

ARATA thanks TGA for the opportunity to respond to *'Consultation: Proposed regulatory scheme for personalised medical devices, including 3D-printed devices'* released Wednesday, 13 February 2019. This shall be referred to as the 2019 Consultation throughout this submission.

## 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 product and service providers/suppliers
- 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 and similar consultations such as this one with the TGA
- 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.

## ARATA Response to questions in the 2019 Consultation

1. Do you support the proposal to change the way personalised medical devices are regulated? Why or why not? If you do not support the proposal, do you have any suggestions for an alternative that would be acceptable to you?

ARATA supports the increased regulation of devices that pose significant risk. The 2019 Consultation provided the example of 'patients receiving high risk custom-made devices such as permanent implants' as the main area of concern giving rise to a review of definitions, annual documentation provided to the TGA and inspection of premises. ARATA has no issue with this high-risk category having greater regulation at this time, as it is clearly in the interests of patient safety.

ARATA however does not support proposed changes that appear to include class 1 custom made and patient matched devices that are not implantable at this time.

It is unclear from the definitions of custom-made and patient-specific medical devices [from IMDRF Final Document: Definitions for Personalized Medical Devices (*IMDRF PMD WG/N49 FINAL: 2018*)], whether significant numbers of assistive technology (AT) devices that were exempt in the past will need increased compliance in future.

The example provided of ‘custom-made medical devices that were low risk products such as glass eyes, prosthetic limbs, prescription lenses, etc’ should also apply to the vast majority of AT devices prescribed, produced and supplied by ARATA members and the variety of contexts in which they practice. Examples of AT devices that are custom-made for the individual, that should continue to be exempt include:

- Custom seating, as is commonly provided in wheelchairs for posture and pressure management, and to improve functioning and quality of life. This area has seen rapid growth in the use of digital shape capture technology to fit an individual. ARATA views this area of technology to produce anatomic models as lower risk than imaging models used to produce implantable devices.
- Prosthetics and orthotics made to fit an individual that involve external body worn materials. Some of these devices fit within the definition of adaptable medical devices, while others may fit the custom-made medical device definition. Osseointegrated implants to fit artificial limbs however should *not* be exempt due to the potential for harm to implanted patients.
- 3D printed devices to facilitate functional goals for an individual, such as joystick handles, or devices used by another body part, such as headrest RIM controls for powered wheelchair driving.

The risk that these devices pose does not warrant the increased regulatory burden. The existing provisions for listing AT devices on the ARTG is sufficient for the vast majority of AT devices and related technology to produce anatomic models and customised fitting.

Further examples of custom-made, patient-matched and adaptable AT devices is provided in Attachment 1 with links to enable a clearer view of AT devices.

## 2. What do you consider to be the benefits and disadvantages of particular proposals for change?

ARATA believes that custom-made high-risk devices should have greater regulation to ensure patient safety for implants produced from anatomic models.

This regulatory framework should not, as an unintended side effect, impact on the availability and cost of low risk custom-made AT devices. It is unclear whether AT devices produced from anatomic models such as those described in 1. above, would be required to meet increased compliance proposed in the 2019 Consultation, including:

- that the TGA be allowed to enter and inspect custom-made device manufacturing sites, in accordance with the authority it has to inspect all other medical device manufacturers
- provide an annual report to the TGA of the custom-made devices it has supplied

ARATA has concerns that such regulation could act as a disincentive for practitioners and suppliers to introduce new technologies that may benefit individuals in rehabilitation settings and people with disability in the wider Australian community.

ARATA is aware there are some suppliers/AT providers with limited documentation of manufacturing processes and record keeping; for example, an individual complains that the supplier was unable to reproduce a urine deflector/slash guard for a mobile shower commode to the same specification provided on a model supplied to them 10 years prior. As a broad association with the interests of both end users and suppliers in mind, we acknowledge there is a fine line between encouraging innovation and the regulation of high-risk and custom-made devices. Further consultation is recommended to ensure the interests of the patient or person with disability are balanced with the need to encourage supply of custom-made devices that provide working solutions where ready-made products are not available, such as custom joysticks or urine deflectors mentioned above.

