



IMDRF

International Medical
Device Regulators Forum

Regulatory Update from Australia



Tracey Duffy

First Assistant Secretary

Medical Devices and Product Quality Division

Therapeutic Goods Administration - Department of Health

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Australia is implementing 3 medical device reform programs

IMDRF Strategic Plan

Implementing the **IMDRF Strategic Plan 2016 to 2020** and work items developed by the IMDRF working groups

Australian Government Reviews

Implementing recommendations of the Australian Government to the **Medicines and Medical Devices Review** and the **Inquiry into urogynaecological mesh and other matters**

An Action Plan for Medical Devices

Progressing Australian reforms that focus on patient safety as outlined in **An Action Plan for Medical Devices**



IMDRF Strategic Plan 2016 to 2020

“Support innovation and timely access to safe and effective medical devices”

Primary objective of IMDRF Strategic Plan 2020

Focus areas:

- Aligning regulatory requirements and practice
- Broadening access to medical devices of public health importance across jurisdictions

Australian progress

Fully implemented

- Medical Device Single Audit Program
- Medical device cybersecurity
- National Competent Authorities Reports Exchange Program
- Edition 3 of adverse event terminology

Partially implemented or still in progress

- Common principles on registries
- Edition 4 of adverse event terminology
- Development of Regulatory Product Submissions
- Good Review Practices for pre-market reviews
- Improving medical device standards (via Standards Australia)
- Improving quantity and quality of clinical data
- Software as a Medical Device
- Personalised medical devices
- Rules for unique device identifiers



Utilisation of IMDRF outputs, support to IMDRF members and engagements

- Participation in IMDRF Management Committee and Working Groups
- Referenced IMDRF final documents in our consultations on Australian medical device reforms
- Referenced IMDRF documents to other stakeholders
- Referenced IMDRF documents in advice to the Australian Government
- Changes to TGA internal processes and forms to implement IMDRF documents
- Continued hosting of IMDRF website
- Information exchange with IMDRF members on various topics
- Hosted visits from IMDRF representatives (some planned visits postponed due to COVID)
- Engagement with WHO, ISO, IEC, APEC, AHWP, PAHO
- Discussions and sharing of information about COVID-19 pandemic



Australian medical device reforms

- **19 consultation papers** and all responses now published on the TGA website on a wide range of proposed changes to medical device regulation
 - Proposed changes take into consideration EU MDR, IMDRF documents and any Australian-only regulatory requirements
 - Some challenges given EU MDR guidance not published on all their changes – but we have still progressed
 - Meetings and workshops held with stakeholders to clarify details and understand their views about the impacts of the proposed changes
- Australian Government has **approved regulatory changes** to be implemented with a number of transitional arrangements
- **Guidance material** has been published on some of the changes or is in draft development for other changes
 - Used a collaborative approach with medical device stakeholders in drafting guidance materials to assist implementation.
 - Developing fact sheets and Q&A to support the implementation of complex changes
 - Planning webinars and other education methods with stakeholder groups to support implementation



Australian Government Reviews - progress

Recommendations from the Medicines and Medical Devices Review

- **Priority review pathway** for medical devices – expedited process for Australian conformity assessment of new novel devices or that meet an unmet need
 - 6 applications have been approved using this pathway
 - Average time to complete assessments has been 70 days
- **Aligning with EU** where appropriate with the MDR – still progressing
- **Use of comparable overseas regulator approvals**: new process has allowed 225 approvals from a broader range of comparable overseas regulators to be used for TGA approval - reducing duplication of effort
- **Australian conformity assessment bodies** – still developing the implementation arrangements for Australian ‘notified bodies’
- **Benchmarking TGA timeframes** with other regulators – completed and published on TGA website



Australian Government Reviews - progress

Recommendations from the Inquiry into Urogynaecological mesh

- Implementation of [upclassification to Class III](#) for mesh devices continues
- Implementation of [patient information leaflets and cards](#) continues with guidance being finalised with input from consumer groups, patients and medical device industry
- New Australasian [pelvic floor procedure registry](#) funded by the Government commences mid-late 2020
- Planned [public consultation](#) on:
 - Proposal to remove some existing exemptions on adverse event reporting requirements
 - Proposal for mandatory reporting of adverse events by hospitals
 - How UDI can assist tracking and tracing devices through the healthcare system
 - Proposal for onsite auditing of adverse event reporting processes



Implementation dates for mesh upclassification and patient information materials in Australia

	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



Action Plan for Medical Devices reforms

Overview

- The Action Plan for Medical Devices is a three-part strategy to strengthen Australia's medical device regulatory system

Action Plan's 3 Strategies:

1. Improving how new devices get on the market
 2. Strengthening monitoring and follow-up of devices already in use
 3. Provide more information to patients about the devices they use
- Our strategies and proposals take into consideration harmonisation with IMDRF, balanced with patient safety considerations and identified issues particular to the Australian healthcare and regulatory systems



An Action Plan for Medical Devices - progress

- Significant progress has been made
- A progress report has been published on the TGA website
- Details are outlined below and on the next slide

