IMDRF International Medical Device Regulators Forum

Australian Jurisdictional Update

September 2018

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Overview

- The Australian Government's Expert Review of Medicines and Medical Devices Regulation (MMDR) - Implementation
- Recently Published Guidance
- Other activities

Summary of MMDR Implementation

Recommendation	Legislation/Guidance Published	Implementation	
Expedited review process for certain 'novel' devices	Legislation January 2018 Guidance January 2018	2 January 2018	✓
Designation of Australian conformity assessment bodies	Legislation March 2018 Guidance September 2018	20 March 2018	✓
Use of approvals from comparable overseas regulators	Legislation September 2018 Guidance August 2018	13 September 2018	✓
Continued alignment with the European Union	Staged Approach to Harmonise with MDR 2017/745 and IVDR 2017/746	First Changes Commence 1 December 2018	
Review of Low Risk Products in the ARTG	Legislation to exempt Tampons/Menstrual Cups (Other reviews ongoing)	1 July 2018	
Strengthening of post market monitoring	Guidance to encourage consumer reporting eg Consumer Story BIA-ALCL (Other guidance in development)	7 September 2018	

Comparable overseas regulators

- Approvals by comparable regulators (or their designated bodies) will be accepted as supporting evidence for ARTG* applications
- Comparable overseas regulators will initially be:
  - European Union through notified body certification (in place since 2002)
  - USA
  - Canada
  - Japan
- MDSAP certification is required as QMS evidence in many cases

*Australian Register of Therapeutic Goods

Alignment with Europe – First changes

- Up-classification of surgical mesh
- Patient implant cards / patient information leaflets

	Up-classification	Device info leaflet	Patient implant card
Urogynaecological mesh			
New devices	1 Dec 2018	1 Dec 2018	1 Dec 2018
Existing devices	1 Dec 2020	1 Dec 2019	1 Dec 2019
Surgical mesh			
New devices	1 Dec 2018	1 Dec 2018	1 Dec 2020
Existing devices	1 Dec 2021	1 Dec 2021	1 Dec 2021
Implantable devices (other than those exempted)			
New devices	NA	1 Dec 2018	1 Dec 2020
Existing devices	NA	1 Dec 2021	1 Dec 2021

Strengthening of post market monitoring

- From August 2018, IMDRF terminology and codes have been integrated into TGA databases and are being used by TGA in its assessment of medical device adverse event reports.
- Redesign of analytics tools for signal detection and risk frameworks for triaging adverse events for investigation
- Web-based adverse event reporting forms being redesigned to address needs of healthcare providers and consumers
- Increasing capacity for targeted post-market reviews
- Greater use of expert panels for significant post-market issues, recent examples:
  - Breast Implant Associated Anaplastic Large Cell Lymphoma
  - Critical care ventilators

Recent Guidance

Consumer story: Georgia and breast implant associated cancer

- **7 September 2018**
- Learn how to spot the warning signs for breast implant associated cancer in our new consumer story

Comparable overseas regulators for medical device applications

- **20 August 2018**
- Use of market authorisation evidence from comparable overseas regulators for medical devices

Application requirements for medical devices - preliminary assessment

- **20 August 2018**
- Applications for the inclusion of medical devices in the ARTG must meet certain requirements in order to pass preliminary assessment

Recent Guidance

Electronic Instructions for Use - eIFU

- **15 August 2018**
- New guidance on electronic instructions for use for medical devices

Guidance on the regulation of tampons in Australia

- **2 August 2018**
- Updated to reflect the exemption of tampons from the regulatory requirement to include them on the ARTG

Other key activities

- Personalised Medical Devices
  - 2nd Stakeholder Workshop – 4 July 2018
  - Consultation to be conducted on the adoption of IMDRF definitions
- Software as a Medical Device & Cyber Security for Medical Devices
  - TGA is working with the Commonwealth Scientific and Industrial Research Organisation (CSIRO)
  - Webinar on Cyber Security 14 September 2018
  - Consultation to be conducted on the adoption of IMDRF SaMD risk framework
- Companion Diagnostics
  - Preparing to conduct a public consultation on regulatory changes

Thank you