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

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<thead>
<tr>
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<th>Up-classification</th>
<th>Device info leaflet</th>
<th>Patient implant card</th>
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<tr>
<td><strong>Urogynaecological mesh</strong></td>
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<td>New devices</td>
<td>1 Dec 2018</td>
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<td>Existing devices</td>
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<td><strong>Surgical mesh</strong></td>
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<td>Existing devices</td>
<td>1 Dec 2021</td>
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<td><strong>Implantable devices (other than those exempted)</strong></td>
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<td>New devices</td>
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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](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](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](https://www.tga.gov.au/about-consultations)
Recently published guidance

- **The Poisons Standard and medical devices**
  10 September 2018
  Information for medical device manufactures and sponsors on complying with Australia’s Poisons Standard

- **Medical device patient cards and leaflets**
  15 October 2018
  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
  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
  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
  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
  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

- **ISO 13485**
  1 March 2019

- **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
Thank you