Overview

• The Australian Government’s Expert Review of Medicines and Medical Devices Regulation (MMDR) - Implementation

• Recently Published Guidance

• Other activities
<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Legislation/Guidance Published</th>
<th>Implementation</th>
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</thead>
<tbody>
<tr>
<td>Expedited review process for certain ‘novel’ devices</td>
<td>Legislation January 2018 Guidance January 2018</td>
<td>2 January 2018</td>
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<td>Designation of Australian conformity assessment bodies</td>
<td>Legislation March 2018 Guidance September 2018</td>
<td>20 March 2018</td>
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<tr>
<td>Use of approvals from comparable overseas regulators</td>
<td>Legislation September 2018 Guidance August 2018</td>
<td>13 September 2018</td>
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<tr>
<td>Continued alignment with the European Union</td>
<td>Staged Approach to Harmonise with MDR 2017/745 and IVDR 2017/746</td>
<td>First Changes Commence 1 December 2018</td>
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<tr>
<td>Review of Low Risk Products in the ARTG</td>
<td>Legislation to exempt Tampons/Menstrual Cups (Other reviews ongoing)</td>
<td>1 July 2018</td>
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<tr>
<td>Strengthening of post market monitoring</td>
<td>Guidance to encourage consumer reporting eg Consumer Story BIA-ALCL (Other guidance in development)</td>
<td>7 September 2018</td>
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Comparable overseas regulators

- Approvals by comparable regulators (or their designated bodies) will be accepted as supporting evidence for ARTG* applications

- Comparable overseas regulators will initially be:
  - European Union through notified body certification (in place since 2002)
  - USA
  - Canada
  - Japan

- MDSAP certification is required as QMS evidence in many cases

*Australian Register of Therapeutic Goods
Alignment with Europe – First changes

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

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<thead>
<tr>
<th></th>
<th>Up-classification</th>
<th>Device info leaflet</th>
<th>Patient implant card</th>
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<tbody>
<tr>
<td><strong>Urogynaecological mesh</strong></td>
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<td>New devices</td>
<td>1 Dec 2018</td>
<td>1 Dec 2018</td>
<td>1 Dec 2018</td>
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<tr>
<td>Existing devices</td>
<td>1 Dec 2020</td>
<td>1 Dec 2019</td>
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<tr>
<td><strong>Surgical mesh</strong></td>
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<tr>
<td>Existing devices</td>
<td>1 Dec 2021</td>
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<tr>
<td><strong>Implantable devices (other than those exempted)</strong></td>
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Strengthening of post market monitoring

- From August 2018, IMDRF terminology and codes have been integrated into TGA databases and are being used by TGA in its assessment of medical device adverse event reports.
- Redesign of analytics tools for signal detection and risk frameworks for triaging adverse events for investigation
- Web-based adverse event reporting forms being redesigned to address needs of healthcare providers and consumers
- Increasing capacity for targeted post-market reviews
- Greater use of expert panels for significant post-market issues, recent examples:
  - Breast Implant Associated Anaplastic Large Cell Lymphoma
  - Critical care ventilators
Recent Guidance

**Consumer story: Georgia and breast implant associated cancer**

- 7 September 2018
- Learn how to spot the warning signs for breast implant associated cancer in our new consumer story

**Comparable overseas regulators for medical device applications**

- 20 August 2018
- Use of market authorisation evidence from comparable overseas regulators for medical devices

**Application requirements for medical devices - preliminary assessment**

- 20 August 2018
- Applications for the inclusion of medical devices in the ARTG must meet certain requirements in order to pass preliminary assessment
Recent Guidance

Electronic Instructions for Use - eIFU

- 15 August 2018
- New guidance on electronic instructions for use for medical devices

Guidance on the regulation of tampons in Australia

- 2 August 2018
- Updated to reflect the exemption of tampons from the regulatory requirement to include them on the ARTG
Other key activities

• Personalised Medical Devices
  – 2\textsuperscript{nd} Stakeholder Workshop – 4 July 2018
  – Consultation to be conducted on the adoption of IMDRF definitions

• Software as a Medical Device & Cyber Security for Medical Devices
  – TGA is working with the Commonwealth Scientific and Industrial Research Organisation (CSIRO)
  – Webinar on Cyber Security 14 September 2018
  – Consultation to be conducted on the adoption of IMDRF SaMD risk framework

• Companion Diagnostics
  – Preparing to conduct a public consultation on regulatory changes
Thank you