



Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Point-of-care Manufacturing of Medical Devices Dental Sector Working Group

Meeting Statement

Meeting 1, 29 November 2023

The Point-of-care (POC) Manufacturing of Medical Devices Dental Sector Working Group met for the first time on 29 November 2023 via videoconference.

Key discussion points included:

- The Working Group is an extension of the [Personalised medical devices: Dental Sector Working Group](#) (established in 2021) to provide input, advice, and feedback to the TGA on the implementation of the [personalised medical device framework](#).
- The regulation of [point-of-care manufacturing](#) and convening a [National Symposium](#) attended by state/territory government health departments and federal regulators.
- The role and purpose of the POC Manufacturing of Medical Devices Steering Committee and maintaining active channels of communication to facilitate the timely sharing of information between the Steering Committee and the Working Group.
- The importance of leveraging the collective experience of Working Group participants and feedback from their members to ensure any potential options/solutions put forward by the Steering Committee are fit-for-purpose, focus on patient safety and do not introduce any unnecessary regulatory burden.
- What the roles and responsibilities of dental practitioners and professionals in the manufacture and supply chain including:
 - skills, training, and qualifications
 - potential regulatory arrangements for non-Ahpra registered dental professionals
 - Ahpra and the National Boards' shared Code of Conduct
 - standards for dental practitioner registration in mitigating the risks associated with manufacture and supply of medical devices at the POC
- Administrative, resourcing, and cost impacts for dental laboratories in complying with the requirements for documenting Quality Management Systems in their facilities.

More information

Meeting statements and information on the Point-of-care Manufacturing of Medical Devices Dental Sector Working Group, visit [POC Manufacturing of Medical Devices Steering Committee and Working Groups](#).