IMDRF International Medical Device Regulators Forum

Regulatory Update from Australia

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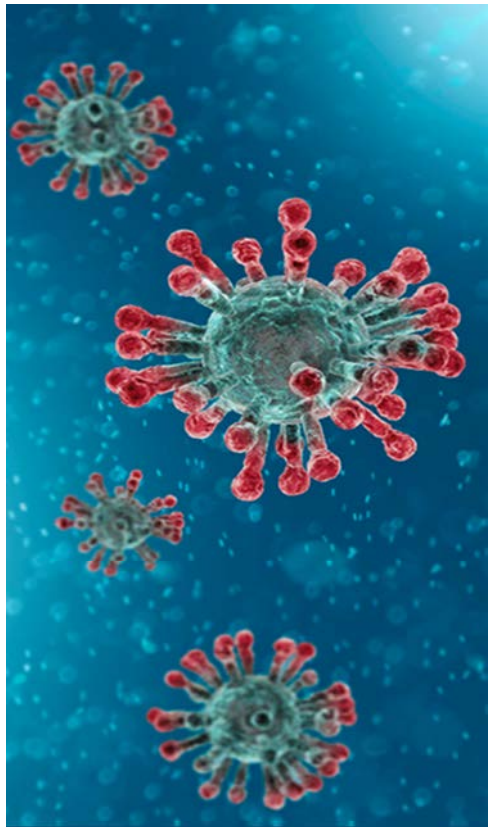
Overview

- IMDRF Strategic Plan
- Progress with Medical Device Reforms
  - Australian Government Reviews
  - An Action Plan For Medical Devices
- COVID-19 update
- TGA's new accommodation



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Australia is implementing three medical device reform streams

IMDRF Strategic Plan	Australian Government Reviews	An Action Plan for Medical Devices
IMDRF Strategic Plan for 2021 to 2025 **IMDRF Strategic Plan for 2016 to 2020** **Work items of** the IMDRF working groups	Recommendations of the Australian Government to the **Medicines and Medical Devices Review** and the **Inquiry into urogynaecological mesh and other matters**	Progressing Australian reforms that focus on patient safety as outlined in **An Action Plan for Medical Devices**

Medical Devices Reforms

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IMDRF Strategic Plan 2016 - 2020

"Support innovation and timely access to safe and effective medical devices"

Primary objective of IMDRF Strategic Plan 2016-2020

Focus areas:

- Aligning regulatory requirements and practice
- Broadening access to medical devices of public health importance across jurisdictions

Australia's progress

Fully implemented

- ✓ Medical Device Single Audit Program
- ✓ Medical device cybersecurity
- ✓ National Competent Authorities Reports Exchange Program
- ✓ Edition 4.1 of adverse event terminology

Partially implemented or still in progress

- Common principles on registries
- Development of Regulatory Product Submissions
- Good Review Practices for pre-market reviews
- Improving medical device standards (via Standards Australia)
- Improving quantity and quality of clinical data
- Software as a Medical Device
- Personalised medical devices
- Rules for unique device identifiers

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IMDRF Strategic Plan 2021 - 2025

Australia will support the IMDRF to continue to build on its achievements from the 2020 Strategic Plan, with an emphasis on the two key objectives below:

1. Managing regulatory challenges for medical devices and innovative technologies by providing timely and appropriate guidance
2. Strengthening post-market surveillance for medical devices and implement regulatory life cycle processes

Priorities

Australia will contribute to the delivery of the Strategic Plan key priorities:

- Pre-market - *Develop a risk calibrated regulatory approach for innovations and promote harmonized pre-market review requirements for medical devices*
- Post-market - *Leverage post-market monitoring and surveillance to ensure accessibility to safe and effective innovations for patients*
- Relationships with Stakeholders

How we contribute and support the IMDRF

- ✓ Participation in IMDRF Management Committee and Working Groups
- ✓ Reference to IMDRF final documents in our consultations on Australian medical device reforms where appropriate
- ✓ Changes to TGA processes to harmonise and implement IMDRF documents
- ✓ Information exchange with IMDRF members on various topics including COVID
- ✓ Continued engagement with WHO, ISO, IEC, APEC, AHWP, PAHO
- ✓ Continued hosting of IMDRF website

IMDRF website update

Australia has proposed modernising the IMDRF website to reflect that the Forum is a strong, well-organised, contemporary group of Medical Device Regulators.

Management Committee considerations:

- Changes to structure and layout
- Review font type and logo
- Homepage navigation
- Multiple ways to find documents
- More information about Working Groups
- Language translation function

Australia's Medicines and Medical Devices Review

Implemented

Priority review pathway for medical devices (averaging 70 days)
Use of comparable overseas regulator approvals (341 used as of 5 February 2021) from USA, Canada and Japan
Benchmarking TGA timeframes with other regulators (published)
Review of Class 1 medical devices
Improvements to post market surveillance and adverse event reporting processes

Under way

Establishment of Australian Conformity Assessment Bodies
Guidance to support the reclassification of certain devices (non IVD)

Government Inquiry into urogynaecological mesh – progress

- Upclassification to Class III for mesh devices, deadline for urogynaecological mesh products was 1 December 2020
- Patient Implant Cards and Patient Information Leaflets required for surgical mesh and implantable devices after 1 December 2018
- Pelvic Floor Procedure Registry commenced January 2021
- Consultations on UDI and enhancements to adverse event reporting closed on 2 December 2020. Analysis of responses is underway. Consultation on mandatory reporting of adverse events by healthcare facilities commenced.

