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’. 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.

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

1. **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”.

2. **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”.

3. **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.

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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 devices².

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 use³. Specifically, the Assistive Technology Complexity Table⁴.

Secondly, ARATA note the taxonomy and classification of assistive products listed in Appendix A⁵ is outdated and inconsistent with current international standards adopted by Australia⁶. 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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³NDIS. Assistive Technology Strategy. 2015.
⁴https://www.ndis.gov.au/providers/essentials-providers-working-ndia/providing-assistive-technology#identifying-at-complexity-levels
⁵Appendix A – List of certain products used by or for adults and children with disabilities