IMDRF International Medical Device Regulators Forum

Australian Jurisdictional Update

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Overview

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

2015 review - Medicines and Medical Device Regulation

Key projects for medical devices

- Designation of conformity assessment bodies in Australia
- 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

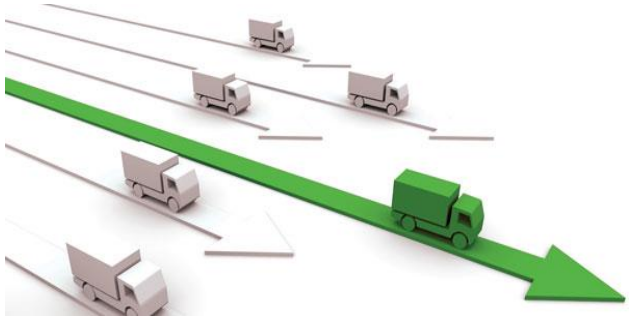
Implementation scheduled for January 2018

- Legislative change in progress
- Key processes being designed
- Implementation will be complex

Expedited review process – certain 'novel' devices

Implementation scheduled for January 2018

- Legislation in place
- 'Front of queue' approach
- Implementation will be complex



Comparable overseas regulators

Implementation scheduled for January 2018

- TGA consultation closed 30 June 2017
- Proposed criteria:
  - Scope
  - Operational alignment
  - IMDRF member
  - Life cycle approach
  - Communication and cooperation
  - Expertise
- Implementation will be complex

Harmonisation with Europe

New European regulations – 25 May 2017

- Consultation has recently commenced on two specific aspects (closes 25 August 2017):
  - Up-classification of surgical mesh from Class IIb to Class III
  - Requirement for patient medical device ID cards (patient implant cards)
- Further consultations on harmonisation with Europe will be released in 2018

Post market monitoring

Enhanced Post Market Monitoring and Analytics (EPMMA)

- The first stage has focused on improved analytics capability of data holdings
- The next stages in the project will deliver:
  - electronic data interchange (EDI) for reporting of medical device incident reports
  - improved TGA adverse event report management systems (AEMS).

Other activities

- 3D printing of medical devices
  - Stakeholder workshop held August 2017
- Clinical Evidence Guidelines (Feb 2017)
  - Webinars being developed
- Publishing outcomes of TGA Labs testing commenced June 2017
- Transition period for in-house IVD regulation completed 30 June 2017


Thank you