Australian Government
Department of Health
Therapeutic Goods Administration

Medical Device and Product Quality Division

Industry bilateral meetings - 2020

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TGA Health Safety Regulation

Overview

1. Snapshot Statistics
2. COVID-19 Response
3. Medical Device Reforms

Key Message: Industry engagement has been highly collaborative throughout 2020

1. Snapshot Statistics

Work completed:

- ✓ 9 Mar – 13 Nov 2020: TGA approved 7,688 applications for medical devices (including IVDs)

Other notable statistics (FY19-20):

- ✓ 342 conformity assessment applications completed
- ✓ 435 post market reviews
- ✓ 128 medical devices tested by labs with a 44% fail rate
- ✓ 187 medical device investigations
- ✓ Conformity assessment applications finalised within 255 day time frame – average 129 days for new devices and 137 days for variations
- ✓ 1,850 medical device and 86 IVD applications completed without audit
- ✓ Adverse event reports increased by 6% to 6,230
- ✓ Recall actions for medical devices including IVDs increased by 3% to 614

1. Snapshot Statistics

Key statistics (FY19-20):

- ✓ 6,414 GMP Clearances approved from 7,051 applications processed
- ✓ 214 GMP manufacturing inspections conducted domestically and overseas
- ✓ 254 Australian companies holding manufacturing licences covering 396 sites
- ✓ 187 overseas manufacturers covering 222 manufacturing sites that are subject to TGA inspection
- ✓ 81% of all manufacturers had a satisfactory or marginal compliance rating for completed inspections
- ✓ 790 recall actions during FY19-20, up from 768 in FY18-19

2. COVID-19: Our Response

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

- ✓ Priority to applications seeking to import and supply devices for the prevention, detection and treatment of COVID-19
- ✓ Conditions of approval on some full regulatory assessments

Expedited recall pathway

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

2. COVID-19: Our Response – GMP Program

- ✓ Amended regulations to continue supply of radiopharmaceuticals and radiopharmaceutical active ingredients during the pandemic
- ✓ Developed new arrangements and processes for remote GMP inspections
- ✓ Temporary change to documentation required for GMP Clearance applications

Review of manufacturing quality functions and work processes complete, with recommendations arising from the review being implemented

2. Keeping Everything in Check

Support and Information

- ✓ Clarification of regulatory requirements
- ✓ Information for consumers and new businesses
- ✓ Emails and enquiries line

Compliance

- ✓ Increase in non-compliance, including businesses trading in therapeutic goods for the first time, and those seeking to take advantage of the pandemic
- ✓ Cease and desist letters encouraging compliance in most cases

Post market reviews

- ✓ Point-of-care serology tests
  Peter Doherty Institute - reporting
- ✓ Face masks review
- ✓ Planning for when exemptions cease
- ✓ Class 1 validation to increase integrity and confidence

Infringement notices for Alleged COVID-19 breaches (including advertising and false or misleading statements)

2. Laboratories Response

Post Market Review of Face Masks:

- ✓ **Visual inspection** - a visual and physical examination
- ✓ **Fluid resistance** - testing of the barrier against penetration by blood and/or other body fluids
- ✓ **Particle filtration** - testing of the ability to filter out small, aerosolised particles (for respirators)
- ✓ **Sterility** - where a face product claims to be provided in a sterile state, this is tested
- ✓ Consulting with comparable overseas regulators to resolve **deficiencies in the technical requirements in standards for masks and respirators**

809 samples of face masks and respirators received = 595 ARTG entries, ~84,000 units

Test	Samples complete
Visual inspection	210
Fluid resistance	230
Particle filtration	70
Sterility	11

2. Delays to medical device reforms

Reclassification of certain devices (non *in-vitro* diagnostic devices) including:

- spinal implantable medical devices
- active implantable medical devices
- medical devices that administer medicines or biologicals by inhalation
- medical devices that are substances (or combinations of substances) for introduction into the body
- active medical devices for therapy that include a diagnostic function to significantly determine patient management
- medical devices that are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system.

25 August 2020 → **25 November 2021**

Medical device software	**25 August 2020** →	**25 February 2021**
Personalised medical devices	**25 August 2020** →	**25 February 2021**
Systems or procedure packs	**25 August 2020** →	**25 November 2021**
Amendments to the Essential Principles	After the commencement of European Union Medical Device Regulation changes (i.e. May 2023)	
IVD Medical Device Regulations	Still to be confirmed by the European Parliament, but is likely to be May 2022, so two years after that date.	

