Therapeutic Goods Administration

Consultation Paper

Proposed Refinements to the regulation of Personalised Medical Devices

Occupational Therapy Australia submission

July 2021

Introduction

Occupational Therapy Australia (OTA) thanks the Therapeutic Goods Administration (TGA) for the opportunity to provide feedback on the proposed refinements to the regulation of personalised devices consultation paper (version 1.0, June 2021: the Proposed Refinements).
OTA is the professional association and peak representative body for occupational therapists in Australia. As of March 2021, there were more than 24,600 occupational therapists working across the government, non-government, private and community sectors in Australia. Occupational therapists are allied health professionals whose role is to enable their clients to engage in meaningful and productive activities.

Occupational therapy is a person-centred health profession concerned with promoting health and wellbeing through participation in occupation. Occupational therapists achieve this by working with participants to enhance their ability to engage in the occupations they want, need, or are expected to do; or by modifying the occupation or the environment to better support their occupational engagement. Occupational therapists provide services across the lifespan and have a valuable role in supporting participants affected by developmental disorders; physical, intellectual, chronic and/or progressive disability; and mental health issues.

Occupational therapists are registered health professionals who typically adapt, modify or fabricate non-invasive low risk patient matched personalised medical devices as part of their clinical intervention. These devices are prescribed by occupational therapists following a comprehensive assessment to determine what will best meet their client's needs in line with best evidence-based practice. They adapt, modify or fabricate non-invasive low risk patient matched personalised medical devices as part of a specific therapy regime to improve function, comfort, and stability, and/or mitigate potential risks (e.g. pressure injury). Routine monitoring and evaluation of these interventions is a regulatory requirement of all occupational therapists as AHPRA registered health professionals.

OTA welcomes the TGA's proposed refinements to the regulation of personalised medical devices that aim to reduce and/or remove unnecessary regulatory burden for occupational therapists as registered health professionals who adapt, modify or fabricate personalised medical devices. OTA agrees with the observations in the consultation that the regulatory requirements:

- Were a duplication of existing regulation already provided by professional accrediting bodies or other regulatory bodies;
- In the case of some devices, were excessive compared with the actual risk posed by the device; and
- As imposed by the introduction of the Framework, were an unreasonable regulatory burden.

OTA notes the excessive administrative burden which would be imposed if every provider of patient-matched medical devices had to request transition for all their different types of devices by 25 August 2021. There would be thousands of health practitioner employers and sole traders having to request such transition, some of them for many different types of devices. All these devices would then need to be included in the ARTG by 1 November 2024.
OTA provides the following responses to TGA's consultation questions.

Proposed Exclusions (Your Questions 1-3)

1. Do you agree with the rationale for the proposed exclusion of products?

OTA agrees that Personalised Medical Devices proposed for Exclusion, covered by questions 1 to 3 in the consultation (for example ear moulds and mouth guards for sports) are lower risk devices, and are adequately regulated by consumer law protection.

Proposed Exemptions (Your Questions 4-6)

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?

OTA agrees with the rationale for the proposed exemption of Class 1 non-sterile, non-measuring patient-matched devices if they are manufactured by a trained, accredited professional, or there are other third-party mechanisms of oversight in place that are suitable to manage the low risk that may be posed by the device. OTA therefore agrees with the inclusion of a broad range of third parties to facilitate such conformity assessment, including:

- Within a healthcare facility accredited against the National Safety and Quality Health Service (NSQHS) Standards by a body recognised by the Australian Commission on Safety and Quality in Health Care (ASCQHC); **or**
- By a provider who has been registered with the National Disability Insurance Scheme Quality and Safeguards Commission (NDISQSC), and the scope of their registration encompasses the patient-matched medical devices that they are producing; **or**
- By a health professional registered with the Australian Health Practitioner Regulation Agency (AHPRA) under the *Health Practitioner Regulation National Law Act 2009*, and whose scope of practice encompasses production of the patient-matched medical devices that they are producing; **and**
- When the devices they produce are intended to be used by a patient of the healthcare facility, registered provider or AHPRA-registered health professional.

The class I non-sterile, non-measuring patient-matched personalised medical devices that qualified and AHPRA registered occupational therapists would adapt, modify or fabricate do not pose

significant risk of harm and, given this low likelihood of injury, should not require close monitoring or oversight by TGA. These devices are prescribed to individual patients based on clinical need and best available evidence as part of a specific therapeutic regime to improve function, comfort, and stability, and mitigate risks (e.g. pressure areas). They are typically non-invasive patient matched personalised medical devices that are adapted, modified or fabricated by occupational therapists and typically meet the definition of patient-matched devices from TGA outlined below:

> A patient-matched medical device is a medical device that:
>
> (a) is manufactured by the manufacturer, within a specified design envelope, to match:
> (i) either or both of the anatomical and physiological features of a particular individual; or
> (ii) a pathological condition of a particular individual; and
>
> (b) is designed by the manufacturer (even if the design is developed in consultation with a health professional); and
>
> (c) is manufactured using production processes that are capable of being:
> (iii) either or both validated and verified; and
> (iv) reproduced.

