IMDRF International Medical Device Regulators Forum

Harmonising International Regulatory Approaches for Efficient Post-Market Conformity

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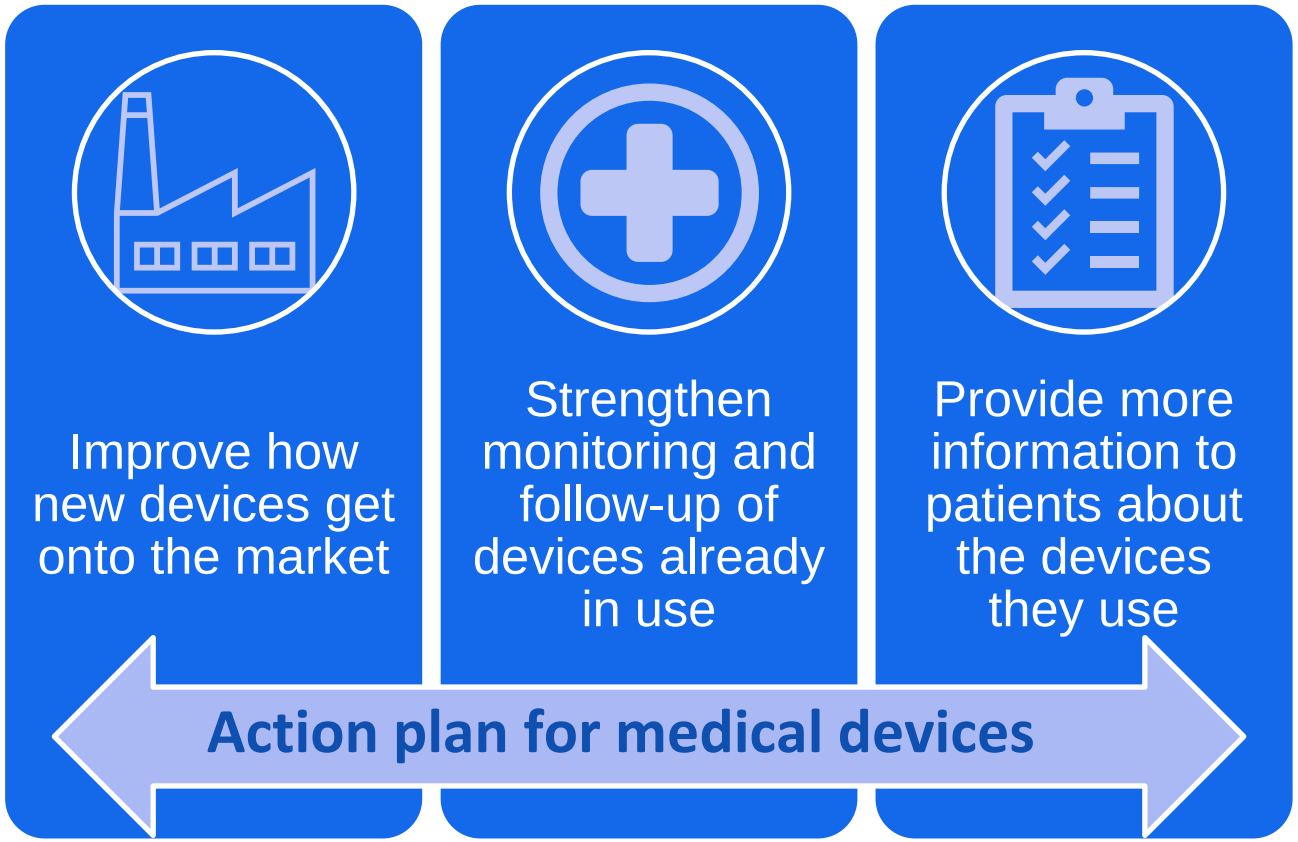
Harmonised life-cycle approach to compliance



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Adoption of IMDRF guidance – alignment supports efforts!

Fully implemented	Partially implemented	Not yet implemented
Adverse event terminology	Good regulatory review practices - Competence, training and conduct requirements, recognition and assessment of conformity assessment bodies	Machine learning-enabled medical devices
Software as a medical device – risk framework, clinical evaluation, and QMS	Software as a medical device – definitions and principles and practices for software bill of materials	Cybersecurity for legacy devices
Clinical evidence, investigation and evaluation	Unique device identification	
Medical device single audit program – requirements for recognition, competence and training, and reports	Medical device single audit program – assessment and decision process	
Personalised medical devices - definitions	Personalised medical devices – regulatory pathways, production verification and validation	
Essential principles	Optimizing standards for regulatory use	
Cybersecurity principles and practices	Competence, training and conduct requirements for regulatory reviewers	

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Improving post-market surveillance – specific examples