2. Challenges

- ✓ 122% increase in medical device inclusions in ARTG and 200% increase in general enquiries (March to September 2020)
- ✓ Slower application audits due to COVID-19 priorities and increased workload
- ✓ Spike in applications for Other Therapeutic Goods (OTGs) with 107 disinfectants approved
- ✓ All teams are facing competing priorities and resourcing challenges

3. Action Plan: Achievements

Strategy 1: Improve how new devices get on the market

- ✓ 6 legislative changes commenced
- ✓ 5 items of guidance material published on the TGA website
- ✓ Introduction of a validation process for Class 1 medical devices
- ✓ Pilot of ‘low risk’ medical devices self-assessment tool to reduce number of incorrect applications
- ✓ 4 consultation papers published, 5 consultation outcomes / summaries published
- ✓ Government agreement to a number of proposed changes including certain self tests

3. Action Plan: Achievements

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

- ✓ $7.7 million (over four years) in the Federal Budget for the TGA to implement the Australian Unique Device Identification Database (AusUDID), Consultation currently underway (closed 2 Dec)
- ✓ Consultation on enhancements to adverse event reporting for medical devices underway (closed 2 Dec). A number of webinars supported the consultation process to provide opportunities to clarify options or ask questions.
- ✓ New format to seek feedback from consultations
- ✓ A Post Market Review Compliance system implemented for sponsors (following extensive user testing with industry)
- ✓ System for recalls enhanced to allow searchable database

3. Action Plan: Achievements

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

- ✓ Targeted working groups supported our work on breast implants and mesh, including the website hubs and information materials
- ✓ Consumer input into updated guidance to support implementation from 1 Dec 2020, all new implantable devices will require a patient implant card (PIC) and patient information leaflet (PIL) prior to inclusion in the ARTG. Existing implantable devices will require a PIC and PIL from Dec 2021
- ✓ Consumer Working Group established – 10 consumer representative organisations including Choice and the Consumers Health Forum to progress strategy 3 in particular, consumer-friendly information
- ✓ *'Five questions to ask your health professional before you get a medical implant'* published
- ✓ Currently consulting on a number of Action Plan Strategies, including information about how the TGA makes regulatory decisions on individual devices, the updated reforms website with a specific consumer focused area

4. Upcoming reforms: Software as a Medical Device (SaMD)

Commencement: 25 Feb 2021

Upcoming – Dec 2020:

- ✓ Agreement from the Minister, drafting of legal instruments, and consideration by the Executive Council
- ✓ Consultation with stakeholders on guidance and other materials and publication on TGA website

Already completed:

- ✓ Consultations to inform clarification of regulatory framework and carve-out of low risk medical device software

4. Upcoming Reforms: Personalised Medical Devices (PMD)

Commencement: 25 Feb 2021

Upcoming:

- ✓ Co-design of fact sheets and other materials with industry
- ✓ Work with the International Medical Devices Regulators Forum planned in 2021 to support the new framework for MDPS

Already completed:

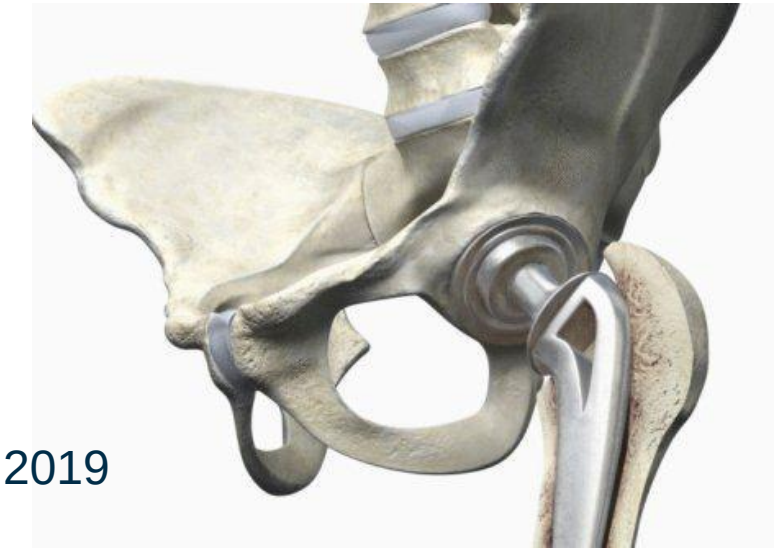
- ✓ Consultations on regulatory changes for PMD
- ✓ Co-design of guidance with industry and publication on the TGA website

4. Upcoming Reforms: Unique Device Identification (UDI)

Commencement: Federal Budget 2020-21 provided $7.7m for the TGA to implement the Australian UDI Database (AusUDID)

Upcoming:

- ✓ Second UDI consultation paper (closes 2 Dec 2020)
- ✓ Changes to the Therapeutic Goods Act being drafted
- ✓ Technical requirements being developed for the AusUDID



Already Completed:

- ✓ First consultation undertaken, 49 submissions received, results published Aug 2019
  - A strong consensus for the need to introduce the UDI system in Australia
  - The majority considered the TGA should be responsible for establishing and managing the repository
  - Most submissions also supported the use of the IMDRF guidance as the basis for establishing AusUDID

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