

Occupational Therapy Australia

**Response to Department of Health Therapeutic Goods
Administration *Consultation on Products used for and by
people with disabilities: Options for the amendment to the
Therapeutic Goods (Excluded Goods) Determination 2018***

October 2019

Introduction

Occupational Therapy Australia (OTA) thanks the Department of Health Therapeutic Goods Administration for this opportunity to respond to the *Consultation on Products used for and by people with disabilities: Options for the amendment to the Therapeutic Goods (Excluded Goods) Determination 2018*.

OTA is the professional association and peak representative body for occupational therapists in Australia. As of June 2019, there were more than 21,000 registered occupational therapists working across the government, non-government, private and community sectors in Australia.

Occupational therapists provide services such as physical and mental health therapy, vocational rehabilitation, chronic disease management, assessments for assistive technology and home modifications, and key disability supports and services.

Response to Questions

Option 1(a)

Do you agree that the exclusion in the Determination currently described as “household and personal aids, or furniture and utensils, for people with disabilities” should be replaced with a definition and description of products known as “assistive technology”?

OTA supports the exclusion definition in the Determination being replaced with a definition and description of products known as “assistive technology” (AT). This definition would help ensure increased clarity and consistency in the application of the Determination. OTA however does support Option 1 (b) rather than 1 (a) for reasons outlined in the response to Option 1(b) below.

If ‘yes’, do you have a proposed definition or consideration to be given when preparing the definition?

OTA supports the TGA’s proposal that the WHO definition of AT be used: “An umbrella term for any device or system that allows individuals to perform tasks they would otherwise be unable to do or increases the ease and safety with which tasks can be performed.” The WHO definition is aligned with occupational therapy practice, in that assistive technology is used by occupational therapists to support the functional capacity of their clients to perform tasks that are meaningful, necessary and important for these clients. As such, the WHO definition aligns with the occupational therapy understanding and use of AT.

Option 1(b)

Do you agree rather than excluding all assistive technologies, the exclusion should be limited to only low risk assistance technologies?

OTA in particular supports Option 1(b), and agrees that a subset of the WHO definition of AT be used that limits the definition for excluded AT goods to low risk products (specifically those products that would otherwise be classed as Class 1 medical devices – shower chairs, walking frames, motorised wheelchairs but not hearing aids which the TGA identifies are Class II typically). Option 1 (b) provides the required clarity and regulatory measure to provide protection against “too broad” a definition of AT that creates a space in which sponsors could be interpreting the definition of AT for exclusion with a greater degree of variability, which subsequently creates higher risk for consumers.

Option 1(b) is preferred to Option 2 by OTA as Option 1(b) provides a degree of capacity to deal with emerging technologies without further regulatory amendment.

What impacts—including any that are unintended—do you anticipate this change may have for yourself and other stakeholders (such as consumers, healthcare professionals, health organisations, industry etc.)?

OTA anticipates that this change will have limited impact on OTA members. OTA members to date have not raised significant concerns with OTA regarding the Therapeutic Goods (Excluded Goods) Determination 2018, or the application of the Determination in practice. As such, OTA supports limited change to existing regulatory arrangements, but does believe a clearer definition of AT products for exclusion from TGA regulation/ARTG, one that specifies excluded AT products as those products that are low risk, would better support consumer safety.

Option 2

Do you agree that the definition “household and personal aids, or furniture and utensils, for people with disabilities” should be replaced with a list of specified products determining these products to be excluded goods and of another list in Schedule 2 determining the products to be excluded goods when these products are used, advertised or presented for supply in a particular way?

OTA does not support Option 2. The need for a list of specified products determining inclusion, exclusion or conditional exclusion status would create additional, and in the view of OTA, unnecessary regulatory burden. Further, this Option is likely to negatively impact the efficiency of new technologies being made available to consumers for use. OTA supports measures that will ensure consumers have fast and safe access to new technologies that can assist their functional capacity, that is, their ability to engage in activities of daily life that are meaningful, necessary and important to them.

Conclusion

OTA thanks the Department of Health Therapeutic Goods Administration for this opportunity to respond to the *Consultation on Products used for and by people with disabilities: Options for the amendment to the Therapeutic Goods (Excluded Goods) Determination 2018*. OTA would be pleased to assist the TGA in any further consultation on the Determination should the TGA believe this to be of benefit.