IMDRF International Medical Device Regulators Forum

Regulatory update from Australia

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Therapeutic Goods Administration – Department of Health and Aged Care
13 September 2022

Overview

- **An Action Plan for Medical Devices**
  - **Reforms since June 2021 (snapshot only)**
- **COVID-19**
- **New IMDRF website**
- **IMDRF Secretariat**

An Action Plan for Medical Devices

Continues to guide reforms that strengthen our regulatory system, whilst remaining patient focused, having greater transparency, and increasing 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

a. Personalised medical devices:

- 25 February 2021: A new framework for the regulation of personalised medical devices commenced
- The framework includes new definitions adopted from IMDRF N49 – *Definitions for Personalized Medical Devices*
- Most custom-made medical devices will need to transition to ARTG inclusion

Challenges:

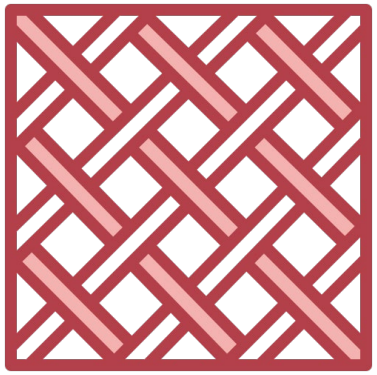
- Work is still underway on IMDRF validation guidance for patient-matched medical devices and Medical Device Production Systems (MDPS).
- Australia continues to work towards harmonisation but not all jurisdictions have adopted the new definitions.
- More work is needed before MDPSs can be introduced

b. Software-based medical devices:

- Regulatory changes for software-based medical devices took effect from 25 February 2021, including new classification rules, essential principles and carve-outs for certain products.
- Many new players innovating who are new to regulation (or not aware)
- Largely aligned with IMDRF guidance, with some differences such as the software classification rules that apply more broadly to all programmed/programmable medical devices and whether information is provided to a health professional (lower risk) or a consumer (higher risk).
- Taking an adaptive approach to digital health regulation

c. Surgical mesh reclassification:

- Since 1 December 2018, all new applications for surgical mesh are assessed as Class III devices
- Sponsors of previously Class IIb surgical meshes needed to apply for reclassification before 1 December 2021
- All Class IIb surgical meshes that did not transition to Class III have been cancelled from the ARTG

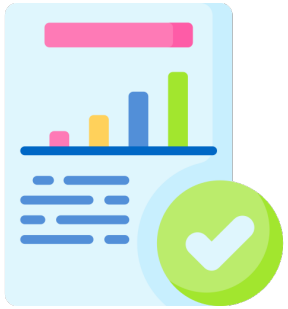


d. Reclassification of certain medical devices (non IVD)

- On 25 November 2021, the following devices were reclassified:
  - Active medical devices for therapy with diagnostic function
  - Spinal implantable medical devices
  - Devices used in direct contact with the heart, central circulatory system (CCS), or central nervous system
  - Medical devices that administer medicines or biologicals by inhalation
  - Active implantable medical devices (AIMD)
  - Medical devices that are substances introduced into the body via body orifice or applied to the skin
- Sponsors qualifying for transitional arrangements will need to submit applications with the revised classification by 1 November 2024 to continue supply.

e. Changes to the Medical Device Regulations

- Changes to the *Therapeutic Goods (Medical Devices) Regulations 2002* from July 2021. This removes the requirement for certain medical devices to have TGA Conformity Assessment Certification including devices:
  - that contain medicines or materials of animal, microbial, recombinant or human origin; and
  - Class 4 in vitro diagnostic (IVD) medical devices.
- Before the regulation change, such devices could only rely on conformity assessment certification issued by the TGA.
- Sponsors can now use conformity assessment documents issued by notified bodies designated by a member state of the EU, including IVD medical devices.
- However the TGA will continue to audit applications for high risk medical devices to ensure Australian requirements are met.



g. Australian conformity assessment bodies (Australian CABs)

- Australian corporations can apply to become an Australian CAB for medical devices from 1 July 2021
- The Therapeutic Goods Administration (TGA) remains responsible for including medical devices in the Australian Register of Therapeutic Goods
- The TGA will accept certificates issued by Australian CABs for all medical devices including:
  - Medical devices that contain medicines or materials of animal, microbial, recombinant or human origin
  - Class 4 in vitro diagnostic (IVD) medical devices