Strategy 1: Improve how new devices get on to the market in Australia

Complete ● Underway ● Yet to commence ●

TARGET	ACTIVITY DESCRIPTION	STATUS	SUMMARY
Early 2019	Identify options for increasing oversight of the evaluation and market approval process for particular devices.	●	<i>4 out of 6 actions complete, work ongoing</i> <i>All actions progressed</i> <i>Regulatory changes scheduled to commence in 2020</i> <i>Work to increase capacity of review teams continues in 2020</i> <i>18 public consultations held</i> <i>Regulation changes by Government for certain devices</i>
Early 2019	Conduct public stakeholder consultations on proposed regulatory changes and guidance materials.	●	
Mid 2019	Consult with stakeholders on proposed changes that affect change to industry fees and charges or change the regulatory burden on healthcare professionals of industry.	●	
Mid 2019	Establish a specialist unit in the TGA to increase capacity in assessing and monitoring digital health.	●	
End 2019	Draft regulatory changes as agreed by the Government.	●	
End 2019	Increase the capacity of the TGA medical device review teams.	●	



An Action Plan for Medical Devices - progress

Strategy 2: Strengthen monitoring and follow up of devices already in use

Complete ● Underway ● Yet to commence ●

TARGET	ACTIVITY DESCRIPTION	STATUS	SUMMARY
Early 2019	Establish a working group with state and territory health departments and the Australian Commission on Safety and Quality in Health Care.	●	<i>Foundation work complete, is ongoing</i>
Mid 2019	Consult on proposed changes to adverse event reporting requirements and systems and strengthened tracking of devices.	●	<i>Consultation on proposed changes underway</i>
Mid 2019	Consult publicly on proposed changes that potentially incur a change in fees or charges and/or regulatory burden.	●	<i>Consultation with industry scheduled to continue in 2020</i>
Mid-late 2019	Consult with consumer groups, healthcare industry representatives on opportunities for collaboration and proposed changes.	●	<i>New legislation to implement regulatory changes scheduled to commence 2020</i>
Early 2020	Government to introduce legislation to implement agreed regulatory changes.	●	<i>Australian Health Ministers Advisory Council project to improve information sharing</i>

Strategy 3: Provide more information to patients about the devices they use

Complete ● Underway ● Yet to commence ●

TARGET	ACTIVITY DESCRIPTION	STATUS	SUMMARY
Mid 2019	Consult with consumer advocacy, support groups and industry on proposed changes to transparency.	●	<i>Action plan consumer working group established</i>
Mid 2019	Publish regulatory assessment timeframe.	●	
Late 2019	Government decision on any changes to regulations required to support publication of additional information on medical devices.	●	<i>Consumers providing feedback on specific devices of concern</i>
End 2019	Establish new consumer working groups and publish their Terms of Reference.	●	



Challenging areas

We continue to consult regularly with medical device stakeholders on our reforms including on areas that are complex and challenging. We take into consideration the broader global context and how alignment can be achieved with other regulatory systems. Some challenges include:

- Implementation of regulatory changes ahead of other jurisdictions who are yet to introduce / adopt changes
- Development of guidance material in the absence of IMDRF guidance (eg: personalised medical devices and production systems)
- Regulatory changes that are particular requirements in Australia
- Differences between various regulatory frameworks (eg: EU and USA) and which regulations are appropriate for Australia



COVID-19 – TGA responds

PRE-MARKET

TIME LIMITED EXEMPTIONS

- Medical device personal protective equipment (PPE) for the National Medical Stockpile
- COVID-19 tests to accredited laboratories
- Domestically manufactured ventilators

EXPEDITED ASSESSMENTS

- Prioritised and expedited 5,364 applications seeking regulatory approval to import and supply devices for the prevention, detection and treatment of COVID-19
- Full regulatory assessments are still occurring. Some approvals given with conditions based on information available at the time of application
- Disinfectants with specific claims, thermometers, ventilator accessories, PPE



Expedited approvals:
(as at 20 August 2020)
23 Ventilators
51 Lab COVID-19 Tests
36 POC Serology tests



COVID-19 – TGA responds

POST-MARKET

OTHER STEPS

- Formal post market reviews of all face masks on the Australian market including laboratory testing – results published on TGA website
- Formal independent validation studies of all POC COVID-19 tests to support the performance claims of the tests – full reports published on TGA website
- Changes to Class I processes to include manual audits that include requesting evidence of performance validation

EXPEDITED RECALL PATHWAY

- Notification on website and via letter
- Recalls will be initiated within 24 hours
- Media scrutiny high



Impact of COVID-19

Many medical device stakeholders and regulators placed their priority on COVID efforts and **all other work stopped**

- TGA staff focused on assessments of devices used for COVID-19 efforts therefore **difficult to progress** reform activities
- Some conformity assessment **certificates lapsing** or will lapse
- Inability to conduct **on-site audits**, arrangements for how to conduct virtual/remote audits developed
- Difficulty in engaging stakeholders in consultations
- Australian Government agrees to **delay implementation** start dates for some reforms:
 - Medical device software and personalised medical devices from 25 August 2020 to 25 February 2021
 - Reclassification of certain devices and changes to system and procedure packs from 25 August 2020 to 25 November 2021
 - Amendments to essential principles – 2 years after EU MDR commencement



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Thank you

Stay safe