Australian Podiatry Association's detailed response to the Consultation: Proposed refinements to the regulation of personalised medical devices (Version 1.0, June 2021).

Exclusions

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

   The APodA encourages the continuing regulation of personalised medical devices via the TGA. With some notable exceptions, AHPRA registered health professionals working in the public health system and those manufacturing products at universities for educational purposes.

   With emerging markets and new technologies, the production and supply of personalised medical devices has grown exponentially over the last 10 years. The industry has seen a rise in internationally manufactured medical products and the emergence of innovative technologies such as 3D printing. Such innovations in product manufacturing have seen a surge in new, non-AHPRA registered providers, entering the health market place.

   The APodA strongly supports TGA regulation that maintains the quality and safety of personalised medical devices. To keep the industry, the profession and the public safe, a continuing level of regulated structure as proposed through the TGA would be encouraged.

   The APodA understands and recognises specific areas of the profession which are adequately regulated and should have the option for exclusion:

   - Podiatry Board of Australia (AHPRA) registered podiatrist **manufacturing** personalised medical devices through a **public health system** (public hospitals, community centres)
   - Podiatry Board of Australia (AHPRA) registered podiatrist **supplying** personalised medical devices through a **public health system**
   - **Australian Universities** - where they offer/run an AHPRA approved qualification in podiatry – student and academics manufacturing PMDs for the purpose of education (not for public supply)

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.

Yes, the risks posed by the products would be adequately managed if excluded from the regulation by the TGA.

i. **Public health system**:
- the device is manufactured by a Podiatry Board of Australia registered podiatrist, employed by the respective state health body/institution;
- other third-party mechanisms of oversight are in place that are suitable to manage the low risk that may be posed by the device - National Safety and Quality Health Service (NSQHS) Standards by a body recognised by the Australian Commission on Safety and Quality in Health Care (ASCQHC)

ii. **University environment (Podiatry Board of Australia accredited podiatry course)**:
- the device is manufactured by a student under the supervision of a podiatrist registered with the Podiatry Board of Australia (and employed by the university).
- The manufacturing of the device is done so in a teaching environment
- It is not to be supplied to the public (purely training academic reasons)

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

- The Australian Podiatry Association does not propose to exclude any specific products.

Exemptions

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

Yes, Australian Podiatry Association agrees with the rationale for the proposed exemption ruling for Class 1 patient-matched personalised medical devices.

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.

Yes, the risks posed by Class 1 non-sterile, non-measuring patient-matched personalised medical devices can be adequately managed if they are exempt from inclusion in the ARTG.

Class 1 patient-matched personalised medical devices are medical devices that pose extremely low risk to consumer safety.

These devices are manufactured by a university trained, AHPRA registered Podiatrists, who additionally hold the option of membership with the Australian Podiatry Association. AHPRA registration confers a minimum standard of education, continuing professional development obligations and regulatory mechanisms to protect consumer safety.

This additional regulatory oversight reduces the residual risk of these low-risk medical devices and therefore demonstrates adequate risk management if exempted from inclusion in the ARTG.

Example:
An Australian registered podiatrist, diagnose, prescribes, manufactures (in-house) and then proceeds to supply a class 1 non-sterile, non-measuring device to their patient.

In this scenario, as the Podiatrist is degree qualified and trained, is registered through the Podiatry Board of Australia and follows TGA's manufacturing and sponsorship requirements (noted below).

The manufacturer and sponsor would still need to meet all other regulatory requirements for medical devices including:

- ensuring their device(s) meet all relevant Essential Principles, including supplying the devices with adequate labelling and instructions for use;
- documenting evidence of conformity assessment (holding a declaration of conformity for the devices); and
- reporting adverse events associated with the use of their device(s). A further impact of exempting these kinds of devices from inclusion in the ARTG is that they would not be able to be advertised to consumers

6. **Are there further circumstances where Class I non-sterile, non-measuring patient-matched devices could be exempt?**

   No

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?**

   N/A

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.**

   N/A

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?**

   N/A

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? General question**

    N/A

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?**