Strategy 2: post-market medical device reforms

a. Proposed mandatory reporting of medical device adverse events by hospitals

- Targeted discussion with Australian hospitals, peak bodies, state and territory governments, and international regulators
- Discussion Paper for public feedback from October to December 2021
- 56 submissions received
- Majority of respondents in favour of introducing mandatory reporting by healthcare facilities
- TGA is working closely with stakeholders to progress this project

b. Implementation of Unique Device Identification system

- Regular webinars (13 to date, including guest speakers) and a UDI website landing page to share information
- Two early adopter projects into healthcare (hospital) settings
- First working group (UDI-DI Triggers) complete, Technical Working Group established
- ‘Sandpit’ Australian UDI database launched for feedback, including machine to machine and National Product Catalogue (Australian Global Data Synchronisation Network) provision of UDI data
- Consultation Paper 3 – Detailed considerations for implementing the proposed regulatory framework - opened on 31st August 2022, closes 11th October 2022
- Voluntary compliance from January 2023

Strategy 3: consumer focused reforms

a. Medical Device Consumer Working Group

- Engagement with 21 health consumer organisations to progress the *Action Plan for Medical Devices* reforms from a consumer perspective, including the development of a range of consumer-focused products about medical devices.

b. Women's Health Products Working Group

- 12 member organisations advise the Minister and the TGA on the safety, quality and efficacy or performance of medicines and medical devices.

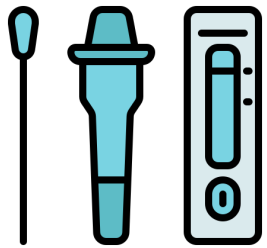
c. Patient information Leaflets (PILs) and Patient Implant Cards (PICs):

- All applicable implantable and active implantable medical devices must have a PIL and PIC made available for patients from 1 December 2021
- The TGA continues to work with stakeholders to improve awareness and accessibility of patient information materials

COVID-19 update

COVID-19 rapid antigen tests

- In November 2021, legislation amendment to enable supply of COVID-19 self tests
  - ✓ There are 99 approved COVID-19 rapid antigen tests, including 46 point-of-care tests and 53 self-tests
- The TGA has engaged the Peter Doherty Institute for Infection and Immunity to undertake laboratory testing of approved tests
  - ✓ As of 3 August 2022, 55 test of these have been tested with the wildtype, delta, and omicron variants
- Current focus is combination Rapid Antigen Tests that detect Flu and COVID.

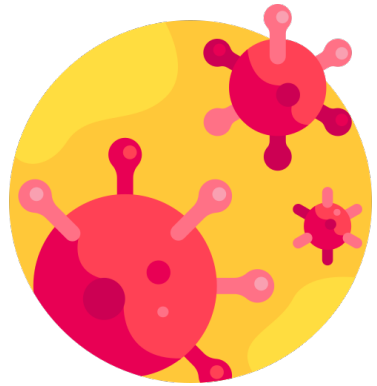


Disinfectant products making COVID-19 claims or residual activity claims

- In July/August 2021, we amended legislative instruments to clarify the regulation of borderline products and published guidance
- In December 2021, we amended our regulations to include specific test requirements that must be used to support claims of residual activity

