IMDRF International Medical Device Regulators Forum

Regulatory update from Australia

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Overview

Medical Device Reforms since March 2021	1	Australian conformity assessment bodies, Unique Device Identification, Repeal and amendments to Australian Medical Devices Regulations
Medical Device Reforms starting in November 2021	2	Reclassification of certain devices (non IVD) including surgical mesh, requirement of patient information materials
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New IMDRF website	5	Progress update
New IMDRF Secretariat	6	Australia to become IMDRF Secretariat in 2022

Medical Device Reforms

March 2021 to current

- **Australian conformity assessment bodies (CAB)**
  - Australian corporations can apply to become an Australian CAB for medical devices from 1 July 2021.
  - The determination of an Australian CAB requires demonstrated competency and recognition for undertaking medical device product assessments and quality management system auditing.
  - The Therapeutic Goods Administration (TGA) remains responsible for including medical devices in the Australian Register of Therapeutic Goods (ARTG).
  - The TGA will continue to provide product assessments and quality management assessments
  - The TGA will accept conformity assessment documents issued by Australian CABs including those issued for medical devices that contain medicines or materials of animal, microbial, recombinant or human origin; and Class 4 in vitro diagnostic (IVD) medical devices.

Medical Device Reforms

March 2021 to current

- **Implementation of Unique Device Identification system**
  - Legislative changes in place to establish the UDI database
  - Pilot project commenced to implement device identifiers within health system (selected hospitals and devices)
  - Technical delivery partner engaged
  - Foundational version of the Australian UDI database established to support early use projects
  - Regular webinars and UDI website landing page established to share information
  - First working group being established

Medical Device Reforms

March 2021 to current

- **Changes to the Medical Devices Regulations**
  - Changes to the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations) came into effect from 28 July 2021. This changes the conformity assessment certification requirements for high-risk medical 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 for inclusion in the Australian Register of Therapeutic Goods (ARTG).
  - Sponsors can now use conformity assessment documents issued by notified bodies designated by a member state of the EU, including IVD medical devices and active implantable medical devices.
  - However there are new review requirements to ensure Australian requirements are met.

Medical Device Reforms

Still coming in 2021

- **Reclassification of certain medical devices (non IVD)**
  - **25 November 2021** the following devices will be reclassified:
    - Active medical devices for therapy with diagnostic function
    - Spinal implantable medical devices
    - Medical devices that are storage solutions for human cells, tissues and organs, and IVF media
    - 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
    - Personalised Medical devices
- **Personalised medical devices**
  - Potential refinements to the Framework
  - 137 responses received from recent consultation
  - Approximately 50,000 stakeholders impacted

Medical Device Reforms

Still coming in 2021

- **Surgical mesh**
  - Sponsors of Class IIb surgical mesh ARTG entries will need to apply for a Class III entry into the ARTG before **1 December 2021**
- **Scope of Medical device framework**
  - Changes to the medical device regulations affecting devices without intended medical purposes. This will regulate cosmetic contact lenses, which have not been regulated devices previously, and clarify the regulatory status of a range of other devices.
- **Patient information Leaflets (PILs) and Patient Information Cards (PICs)**
  - all applicable implantable and active medical devices must be provided with a PIL and PIC from **1 December 2021**
- **Software-based medical devices**
  - Transition arrangements closed on **24 August 2021**

Senate inquiry

Transvaginal mesh implants in Australia

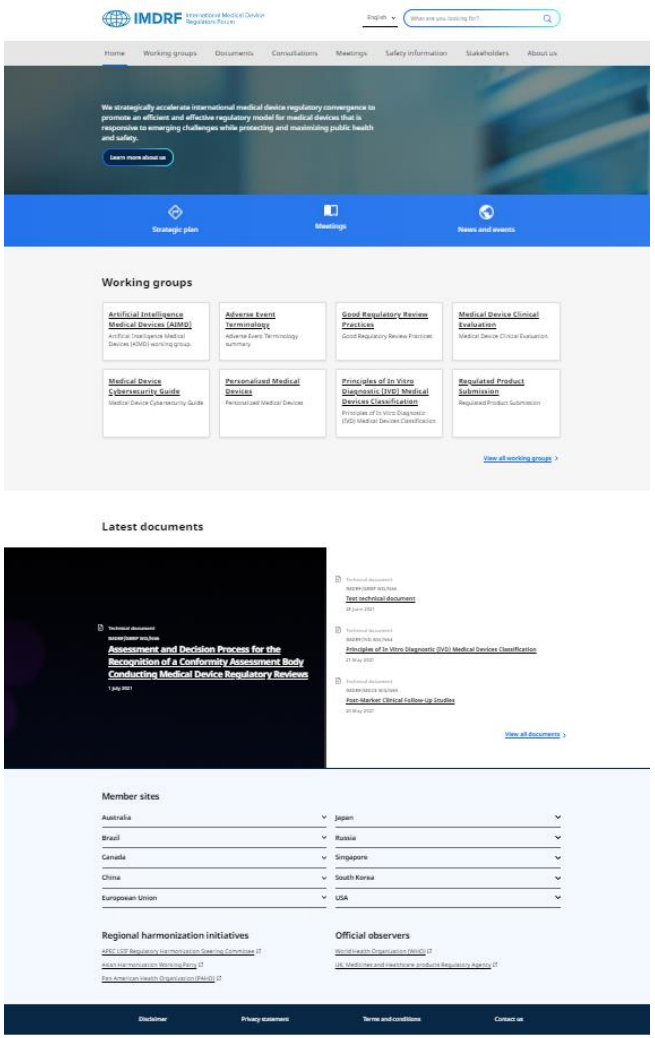
- The Australian Government final report in response to the Senate inquiry into the 'Number of women in Australia who have had transvaginal mesh implants and related matters' was published on the Parliament of Australia's website on 3 August 2021.
  - Recommendations from the Inquiry centred on enhancing the safety of medical devices by improving post market vigilance and adverse event reporting including mandatory reporting by medical professionals, ensuring quality, training and appropriate accreditation of doctors.
  - The report recommended increasing the information of the medical devices to available to patients.
  - We have implemented eleven out of the twelve recommendations that were supported or supported-in-principle by the Government.

COVID-19 Update

- **COVID-19 tests**
  - 128 tests approved including more than 24 rapid antigen tests
  - Conditions have been imposed on the supply of COVID-19 serology-based and rapid antigen point of care tests.
- **Disinfectant products making COVID-19 claims**
  - Increased enquiries about the regulation of disinfectant and related products with claims that the products can remove, kill or inhibit viruses (such as the virus that causes COVID-19).
  - We amended legislative instruments to clarify the regulation of these products and published guidance.
- **Enquiries to the Medical Devices information line**
  - During 2020-21,the medical devices information line has received:
    - 8,923 calls
    - 23,751 emails

New IMDRF website

- **The build of the new website is well advanced**
- **Website showcase to Management Committee in September**
  - New features such as Google Translate and RSS feed
  - New page layout improves the user experience
  - A dedicated news and events page
  - Consultation page tracks progress of the consultation
- **Migration of content from current to new website is under way**



IMDRF Secretariat 2022

- **Australia is honoured to be the IMDRF Secretariat in 2022**
  - Ms Tracey Duffy will be the IMDRF Chair
  - A team is being assembled to support the Chair next year

Australian Government
Department of Health
Therapeutic Goods Administration

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Thank you