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SUBMISSION:

Consultation on proposed refinements to the regulation of personalised medical devices

16 July 2021

Audiology Australia (AudA) is the peak professional body for the health profession of audiology with over 3000 members practising across Australia. We welcome the opportunity to respond to the Therapeutic Good Administration's (TGA) *Consultation on Proposed Refinements to the Regulation of Personalised Medical Devices*.

Our submission addresses relevant consultation questions as set out below.

PROPOSED REFINEMENTS TO THE REGULATION OF PERSONALISED MEDICAL DEVICES – CONSULTATION QUESTIONS

Exclusions

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

   AudA agrees with the rationale for the proposed exclusion of products, noting that the exclusion would be limited to products that either do not meet the definition of a medical device, meet the definition of a medical device or is an accessory to a medical device but is considered to pose a low level of risk.

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.**

   AudA supports the TGA's proposed principles by which products are considered for exclusion from regulation. AudA considers that the low risk of harm posed by these products can be adequately managed by the Australian Consumer Law (ACL), which includes a national product safety law and enforcement system.

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.**

   The new TGA framework will affect anyone who manufactures, imports, or supplies personalised medical devices, including health professionals who produce devices for their patients/clients. It also means the majority of existing custom-made medical devices will now need to be included in the Australian Register of Therapeutic Goods (ARTG) whereas they had been previously exempt from this requirement.

   Under TGA rules, ear moulds fall within the definition of "medical device" given they are accessories to hearing aids, which are also "medical devices".

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Ear moulds are customised to fit to an individual's unique ear canal. To make an ear mould, audiologists make a cast or impression of the ear canal and outer ear with a soft moulding compound. The cast is then used to make the actual ear mould.

They are also an important part of hearing devices. For instance, the main section of the behind-the-ear hearing aid is worn behind the ear and is connected to an ear mould that fits in the outer ear and anchors the hearing aid in the ear.

Ear moulds may need adjustment over time to ensure they continue to fit correctly, therefore, it is common for ear moulds to be checked and/or refitted at a patient's annual hearing review.

We consider ear moulds to be products that meet the TGA's proposed principles for exclusion from regulation given they are an accessory to a medical device and pose a very low risk to patients.

In AudA's view, there needs to be an appropriate balance between making sure patient safety is maintained and ensuring that health professionals are not excessively burdened. If ear moulds were to be included in the TGA's personalised medical devices regulation, the impact on those in the audiology profession who manufacture, import or supply ear moulds in terms of time, resourcing and administration to meet associated regulatory requirements is likely to be disproportionate to the low risk the product presents.

We also submit that the existing ACL administered by the Australian Competition and Consumer Commission is sufficient in regulating the safety and quality of ear moulds.

For these reasons, AudA strongly supports the proposed exclusion of a plastic mould used to anchor a hearing aid in the ear canal from TGA's regulation of personalised medical devices.

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?

Under the new TGA personalised medical devices regime, all personalised medical devices that are 'patient-matched medical devices' – devices that are produced within a 'specified design envelope' or a standardised produced process which can be validated, verified and reproduced - will have to be entered in the ARTG.

The consultation paper proposes that Class I non-sterile, non-measuring patient-matched medical devices could be exempted from inclusion in the ARTG where it can be demonstrated that the risks associated with the manufacture and use of the device can be adequately managed. It is considered that where a medical device has been prescribed by a registered health professional and is manufactured by a qualified or accredited health care practitioner, risks can be adequately mitigated.

Under this proposal, qualified and accredited health professionals include:

- a provider registered with the National Disability Insurance Scheme Quality and Safety Commission and the scope of their registration encompasses the patient matched medical devices that they are producing; or
- a health professional registered with the Australian Health Practitioner Regulation Agency (AHPRA) whose scope of practice encompasses production of the patient-matched medical devices they are producing; and the devices they produce are intended to be used by a patient of the healthcare facility, registered provider or AHPRA-registered health professional.

However, we note that membership of the National Alliance of Self Regulating Health Professions (NASRHP) is not listed. NASRHP is a membership body of self-regulating health professions whose members set and meet standards equivalent to those that AHPRA registered practitioners are required to meet. All health practitioners who are registered with NASRHP membership bodies are required to be accredited, competent health professionals who operate within their own scope of practice.

NASRHP was established by professional associations for self-regulating health professions who do not meet the criteria and are therefore not eligible for AHPRA registration. Full members of NASRHP include AudA and the Australian Orthotic Prosthetic Association.

We note the Commonwealth Government's 2018 statement that the purpose of the National Registration and Accreditation Scheme (NRAS) is to protect the public from harm and that its purpose is not to confer standing or credibility on individual professions. Inclusion of a profession in the NRAS is also not indicative of that profession's value or its contribution to health service delivery.

AudA is concerned that this proposal reinforces the unintended two-tier system of allied health professionals between those who are members of AHPRA registered professions and those who are members of self-regulating health professions and operate under equivalent standards, including scope of practice.

We therefore recommend the inclusion of health professionals from NASRHP membership bodies in the list of qualified and accredited health professionals and consider that the exemption principle should also be applied to these health professional groups in regard to the manufacture of Class I (low risk) patient-matched 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.

In principle, AudA considers that the risks posed by Class I non-sterile, non-measuring patient-matched medical devices as outlined in the consultation paper can be

adequately managed if there are suitable alternative mechanisms of oversight in place for the manufacture and use of these medical devices.

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?

Hearing aids (behind-the-ear, air-conduction) are classified as Class IIa medical devices in the ARTG. AudA considers that hearing aids should not be subject to an alternative conformity assessment procedure. The current regulation of the safety, quality and performance of hearing aids under the TGA is rigorous and necessary – this includes the certification of a quality management system by the TGA for the manufacturing of these devices.

AudA is concerned that should hearing devices be subject to an alternative conformity assessment procedure, there may be decreased attention placed on the products' safety, quality and performance prior to its use in the population. With the number of people who are deaf or hard of hearing expected to grow from an estimated 3.6 million people to around 7.8 million people by 2060 (Deloitte 2017), it is crucial that the safety, quality and performance of hearing devices are rigorously maintained.

Reference: *The Social and Economic Cost of Hearing Loss in Australia* (2017) prepared by Deloitte Access Economics for Hearing Care Industry Australia (HCIA).