Regulatory Update from Australia

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13 – 16 February 2023

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Overview

- An Action Plan for Medical Devices
- EU MDR Impact
- COVID-19
- IMDRF Participation

An Action Plan for Medical Devices

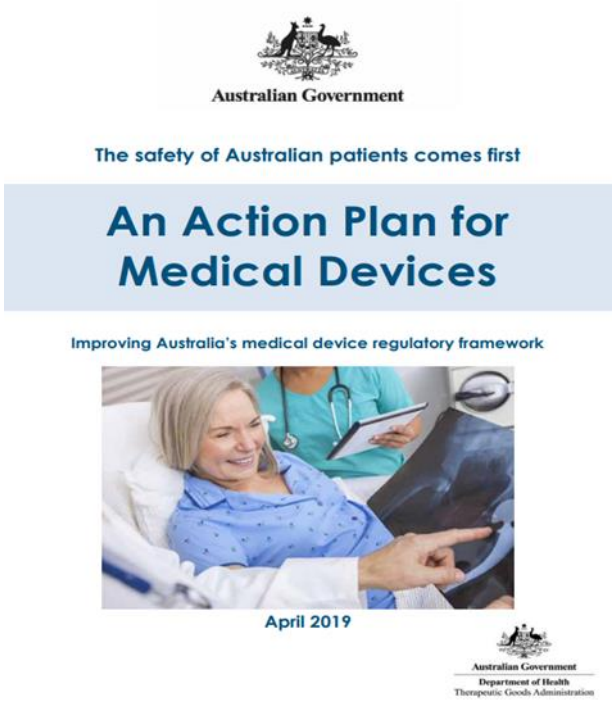
Continues to guide medical device reforms that:

- **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**



Strategy 1: Pre-market medical device reforms

The reforms include:

- **Personalised medical devices (PMD)**
- **Software-based medical devices**
- **Reclassification of certain medical devices (non IVD)**
- **Changes to Medical Device Regulations**
- **Australian conformity assessment bodies (Australian CABs)**
- **Streamlining our processes and timeframes**

Strategy 2: Post-market medical device reforms

The reforms include:

- **Targeted post-market reviews of specific devices**
- **Proposed mandatory reporting of medical device adverse events by hospitals**
- **Implementation of Unique Device Identification system**
- **Review of recall processes and procedures**

Strategy 3: Consumer focused reforms

The reforms include:

- **Establishment of Women's Health Products Working Group**
- **Mandatory Patient information Leaflets (PILs) and Patient Implant Cards (PICs)**
- **Creation of Medical Device Consumer Working Group**
- **Review of website materials and processes for consumer engagement**

Impact of European Union Medical Device Regulations (EU MDR)

Significant impact as more than 90% of marketing approvals in Australia is based on EU certification:

- **Reclassifications: parallel reclassifications of certain medical devices**
- **Definitions and scope: potential alignment on definitions and scope of regulations**
- **Recertifications: also require changes to Australian approvals**
- **Conformity assessment and essential principles: Possible alignment to new EU requirements**
- **Transition extension: to align in Australia (timed 6 months after the EU)**
- **Unique Device Identifier (UDI): alignment with both EU and USA**
- **Mutual Recognition Agreement (MRA): TGA unable to issue MRA certification as expired**
- **In Vitro Diagnostic Regulations (IVDR): options for further alignment**

Development with industry involvement - a risk based process and communication strategy to communicate changes to the hospital sector and clinicians about changes

COVID-19

COVID-19 rapid antigen tests

- Legislation amendment to enable supply of COVID-19 self tests and published guidance
- Full regulatory approval of more than 100 tests
- Peter Doherty Institute engaged to undertake laboratory testing to validate performance of approved tests
- Focus on combination Rapid Antigen Tests that detect Flu and COVID (7 approved)

Disinfectant products making COVID-19 claims or residual activity

- Legislation amendment to clarify borderline products and published guidance
- Includes specific test requirements that must be used to support claims of residual activity

Other considerations

- **Supply chain resilience and disruption management**
- **Compliance and supply chain transparency measures**
- **Adopted different ways of working including to mitigate and manage risks - ??? What to take forward ???**

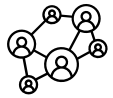
COVID-19 Lessons and Changes

- Revised the Class I inclusion process 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 premarket and post-market
- Stronger emphasis on communication with stakeholders:

  - Industry – publishing new and targeted guidance and webinars for preparing applications, collecting evidence and meeting ongoing obligations

  - 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

International Medical Device Regulators Forum (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

IMDRF International Medical Device Regulators Forum


Thank you/Questions

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration