audiology australia

2 November 2019

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

Dear Ms Duffy

Re: Consultation on Options for amendment to the Therapeutic Goods (Excluded Goods) Determination 2018

Audiology Australia (AudA) welcomes the opportunity to provide a response to the current Therapeutic Goods Administration's (TGA) consultation on proposed options for amendment to the *Therapeutic Goods (Excluded Goods) Determination 2018* (the Determination) relating to low-risk medical devices used as assistive technology for people with disability.

AudA is the member association for the profession of audiology with over 2,900 members practising across Australia. Our members provide a range of aural (re)habilitation services to the population which include the prescription and fitting of hearing aids, bone conduction aids, FM and other remote sensing systems and hearing assistive technology.

In principle, AudA supports an amendment to Schedule 1, Item 9 of the Determination to improve the transparency of which items, products and equipment within the 'assistive technology' category are excluded from the *Therapeutic Goods Act 1989* (TG Act).

As assistive technology products vary greatly in their functionality, design, safety and performance requirements, we consider that a clearer descriptor for Item 9 will help product suppliers, health professionals such as audiologists who utilise these products on a daily basis and the patients who will use and benefit from them.

AudA's comments on the specific options proposed by the TGA are set out below.

General comments on amendment options

Option 1(a)

Option 1(a) proposes to replace the current definition of "household and personal aids, or furniture and utensils, for people with disabilities" with the even broader definition of "assistive technology" in Schedule 1 of the Determination.

We consider the proposed change to be positive in terms of language as it broadens the scope of Australians who could potentially benefit from using these devices, for example, to support health needs and not just people with a disability.

However, AudA does not support this option. We note that under this definition a range of moderate risk technologies currently classified as Class IIa, such as hearing aids, are likely to then be categorised as "excluded goods" from the therapeutic goods regulatory framework and would then become subject to the Australian Consumer Law (ACL) and regulated by the Australian Competition and Consumer Commission (ACCC).

AudA is concerned about the impacts that this proposed change would have on the Australian Government Hearing Services Program (HSP), and the direct flow-on effects changes to the HSP would have for National Disability Insurance Scheme (NDIS) clients and Department of Veterans' Affairs (DVA) clients accessing hearing services and assistive technology through the HSP.

Since 1947, the HSP has provided hearing services to those most vulnerable in our community. A significant benefit of the HSP is that - for eligible Australians - the Government provides subsided access to hearing services and a wide range of quality hearing devices and assistive listening devices through the delivery of the voucher component of the HSP. From 2017 to 2018, 733,400 clients accessed the voucher component of the HSP at a cost of $449.2 million.[1] In 2018-19, the HSP is expected to support an estimated 811,000 clients, providing them with access to high quality hearing services, and fully and partially subsidised devices.[2] A significant, and increasing, number of clients are accessing the HSP and this number is expected to continue to increase, largely due to the growth in the proportion of older Australians in the population. As a result, there will be a greater demand for subsidised access to hearing services and devices.

Before hearing aids are offered to HSP clients, they must first be listed on the Australian Register of Therapeutic Goods (ARTG) as "medical devices" in accordance with the TG Act.

If the current definition under Schedule 1, Item 9 of the Determination is amended to "assistive technology", we understand that hearing aids falling into this category and currently approved for use for HSP clients would then have to be removed from the HSP's Device Schedule. This is because these hearing aids would now be considered consumer goods under the ACL and fall under the jurisdiction of the ACCC rather than a therapeutic good – a "medical device" - eligible for listing on the ARTG and under the TGA's jurisdiction.

AudA is concerned that this proposal – if implemented - would have a significant impact on the ranges of devices that are available through the HSP and on the devices available on the fully subsidised list in particular – which are intended to be of use for older Australians with limited financial means. In turn, this may detrimentally impact the hearing health of new and existing HSP clients who may therefore have limited choice or access to subsidised devices that are appropriate to their hearing health care needs.

Furthermore, the HSP also provides services to eligible Australians in other government funded schemes. Through the HSP, the Department of Health currently supplies subsidised hearing services and devices to eligible DVA veterans with an accepted hearing disability and eligible participants with hearing loss in the National Disability Insurance Scheme. These two significant government schemes also rely on the TGA safeguards that are in place for hearing devices to ensure client safety and device quality.

Therefore, AudA recommends that all classes of hearing aids continue to be regulated by the TGA. We consider that TGA regulation of hearing aids as medical devices provides an extra safeguard for people seeking to utilise this technology. Clients with hearing loss can be a vulnerable population and depending on their circumstances they may also have spent significant funds to purchase hearing aids. We consider that the regulatory safeguards currently in place through the TGA help provide an extra level of protection and ensure that hearing devices available in Australia through the HSP are quality products that are safe to use for their intended purpose.

[1] *Annual Report 2017-18* (Canberra: Department of Health, 2018), 82.
[2] *Heath Portfolio Budget Statements 2019-20*, (Canberra: Department of Health, 2019), 91.

All hearing aids and many assistive listening devices require specialised programming and adjustment from a clinician who is qualified to provide this service. There is a real risk of hearing damage to clients should these products not be set up properly.

