# RECENT AND UPCOMING REGULATORY CHANGES - TGA

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**May 2018**

# MMDR

## MEDICINES AND MEDICAL DEVICES REVIEW

# MMDR Related Changes

Legislation passed in June 2017 and Feb 2018.

- Designation of conformity assessment bodies for Australia.
- Accelerated assessment for ‘novel’ devices (priority review).
- Use of approvals from comparable overseas regulators.
- Maintain harmonization with the European Union.

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# Designation of conformity assessment bodies (CABs)

- Based on European MD and IVD Regulations and aligned with MDSAP criteria for AO's.
- TGA as designating authority
- TGA will continue to issue CA certificates.
  - For some excluded high risk devices;
  - Combination products, animal origin etc and Class IV IVDs.
- TGA conformity assessment processes
  - similar to MDSAP for QMS
  - will include design examination and technical document reviews
- Guidance expected to be published in May 2018.

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# Accelerated assessment for 'novel' devices

- For medical devices the proposal is for a **'front-of-queue'** approach:
  - includes TGA business processes associated with applications for conformity assessment, and inclusion on the ARTG for medical devices.
- Criteria for Priority Review designation:
  - device prevents, diagnoses or treats a life threatening or seriously debilitating disease or condition
  - device addresses an unmet clinical need in Australian patients
  - breakthrough technology or clinical advantage or major public health benefit
- Guidance Released February 2018
- https://www.tga.gov.au/sites/default/files/priority-review-designations-for-medical-devices.pdf

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# Comparable overseas regulators

- For abridgement of TGA conformity assessment and for ARTG inclusion applications
- Overseas Evidence which can be submitted:
  - Certificates issued by EU NB's
  - Decisions of the FDA (PMA, 510k)
  - Licenses issued by Health Canada
  - Premarket approvals from Japan
  - Certificates and reports issued under MDSAP program
- Guidance expected to be released in May 2018

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# Harmonisation with the European Union

- MMDR recommendation 20 recommends:
  - **Recognises new European regulations commenced 25 May 2017**
  - **“Australian regulation of medical devices is to be, wherever possible, aligned with the European framework”**
- Commenced detailed comparison of Australian and new European regulatory requirements.
  - Up classification of surgical mesh and introduction of patient implant cards
    - https://www.tga.gov.au/sites/default/files/consultation-alignment-european-medical-device-regulatory-framework.pdf released July 2017

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# Recently Published MD Guidance

- Clinical Evidence Guidelines
  (relates to ISO 13485:2016 Cl 4.2.3 and 7.3.7)
  - https://www.tga.gov.au/sites/default/files/clinical-evidence-guidelines-medical-devices.pdf
- Defn of Substantial Changes Affecting a TGA Conformity Assessment Certificate and Transfer of Certificates
  (relates to MDSAP DMA&FR Task 3)
  - https://www.tga.gov.au/sites/default/files/substantial-changes-affecting-tga-conformity-assessment-certificate-and-transfers-certificates.pdf
- Guidance under development
  - Regulation of medical software and mobile medical apps
  - Clinical evidence guidelines (to include IVDs)
  - Guidance on the provision of electronic instructions for use (eIFU)