21 July 2021

Therapeutic Goods Administration
Medical Devices & Product Quality Division
Health Products Regulation Group
Department of Health
PO Box 100
WODEN ACT 2606

Via email: [redacted]

Dear [redacted]

Response to proposed refinements to the regulation of personalised medical devices

The Australian Health Practitioner Regulation Agency (Ahpra) and the National Boards welcome the opportunity to provide feedback to the Therapeutic Goods Administration's (TGA) consultation on proposed refinements to the regulation of personalised medical devices. We recognise the substantial work undertaken to develop a new regulatory framework for personalised medical devices to ensure an appropriate level of regulation is applied in order to manage the risk they may pose.

Our submission provides an overview of the aspects of our work relevant to the issues raised in the consultation paper and our experience as a regulator. While the timeframe available has been relatively short, we have identified a range of issues which vary depending on the relative impact on the professions involved. We would be happy to meet with the TGA to discuss our response further.

Please note this submission is from Ahpra and the following National Boards:

- Dental Board of Australia
- Medical Board of Australia
- Optometry Board of Australia
- Occupational Therapy Board of Australia
- Osteopathy Board of Australia, and
- Podiatry Board of Australia.

About us

Ahpra and the National Boards regulate Australia's health practitioners through the National Registration and Accreditation Scheme (the National Scheme) under the Health Practitioner Regulation National Law, as in force in each state and territory (the National Law). Our primary role is to protect the public.

Submission

While some of the issues raised in the consultation paper are beyond the scope of our regulatory role, we would like to provide feedback on issues with some connection to our work as the health practitioner regulator and that may intersect with the National Scheme as summarised below.

Overall, the National Boards and Ahpra broadly support the proposed refinements to the regulation of personalised medical devices and commends the TGA on its focus on reforms to ensure that its regulatory standards keep pace with the rapid development of medical technology. We are supportive of the proposed refinements to the regulation of personalised medical devices to ensure risks associated with personalised medical devices are appropriately mitigated without imposing unnecessary administrative and regulatory burden.

We support the proposed exemptions or modifications to the requirements for patient-matched devices manufactured by a practitioner registered with the Australian Health Practitioner Regulation Agency (Ahpra) under the Health Practitioner Regulation National Law as in force in each state and territory, and whose scope of practice encompasses production of the patient-matched medical devices that they are producing; and where the devices they produce are intended to be used by a patient of the healthcare facility, registered provider or Ahpra-registered health professional.

This appears to be a proportionate approach to managing public safety.

Administration of the National Law

We do not consider that the proposed refinements to the regulation of personalised medical devices will impact on the National Boards and Ahpra's ability to administer the National Law in relation to the health, performance or conduct of registered health practitioners.

We note the proposed provisions relating to the exemption of the listed Class I non-sterile, non-measuring patient-matched medical devices will exempt them from inclusion in the ARTG and from being advertised to consumers. Any advertising of regulated health services would continue to be regulated by the provisions set out under section 133 of the National Law.

Profession-specific feedback

In addition to the information above, the Occupational Therapy Board of Australia, Optometry Board of Australia, and Podiatry Board of Australia have provided the profession-specific feedback at Attachment A for your consideration.

Thank you for the opportunity to provide this response. We support and share the TGA's commitment to consistent and evidence-based standards to achieve safe and high-quality healthcare.

If you have any queries regarding the information provided, please contact Helen Townley, National Director, Policy by emailing [redacted].

Yours sincerely

[redacted]

Martin Fletcher
Chief Executive Officer
Australian Health Practitioner Regulation Agency

Attachment A: National Board specific feedback

Occupational Therapy Board of Australia (OTBA)

The OTBA advises that the requirements of the new framework for the regulation of medical devices will likely have a significant impact on the occupational therapy community. Specifically, the OTBA is concerned that the regulatory burden is quite significant when compared to the low risk of harm associated with the devices made by occupational therapists.

The OTBA notes the proposed refinement to this framework, in particular, *Principle 2. Patient-matched medical devices that could potentially be exempt from inclusion in the ARTG* would be applicable to occupational therapists who manufacture devices such as splints for their patients as part of their practice. The exemption would adequately manage the risk and impose less regulatory burden on occupational therapists.

Optometry Board of Australia (OptomBA)

The OptomBA notes that the new TGA requirements for personalised medical devices now capture custom made contact lenses prescribed and ordered by registered optometrists. The OptomBA advises that this implements additional regulatory requirements on optometrists who source both Australian made and overseas manufactured contact lenses custom made for their patients. When imported from overseas suppliers, these optometrists become sponsors of the contact lenses, however the optometrist is unlikely to be in a position to provide the necessary information as required by the TGA from sponsors.

Custom designed contact lenses, supplied by numerous suppliers involving incalculable combinations of fitting designs parameters and materials, have been used in very significant numbers by optometrists for over the last 50 years. The OptomBA is unaware of any evidence of public harm. Further, the OptomBA believes that the prescription of custom-made contact lenses remains low risk, and the additional requirements are not warranted to protect the public.

The OptomBA suggests that custom made contact lenses be exempt from inclusion in the ARTG when prescribed by a registered optometrist. It is not clear to the OptomBA which class custom made contact lenses are classified under, however the OptomBA believes that its regulatory requirements provide sufficient oversight of optometrists prescribing these devices. Optometrists are required to annually declare that they comply with continuing professional development, professional indemnity insurance and recency of practice registration standards, and comply with the Board's Guidelines for advertising a regulated health service. Optometrists must also comply with the Guidelines on the prescription of optical appliances.

The OptomBA supports the proposed exemption of Class I non-sterile, non-measuring patient-matched devices. In addition to the above suggestions, the OptomBA recommends that prescription spectacles be excluded from the ARTG as they are a class I non-sterile product. The Board requires that spectacles be prescribed in line with the *Guidelines on the prescription of optical appliances*.

Podiatry Board of Australia (PodBA)

The PodBA notes that *Principle 2 Patient-matched medical devices that could potentially be exempt from inclusion in the ARTG*, proposes that some Class I patient-matched medical devices could 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.

This principle is applicable to podiatrists registered under the National Law who manufacture and use patient-matched orthotic devices for their patients. The Board supports the proposed exemption of these devices. The risks associated with their manufacture and use are adequately managed as the capabilities of registered podiatrists encompass production of these devices.