AudA is therefore concerned that should a range of hearing devices be excluded from the TG Act and be singly regulated under the ACL, there may be decreased attention placed on the products' safety, quality and performance prior to, and during, its use in the population. With the number of people who are deaf or hard of hearing expected to grow from an estimated 3.6 million people to around 7.8 million people by 2060[3], it is crucial that the safety, quality and performance of hearing devices are rigorously maintained.

Recommendation 1: AudA does not support Option 1(a) as we are concerned that this will result in the removal of a range of subsidised hearing aids from the Australian Government's Hearing Services Program given the current requirement for them to be listed on the Australian Register of Therapeutic Goods as "medical devices" before being offered through the HSP.

Recommendation 2: AudA recommends that all classes of hearing aids continue to be subject to the regulatory safeguards established by the Therapeutic Goods Administration so that the safety, quality and performance of hearing aids available in the Australian market are maintained.

Option 1(b)

AudA does not support the option to replace the current definition of "household and personal aids, or furniture and utensils, for people with disabilities" with the definition "low risk assistive technology". AudA notes that under this definition only low risk items used to increase, maintain or improve different functional capabilities of people with disabilities, irrespective of its complexity or technology, would be excluded from the TG Act.

Assistive technology products exist along a spectrum of design and technological complexity. Similar products can have different levels of safety and performance requirements. For instance, of the ten hearing aid remote control products currently listed in the ARTG, six are Class 1 Medical Devices (low risk) and four are Class IIa Medical Devices (moderate risk).

If the current definition under Schedule 1, Item 9 of the Determination is amended to the definition "low risk assistive technology", many assistive technology products, such as hearing aid remote controls, may potentially become divided into two categories: those that are low risk and therefore excluded from the TG Act, and those that are moderate risk and included in the TG Act. We believe that it would be inappropriate for similar products to be separated and regulated under two separate legislative regimes as it will lead to confusion on the part of manufacturers, suppliers and health professionals, likely impose extra administrative costs and potentially undermine a reform that is intended to simplify rather than complicate regulation in this area.

In addition, AudA notes that while hearing aids are often moderate risk Class IIa Medical Devices, many assistive listening devices are low risk Class 1 Medical Devices. AudA does not recommend separating the regulation of assistive listening devices from that of hearing aid devices. As assistive listening devices are often used in conjunction with hearing aids, it would be more practical for these products to be regulated by the same governing body.

[3] *The Social and Economic Cost of Hearing Loss in Australia* (Deloitte, 2017), 3.

Recommendation 3: AudA does not support Option 1(b) as we are concerned that this may result in a scenario whereby the same assistive technology product (i.e., hearing aid remote control) is separately regulated by the Australian Competition and Consumer Commission and the Therapeutic Goods Administration as a result of the product's different risk classification.

Recommendation 4: AudA recommends that both hearing devices and assistive listening devices should continue to be regulated by the Therapeutic Goods Administration as a therapeutic good.

Option 2

AudA supports the option to replace the current definition of "household and personal aids, or furniture and utensils, for people with disabilities" with a list of specified products that are determined to be excluded from the therapeutic goods regulation.

While AudA acknowledges that the introduction of this option may result in a higher administrative burden as new types of technology are introduced to the market, we believe that Option 2 provides a very clear approach as to which assistive technologies will and will not be excluded from the TG Act. It also minimises differences in interpretation that can arise if a definition is used, such as in the case of Options 1(a) and 1(b).

AudA strongly recommends that hearing aids continue to be regulated by the TGA as a medical device and that hearing aid products should not be included on the list of specified products that are determined to be excluded from the therapeutic goods regulation.

As outlined in Option 1(a), government funded hearing aids in the HSP must be approved by the TGA in order to be accessible to eligible Australians and it is, therefore, vital in our view that hearing aids continue to be regulated by the TGA.

AudA also recommends that all assistive listening devices should continue to be regulated by the TGA. As assistive listening devices are frequently used in combination with hearing aids, we believe that they should continue to be used as "medical devices" under the TGA rather than as a consumer good. This ensures consistency in the regulatory approach to both hearing devices and any associated assistive technology products and may also help minimise confusion amongst product suppliers, health professionals and patients.

Therefore, we consider that assistive listening devices listed in Appendix A such as the hearing aid neck induction loop, hearing aid enhanced audio attachment and hearing aid remote control device should also not be included on the list of specified products that will be excluded from the TG Act.

Option 2 also proposes the introduction of a new item to the Determination's Schedule that will list specified products that will be determined to be excluded goods if they are used, advertised or presented in a particular way.

If Option 2 is adopted, AudA recommends that there be extensive information provided to stakeholders about the criteria involved that is used to determine which products are excluded on the list, including the way in which they are used, advertised and presented.

Recommendation 5: AudA supports Option 2 and recommends that:

- **the TGA continue to regulate hearing aids (air-conduction, receiver-in-canal), hearing aid neck induction loop (active), hearing aid enhanced audio attachment and hearing aid remote control as medical devices.**
- **if Option 2 is adopted, more information should be provided to inform stakeholders about the criteria and/or selection process used to determine which products are included on the list and are therefore excluded from the TG Act.**

We would welcome the opportunity to discuss any aspect of the submission with you further. I can be contacted via [redacted], Advocacy and Policy Manager at [redacted]

Yours sincerely

[redacted]

Dr Jessica Vitkovic
President