Dental Health Services

Dental Health Services in Western Australia (WA) is a State Government funded public dental service provider that undertakes state-wide dental care to the eligible population via 190 dental clinics. DHS provides care to the most vulnerable communities in WA including the financially and geographically disadvantaged people, Aboriginal communities, Culturally and Lingually Diverse communities, high risk medical patients suffering with physical and mental illness, non-ambulant patients, prisoners and those with special needs.

Governance

DHS has rigorous corporate and clinical governance systems in place which includes –

- All dental practitioners are registered with the Dental Board of Australia (DBA) and are credentialed by senior practitioners to approve their scope of practice which includes the provision of patient matched medical devices.
- The DBA has a Code of Conduct which all practitioners must adhere to which includes – "practising in accordance with the current and accepted evidence base of the health profession, including clinical outcomes" and "facilitating the quality use of therapeutic products based on the best available evidence and the patient or client's needs".
- The DBA has a notification process which enables the public to raise concerns about the quality of dental care provided by practitioners including any issues relating to patient matched medical devices.
- All dental technicians employed by DHS are qualified to construct patient matched medical devices.
- DHS trains apprentice dental technicians and has relationships with the Department of Training and Workforce Development – TAFE Colleges.
- Successful Accreditation under the National Safety and Quality Healthcare Standards in 2015, 2018 and 2020.
- Safety and Quality systems that are monitored by the Service and reported to the North Metropolitan Health Service Board which has overall Governance.

DHS thanks the Therapeutic Goods Administration (TGA) for an opportunity to provide feedback via the June 2021 Consultation Paper regarding Patient Matched medical Devices. DHS acknowledges the effort of the Australian Government to reform the regulation of therapeutic goods in Australia and the TGA introduction of a new framework to regulate medical devices that are designed and manufactured for individual patients. However, DHS believes that dental patient matched medical devices are very low risk and any further compliance requirements in addition to those imposed by the DBA, the Australian Commission for Safety and Quality in Healthcare, existing State and Commonwealth regulations and Policies instigated by the WA Department of Health will divert resources away from the delivery of frontline dental services to the most vulnerable population of WA without increasing patient safety.

Dental Patient Matched Medical Device Classification and Risk

Patient matched medical devices used in dentistry are evidenced based, have a multitude of years of evidence regarding their safety and have restored the dental aesthetics and function of patients for generations. All materials used by DHS in the manufacture of patient matched medical devices

are TGA approved. DHS is of the view that the vast majority dental patient matched medical devices are low risk Class I devices.

The classification of fixed restorations such as crowns, bridges, veneers, onlays, inlays, orthodontic appliances and bonded retainers as low-medium risk Class IIa devices is contra to published dental literature. These devices and those similar have been safely used for up to a hundred years. The most common reason for the failure of these devices is biological, that is, dental decay due to the presence of dental plaque and a diet high in sugar – these are patient risk factors, not device risk factors.

DHS does not agree with the statement 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*".

As stated above, 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.

DHS also does not agree with another statement on page 13 of the consultation paper which says –

"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".

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

Most Dental Patient Matched Medical Devices are Low Risk

DHS proposes that all non-implantable dental devices be considered low risk, that is, be classified as Class I. Indeed, crowns, bridges, veneers, inlays, onlays, pontics, orthodontic appliances and similar devices are non-sterile, non-measuring patient matched devices", the dental literature and the history of these devices justifies this classification. As such the majority of dental devices could be managed as proposed in the discussion paper under the Exclusion process if regulation via the framework is required.

DHS believes non-implantable dental patient-matched medical devices be exempted from inclusion in the ARTG where it can be demonstrated the risks associated with the manufacture and use of the device can be adequately managed:

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.

DHS acknowledges that implantable dental devices such as dental implants are placed on the ARTG by the supplier and are classified accordingly as medium risk.