It is also important for the TGA to recognize that any change to the regulation of custom-made or patient-matched medical devices at this time coincides with the implementation of the NDIS. The NDIS has provided the greatest stimulus ever seen in the AT sector, driving innovation and supply of new technologies to a much larger number of people. Both the NDIS and AT providers are on a steep learning curve with the transition to new funding arrangements. Please refer to notes in Q6 below for further consideration of regulatory changes occurring in the AT sector at this time.

### 3. Do you believe there will be any unintended consequences arising from the proposed changes?

ARATA believes that the unintended consequence could be the decreased availability of custom-made and patient-matched AT devices that are externally worn, used to support the body, or to otherwise enable an individual to function (e.g. joystick handle or other body interface in 1. above, and urine deflector example in 2. above), as the regulation may be perceived to be too onerous, particularly for small/niche market suppliers.

ARATA supports a staged introduction of increased regulation of custom-made and patient-matched AT devices, with consideration of other burdens on the AT sector related to the NDIS mentioned in 2. above and 6. below. Light touch regulation is recommended in this transition period where the NDIS is at 'build' stage and 'thin markets' are being encouraged to grow to meet NDIS participant needs.

### 4. What changes would you need to make (if any) to meet the new arrangements? If not, what are the impediments?

Changes that would need to be made relate to record keeping and documentation: Development of better device design information records to enable reproduction, better tracking and reporting systems, with records maintained for custom-made and patient-matched devices for 15 years.

- Provide an annual report to the TGA of the custom-made devices they have supplied
- Be willing to have TGA inspection of their manufacturing facilities.

5. What financial impact (both costs and savings) would implementing the proposed amendments have for you? If possible please provide a breakdown of the impacts. This information will be used to quantify the financial impact to all affected stakeholders.

Class 1 devices are frequently used in the disability field, ARATA members have indicated that this is a significant proportion of their work. Reporting and compliance could amount to devices in the tens to hundreds of thousands per annum. The administration costs involved in reporting would amount to a high cost for many AT providers and could be a disincentive to continue to provide these products and services.

6. What period would be needed for your organisation to implement the proposed changes? This information will be used to inform any transitional arrangements.

ARATA would recommend a period of no less than 3 years. Currently the assistive technology sector is experiencing significant regulatory burden with the introduction of the NDIS Quality and Safeguards Commission, with a staged roll out of compliance occurring throughout Australia through to the end of 2020. Also, the NDIS operational guidelines are under constant review, with providers having to regularly re-read guidelines for the provision of AT devices and home modifications provided under NDIS funding arrangements.

It would be particularly concerning for some NDIS providers to meet increased regulatory compliance with two Federal Government agencies at the same time. ARATA has concerns that increasing regulation could drive some providers away from the sector, at a time where the NDIA is working hard to encourage supply of products and services in areas where there are 'thin markets'.

Thank you again for the opportunity to submit to the *'Consultation: Proposed regulatory scheme for personalised medical devices, including 3D-printed devices'*.

Any correspondence related to this submission can be directed to [president@arata.org.au](mailto:president@arata.org.au)  
and [treasurer@arata.org.au](mailto:treasurer@arata.org.au)

## **Attachment 1: Examples of custom-made, patient-matched and adaptable AT devices**

### **Custom-made and Patient-Matched AT Devices**

Ride Designs Custom Cushions: <https://www.ridedesigns.com/>

Custom-made cushions, backrests, head and other body support, and/or modifications available from the Rehabilitation Engineering Centre: <https://metronorth.health.qld.gov.au/rbwh/healthcare-services/rehabilitation-engineering-centre>

3D printed joystick handles: <http://activehs.ca/products/3d-printer/joystick-handle/>

### **Adaptable AT Devices:**

Spex Supershape Back Support: <http://www.spexseating.com/products/backrests/supershape-back-support>

Matrix Seating: <https://www.matrixseating.com/en/index.php>