# Regulatory Update

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# MMDR

## MEDICINES AND MEDICAL DEVICES REVIEW 2015

# MMDR Review

- Accelerated assessment for ‘novel’ devices
  - aka priority review, implemented
- Designation of conformity assessment bodies for Australia.
  - Legislation implemented
- **Use of approvals from comparable overseas regulators.**
  - **Implemented**
- Maintain harmonisation with the European Union
  - In progress

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

# Comparable overseas regulators

- Formalises the use of regulatory approvals from the EU, USA, Canada and Japan for marketing authorisations
  - **includes MDSAP Certs / Reports**
  - legislation commenced October 2018
  - reduces duplication of regulatory assessments.
- *http://www.tga.gov.au/comparable-overseas-regulators-medical-device-applications*

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# MDSAP usage

- Refer to the May, 2018 MDSAP Forum presentation
  - Brief overview of the Australian Regulatory Scheme
  - How the TGA uses MDSAP Audit Reports and Certificates for Regulatory Decisions
  - *https://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM608656.pdf*

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# MDSAP usage

- 20 MDSAP Certificates have been submitted to support applications for Marketing Authorisation (ARTG inclusion)
- 108 TGA on-site audits have been postponed pending the availability and review of MDSAP audit reports.
- Primarily used by manufacturers who don’t hold EU Certification.

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# European Alignment

- MMDR recommendation that the Australian medical device regulatory framework, wherever appropriate, is to align with the European Union framework
  - MDR and IVDR
  - Changes to the Australian regulations are expected.
  - Feedback on any proposal will be sought through consultation before implementation.

# Other Projects

- Surgical mesh - 1 December 2018
  - reclassification from Class IIb to III
  - *http://www.tga.gov.au/publication/reclassification-surgical-mesh-devices*
- Patient information – 26 October 2017
  - Introducing patient implant card and information leaflet for implantable and active implantable medical devices
  - *http://www.tga.gov.au/publication/medical-device-patient-cards-and-leaflets*

# Other Projects

- Companion IVDs (CDx)
  - Proposal for the regulation of CDx.
  - Consultation closes 14 December, 2018
  - *http://www.tga.gov.au/consultation/consultation-proposal-regulation-ivd-companion-diagnostics*

- Cyber security and software as a medical device
  - Initial consultations are in progress

# Other Consultations / Guidances / Projects

- TGA
  - See: https://www.tga.gov.au/standards-guidelines-publications-medical-devices-ivds
  - http://www.tga.gov.au/open-consultations
  - http://www.tga.gov.au/closed-consultations-reviews

- IMDRF
  - http://imdrf.org/workitems/work.asp