HEARING CARE INDUSTRY ASSOCIATION

24 October 2019

Medical Devices Reform Unit
Medical Devices Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

HEARING CARE INDUSTRY ASSOCIATION RESPONSE

Consultation - Products used for and by people with disabilities
Options for amending the Therapeutic Goods (Excluded Goods) Determination 2018

The Hearing Care Industry Association (HCIA) welcomes the opportunity to contribute to the TGA's consultation about options for amending the Therapeutic Goods (Excluded Goods) Determination 2018 in relation to products used for and by people with disabilities.

HCIA recommendation: Retain status quo for TGA regulation of hearing aid devices.

Rationale

HCIA acknowledges the TGA's purpose in reviewing the Therapeutic Goods (Excluded Goods) Determination is to ensure regulation keeps pace with evolving technology and uses and to minimise unnecessary and costly regulation which may affect accessibility and/or affordability for people with disabilities.

HCIA notes the consultation paper's proposal to draw on the World Health Organisation's definition of assistive technology. The WHO definition cites hearing aids as an example of assistive technology. It is important to note the WHO definition forms part of a policy aimed at improving access to affordable and high quality assistive technology – an objective largely fulfilled in Australia through the Commonwealth's Hearing Services Program.

HCIA considers there is no compelling case to exclude hearing aids from the operation of the Therapeutic Goods Act.

The current classification of hearing aids as a Class II medical device – with a risk rating from low to high – is appropriate for these increasingly sophisticated devices which must be fitted by qualified practitioners (ENTS, audiologists or audiometrists). Excluding hearing aids from the operation of the Therapeutic Goods Act risks the influx of poor quality and ineffective devices into the Australian market.

Devices which are not appropriately manufactured to include suitable output limiting circuitry or are inappropriately fitted have the potential to cause temporary worsening of hearing (or temporary threshold shift). Repeated exposure to the shortcomings of these devices may cause permanent hearing loss (or permanent threshold shift).

Furthermore, the longer term consequences of poorly treated hearing loss can be devastating for individuals including lack of speech and language development for pre-lingual individuals and cognitive impairment and increased risk of dementia in post-lingual individuals.

At present, all hearing aids supplied in Australia have been rigorously assessed for quality, efficacy and safety before entering the market. This assessment process ensures that hearing devices supplied in Australia have the infrastructure available for consumers such as technical services to support warranty and other workmanship and usage issues.

Listing on the Australian Register of Therapeutic Goods (ARTG) is also the entry point for devices to be supplied through the Commonwealth's Hearing Services Program. Most hearing aids provided in Australia are funded by this Program which is regarded as one of the best in the world in terms of providing access to affordable, quality devices while enabling individual choice.

Options

Option 1a – HCIA does not support this option because regulation of "behind the ear" hearing aids would be removed from the auspices of the TGA.

Option 1b – HCIA would support this option only if the definition of low risk medical devices specifically excludes hearing aids.

Option 2 – HCIA would not support a list of goods excluded from the TGA's regulation if that list included hearing aids.

- While a list of assistive technologies may be a more transparent approach to what is considered to be an "excluded good", maintaining a list will require constant monitoring and review to ensure the list keeps pace with evolving technology and remains current.
- Of the three options, Option 2 would appear to be the most inefficient means of managing regulatory standards.

ABOUT HCIA

The Hearing Care Industry Association (HCIA) represents private sector providers who care for thousands of hearing impaired Australians across the country. HCIA members collectively represent approximately 60% of the adult hearing rehabilitation sector.

HCIA members provide diagnostic audiometry, hearing aids, custom ear moulds and earplugs, assistive listening devices, industrial audiology services, and educational seminars. One of our members provides specialised paediatric services, vestibular services and a comprehensive implant program.

All HCIA members are registered to provide services under the Australian Government Hearing Services Program which means, among other things, that our employees have ongoing training, are members of professional bodies and our clinics are audited.

All our employees are members of professional bodies such as Audiology Australia, the Australian College of Audiology (AcAud) or the Hearing Aid Audiometrist Society of Australia (HASSA). In addition, they comply with the Council of Australian Governments (COAG) National Code of Conduct for all Health Workers.

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