



# Australian Dental Sector Working Group

## Meeting statement

### Meeting 1, 19 April 2021

Seven (7) peak professional and industry bodies representing the dental and oral health sector were invited to participate in a workshop convened by the Therapeutic Goods Administration (TGA) on 9 April 2021 to discuss the implementation of the [new regulatory framework for personalised medical devices](#).

The workshop offered an opportunity to discuss the background to how and why the new personalised medical devices framework was developed and in particular, to discuss the key elements of the framework that peak bodies or their members had identified concerns with. Feedback on the TGA's communication and engagement activities was provided, along with participants discussing how they were assisting their members in understanding and transitioning to the new framework.

Key points discussed at the workshop included:

- The level of understanding across the dental and oral health sector about the Australian regulatory framework for medical devices
- Clarification on the existing requirements and exemptions for custom-made medical devices;
- The definition of a medical device and how this relates to dental products, including potential risks and classification levels;
- The regulatory obligations and evidence requirements for suppliers and manufacturers of patient-matched medical devices under the new regulatory framework including classification rules, nomenclature, Essential Principles (including conformity assessment procedures);
- Regulatory and cost impacts associated with the new framework balanced with ensuring consumer safety; and
- Concerns raised by the sector including roles and responsibilities along the request, design, manufacture, supply and patient-fitting pathway.

Participants agreed that a time-limited Dental Sector Working Group (DSWG) be established to continue to work closely with the TGA, providing input, advice and feedback on the implementation and concerns raised by the sector. The discussions and work undertaken by the DSWG would be important to progress potential refinements to the framework, for consideration by the Minister, the Australian Government or Parliament (if the refinements relate to legislation or regulation) or to the TGA for guidance or delegations.

Meeting statements will be made publicly available after each DSWG meeting. For further information on the DSWG, contact [personaliseddevices@health.gov.au](mailto:personaliseddevices@health.gov.au).

If you would like to receive information and updates about the personalised medical devices framework as they become available, you can subscribe to the TGA personalised medical devices newsletter by sending an email to [devices@health.gov.au](mailto:devices@health.gov.au) with 'SUBSCRIBE PMD' in the subject line. Information and resources that are sent out via the newsletter will also be available on the [personalised medical devices landing page](#) on the TGA website.

## **Further information**

Meeting statements are made publicly available after each meeting.

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