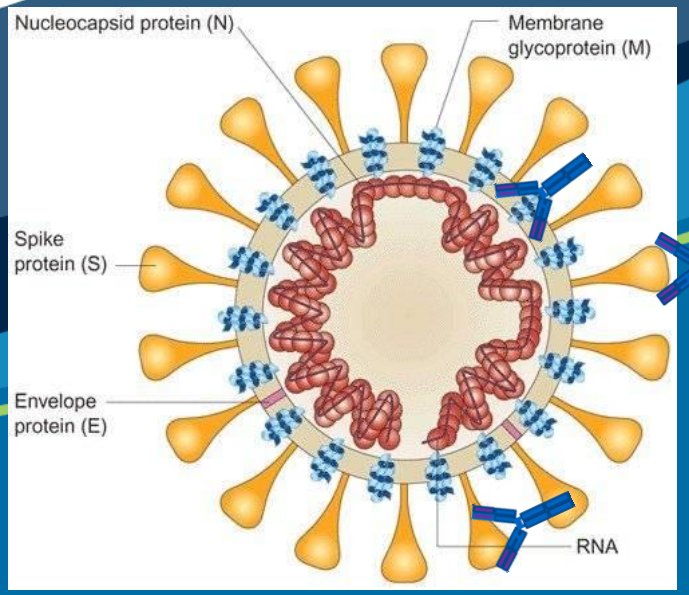
Australian Government
Department of Health
Therapeutic Goods Administration

COVID-19: Unprecedented times brought unprecedented collaborations…and other unconventional approaches

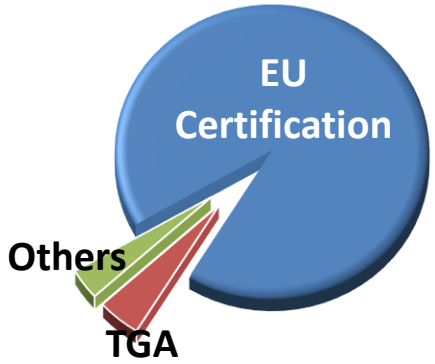
Tracey Duffy
Medical Devices and Product Quality Division
Australian Department of Health – Therapeutic Goods Administration
IMDRF-DITTA Workshop March 2021



COVID-19 – Australian context

- impact and response **maybe different from other countries**
- heavily **dependent on international regulators** and assessment bodies. Some EU conformity assessment certificates scheduled to lapse
- strike the right balance between usual assessment processes and timelines challenged by a focus to **prioritise on COVID-19 efforts**
- some work delayed, **slowed** or stopped (including reforms)
- required a number of government agencies, the regulator and manufacturers to **collaborate quickly**

Others: MDSAP, Health Canada (MDALL), U.S. FDA (DeNovo+510K + PMA), Japan (PMDA/RCB)



Disrupted access and shortages

Unprecedented times

- **sharp increase in demand** for PPE, ventilators, test kits
- usual availability and **access pathways challenging or non-existent**
- most **international shipping cancelled,** with domestic shipping also disrupted by border closures
- **new unknown manufacturers appearing** with limited track record or **products with limited evidence**

Use of regulatory flexibilities

- To facilitate development and access to COVID-19 tests, PPE and other devices
- Managing PPE and device shortages during the COVID-19 pandemic period and related lockdowns
- To facilitate continuity of regulatory services during COVID-19 related restrictions

Enquiries and support for new sponsors

Unprecedented times

- Flood of enquiries April-June 2020
  - General enquiries to TGA up by 250%
  - Medical Devices information line call volumes increased by over 200%
  - Compliance referrals increased by 150 %
- Many enquiries were from potential new sponsors, who had not marketed therapeutic goods before

Unconventional approaches

- Stronger partnerships with established sponsors enabled rapid access to products
- Establishment of national taskforces for ventilators, test kits and PPE (government partnering with industry) including a supply / demand “matching service”
- Provision of advice to new and established sponsors through website redevelopment and support provided 7 days a week during first national COVID wave

New approaches

Unprecedented times

- Potential demand for **thousands of ventilators for ICU patients**
- Required **expedited assessment** of applications as well as development of **specifications for locally manufactured ventilators**
- **Procurement by government** of face masks, other PPE and COVID tests in a competitive global environment
- Greatly enhanced **focus on cleaning and use of disinfectants** with antiviral activity

