Reprocessing, Remanufacturing and Refurbishment of medical devices

Australia is progressing work to clarify the regulatory treatment of reprocessing, refurbishment and remanufacturing of medical devices, with a focus on patient safety, transparency and traceability.

Key areas of work

Clarifying terminology and regulatory pathways
Refining the distinction between reprocessing, refurbishment, remanufacturing, repair, servicing/maintenance, component reuse and related concepts, including practical examples of when a new regulatory entry may be required.

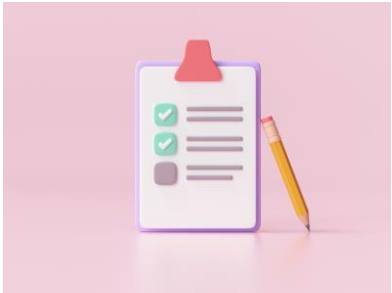
Key policy issues under consideration
Targeted engagement with jurisdictions and stakeholders has highlighted issues including terminology alignment, infection prevention and control, ARTG treatment, GMDN/UDI implications, labelling, transparency and traceability.

Developing consolidated guidance
TGA is developing more comprehensive guidance to bring together terminology, regulatory pathways, practical scenarios and application of the current framework, with further stakeholder review prior to finalisation.

Potential regulatory reform
Consider need for public consultation and regulatory refinements to our existing framework.

Recent consultations conducted

- Information sharing - refining TGA's information sharing arrangements for post market reviews
- Conformity Assessment Procedures for Medical Devices
- Predetermined Change Control Plans (PCCP) draft guidance
- Personalised Medical Devices Consumer Survey
- Clinical Evidence for IVD Medical Devices – Definitions and Principles of Performance Evaluation
- Proposed UDI update to audit selection guidance: Understanding selection criteria for medical device application audits



Recent/upcoming regulatory amendments

Strengthening preparedness for medical device shortages

- Amendments commencing 1 May 2026 expanded the section 41HD emergency access pathway for overseas medical devices.
- The pathway now enables temporary access to all medical devices and IVDs during supply emergencies, supporting continuity of patient care where suitable alternatives are unavailable.

Clinical Decision Support System (CDSS)

- Amendments expected September 2026 provide greater regulatory clarity for clinical decision support software, helping distinguish regulated medical devices from lower-risk software that remains outside the medical device framework.

Risk classification of pre-filled saline flush syringes (PFSFS) and vascular access device (VAD) locking solutions

- Amendments expected September 2026 clarify that these products are class IIa if they contain saline only with no other medicinal substances

Upcoming public consultations

Consultation Topic	Intent
Exempt Devices and Other Therapeutic Goods	A second consultation to refine regulatory requirements for medical devices and other therapeutic goods that are exempt from certain pre-market requirements, including a notification model.
Patient-matched medical devices	Consultation on proposed refinements to the regulation of personalised medical devices, specifically patient-matched medical devices, including those manufactured at the point of care.
Boundary Products	Consultation on clarifying the regulatory categories of additional boundary products, and guidance
Adverse event reporting forms	Targeted consultation on requiring adverse event reports submitted by medical device sponsors to be provided in a specified form
Digital mental health tools	Consultation on proposed amendments to the way we regulate digital mental health tools (DMHTs) including consideration of the current DMHT exclusion
Software and Artificial Intelligence	Conduct targeted and public consultations on proposed refinements to the current arrangements for the regulation of software and AI.
Regulatory pathways for innovative medical devices	Consultation on options to improve the regulatory pathway for innovative medical devices, including the priority pathway
Review of ARTG variation processes	Consultation on refining the current regulation, processes and policies, including fees, for varying ARTG entries
Digital Scribes	Consultation on proposed options to amend the way we regulate digital scribe and similar generative AI-based CDSS tools.
Conformity Assessment Procedures	A second consultation on clarifying post-market requirements under conformity assessment procedures
Assistive Technologies	Consultation on refining the regulatory framework including any potential impacts on the NDIS and aged care programs
Adverse Event reporting requirements	Targeted consultation on requiring sponsors to provide IMDRF codes in their submissions.

Thank You!