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
Comparative 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
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