22 October 2021

ARATA thanks TGA for the opportunity to respond to ‘Consultation: Proposed amendment to the Therapeutic Goods (Excluded Goods) Determination’.

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.
ARATA has responded to the consultation questions below:

1. Scope: The continuing regulation of products which have a risk of significant injury should they malfunction means that some categories of assistive technology product will be regulated as medical devices. In addition to weight bearing and pressure management devices, are there other categories which may continue to be regulated as medical devices and what are the associated risks?

Weight bearing and pressure management are sufficient criteria to define devices that should continue to be regulated as medical devices.
Additional criterion which are advisable to list:
- “Mounting of life maintaining equipment” such as mounting brackets for ventilators;
- “Maintaining or correcting anatomical alignment” could be considered, as it relates to patient matched medical devices which should be included in the ARTG unless they are specifically exempted by Amendments dated 20 August 2021\(^1\). https://www.legislation.gov.au/Details/F2021L01160

2. Practicality: Does the proposed scope for assistive technology exclusion work in practice? Are there products which would be excluded which should continue to be regulated? Are there products which would continue to be regulated which would be better treated as consumer products?

The proposed amendment is very broad:

<table>
<thead>
<tr>
<th>Schedule 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specified goods</td>
</tr>
<tr>
<td>Column 1</td>
</tr>
<tr>
<td>Item</td>
</tr>
</tbody>
</table>

assistive technology products that are intended by the manufacturer to maintain or improve functional capacity of persons with disability to undertake activities of daily living in settings other than health care settings and:

a) are not IVD medical devices, or medical devices classified under the Medical Devices Regulations as Class IIa or higher; and

b) do not have a measuring function and are intended by the manufacturer to be supplied in a non-sterile state; and

c) would not pose a risk of harm that requires medical attention in circumstances where:

i. the products are used in accordance with the labelling, instructions for use, advertising, or technical documentation describing the mechanism of action of the products; and

ii. there is a malfunction or deterioration in the characteristics or performance of the products

Paragraph (c) is open to interpretation by sponsors who may seek to avoid the costs and work associated with inclusion of products in the ARTG. A strategic approach to ongoing review and education of the sector is recommended. ARATA would be happy to host TGA in our webinar series, to connect with AT stakeholders.

The problem is not seen as devices could be excluded that should be included. The issue will be getting all sponsors and suppliers of products that meet these criteria to be aware that this regulation exists. ARATA suspects there are numerous sponsors and suppliers who provide such assistive technologies to consumers who are not aware of the need to include them in the ARTG.

Clarity

3. Clarity: Is the proposed text of the exemption sufficiently clear for stakeholders? If not, do you have suggestions on how it might be better framed or worded?

The exemption is clear. “A risk of harm that requires medical attention in circumstances where the products are used in accordance with labelling, instructions for use” is the criteria that will be tested when incidents involving a device to facilitate weight bearing transfers ends up causing harm, when the device was not used as it should have been. There have been serious injuries and deaths related to incorrect use of devices to facilitate weight bearing transfers.

Likewise, there have been “malfunction or deterioration in the characteristics or performance of the products” for devices to facilitate weight bearing transfers, wheeled mobility aids and
walking aids, and pressure redistribution cushions or mattresses that have caused harm or have been at risk of causing harm requiring medical attention.

We propose the Examples of Goods NOT Excluded by the Determination includes:

- 12 06 Assistive products for walking, manipulated by both arms
- 12 22 Manual wheelchairs

ARATA views the risk of harm associated with the above devices to be sufficient to require medical attention, and to cause serious injury and death.

4. Products coming into the ARTG: Do you anticipate the need for products to be newly included in the ARTG? Can you provide examples of those products, the scope of changes you expect, etc? Are these higher risks medical devices, or additional low risk (but potentially harmful) products?

Yes, with the stimulus provided by the NDIS and Aged Care reforms, together with innovation and product development trends to meet new markets worldwide, there has been a significant increase in the number of devices to facilitate weight bearing transfers, wheeled mobility aids and non-wheeled walking aids, and pressure redistribution devices.

New sponsors and suppliers will need to have their devices included in the ARTG and existing suppliers will have new devices to add.

5. Products cancelled from the ARTG: Do you anticipate cancellations of ARTG entries for existing assistive technologies to be required? Can you provide examples of those products, the scope of changes you expect, etc?

We anticipate there will be very few if any products coming out of the ARTG

6. Education and communication: Does the approach to the transition seem reasonable? Is 12 months an appropriate timeframe for managing the transition?

Yes, 12 months is sufficient. Devices that should be included in the ARTG are not changing significantly as the higher risk weight bearing and pressure management devices should have already been included in the ARTG. However, as we know there is a significant number of devices sold in Australia without being included in the ARTG that would meet the definition of weight bearing and pressure management.
TGA should work with peaks in the assistive technology sector to facilitate increased awareness among providers of these devices, including Assistive Technology Suppliers Australia, The Australian Orthotic Prosthetic Association (AOPA) and ARATA.

7. Transition arrangements: Are any additional transitional arrangements required for this change? If so, what are the issues to be addressed by such arrangements? Are some sectors likely to be more impacted than others?

Clear communication and advertising to sponsors and suppliers of assistive technology about the changes.

8. Do you have any feedback on the draft guidance document?

We propose the Examples of Goods NOT Excluded by the Determination includes:

- 12 06 Assistive products for walking, manipulated by both arms
- 12 22 Manual wheelchairs

ARATA views the risk of harm associated with the above devices to be sufficient to require medical attention, and to cause serious injury and death.

9. Do you have any other feedback on the proposed exclusion of low risk assistive technologies from the therapeutic goods regulatory framework?

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.

Stephen Hales
Treasurer, ARATA
treasurer@arata.org.au

Kristen Morris
Board Member, ARATA
kristenlouisemorris@gmail.com

Dr Natasha Layton
International Lead, ARATA
international@arata.org.au