Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

National Symposium on Point-of-care Manufacturing of medical devices

Meeting Summary

19 June 2023

The Therapeutic Goods Administration (TGA) hosted a National Symposium on point-of-care (POC) manufacturing of medical devices on 19 June 2023 in Melbourne.

Participants met to discuss the regulation of medical devices manufactured and supplied by healthcare providers, health practitioners and professionals at the POC. Attendees included nominated representatives and observers from:

- Therapeutic Goods Administration (TGA)
- Australian Health Practitioner Regulation Agency (Ahpra) and its National Boards
- National Alliance of Self Regulating Health Professions (NASRHP)
- National Disability Insurance Agency (NDIA)
- The Australian Commission on Safety and Quality in Healthcare (ACSQHC)
- The Aged Care Quality and Safety Commission (ACQSC)
- State and territory government health departments.

The TGA opened the meeting with a series of presentations. The first included an overview on medical device regulation and the personalised medical device framework. Of note:

- The Essential Principles are legislative requirements relating to safety, quality and performance characteristics of medical devices. Companies or individuals who manufacture medical devices must demonstrate that their devices meet (and continue to meet throughout their life-time) the Essential Principles to ensure medical devices are safe, are made to quality standards and perform as intended.
- Manufacturers must hold evidence (regulatory evidence) to demonstrate that medical devices meet the Essential Principles. Manufacturer's evidence can include application of conformity assessment procedures such as certification of Quality Management Systems (QMS) and type/design examinations.
- Regulatory changes meant that most custom-made devices are known as patient matched medical devices and are now regulated by the TGA under the personalised medical devices framework
- There are challenges related to the implementation of the personalised medical devices framework for POC manufacturing.

The TGA presented an overview of results from four POC manufacturing surveys targeted to the following stakeholder groups:

- Dental and oral health sector
- Allied health sector
- Medical device manufacturing hubs at the POC
- Hospital and healthcare facilities.

Key emerging themes and issues identified from the four POC surveys include:

- Health care organisations, health practitioners and professionals are often unaware of their regulatory obligations to the TGA, and may not be compliant with previous or recently introduced TGA regulatory requirements
- Increasing regulatory burden for healthcare sectors could lead to supply disruptions, causing negative impacts for consumers and patients.

Other regulators and state/territory health departments presented on their POC manufacturing experiences:

- Queensland Health presented results from surveyed POC manufacturing hubs in Queensland
- New South Wales (NSW) Health presented a summary of work being undertaken by the Clinical Excellence Commission to coordinate compliance with TGA medical device reforms in NSW
- NDIA provided an overview of innovations in assistive technology, such as the use of 3D printing to manufacture devices at the POC, highlighting the need for regulators to collaborate more closely

Participants contributed to guided discussions on topics including:

- Risk management for device manufacture
- The importance of patient consent and transparency
- Communication and education
- Roles and responsibilities.

Notably the following points were made:

- Risk management for device manufacture
    - Consideration is needed regarding the requirements for documenting Quality Management Systems (QMS) for hospital based POC manufacturing noting that ISO requirements are not always easily applicable to hospital-based manufacturing.
    - Manufacture and supply models for POC manufacturing often differ from traditional models. Consideration needs to be given for how well existing regulation manages risks in these models, including whether the TGA's regulation of materials and equipment is needed, and whether the definition of a manufacturer continues to be appropriate.
    - Regulation should be tailored to the different health sectors and/or allow flexibility for futureproofing
    - A clear, consistent definition of what is an adverse event is required across the different sectors to facilitate adverse event reporting.

- Communication and education
    - The TGA is responsible for communicating the regulatory requirements to stakeholders.

- State/territory governments, other regulators and peak professional bodies have a role to play in the co-design of education and communication of resources.
- Clinicians have a role in ensuring patient consent and providing sufficient information about the medical device (especially implanted medical devices) to patients.

- Roles and responsibilities
  - The potential for the manufacture of medical devices using new technologies such as 3D printing to be regulated as part of clinical practice by linking manufacturing to a health professional/practitioner's Continuing Professional Development (CPD).
  - The potential for the TGA and other regulators to develop tools to assist individuals manufacturing devices at the POC, identify gaps in their regulatory knowledge and provide educational resources such as general training on medical device regulations in emerging technologies, to support them in understanding their regulatory obligations.
  - Consideration of the role educational institutions could have in improving practices in this emerging sector.
  - Improvement of reimbursement pathways for sponsors who can demonstrate compliance with regulatory compliance.

Follow up actions

Agreement was reached on the following action items by those in attendance:

- The TGA, other regulators and the state and territory governments will collaborate to map current regulation of POC manufacturing, particularly where it takes place as a component of clinical practice
- The TGA will establish sector-specific working groups (WGs) to discuss and inform the design of appropriate regulatory pathways for POC manufacturing in each sector. The WGs will comprise of representatives from other regulators, state and territory governments, peak professional and industry bodies
- The TGA, in collaboration with other regulators and state and territory governments, will establish an overarching steering committee to provide oversight of WGs and progress activities.
- The TGA to publish information and resources about POC manufacturing on the TGA website.
- The TGA to provide de-identified POC manufacturing survey results to jurisdictions for review and analysis.