Improvements to monitor and manage safety, quality, and performance of medical devices:

- **Dedicated branch** working on post-market monitoring and surveillance – Medical Devices Surveillance Branch
- Established a Team focussed on **horizon scanning** of safety signals and **targeted post-market reviews**
- Online form for **consent to supply** devices that may be temporarily non-compliant with the Essential Principles
- **Imposed conditions** on conformity assessment certificates for certain devices
- **Engaging with stakeholders** to improve how they can report problems and how they can receive information including hospitals, manufacturers, healthcare professionals, consumers
- Data **analytic tools, staff skills** to improve triage methods, identify trends, data literacy and proficiency

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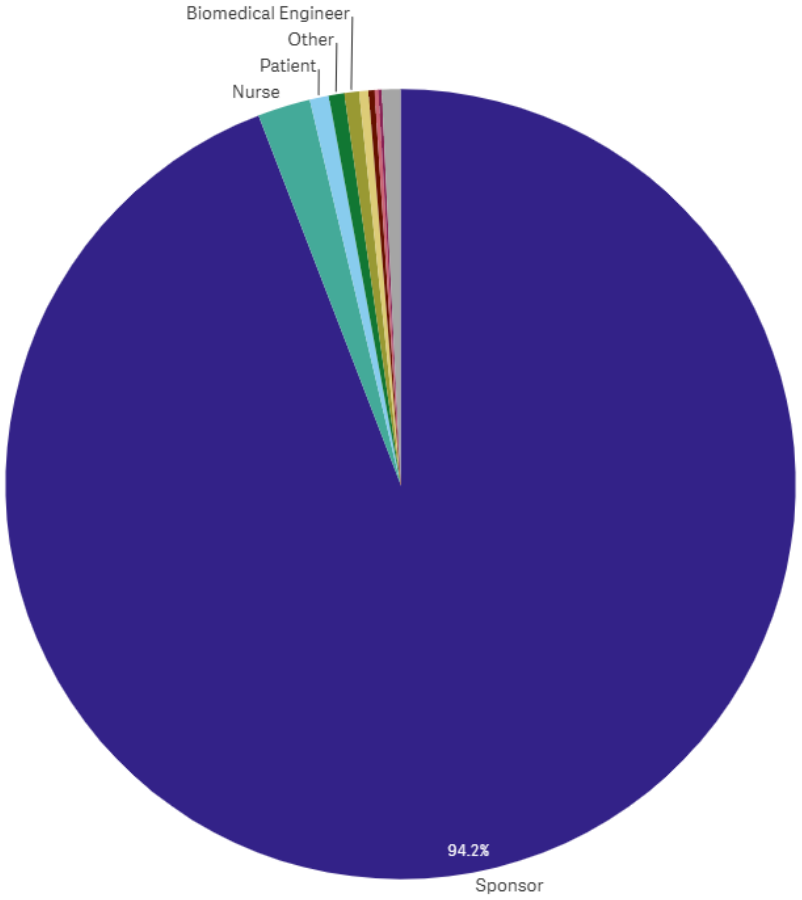
Adverse event reporting – gaps and missing data?



Source of report	2024	2025 so far
Sponsor	11,251	11,107
Healthcare professional	520	360
Patient	119	67
Others (unknown source of data)	210	113
Total	12,100	11,647

Reports received between
01 January 2024 – 31 July 2025

Reports are published on a database of adverse event notifications and publicly accessible.

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Mandatory reporting of adverse events by healthcare facilities

Implementation Stages

2025 – 2030

1 year	2 years	2 years	April 2030 onwards
Voluntary Reporting Period	**Stage 1** • Death • Serious deterioration • High-risk medical devices	**Stage 2** Stage 1 + • Near misses • Medium-risk medical devices	**Stage 3** Stage 1 & 2 + • Provision of treatment
Current stage			

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Impact on patients

Enhance patient safety

- Faster detection of safety issues
- More targeted safety alerts

Support information sharing

- Better information for informed decisions

Support patient decision making

- Supports a stronger safety culture
- Consumer reports remain important

Australian UDI Database (AusUDID) – faster identification

Repository for UDI-DIs and related data for devices supplied in Australia

Sponsors and manufacturers submit and maintain device data

Health professionals and clinical quality registries can access medical device information

