IMDRF International Medical Device Regulators Forum | EU2023 EUROPEAN UNION Chair

08:40 – 08:55

Australia

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European Commission | European Union

IMDRF International Medical Device Regulators Forum

Regulatory Update - Australia

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28 March 2023

Overview

- An Action Plan for Medical Devices
  - Reforms since June 2021 (snapshot only)
- EU MDR Impact
- COVID-19
- TGA Strategic Activities
- TGA Transformation Program - Purpose
- IMDRF Participation

An Action Plan for Medical Devices

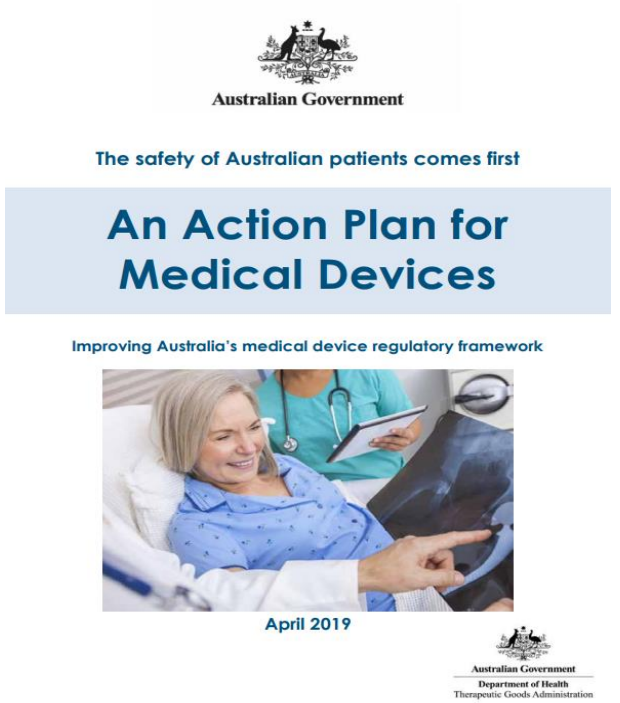
Continues to guide medical device reforms that:

- 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

Strategy 1: Pre-market medical device reforms

- **15 public consultations undertaken; 25 guidances published**

- **Personalised medical devices (PMD)**
  - New framework commenced in 2021, impacts more than 10,000 stakeholders previously manufacturing custom-made devices. Focus has now shifted to point-of-care manufacturing

- **Software-based medical devices**
  - Clarification, refinements and "carve outs" commenced in 2021, focus on an adaptive approach to regulation
  - Specialist unit established to increase capacity in assessing and monitoring

- **Reclassification of certain devices**
  - Eg: mesh, spinal devices, devices that come into contact with the central nervous system – devices not able to transition are cancelled from the Australian Register of Therapeutic Goods (ARTG)

- **Australian conformity assessment bodies (Australian CABs)**
  - Australian corporations can apply to become an Australian CAB for medical devices

- **Nanomaterials**
  - Regulatory amendments define nanomaterials and make explicit the requirement to minimise risks associated with nanomaterials, but (unlike the EU MDR) do not add nanomaterials characteristics to the classification rules.

Strategy 1: Pre-market medical device reforms (Cont.)

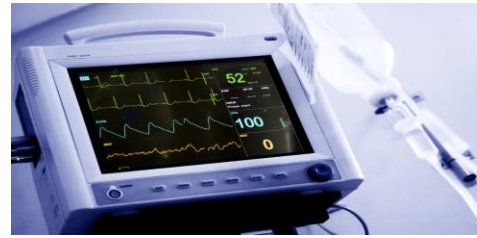
- **Streamlining processes and timeframes**
  - Global benchmarking of conformity assessment timeframes
  - Development of new risk based application audit/review approach rather than mandatory approach
  - Recognition of other regulators and mutual recognition agreements

- **Clinical trials**
  - Proposed involvement by TGA for very high risk devices

- **Changes to the Medical Device Regulations**
  - Changes to the Therapeutic Goods (Medical Devices) Regulations

Strategy 2: Post-market medical device reforms

- **Undertaken 4 public consultations; will be our focus until 2024-25**
- **Review of adverse event reporting arrangements**
  - Improvements to reporting forms, processes and internal TGA analysis processes
  - Changes to existing exemptions
  - Mandatory reporting by hospitals – required change to primary legislation and partnership with other governments and agencies to implement in coming 3 years
  - Introduction of a pilot vigilance program including self-assessment tool, desk top review and onsite inspection
- **Review of recall processes**
  - Including greater transparency of supply chains; simplified terminology; ability to share information quicker
- **Targeted reviews of specific kinds of devices**
  - Established dedicated team, examples include spinal cord stimulators, metal backed patella, RATs
- **Implementation of Unique Device Identification system**
  - Australian UDI "test" database (AusUDID) with 400 users including manufacturers, healthcare stakeholders; established Technical Working Group; webinar program; regulatory changes currently being finalised, including voluntary and mandatory compliance dates
  - Two "Early Adopter" projects to assess adoption and benefits of UDI in healthcare (hospital) settings