COVID-19 Lessons and Changes

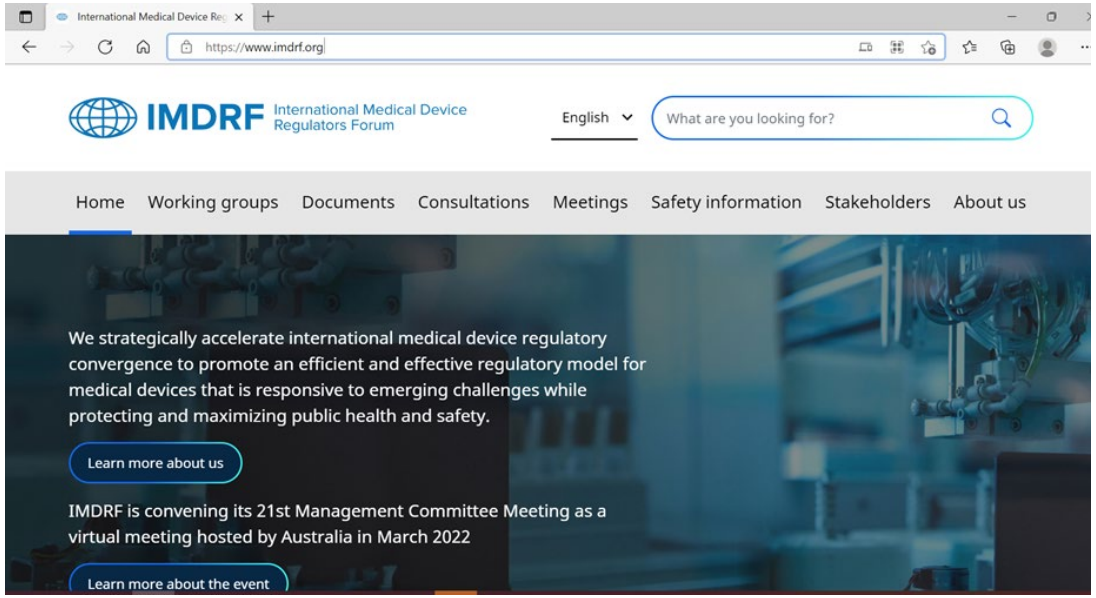
- We became more agile in balancing pandemic priorities with usual business needs
- We strengthened relationships to collaborate with health delivery sectors
- We shared knowledge with international regulators
- We improved how we communicate with consumers (e.g. rapid antigen self-tests)
- New ways of working due to restrictions and remote management especially with staff working from home
- Supporting sponsors new to the regulatory system through the processes and published guidance
- Better links between pre-market and post-market work (e.g. COVID tests)
- Improved the Class I inclusion process to enable greater scrutiny of products when needed

