IMDRF International Medical Device Regulators Forum

Regulatory and Policy Update

Therapeutic Goods Administration
Australian Department of Health

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Overview

- Recent regulatory reforms
- Consultations for regulatory reforms
- Recently published guidance
- Other activities

Recent regulatory reforms

Effective 1 December 2018:

- Up-classification of surgical mesh
- Patient implant cards / patient information leaflets

	Up-classification	Device info leaflet	Patient implant card
Urogynaecological mesh			
New devices	1 Dec 2018	1 Dec 2018	1 Dec 2018
Existing devices	1 Dec 2020	1 Dec 2019	1 Dec 2019
Surgical mesh			
New devices	1 Dec 2018	1 Dec 2018	1 Dec 2020
Existing devices	1 Dec 2021	1 Dec 2021	1 Dec 2021
Implantable devices (other than those exempted)			
New devices	NA	1 Dec 2018	1 Dec 2020
Existing devices	NA	1 Dec 2021	1 Dec 2021

Consultations for regulatory reforms

Current consultations

Closing 31 March 2019:

- Personalized medical devices (including 3D printed devices)
  - Incorporates IMDRF Definitions for personalized medical devices
- Software including software as a medical device
  - Incorporates IMDRF SaMD concepts
- Spinal implantable medical devices

Closing 29 April 2019:

- Medical devices that administer medicines or biologicals by inhalation
- Active implantable medical devices and their accessories
- Human cells, tissues and organs storage solutions and IVF media
- Substances introduced into the body via a body orifice or applied to the skin
- Medical devices used in direct contact with the heart, central circulatory or central nervous systems

Consultations for regulatory reforms

Recently closed consultations

Closed 7 January 2019:

- Changes to a number of definitions and the scope of the medical device regulatory framework in Australia
- Potential reclassification of active medical devices for closed-loop diagnosis and patient therapy
- Proposal to introduce a Unique Device Identification (UDI) system

Closed 20 December 2018:

- Medical device cyber security – Guidance for manufacturers and users
- Changes to the regulation of IVD companion diagnostics

Consultations for regulatory reforms

Upcoming consultations

- Reclassification of devices containing nanomaterials
- Systems and procedure packs
- Essential Principles / General safety and performance requirements
- Conformity assessment procedures
- Post market, including:
  - Periodic Safety Update Reporting – changing from Annual Reporting
  - Electronic reporting of adverse events as the only way to report events
- Excluded Goods Determination – items that are not medical devices

Consultations for regulatory reforms

Where to find information on the consultation documents

Visit the TGA webpage to view the consultations:

- **Current consultations:** https://www.tga.gov.au/open-consultations - Instructions on how to submit is provided in each consultation paper
- **Recently closed consultations:** https://www.tga.gov.au/medical-devices-ivds-closed-consultations-reviews - Submissions to the consultations will be published on these pages
- To know more about TGA's consultation in general see https://www.tga.gov.au/about-consultations

Recently published guidance

- **The Poisons Standard and medical devices**
  10 September 2018
  https://www.tga.gov.au/poisons-standard-and-medical-devices
  Information for medical device manufactures and sponsors on complying with Australia's Poisons Standard
- **Medical device patient cards and leaflets**
  15 October 2018
  https://www.tga.gov.au/publication/medical-device-patient-cards-and-leaflets
  Information for manufacturers and sponsors on new requirements for patient cards and leaflets for implantable medical devices
- **Reclassification of surgical mesh devices**
  27 November 2018
  https://www.tga.gov.au/publication/reclassification-surgical-mesh-devices
  Guidance for sponsors of surgical mesh medical devices, which have been reclassified as Class III with transitional arrangements from 1 December 2018.

Recently published guidance

- **Regulation of Software as a Medical Device**
  11 December 2018
  https://www.tga.gov.au/regulation-software-medical-device
  Guidance on the regulation that applies to software and apps that meet the legislated definition of a medical device in Australia
- **How to determine if your product should be included in the ARTG**
  14 January 2019
  https://www.tga.gov.au/how-determine-if-your-product-should-be-included-artg
  Assistance for sponsors to decide if products are required to be included in the ARTG, and action for incorrectly included products
- **Conditions of approval on the ARTG for HIV POCT**
  30 January 2019
  https://www.tga.gov.au/conditions-approval-artg-hiv-poct
  Text of condition of marketing approval for HIV point of care testing

Other activities

- **Update on Breast Implant Associated ALCL**

  Expert Working Group meeting on 30 Jan 2019

  21 December 2018 update to TGA statement on BIA ALCL

  https://www.tga.gov.au/breast-implant-associated-cancer-or-bia-alcl
- **ISO 13485**

  1 March 2019

  TGA released a statement on the end of the period for transition to ISO 13485:2016 and implications for manufacturers https://www.tga.gov.au/iso-134852016-transition-period-ending
- **Brexit**

  6 March 2019

  TGA released a statement on implications of the UK's withdrawal from the EU for the supply of medical devices in Australia

  https://www.tga.gov.au/brexit-implications-therapeutic-goods-australia

Thank you