Australian Rehabilitation and Assistive Technology Association

arata
participation through technology

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ARATA thanks TGA for the opportunity to respond to '**Consultation: Products used for and by people with disabilities: Options for amendment to the Therapeutic Goods (Excluded Goods) Determination 2018**[1]. We note the focus of this paper is to obtain feedback on options for amending the Therapeutic Goods (Excluded Goods) Determination 2018, to clarify which products intended for use for, or by, people with disabilities are excluded goods, and so regulated as consumer rather than therapeutic goods.

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
- 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.

We note three options for regulatory amendment offered can be summarised as follows:

- Option 1 (a) the current exclusion in Item 9, Schedule 1 of "household and personal aids, or furniture and utensils, for people with disabilities", would be replaced with a definition describing "assistive technology".
- Option 1(b) the current exclusion in Item 9, Schedule 1 of "household and personal aids, or furniture and utensils, for people with disabilities", would be replaced with a definition describing "low risk assistive technology".
- Option 2 the current Item 9, Schedule 1 will be replaced with a list of specified products that are determined to be excluded from the therapeutic goods regulation by the TGA.

[1] https://www.tga.gov.au/consultation/consultation-products-used-and-people-disabilities

ARATA Response

ARATA support Option 1 (b). That is, low risk assistive products are excluded from regulation by the Therapeutic Goods Administration. ARATA notes that low risk assistive products would continue to be regulated under Consumer Protection Legislation overseen by the ACCC and state/territory counterparts. The rationale for this 'light touch' approach to regulation of assistive technology has been discussed in depth within the ARATA response to TGA's February 2019 Consultation: Proposed regulatory scheme for personalised medical devices, including 3D-printed devices[2] .

ARATA support Option 1 (b) on two conditions. Firstly, that the definition of 'low risk assistive technology' requires an evidence-based piece of work. ARATA propose this is based upon the work commenced by NDIA in defining 'low risk' which takes into account the complexity which can arise between technology, person, and environment of use[3]. Specifically, the Assistive Technology Complexity Table[4].

Secondly, ARATA note the taxonomy and classification of assistive products listed in Appendix A[5] is outdated and inconsistent with current international standards adopted by Australia[6]. It is essential to map to the AS/ISO 9999 *Assistive products for persons with disability — Classification and terminology* standards in articulating the list of exclusions. Such a list must comprise prosthetics, orthotics, powered mobility devices, and a range of other product categories as articulated within the NDIA work.

ARATA are available to support the work required to establish a fit-for-purpose definition of low cost assistive products which will take into account near-future innovation and development, as well as consider the role of mainstream but complex technologies within assistive solutions.

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[2] https://www.arata.org.au/public/33/files/Publications/ARATA%20response%20to%20TGA%20consultation%20paper%202019_FINAL.pdf

[3] NDIS. Assistive Technology Strategy. 2015.

[4] https://www.ndis.gov.au/providers/essentials-providers-working-ndia/providing-assistive-technology#identifying-at-complexity-levels

[5] Appendix A – List of certain products used by or for adults and children with disabilities

[6] ISO. AS/ISO 9999 Assistive products for persons with disability — Classification and terminology. 2018.