Patients can find more about the medical devices used on or implanted in them

Australian UDI database

Phased start dates

Voluntary

Device labelling

Data in the AusUDID

Phased introduction

Start with high-risk devices

Lower risk devices follow over later years

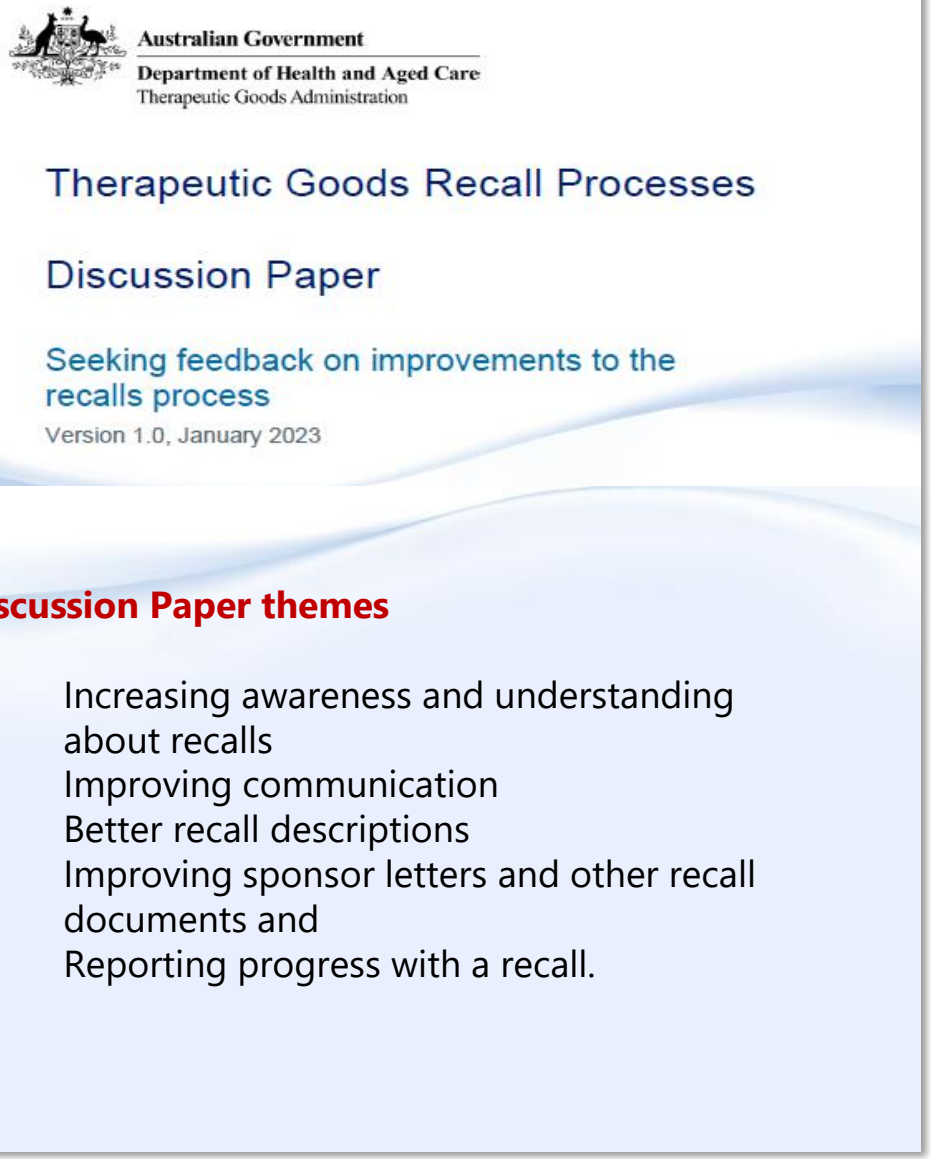
Full compliance

Devices labelled

Data in the AusUDID

Other efficiency measures – Recall process improvements

- **Streamline recall processes**
- **Put key information up front**
- **Change recall action terminology**
- **Provide clarity:**
  - **timing of release of information**
  - **recall action risk assessments**
- **Provide new templates for submitting information**
- **QR Codes/eSurveys to improve response rates**
- **Sponsors review of Early Advice before distribution**



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Therapeutic Goods Recall Processes

Discussion Paper

Seeking feedback on improvements to the recalls process

Version 1.0, January 2023

Discussion Paper themes

1. Increasing awareness and understanding about recalls
2. Improving communication
3. Better recall descriptions
4. Improving sponsor letters and other recall documents and
5. Reporting progress with a recall.

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Current and future efficiencies - conformity assessment

1. **MDSAP** Certificates are used by sponsors when including a device in the ARTG.

2. MDSAP Audit Report Packages are used to support a TGA Conformity Assessment Certificate application or change application. A desk top audit is performed.

3. Outcomes of MDSAP audits are used in post-market surveillance activities. 5 day notices reviewed. Certificate withdrawals, suspensions and scope changes reviewed.

Consultation later this year on aligning the TGA's **conformity assessment** procedures with:

- EU Medical Device and IVD Regulations
- stronger alignment with the IMDRF guidelines
- regulatory approaches of countries that are MDSAP members

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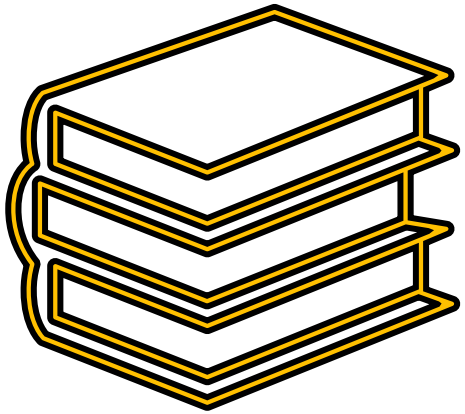
Tricky challenge - software and AI



IMDRF current work on:

- Harmonised approach to predetermined change control plans (PCCPs) – SaMD working group
- Guidance for AI use in medical devices over the entire lifecycle – AI working group

Changes to TGA website:

- Making broad changes to improve usability
- Adding content to fill gaps, e.g., specific guidance for AI in software
- Updating existing content in line with consultation feedback and international alignment

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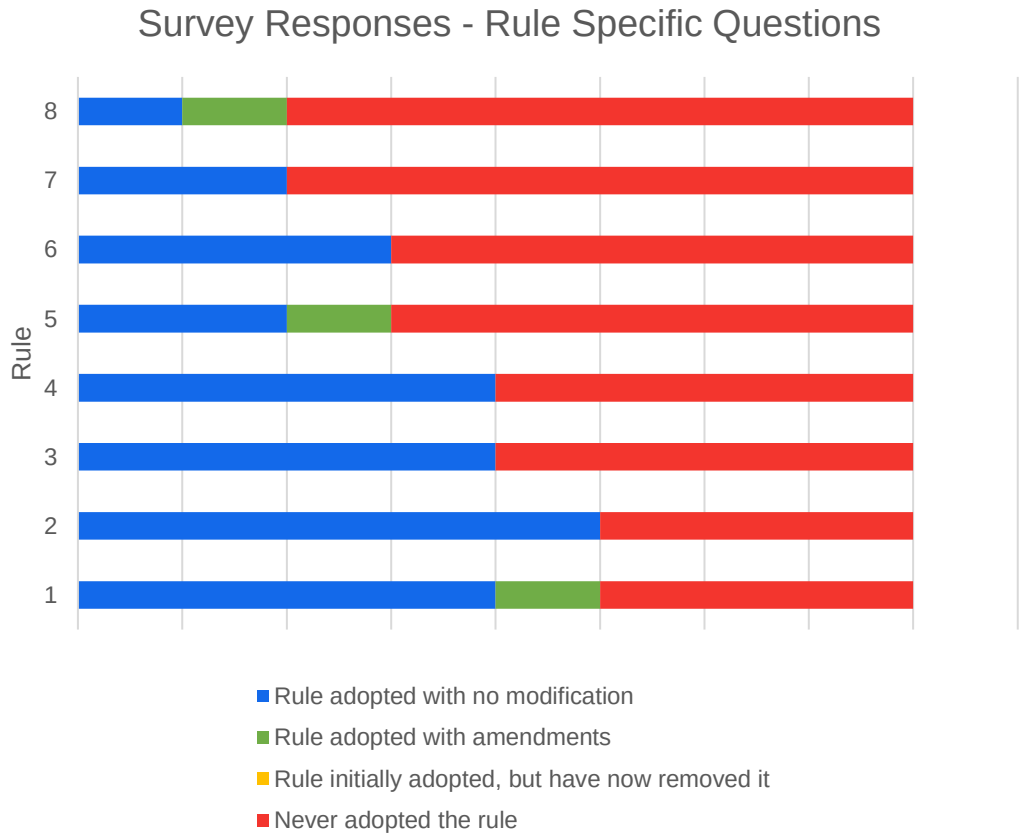
IMDRF Survey – Use of the Exemption Rules for Adverse Event Reporting for Medical Devices

Rules:

1. Deficiency of a device found by the user prior to patient use
2. Adverse event caused by patient conditions
3. Service life or shelf life of the medical device
4. Malfunction protection operated correctly
5. Negligible likelihood of occurrence of death or serious injury
6. Expected or foreseeable side effects
7. Adverse events described in advisory notice
8. Reporting exemptions granted by a National Competent Authority



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Exemption Rules - Next steps for TGA

- Some manufacturers already reporting all adverse events – TGA reviewing data as a pilot over the next 3-6 months
- Encouraging more manufacturers to submit all adverse event reports
- Working with manufacturers to check TGA system capacity to accept reports and review
- Following review seek agreement from government on use and language of exemption rules

OTHER: continued use of NCAR, collaborative information sharing and ensuring confidentiality agreements are in place

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Thank you/Questions