An Action Plan for Medical Devices

Australian Government

The safety of Australian patients comes first

An Action Plan for Medical Devices

Improving Australia's medical device regulatory framework

STRATEGY 1 : IMPROVE HOW NEW DEVICES GET ON THE MARKET

STRATEGY 2: STRENGTHEN MONITORING AND FOLLOW-UP OF DEVICES ALREADY IN USE

STRATEGY 3: PROVIDE MORE INFORMATION TO PATIENTS ABOUT THE DEVICES THEY USE

Our strategies take into consideration harmonisation with IMDRF, balanced with patient safety considerations and identified issues particular to the Australian healthcare and regulatory systems

Action Plan: Strategy 1 Achievements

Strategy 1: Improve how new devices get on the market

- Legislation changes in August 2020 to a number of definitions including ‘medical device’, ‘accessory to a medical device’, ‘reusable surgical instrument’, ‘use’ and ‘user’, ‘system and procedure pack’
- Validation of Class 1 medical devices to increase integrity and confidence of performance
- Regulation changes for products without a medical intended purpose (focussing on cosmetic lasers and IPL equipment), software-based medical devices and personalised medical devices
- Exemptions and exclusions for some low risk software-based medical devices and apps
- Pilot of ‘low risk’ medical devices self-assessment tool to verify classification levels

Open consultations - Central Circulatory System Medical Devices and Medical Devices containing nanomaterials

Action Plan: Strategy 2 Achievements

Strategy 2: Strengthen monitoring and follow-up of devices already in use

- Funding of $7.7 million (over four years) to implement the Australian Unique Device Identification database (AusUDID) by 2024
- Consultation on changes to adverse event reporting for medical devices currently underway
  - Removal of some existing exemptions on adverse event reporting requirements
  - How UDI can assist tracking and tracing devices through the healthcare system
  - Onsite auditing of adverse event reporting processes
  - Feasibility of mandatory reporting of adverse events by hospitals
- A new Post Market Review Compliance IT system implemented – an efficient, secure way to provide evidence and reports

Action Plan: Strategy 3 Achievements

Strategy 3: Provide more information to patients about the devices they use

- Consumer Working Group established – 10 consumer representative organisations including Choice and the Consumer Health Forum to help with consumer-friendly information
- *'Five questions to ask your health professional before you get a medical implant'* published from work of the Consumer Working Group
- From 1 December 2020, all new implantable devices require a patient implant card (PIC) and patient information leaflet (PIL) to demonstrate compliance with essential principles
- Existing implantable devices will require a PIC and PIL from December 2021
- Updated guidance for PIC and PIL released shortly

Action Plan: Stakeholder Engagement

- 27 consultation papers published on the TGA website on proposed changes to medical device regulation
  - Proposed changes consider EU MDR, IMDRF documents and any Australia-only regulatory requirements
  - Submissions to consultations published on TGA website
  - Meetings and workshops held with stakeholders to clarify details and understand their views about the impacts of the proposed changes

- Guidance material has been published
  - Used a collaborative approach with medical device stakeholders to draft guidance
  - Developing fact sheets and Q&As to support complex changes
  - Delivering webinars and other education methods with stakeholder groups

Challenges

- Implementation of regulatory changes ahead of other jurisdictions
- Development of guidance material in the absence of IMDRF guidance
- Regulatory changes that are specific to Australia
- Differences between various regulatory frameworks and what is appropriate for Australia to reduce regulatory burden on manufacturers and suppliers
- Balancing workloads and burdens on industry dealing with change globally

COVID-19 - Update

Unprecedented times……

Australian Government agreed to **delay implementation** start dates for some reforms:

- Medical device software and personalised medical devices (25 February 2021)
- Reclassification of certain devices and changes to system and procedure packs (25 November 2021)
- Amendments to essential principles – 2 years after EU MDR commencement

Time limited exemptions:

- Medical device personal protective equipment (PPE) (ceased 31 January 2021)
- COVID-19 tests for the purpose of donor screening (ceases on 30 June 2021)
- Domestically manufactured ventilators (ceased 31 January 2021)

Processes to validate COVID test kits to ensure their continued performance with the **emerging genetic variants of SARS-CoV-2**

Face mask review continues including TGA **laboratory testing** to validate claims

Significant dialogue and interactions with **other regulators**

COVID-19 - Update

Unprecedented times…..

- Medical Devices information line **call volumes** increased by over 200%
- **Compliance referrals** increased by 150 %
- Many enquiries were from new suppliers/manufacturers who had not marketed medical devices before
- **Procurement by government** of face masks, other PPE and COVID tests in a competitive global environment
- Greatly enhanced **focus on cleaning and use of disinfectants** with antiviral activity
- **Remote "virtual" and hybrid** audits and inspections
- Expedited and **prioritised** COVID related assessments

TGA's new accommodation

The Therapeutic Goods Administration Laboratories building in Canberra was officially opened on 24 May 1993.

Construction of two purpose-built buildings is underway. Plan to move into the new premises in mid-2022

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