Class I non-sterile, non-measuring patient-matched personalised medical devices that occupational therapists typically manufacture include, but are not limited to:

- All types of non-invasive functional splints that are prescribed as part of an occupational therapy treatment regime to improve function, comfort, and stability.
- Cosmetic/aesthetic splints made by occupational therapists to cover/fill out defects from trauma/cancer to recreate a leg contour under clothing for a shin defect, or a thermoplastic insert into glove for a thumb amputation.
- Customised low level compression garments prescribed to match the individual profile/contours and functional needs.
- Wheelchair and seating modifications to improve postural stability, alleviate risk of pressure areas and/or improve the wheelchair user's functional capacity.
- Assistive technology that may require adaptation or modification of components or accessories.
- Accessories of personalised medical devices to help attach the device to the body to make it wearable.

5. **Can the risks posed by the Class I non-sterile, non-measuring patient-matched personalised medical devices when produced under the circumstances listed in this consultation paper be adequately managed if they are exempted from inclusion in the ARTG?**

Yes, occupational therapists are appropriately trained and qualified to adapt, modify or fabricate Class I non-sterile, non-measuring patient-matched personalised medical devices. OTA believes, the essential principles outlined by TGA coupled with the profession's regulatory requirements provide sufficient regulation for the types of low-risk non-invasive devices, components, or accessories occupational therapists would adapt, modify or fabricate. Furthermore, as registered health professionals, occupational therapists have met a minimum tertiary standard of education to practice in Australia; are working within their scope of practice under supervision; and are required to undertake continuing professional development to keep abreast of developments and practice alerts related to their scope of practice.

The risks associated with these devices are low, while the risk of practitioners ceasing to provide these devices due to regulatory burden are high. OTA is concerned that over-regulation of these low risk non-invasive patient matched medical devices may result in providers withdrawing from the market and/or consumers not having the devices they need to meet their individual needs and goals.

OTA therefore agrees with the inclusion of a broad range of third parties to facilitate such conformity assessment, including:

- Within a healthcare facility accredited against the National Safety and Quality Health Service (NSQHS) Standards by a body recognised by the Australian Commission on Safety and Quality in Health Care (ASCQHC); **or**
- By a provider who has been registered with the National Disability Insurance Scheme Quality and Safeguards Commission (NDISQSC), and the scope of their registration encompasses the patient-matched medical devices that they are producing; **or**
- By a health professional registered with the Australian Health Practitioner Regulation Agency (AHPRA) under the *Health Practitioner Regulation National Law Act 2009,* and whose scope of practice encompasses production of the patient-matched medical devices that they are producing; **and**
- When the devices they produce are intended to be used by a patient of the healthcare facility, registered provider or AHPRA-registered health professional.

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?

OTA notes a range of specific examples are not included in the table (e.g. custom pressure cushions, splinting, custom stylus to access speech production device/computer/etc.) as well as a wide variety of potential products prescribed by occupational therapists and other allied health practitioners. We acknowledge that these devices are essentially covered by the principle, however we ask that it be noted that this table is not exhaustive and the principle would extend to other devices.

To avoid any misunderstanding, OTA also recommends that occupational therapists be included in the proposed exemptions lists linked to non-invasive orthoses and prostheses, including hand splints (with or without outrigger) and ankle-foot orthosis.

Inclusion in ARTG using alternative conformity assessment procedures (Your Questions 7-10)

To the best of our knowledge, all patient-matched medical devices manufactured by occupational therapists would be classified Class 1A medical devices. OTA is not aware of any medical devices manufactured by occupational therapists that meet the TGA description of a Class 2A patient-matched devices.

Summary

OTA thanks the TGA for the opportunity to comment on its proposed refinements to the regulation of Class 1 patient-matched personalised medical devices that aim to reduce and/or remove unnecessary regulatory burden for occupational therapists.

OTA agrees with TGA's proposal to introduce an exemption for Class 1 patient-matched personalised medical devices. These devices are manufactured by appropriately trained and registered occupational therapists, and have sufficient third-party regulatory oversight to mitigate the very small remaining risk associated with these devices. As Class 2A patient-matched devices are not manufactured by occupational therapists, OTA offers no comment on the specific proposal around alternative conformity assessment procedures for these devices.

Please note that representatives of OTA would gladly meet with members of the TGA to expand on any of the matters raised in this submission.

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