The mission of Independent Audiologists Australia is to promote and support clinical practices owned by audiologists.

Therapeutic Goods Administration
Medical Devices Reform Unit
Medical Devices Branch
Therapeutic Goods Administration
PO Box 100
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25 October 2019

Dear Medical Devices Reform Team

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

Thank you for the opportunity to provide input to the current consultation that seeks to reform the way that some therapeutic goods are regulated in Australia.

Independent Audiologists Australia Inc (IAA) is a not for profit incorporated association whose members are university qualified audiologists who hold a financial interest in an audiology practice. Our members provide support services to those of all ages affected by the full range of auditory and vestibular (hearing and balance) conditions – be they related to sensory impairment, processing, cognition, or language as stand-alone conditions or co-morbid with others such as Autism. Support, appropriate training, and counselling are provided as (re)habilitation to both individuals and their significant others, along with the provision of a range of devices that they prescribe and dispense in their clinics.

Our members are faced with challenges when providing devices to patients, for whom the risk of wearing a poorly fitted hearing device is not always apparent. Our members attend to patients who are highly influenced by media reports of hearing devices being expensive and commissions paid to some clinicians (largely unregulated in Australia), which may drive them to online purchases and over the counter devices which pose risks if not appropriately prescribed.

Our members offer highly specialised and focussed services related to hearing and balance. We have completed Appendix A (see attached), in the section listing hearing aid related items. We have provided input to the consultation for those specific specialist devices listed there.

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We would be happy to contribute to any further discussion or consultation on this topic in future.

Thank you again for the opportunity to comment on planned reform of how medical devices will be regulated in Australia.

Kind regards

The IAA Executive Committee

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Appendix A – List of certain products used by or for adults and children with disabilities

Table A – seeking stakeholders feedback and views on regulatory pathways for specified devices used for people with disabilities.

Instructions for Table A:

The 1st and 2nd columns in the table provide the product group titles and their descriptions and intended purposes.

The 3rd column has been included to obtain stakeholders' views on whether the specified products should be entered in either Schedule 1 (products to be excluded unconditionally) or Schedule 2 (products to be excluded goods when these products are used, advertised or presented for supply in a particular way), or whether the product should be regulated as a medical device under the TG Act.

The 4th column seeks the reasons for the proposed regulatory pathway.

Therapeutic good	Description	Choose: 1. Exclude unconditionally 1. Exclude when used, advertised or presented in a particular way 2. Regulate as a medical device	Reasons
Hearing aid			
Hearing aid, air-conduction, receiver-in-canal	A battery-powered acoustic device intended to compensate for impaired hearing by transmitting amplified sound waves to the eardrum through air. It consists of a microphone and an amplifier	Regulate as a medical device	Hearing aids need to be set to a prescription based on an audiological assessment to avoid overamplification that can cause noise induced hearing loss, or under-amplification that can mean a device is not optimal. Additionally, the absence of active external / middle ear pathology needs to be determined before the safety of using air conduction hearing aids can be established. Devices cannot always be fitted successfully or appropriately without an audiological assessment and follow up services. Unless regulated as a medical device, air conduction hearing aids will marketed direct to consumers, posing risks to the Australian public, including to very vulnerable populations given that families are often

	in a case behind-the-ear (BTE) connected, via a wire, to a receiver (speaker) in the ear canal [receiver-in-canal (RIC)]; this separation reduces acoustic feedback. The microphone receives sound waves and converts them into electrical signals which are increased by the amplifier and sent as sound waves, by the speaker, to the eardrum. The device is used for mild to profound hearing loss; most types are programmable to enable computerised adjustments for a patient's hearing loss and related factors.		very unfamiliar with hearing devices when their offspring are diagnosed (whether as newborns or later) and could be influenced by direct to consumer marketing if hearing aids lose their TGA classification. Importantly, hearing aids are manufactured outside of Australia. Standards of gain and output limiting in devices may not meet any standards or requirements if left off the TGA listing. Hearing aids have the potential to cause further hearing loss if set with a high power output. Once hearing is damaged, it does not rejuvenate. Newborns, infants, and the elderly who have difficulty communicating may all be at risk for high levels of discomfort and/or damage if devices they wear are not regulated when they enter into Australia. