Government of **Western Australia**
Department of **Health**

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Dear [redacted],

The Western Australian (WA) State Oral Health Advisory Council would like to thank the Therapeutic Goods Administration (TGA) for the opportunity and extension to provide feedback on *Proposed Refinements to the Regulation of Personalised Medical Devices.*

WA considers that dental patient-matched medical devices are very low risk. There are existing regulatory mechanisms which provide sufficient regulation for dental patient-matched medical devices. Any further compliance requirements in addition to these will divert resources away from the delivery of dental services and will lead to higher costs to the population of WA, without increasing patient safety.

Examples of current compliance requirements which adequately manage the low risk associated with patient-matched medical devices include:

Registration with the Dental Board of Australia

All dental practitioners are registered with the Dental Board of Australia (DBA).
The DBA's Code of Conduct states all dental practitioners must:

- Practise in accordance with the current and accepted evidence base of the health profession, including clinical outcomes.
- Facilitate the quality use of therapeutic products based on the best available evidence and the patient or client's needs.
- Participate in systems of quality assurance and improvement.

The DBA also has a notification process which enables the public to raise concerns about the quality of dental care provided by dental practitioners including any issues relating to patient-matched medical devices.

Health Practitioner Regulation National Law

Dental practitioners must also abide by the Health Practitioner Regulation National Law Act 2009.

It is important to note that technical dental work such as the manufacture of a dental device is also captured in the National Law.

Existing TGA Regulations

Alternative mechanisms already exist in the TGA regulation of the materials and equipment used in the manufacturing of patient-matched devices.

The proposed regulation of patient-matched devices manufactured from the materials and equipment that are already regulated through their listing on the Australian Register of Therapeutic Goods (ARTG) appears to provide unnecessary duplication.

Existing State and Commonwealth regulations and policies

- All dental technicians employed in the public sector are qualified to construct patient-matched medical devices.
- Training of apprentice dental technicians occurs in partnership with the Department of Training and Workforce Development – TAFE Colleges.
- Successful accreditation of public dental services under the National Safety and Quality Healthcare Standards. This includes credentialing of dental practitioners to approve their scope of practice which includes the provision of patient-matched medical devices.
- Safety and Quality systems that are monitored by the public sector as part of overall Governance.

The consultation paper refers to three main mechanisms available to refine the regulatory approach for personalised medical devices:
1. Exclusion
2. Exemption
3. Inclusion in the ARTG through an alternative assessment procedure

In response to the consultation paper, WA can provide the following feedback:

1. Exclusions

The definition for the exclusion of products needs to be clarified and appropriate examples listed.

Some examples provided in the consultation paper are not patient-matched medical devices:
- Physical impressions of a patient's anatomy and models cast from these.
- Anatomical models manufactured for educational purposes.

Some examples listed are used in the manufacture of patient-matched medical devices and should continue to be regulated under existing ARTG processes:

- Polymers and resins used in the manufacture of a medical device.

2. Exemptions

WA agrees with the rationale that Class I non-sterile, non-measuring patient-matched devices are low risk and can be exempted. However, the following requirements will need to be met:

- Prescribed by a registered dental practitioner;
- Designing and manufacturing the device in a way that does not compromise health and safety;
- Having evidence demonstrating the long-term safety of the device;
- Meeting packaging and labelling requirements;
- Supplying the device with Instructions for Use to ensure it could be safely used and maintained by the end user;
- Keeping records of supply;
- Reporting adverse events associated with the device to the TGA;
- Manufactured by a dental practitioner whose scope of practice encompasses production;
- Manufactured by the dental practitioner utilising regulatory approved protocols, equipment and materials;
- The dental practitioner provides the device directly to their patient in the dental practice.

WA is also of the view that most dental devices including those listed as Class IIa are low risk and should be reclassified as Class I devices and treated under the proposed exemption process (see below).

3. Inclusion in the ARTG through an alternative assessment procedure

WA does not agree with the proposed alternative assessment procedure. There is no change in the risk profile between the devices proposed to be exempt and the devices proposed to be subject to the alterative conformity assessment procedure. The only difference between the items is the longevity of the item in the oral cavity.

WA does not agree with the following statements on page 13 of the consultation paper which says –

> "*The risks posed by Class IIa devices include the potential for significant harm if the device integrity cannot be assured. Failure of Class IIa fixed dental prostheses such as a crown or bridge can include biological complications such as secondary caries and tooth or root fractures, and technical complications such as device fractures, problems with marginal integrity and loss of retention*".

The most common reason for the failure of these devices is biological risk factors, not device risk factors. Some of the potential harm occurs as a result of patient controlled biological factors, which are also the reason why a patient develops dental caries in an otherwise sound tooth.

> *"Given the risk posed by these kinds of devices, and that most Class IIa patient-matched medical devices cannot be removed without the assistance of a healthcare professional, it is considered inappropriate to exclude or exempt these devices".*

The removal of the device by the patient would place unacceptable risk to the tooth, as it would be exposed to the oral environment including bacteria.

The risk of these devices causing harm at a higher level than most other dental devices is lacking support from peer-reviewed literature. These devices (like all dental devices) have a finite lifespan and are designed to be replaced at end of life.

The risks associated with the manufacture and use of these devices can be adequately managed if:
1. The device is manufactured by a trained, accredited professional; or
2. Other third-party mechanisms of oversight are in place that are suitable to manage the low risk that may be posed by the device.

An example of this can be seen with the manufacture of indirect restorations such as crowns, where the devices/equipment used by registered dental practitioners, dental specialists and technicians/prosthetists to manufacture patient-matched devices (e.g. milling machines) are already registered on the ARTG. Additionally, the material used to manufacture devices (e.g. zirconia milling block) is also listed on the ARTG.

As both the machine and the material used in the manufacture of the device are already listed on the ARTG, the additional regulation proposed is unnecessary where a registered dental practitioner or dental specialist assesses the patient, prescribes and/or manufactures, fits and reviews the device.

Other examples would include fixed and removable appliances, root canal posts and precision attachments. These are all low risk and can be managed via the exemption process.

For the above reasons, WA is of the view that most dental devices including those listed as Class IIa are low risk and should be reclassified as Class I devices and treated under the proposed exemption process.

Finally, WA would also like to draw the TGA's attention to two additional issues:

1. The TGA proposal to exempt dental patient-matched medical devices produced under certain circumstances does not recognise dental practitioners as manufacturers of these devices. Dental practitioners may manufacture the dental device within their own practice laboratory, employ a dental prosthetist or

technician or another suitably skilled team member to make the device to their instructions. Dental practitioners, including specialists, should be included as a profession that can manufacture the devices.

2. There is a risk to the public that comes from direct-to-consumer dental appliances such as clear aligners, sleep apnoea devices and tooth bleaching kits when they are provided by non-dental practitioners. The regulatory framework should seek to address this issue more vigorously rather than place additional compliance on registered health practitioners.

If you would like any further information, please do not hesitate to contact me on ([redacted] or via email: [redacted]

Kind regards,

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CHIEF DENTAL OFFICER
WA DEPARTMENT OF HEALTH

30 July 2021

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