Strategy 3: Consumer focused reforms

❖ **Five working groups with consumer representation have been established**

Eg: Medical Device Consumer Working Group

- 21 health consumer organisations engaged to progress the Action Plan for Medical Devices reforms
- Developed a range of consumer-focused products about medical devices eg: Five things to ask your health professional before you get a medical implant
- Review of website materials and processes for consumer engagement, including co-development of fact sheets (eg: software fact sheets) and adverse event reporting forms and processes
- Feedback on electronic IFUs for consumer facing medical devices
- Feedback on selected Patient Information Leaflets

Eg: Women's Health Products Working Group

- Advice to the Minister and the TGA on the regulation of health products that relate to women's health

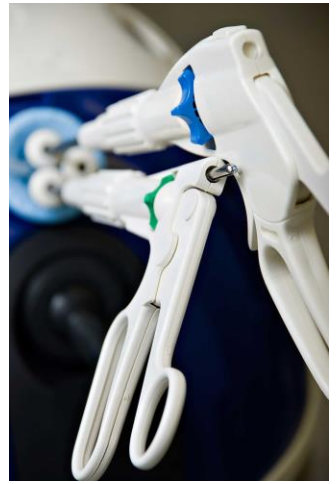
❖ **Patient information Leaflets (PILs) and Patient Implant Cards (PICs)**

- In place since 2021 for implantable medical devices – building a repository on TGA website. Some implementation challenges at hospitals distributing/providing to patients.

Impact of European Union Medical Device Regulations (EU MDR)

Significant impacts as most marketing approvals (above class I) in Australia is based on EU certification:

- **EU MDR Transition:** The TGA has implemented streamlined arrangements to manage the transition for devices supplied in Australia.
- **Transition extension:** Australian transitions are generally 6 months after the EU – need to seek Government approval to account for recent extension arrangements
- **Reclassifications:** medical devices subjected to reclassification may not meet transitional timeframes in Australia due to the EU MDR transition extension. Extending transitional timeframes requires Australian Government approval. A streamlined process for managing the change is being explored.
- **Unique Device Identifier (UDI):** Australia implementing and seeking alignment with both EU and USA
- **Mutual Recognition Agreement:** TGA unable to issue MRA certification until MRA updated (subject to negotiation with EU)
- **In Vitro Diagnostic Regulations (IVDR):** EU IVD certification is also recognised in Australia. We are updating our streamlined arrangements to account for the IVDR transition in the EU and looking at options for further alignment.



COVID-19 update

❖ **COVID-19 rapid antigen tests**

- November 2021, legislation amendment to enable supply of COVID-19 self tests (111 approved)
- Validation laboratory testing of 94 approved tests – results published on website for wildtype, delta and omicron variants
- Focus is combination Rapid Antigen Tests that detect Flu and COVID (7 approved)

❖ **Disinfectant products making COVID-19 claims or residual activity**

- Legislative instruments to clarify the regulation of borderline products and published guidance
- Regulations amended to include specific test requirements that must be used to support claims of residual activity

❖ **COVID-19 Lessons and Changes**

- Class I inclusion process revised to require upfront submission of evidence for devices that are integral to COVID-19 response
- Emphasised life cycle approach to approval and ongoing monitoring of emerging risks in pre-market and post-market

- Stronger emphasis on communication with Stakeholders:

  - Industry
    - publishing new and targeted guidance/checklists and webinars for preparing applications, collecting evidence and meeting ongoing obligations
    - targeted guidance and webinars to aid in promoting sovereign manufacturing

  - State and Territory, government, international regulators – instigated regular meetings and channels for sharing information

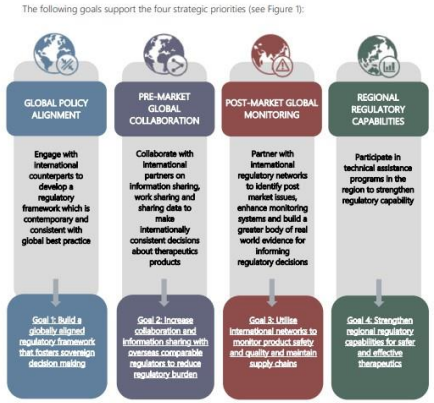
  - Consumers and general public – increased reach and interaction through traditional and social media

TGA Strategic Activities

❖ **Strategic priorities – set out in our International Engagement Strategy**

Focus on four strategic priorities to foster international partnerships:

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



❖ **Mechanisms to facilitate international engagement**

- Mutual Recognition Agreements and Memoranda of Understanding
- Free Trade Agreements and International treaties

TGA Transformation Program - Purpose

- reduce regulatory burden by making it easier and simpler to do business with the TGA
- modernised and streamlined websites to access regulatory information
- a new single portal for regulatory and reimbursement applications
- improved data quality in databases and better search facilities for the Australian Register of Therapeutic Goods (ARTG), recalls and adverse events databases

IMDRF Participation

IMDRF Member since 2012 ; IMDRF Chair and Secretariat in 2022

Participating in the following IMDRF Working Groups

- Adverse Event Terminology
- Artificial Intelligence Medical Devices
- Good Regulatory Review Practices
- Medical Device Cybersecurity Guide
- Personalized Medical Devices (WG Chair)
- Regulated Product Submission
- Software as a Medical Device
- Medical Devices Single Review Program


Thank you/Questions