Medical devices

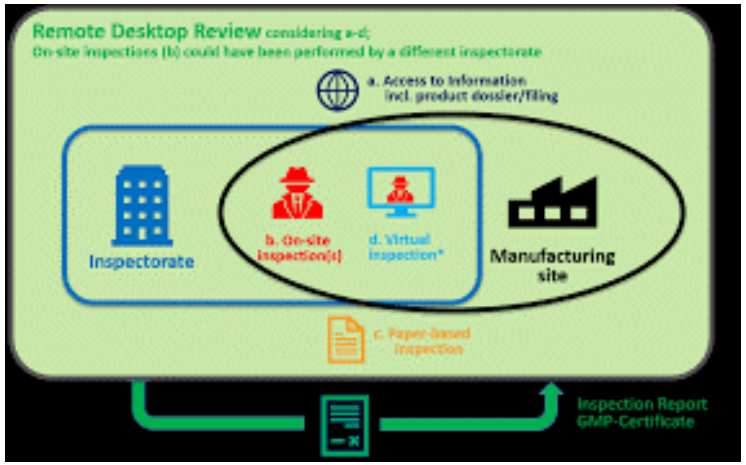
Unconventional approaches

- **Exemptions from requirements for assessment and inclusion on the ARTG enacted**
  - face masks (for purchase for national medical stockpile)
  - hospital ventilators made in Australia (if they comply with requirements set out in formal specifications)
  - IVD tests (for accredited pathology laboratories)
- **Specialist input and advice on ventilators (ARTG-included and exempted) and test kits**
- **Expedited assessment of COVID-19 diagnostics** balanced by imposing conditions of supply and postmarket laboratory performance validation
- **2500 applications for inclusion of PPE** in 3 months. Post-market review of face masks to validate:
  - declarations of conformity (including labelling, audited certificates and compliance with standards)
  - mask performance through TGA laboratory testing
- **83 disinfectants** approved with specific claims of effectiveness against COVID 19 as of 1 October 2020
  - based on test data against surrogate viruses (human coronavirus 229E and murine hepatitis)

Manufacturing Practices

Unprecedented times

- All **international audits/inspections** postponed
- **Domestic inspections** highly constrained
- Different **interpretation** of some standards



Unconventional approaches

- **Remote "virtual"** inspections and increased **desk top audits**
- Clarification on **regulatory expectations** eg: face mask performance testing
- Targeted **post market reviews** for tests and face masks to ensure ongoing performance

Compliance and Enforcement

Unprecedented times

- **Everyone wants to get in on the act** ….
- **COVID "cures", devices and claims** promoted by businesses, TV celebrities, clothing companies
- Inappropriate advertising of IVD kits, disinfectants, masks, other devices
- Illegal importation or supply of IVD test kits and PPE

Unconventional approaches

- **Expedited recall and product defect alert** process in place
- **TGA COVID-19 Enforcement Taskforce** established
- **To 1 Oct:** 1,380 COVID-19 advertising cases and 1,958 COVID-19 import and other compliance cases
- **80 infringement notices** for alleged non-compliance, **1010 warning letters** and **2 court cases**

Unprecedented international collaborations

- **Increased dialogue between regulators** on:
  - a range of issues including fraudulent activity
  - evidence requirements, specifications
  - sharing of guidance, website updates
  - focus on COVID tests and PPE

- Mutual Enforcement Operations (TGA/Border Force /international agencies) targeting imported counterfeit COVID-19 therapeutic goods

.

Benefits of enhanced international collaboration

- **Regular updates**
  - early efficacy and safety signals (eg: test kits)
  - especially important for a medium sized regulator in a country with lower COVID-19 caseload
- **Sharing (and addressing ?) of concerns and other information**
  - availability of evidence as it becomes available from those with higher use / experience
  - regulatory flexibilities and policies (applicable to Australia?)
  - understanding of pipelines, submissions and evaluations (both ways)
- **Better collaboration** – better approach than independent duplication of effort !

The new normal – lasting impacts on regulation ?

- **Nimbleness** – sharing, coordination, more facilitated pathways, flexible regulatory approaches, exemptions, rapid assessments, regulatory support for manufacturing to scale up (as a result of investment and incentives offered by other parts of Government)
- **Strengthened linkages** – with public health and health technology assessment bodies, working groups with industry/manufacturers, research funds, use of digital technologies
- **Access and pipelines** for new products and need for advisory services
  - delays with clinical trials or diversion of product development focus to COVID ?
  - new domestic sovereignty, shipping and supply chain resilience
- **Patient engagement** – greater interest in personal/public health
- Impact of less international travel **on audits / inspections**
- **Greater collaboration /** sharing with regulators on other matters
- Development of approaches **to novel or emerging technologies**
- **Early engagement with industry**