TGA REGULATORY UPDATE
December 2020
New and Upcoming Reforms

- Software as a Medical Device (SaMD)
- Personalised Medical Devices (PMD) and Medical Device Production Systems (MDPS)
- Reclassification of Surgical Mesh
- Reclassification of devices
- Unique Device Identification (AusUDID)
- Patient Implant Cards and Leaflets (PIC/PIL)
- IVD Companion Diagnostics
Software as a Medical Device (SaMD)

• Commencing: 25 Feb 2021 (new inclusions)
• Changes
  – New classification rules
  – EP 12.1 and 13.2(3) amended
  – New EP 13B introduced
Personalised Medical Devices (PMD)

• Commencing: 25 Feb 2021 (new inclusions)
• Changes:
  – Reduced scope of custom made devices, now excludes patient matched devices
  – New concept of Medical Device Production System (MDPS)
  – Update to classification rule 5.4
PMD – Overview of changes

25 February 2021 – regulatory amendments commence

- Custom-made medical devices
  - (new definition)
  - Exempt from inclusion in the ARTG

- Patient-matched medical devices
  - Must be included in the ARTG

- Devices produced using a Medical Device Production System (MDPS)
  - MDPS must be included in the ARTG

- Adaptable medical devices
  - Must be included in the ARTG
PMO - Patient-matched medical devices

- Production processes can be validated, verified or reproduced
- Manufactured within a "design envelope"
- No longer exempt – must be included in the ARTG
- Notify the TGA by 25 August 2021 to access transition arrangements
- Submit an application for inclusion before 1 November 2024
TGA is the first regulator to introduce the concept of a validated, multi-component design and production system that a manufacturer can supply to health professionals and healthcare facilities, to produce a specific type of personalised medical device in-house.
Health professionals (or a suitably qualified person within a healthcare facility) who use an MDPS to produce a medical device will not meet the definition of a manufacturer.

The MDPS must:
- be included in the ARTG;
- classified at the same level as the device it produces; and
- be supplied with comprehensive instructions to allow the healthcare professional (or qualified person) to safely produce a device commensurate with the intended purpose of the MDPS.
Reclassification of Surgical Mesh

- **Commencement:**
  - Existing urogynaecological mesh entries require Class III application by 1 Dec 2020
  - Other surgical mesh entries require Class III application by 1 Dec 2021

- **Changes**
  - Reclassification from Class IIb to Class III

Reclassification of devices

- Commencing: Delayed to 25 Nov 2021
- Changes:
  - Generally changed to align with the EU MDR’s.
  - Includes 6 categories of medical devices, for example:
    - spinal implantable medical devices (some to Class III)
    - medical devices that administer medicines or biologicals by inhalation (to Class IIa or IIb)
    - medical devices that are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system (to Class III)

Unique Device Identification (UDI)

- Second consultation period closed 2 Dec 2020
- Changes:
  - Proposal for both sponsor and manufacturer to have legislated UDI responsibilities
  - Proposal for TGA managed data base (AusUDID) linked to the ARTG.
Patient Implant Cards and Leaflets (PIC/PIL)

- Transition Dec 2018 - Dec 2021
- Changes:
  - Changes have already been added to the MDSAP Audit Approach
  - EP 13A added to MD Regulations

IVD Companion Diagnostics

- Transition: 1st Feb 2020 – 30th June 2022
- Changes:
  - new definition of the term 'IVD companion diagnostic' was introduced into the Therapeutic Goods (Medical Devices) Regulations 2002
  - Australia's definition of IVD companion diagnostic and the regulatory requirements are now aligned with the U.S. Food & Drug Administration and the European Union Regulations
  - Generally classified as Class 3 IVD’s or Class 3 in-house IVD’s.