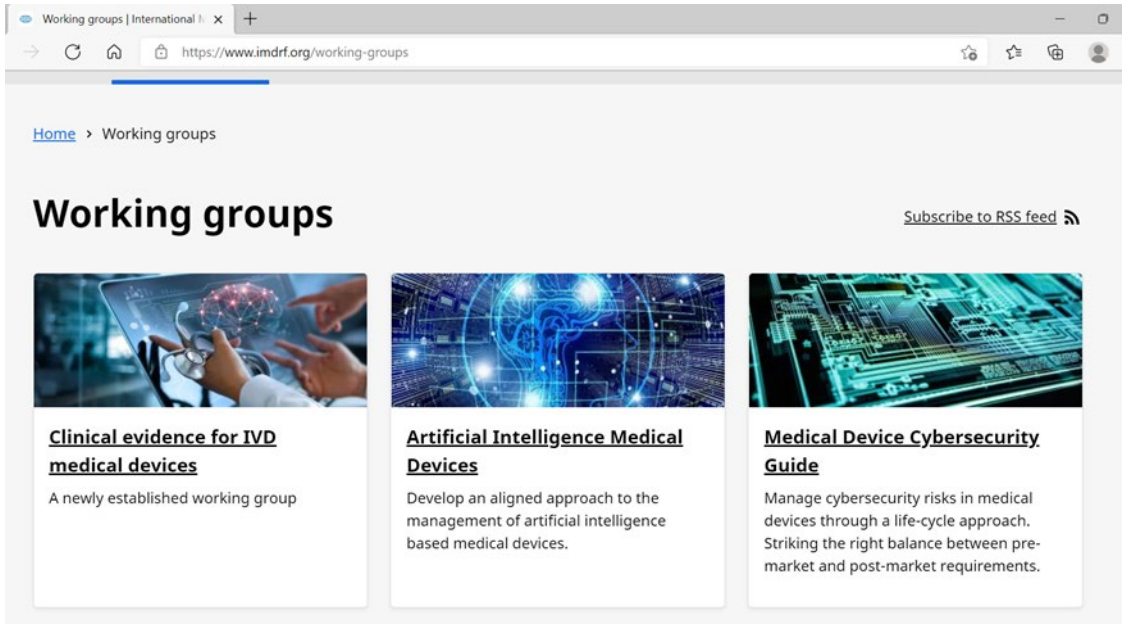


New IMDRF Website

The new IMDRF website was published in December 2021

www.imdrf.org/





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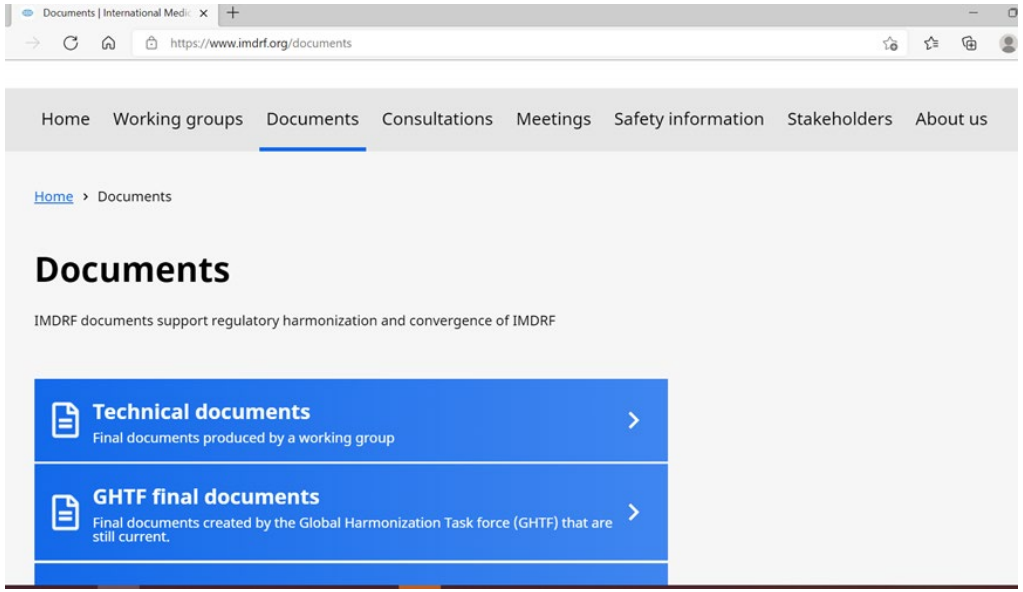
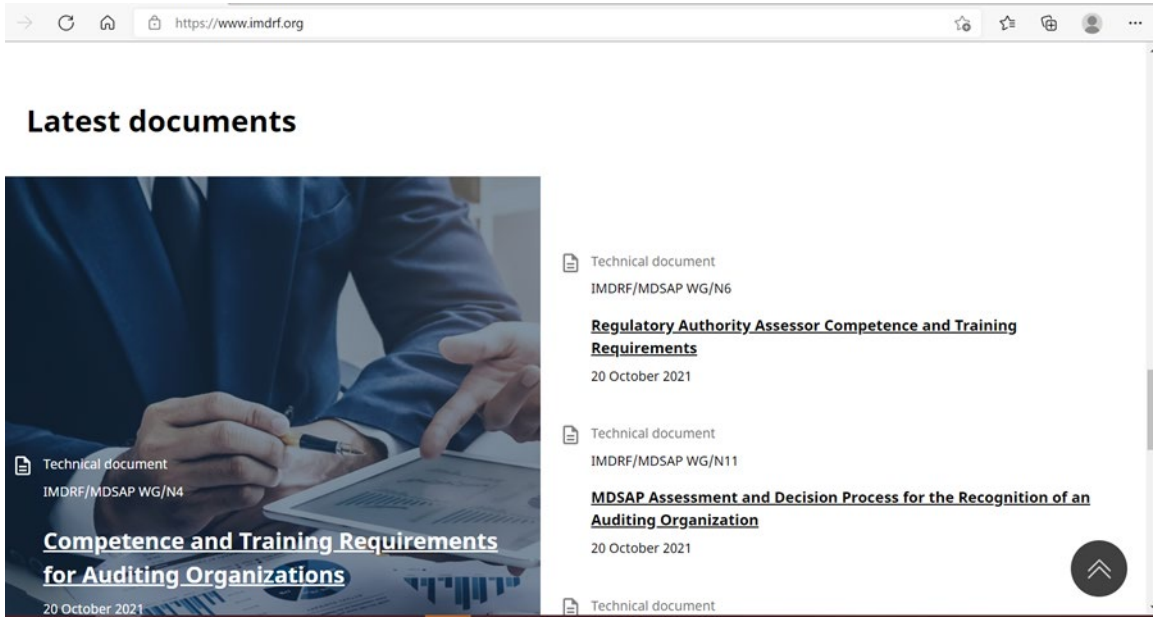
IMDRF website continued





IMDRF documents can be accessed via the Documents page or Latest documents on the home page

IMDRF Secretariat 2022

Australia was honoured to be the IMDRF Secretariat this year

- Ms Tracey Duffy is the IMDRF Chair
- The IMDRF Secretariat can be contacted on imdrf2022@tga.gov.au

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration


Thank you/Questions