



Australian Dental Sector Working Group

Meeting statement

Meeting 4, 31 March 2022

On 31 March 2022, the Australian Dental Sector Working Group met to continue discussions on the implementation of the [new regulatory framework for personalised medical devices](#). Key discussion points included:

- An agreement for continued collaboration between the Working Group and the TGA on proposed changes to:
 - [Therapeutic Goods \(Medical Devices—Specified Articles\) Amendment \(Personalised Medical Devices\) Instrument 2021](#) and;
 - [Refinements to the Personalised Medical Device Framework](#) guidance document

Working Group members outlined the importance of using well known and industry-specific examples to clarify the regulatory requirements to assist stakeholders to understand, apply and comply with the requirements.

- An overview of the recent amendments to the [Therapeutic Goods Advertising Code 2021](#) requirements including specific changes to the advertising requirements for exempt or personalised medical devices transitioning to inclusion in the ARTG.

Working Group members agreed to review and provide input into proposed fact sheets and guidance to support the dental sector with understanding the advertising requirements. It was further agreed that a dedicated advertising information session for the Working Group would be scheduled to go through the changes in more detail and to discuss the best way to communicate, educate and disseminate the fact sheets and guidance.

- Proposals for further communication and education activities to support stakeholders include the need for guidance on the boundaries and intersection of regulation of clinical practice (by Ahpra) and the regulation of devices (by TGA).

Further information

Meeting statements are published after each meeting.

For further information on the Australian Dental Sector Working Group, please visit: [Personalised medical devices: Dental Sector Working Group](#).