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  – Canada
  – USA     – 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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