5 November 2021

Ms Rachel Croome
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Therapeutic Goods Administration
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Re: Draft Guidance: Assistive Technologies and the Therapeutic Goods (Excluded Goods) Determination 2021

Audiology Australia (AudA) welcomes the opportunity to provide a further submission response to the Therapeutic Goods Administration's (TGA) consultation on the Draft Guidance of the Assistive Technologies and the Therapeutic Goods (Excluded Goods) Determination 2021 (the Determination).

AudA is the peak professional body for the profession of audiology, representing over 3000 audiologists across Australia. Our members provide a range of aural (re)habilitation services to clients which include the prescription and fitting of hearing aids, bone conduction aids, FM and other remote sensing systems and hearing assistive technology.

We have noted the TGA's proposed amendment for Schedule 1, Item 9 of the Determination and the intention to exclude low risk assistive technologies as outlined in Option 1B, but to modify this so as to continue to regulate medical devices which, if they malfunction when used as intended, can cause significant injury.

We have provided comments on consultation questions 2 and 9, as set out below.

Consultation Questions

2. Practicality: Does the proposed scope for assistive technology exclusion work in practice?

AudA highlights that assistive technology products exist along a spectrum of design and technological complexity. Similar products may have differing levels of safety and performance requirements. For example, on the Australian Register of Therapeutic Goods (ARTG) there are hearing aid remote control products listed as Class 1 Medical Devices (low risk) and Class IIa Medical Devices (moderate risk).

We seek further information in regard to similar assistive technology products with different risk classifications, such as hearing aid remote controls – as under the proposed amendment, similar products may potentially become divided into two categories: those that are low risk and therefore excluded from TGA regulation, and those that are moderate risk and regulated by the TGA. We believe that it would be inappropriate for similar products to

be separated and regulated under two separate regulatory systems, as it will likely lead to confusion on the part of manufacturers, suppliers and health professionals, and may impose extra administrative costs and potentially undermine a reform that is intended to simplify rather than complicate regulation for assistive technology products.

9. Do you have any other feedback on the proposed exclusion of low risk assistive technologies from the therapeutic goods regulatory framework?

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

We are also concerned about the implications of this proposed change on ALDs available through the Department of Health's Hearing Services Program (HSP). Under the HSP, if you have a hearing loss you can be fitted with either a fully subsidised hearing aid or an ALD. ALDs may be recommended if a hearing aid is not clinically suitable or if a person wishes to hear better in a particular situation.

The Deed of Standing Offer sets out the ways that devices may be supplied to HSP clients. Under section 5 of the Deed, devices offered for inclusion on the HSP must already be listed on the ARTG if and where such registration is required under s 9A of the *Therapeutic Goods Act 1989*. The Department may also audit devices which have been listed in the device schedule against the applicable device specifications. Any device found not to meet the device specifications will be withdrawn from the device schedule and therefore not eligible for provision and subsidy under the HSP.

Under the Deed, ALDs are "non-standard devices", meaning that they are a device that has special application to a person's particular clinical requirements. This means they are able to be listed on the fully subsidised device schedule, be fully subsidised by the government and available to eligible HSP clients. There are currently 34 ALDs on the fully subsidised device schedule of the HSP.

We are concerned that the change – if implemented - will mean many of these ALDs may be removed from the ARTG, can no longer be listed on the fully-subsidised device schedule and therefore available and accessible to HSP clients given it is a pre-requisite that they be listed on the ARTG. The HSP provides hearing health care services to pensioners, veterans and people who often have limited financial means and will not be able to access these devices to assist with their communication needs elsewhere. This is a problem when the current low numbers of ALDs and variety of choice is already an identified issue of concern in the HSP and will reduce the choice even further.[1] The proposed change also means that new ALDs that come onto the market may not be able to be offered under the HSP either given they will not be eligible to be registered on the ARTG.

[1] Prof Michael Woods and Dr Zena Burgess (August 2021) *Report of the Independent Review of the Hearing Services Program.* Available at: Report of the Independent review of the Hearing Services Program Recommendations, Learnings and Ideas for the Future (health.gov.au)

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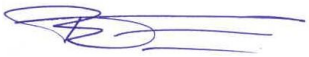
We would welcome the opportunity to discuss any aspect of our letter with you further. I can be contacted via Elissa Campbell, Advocacy and Policy Manager on (03) 9940 3900 or elissa.campbell@audiology.asn.au.

Yours sincerely



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