Please see responses to the specific questions below in red font –

Questions

Exclusions

1. **Do you agree with the rationale for the proposed exclusion of products? If not, why not?**

   The definition for the exclusion of products needs to be clarified and specific examples listed. Examples provided in the consultation paper:

   - **Physical impressions of a patient's anatomy and models cast from these**
   - **Anatomical models manufactured for educational purposes**

   Are not patient matched medical devices.

2. **Are the risks posed by the products adequately managed if they are excluded from regulation by the TGA? Please explain your response, including by providing examples that illustrate and/or support your position.**

   Please see response under Governance above

3. **Are there further products that meet the principles proposed for exclusion? What are they and why should they be excluded?**

   Please provide an explanation for why:

   - **the product represents no, or insignificant levels, of risk; or**
   - **the product does not meet the definition of a medical device.**

   Nil

Exemptions

4. **Do you agree with the rationale for the proposed exemption of Class I non-sterile, non-measuring patient-matched devices when produced under the circumstances listed in this consultation paper? If not, why not?**

   DHS agrees that the rational that these devices are low risk and can be exempted however the following requirements will need to be met -

- **meeting all relevant Essential Principles including;**

- 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; and
- reporting adverse events associated with the medical device to the TGA.

DHS 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.

5. **Can the risks posed by the Class I non-sterile, non-measuring patient-matched medical devices when produced under the circumstances listed in this consultation paper be adequately managed if they are exempted from inclusion in the ARTG? Please explain your response, including by providing examples that illustrate and/or support your position.**

   Please see response under Governance and Dental Patient Matched Medical Device Classification and Risk above

6. **Are there further circumstances where Class I non-sterile, non-measuring patient-matched devices could be exempt? If so, what measures are in place to manage the risks associated with the devices?**

   Please provide details:

   - **describe the specific circumstances that are in place (such as qualifications, accreditation, certification, etc) to ensure that the risks associated with the manufacture of the devices have been managed and the Australian regulatory requirements for medical devices have been met before they are supplied.**

   Please see response under Governance and Dental Patient Matched Medical Device Classification and Risk above.

Inclusion in ARTG using alternative conformity assessment procedures

7. **Do you agree with the rationale for the proposed alternative conformity assessment procedures for Class IIa patient-matched devices when produced under the circumstances listed in this consultation paper? If not, why not?**

   DHS does not agree with the proposed alternative conformity assessment due to the reasons outlined in Governance, Dental Patient Matched Medical Device Classification and Risk and Most Dental Patient Matched Medical Devices are Low Risk sections above.

8. **Do you agree that the risks associated with the proposed Class IIa patient-matched devices when produced under the circumstances listed in this consultation paper could be adequately managed through the proposed**

alternative conformity assessment procedure? Please explain your response, including by providing examples that illustrate and/or support your position.

Please see response to Question 7.

9. **Are there further circumstances where an alternative conformity assessment procedure for Class IIa patient-matched devices would be appropriate? If so, what measures are in place to manage the risks associated with the devices?**

   Please see response to Question 7.

10. **Are there any Class IIa patient-matched devices that should not be subject to an alternative conformity assessment procedure? What are they and why not?**

    DHS is of the view that all non-implantable dental patient-matched medical devices should be exempted from inclusion in the ARTG where it can be demonstrated the risks associated with the manufacture and use of the device can be adequately managed:

    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.**

    Examples of these devices includes, inlays, onlays, crowns and bridges/pontics made of various materials from metal to ceramic, dental veneers, root canal post, precision attachments, and fixed and removable orthodontic appliances - are all low risk and can be managed via the exemption process.

General question

11. **Are there alternative mechanisms for reducing the regulatory burden for patient-matched medical devices without compromising patient health and safety that you would like to propose?**

    DHS believes the existing regulatory mechanisms described in the Governance section above provide sufficient regulation for dental patient matched medical devices and the new framework places additional compliance in an area that is currently well regulated by legislation, oversight, notification processes and has well established safety and quality systems. DHS believes the new framework will not improve patient safety and quality outcomes, however will divert precious resources to compliance rather than caring for the most vulnerable Western Australians.