



IMDRF

International Medical
Device Regulators Forum

Update from Australia September 2019

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Medical Device Regulatory Reforms

- Continued work on reforms to modernise our regulatory framework
- To date, 14 consultation papers publicly released, industry meetings, workshops, webinars – seeking views on international alignment
- Since the last Management Committee meeting in March 2019:
 - **Reclassification of Spinal Implantable Devices**
 - **Software including Software as a Medical Device**
 - **Regulation of Personalised Medical Devices**
 - **Classification rules for a range of products**
 - **Essential Principles**
 - **Conformity Assessment Procedures**



In principle support to progress legislative changes to provide for:

- Introducing a **Unique Device Identification (UDI) System** for medical devices in Australia
- **Next steps:**
 - scope the IT infrastructure requirements
 - consult on how the UDI could be used in the healthcare system – by hospitals, in electronic patient records, device registries
 - start planning for implementation including data definitions, costs, alignment globally – seek experience from other regulators, identification of designation authorities, linkage with the Australian Register of Therapeutic Goods (ARTG)



In principle support to progress legislative or regulatory changes to provide for:

- Enhancing **Software including software as a Medical Device**
- Align with IMDRF 2018 EPs, general principles from IMDRF Draft Cybersecurity guidance, IMDRF SaMD Risk document.
 - Additional detail (clarity but not new requirements) provided on some topics (safety; design and development [in line with IEC 62304]; and data and information management)
 - New requirement => information to be provided with the device [version number and build number to be identifiable to the user]



Enhancing **Software including software as a Medical Device (cont)**

- **Classification rules largely aligning with EU and IMDRF with a few differences:**
 - **Addition of rules for software intended to provide therapy to a patient (e.g., cognitive behavioural therapy, rehabilitation exercise instruction)**
 - **Some software for diagnosis, monitoring, screening (e.g., for infectious diseases), or for treatment or intervention may be a different class than in EU depending on whether a relevant health professional is involved or there is a high risk to public safety. Most software will be same or lower class than EU unless used for therapy. Software for therapy is Class I in EU so Australia likely to be higher in some cases.**



Enhancing **Software including software as a Medical Device (cont)**

- **Personal importation (Australia only):**
 - **Removal of importation exemption for individuals downloading software from overseas (currently captured by the personal importation exemption)**

Challenges:

- ❖ **Lack of understanding of regulatory requirements**
- ❖ **Scope – what is in and what is out?**
- ❖ **Networked medical devices (in hospital, in home)**
- ❖ **Role of clinicians – level of risk reduced**
- ❖ **Consumer and clinician expectations**
- ❖ **Not hindering innovation**
- ❖ **Large number of apps!!!**



In principle support to progress legislative or regulatory changes to provide for:

- Elements of **Personalised Medical Devices**
- Aligning with IMDRF definitions (custom made, patient matched, adaptable) and draft pathways
- Aligning with EU and many other jurisdictions so that medical devices with human origin material will be regulated as a medical device rather than as a biological (no new requirements)
- Introduction of Medical Device Production System
- Classification rules
 - Alignment with EU on software used to record diagnostic images (rule previously applied only to Xrays)
 - New rule to cover anatomical models (virtual or physical)



In principle support to progress regulatory changes to provide for:

- **Reclassification of medical devices** to align with the EU framework for:
 - Spinal implants (with some exceptions)
 - Non-fusion, motion-preserving spinal devices, such as spinal disc replacement, or an implantable device that is intended to come into contact with a person's spinal column will be Class III
 - Fusion devices and implantable instrumentation such as rods, plates, screws, cages, or hooks, intended to be used during spinal fusion surgical procedures will remain Class IIb (as these devices have the same primary intended temporary functionality)



In principle support to progress regulatory changes to provide for:

- A definition of an **IVD companion diagnostic**
 - Will allow for better identification of these devices and ensure they are subject to an appropriate level of pre-market scrutiny
- **Reclassification of medical devices** to align with the EU framework for:
 - Active medical devices for therapy with diagnostic function to Class III (other than continuous positive airways pressure devices which will remain Class II)
 - Surgically invasive medical devices used in direct contact with the heart, central circulatory system or central nervous system to Class III



- **Reclassification of medical devices** to align with the EU framework for:
 - Substances introduced into the body via body orifice or applied to the skin to Class IIa, Class IIb or Class III depending on the location in the body where the device achieves its intended purpose
 - ❖ Some further consultation required on devices containing substances of animal origin
 - Long term surgically invasive and implantable accessories to Active Implantable Medical Devices (AIMD) to Class III (rather than all accessories to AIMD)
 - Medical devices administering medicines or biologicals by inhalation

New rules commencing from August 2020 with a four year transition period for devices already included in the ARTG.



Outreach and Education – Software as a medical device

- Partnered with Commonwealth Scientific and Industrial Research Organisation - cybersecurity guidance
- Monthly webinars to increase awareness or regulatory framework.

7 February 2019	The role of the TGA in Digital Health
7 March 2019	Regulation of Software, including Software as a Medical Device (SaMD)
20 June 2019	Proposed reforms to the Regulation of Software, including Software as a Medical Device – Consultation results
1 August 2019	The difference in regulatory oversight for Class I and Class IIa medical devices
September 2019	Essential Principles

- All available on the TGA website



Other activities

- **Breast Implant Review and new website hub**
 - **Laboratory testing, statistical analysis**
 - **Clearer consumer and clinician guidance fact sheets**
- **Fast track pathways – priority review for new and novel devices, use of overseas comparable regulator assessments, better triaging to reduce time**
- **Direct to consumer genetic tests**
- **Action Plan for Medical Devices**
 - **Accelerating current reforms - consult on some new proposals**
 - **Consumer / patient focused**



Guidance published since last meeting

- **Cyber Security for Medical Devices and IVDs (July 2019)**
- **Patient Information Leaflets and Patient Implant Cards (July 2019)**
- **Comparable Overseas Regulators for Device Applications (July 2019)**
- **Medical Device Incident Reporting (August 2019)**

THANKYOU