IMDRF International Medical Device Regulators Forum

Australian Jurisdictional Update

March 2018

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Overview

- Expert Review of Medicines and Medical Devices Regulation (2015)
  - Medical device projects
- Other activities

Review of Medicines and Medical Devices Regulation (2015)

Key projects for medical devices

- Designation of Australian conformity assessment bodies
- Expedited review process for certain ‘novel’ devices
- Use of approvals from comparable overseas regulators
- Harmonisation with the European Union
- Strengthening of post market monitoring

Designation of conformity assessment bodies

Implementation now scheduled for March 2018

- Legislative change passed in Feb 2018
- Regulatory amendments currently progressing

Expedited review process – certain 'novel' devices

Commenced January 2018

- Legislation in place and regulatory guidance published
- No applications as yet, but some early interest

Comparable overseas regulators

Implementation now scheduled for March 2018

- Legislative change passed in Feb 2018
- Comparable overseas regulators will initially be:
  - Europe
  - USA
  - Canada
  - Japan
- Regulatory guidance being finalised which details:
  - Evidence/documents required for applications
  - Each comparable overseas regulator pathway for each class of device

Harmonisation with Europe

New European regulations – 25 May 2017

- Consulted on two specific aspects in 2017:
  - Up-classification of surgical mesh from Class IIb to Class III
  - Requirement for patient medical device ID cards (patient implant cards)
    - Workshop held with consumers (1 March 2018) to consult on format and requirements
    - Further workshops to be held with health professionals and industry
- Further consultations for 2018 include:
  - Definitions
  - Unique Device Identifiers
  - Companion diagnostics

Post market monitoring

Enhanced Post Market Monitoring and Analytics (EPMMA)

- Project aimed at establishing enhanced post market monitoring and analytics
- The next stages will deliver:
  - Improved TGA adverse event report management (online and internally)
  - Improved TGA post-market review systems (creating online submissions)
  - Improved and expanded sources for all post-market analytics

Electronic Data Interchange (EDI)

- Direct EDI is under review
- Instead, enhanced web submissions will support improved information exchange with sponsors, users, and health facilities

Other activities

- 3D printing of medical devices
  - Stakeholder workshop held August 2017
  - Public consultation conducted Nov/Dec 2017
- Clinical Evidence Guidelines (Feb 2017)
  - Partnering with industry to draft revision of guidelines to include IVDs

Thank you

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