Australian Rehabilitation and Assistive Technology Association

arata
participation through technology

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ARATA thanks TGA for the opportunity to respond to 'Consultation: Proposed refinements to the regulation of personalised medical devices'[1]. We note the focus of this paper is to seek feedback on refinements to reduce the regulatory burden on providers of personalised medical devices. A significant increase in regulation was proposed under the Framework: Personalised medical devices (including 3D-printed devices) Regulatory changes for custom-made medical devices[2].

About ARATA

The Australian Rehabilitation and Assistive Technology Association (ARATA) is a not-for-profit with strategic goals intended to support an Australian based Community of Practice of individuals and organisations in the rehabilitation and assistive technology sectors. ARATA's Membership comprises

- rehabilitation and biomedical engineers, and related individuals with technical skills, such as seating technicians
- assistive technology providers, national distributors, entrepreneurs, volunteers, need-knowers, makers and others working to supply and develop AT nationally and internationally
- assistive technology practitioners working in the health and disability sectors, including occupational therapists, physiotherapists, speech and language pathologists
- individuals who use assistive technology or are directly involved in working with assistive technology with these individuals including carers, teachers and support staff

ARATA's activities include, but are not limited to:

- administering a national email list server for member enquiries and dissemination of information
- biennial Australian Assistive Technology Conference
- submissions related to funding and practices affecting the sector, for example to the NDIA, Aged Care Reforms
- working with associations and other groups nationally and internationally related to standards, practices and development initiatives with broad scope, for example, Standards Australia, Assistive Technology Suppliers Australia (ATSA), agencies working overseas in 'less resourced' settings, National Assistive Technology Alliance and many more.

[1] https://www.tga.gov.au/consultation/consultation-proposed-refinements-regulation-personalised-medical-devices

[2] https://www.tga.gov.au/resource/personalised-medical-devices-including-3d-printed-devices

ARATA will respond mainly to questions 4 to 6 relating to Exemptions proposed for Class I patient-matched medical devices in the Consultation, from page 3 of this submission.

ARATA 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.

ARATA notes questions 7 to 10 relating to Section 3. Inclusion of patient-matched medical devices in the ARTG using an alternative conformity assessment procedure. The invasive nature of these devices, for example orthoses that penetrate the skin, or dental crowns, warrants inclusion in the ARTG and reporting of adverse events. The conformity assessment proposed for inclusion of Class IIa medical devices in the ARTG, requiring the manufacturer to have a quality management system that has been certified by the TGA or another third-party conformity assessment body is an appropriate level of regulation. ARATA noted that device availability could be adversely affected by an unnecessary increase in regulation where existing systems of clinical oversight and systems to report adverse events are already in place, covering both manufacture and supply of these devices. ARATA 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**
  The devices they produce are intended to be used by a patient of the healthcare facility, registered provider or AHPRA-registered health professional.
- By a dental technician who holds a recognised qualification under the Australian Qualifications Framework **and**
  The devices they produce are intended to be used by a patient of the healthcare facility, registered provider or AHPRA-registered health professional.
- By a dental laboratory accredited by the Oral Health Professional Association **and**
  The devices they produce are intended to be used by a patient of the healthcare facility, registered provider or AHPRA-registered health professional.
- By an orthotist or prosthetist who is a full member of the Australian Orthotic Prosthetic Association

ARATA supports the principle that hospital inpatients and people with disability should have a choice of provider, and to see appropriately credentialed providers in the right clinical setting to receive these higher risk devices. The mechanisms proposed for alternative conformity assessment aim to meet the objectives of consumer choice and protection.

ARATA Response to Question 4

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?

ARATA agrees that management can occur if the device is manufactured by a trained, accredited professional, or other third-party mechanisms of oversight in place are suitable to manage the low risk that may be posed by the device.

The assistive technology (AT) sector is broad and growing at pace with technical innovation and the economic stimulus provided by the National Disability Insurance Scheme and Aged Care Reforms in Australia. To facilitate both innovation and consumer protection, regulatory approaches need to balance the potential for harm to the individual without unnecessarily restricting device availability and innovation. Over-regulation runs the risk of providers withdrawing from the market and/or consumers not having devices available to meet their individual needs.

A variety of AT will meet the definition of patient-matched devices from TGA noted 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.

AT products meeting the definition of patient-matched medical device are diverse and include products to support body structures and functions, and to facilitate participation, such as the custom hand splint/orthosis illustrated in Image 1 below.

Image 1: Hand splint/orthoses made for an individual with C4-5 quadriplegia to facilitate access to smartphone using stylus, lift call button, handwriting, page turning and the adjustment of spectacles. The device was produced with rehabilitation engineering and industrial design input, being verified and able to be reproduced with 3D printing with a clinician finishing the fitting to facilitate skin protection.

ARATA Response to Question 5

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.

ARATA agrees with the exemption of Class I devices when are being manufactured:

- 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**
- The devices they produce are intended to be used by a patient of the healthcare facility, registered provider or AHPRA-registered health professional.

Providers of patient-matched medical devices working within the facilities and conditions of registration listed above are adequately regulated by existing mechanisms. Providers are predominantly AHPRA registered, working within their scope of practice under supervision, undertaking continuing professional development activities to keep abreast with developments and practice alerts related to their scope of practice.

ARATA acknowledges that it could be argued that need-knowers, makers, volunteers or technical personnel involved in the production of some patient matched devices may be working outside of the contexts listed for exemption above. For example, a team develops custom orthoses and control adaptations to enable an individual with quadriplegia to control a ride-on mower. For the mower adaptations to be funded by NDIS, insurers or aged care funding bodies, the involvement of a registered health practitioner (often an occupational therapist), will be necessary for the funding of the device/adaptation to be approved. It is incumbent on the health practitioner to provide suitable oversight of the device design, fitting and production, with responsibility to report adverse events as appropriate to their professional registration, and the regulatory body oversighting funded services to a specific population e.g., NDIS Quality and Safeguards Commission.

ARATA agrees with the perspectives reported in the Consultation that the regulatory requirements were:

- a duplication of existing regulation already provided by professional accrediting bodies or other regulatory bodies;
- the requirements for some devices were excessive compared with the actual risk posed by the device; and/or
- the regulatory burden imposed by the introduction of the Framework is unreasonable.

ARATA notes the excessive 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 needing 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.

The risks with these devices are low, while the risk of practitioners ceasing to provide these devices due to regulatory burden were high.

To best meet the needs of end users of patient-matched devices, to get the innovation and customisation they need to function and live well, the risks are adequately managed if Class 1 patient-matched medical devices are exempted from inclusion in the ARTG, provided they are manufactured in accordance with the exemption conditions listed above.

ARATA Response to Question 6.

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:

o 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.

ARATA 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 and a wide variety of potential products from rehabilitation engineering, physiotherapy, occupational therapy, speech pathology and other health practitioners. Nevertheless, we acknowledge they will be covered by the principle. Can it be noted that this table is not exhaustive and the principle would extend to other devices?

ARATA appreciates the work of TGA to consult the sector on these important refinements and notes that as products develop or new technologies evolve, review and research into the actual or potential impacts will be necessary at regular intervals. ARATA is happy to be contacted at any time to discuss this response.

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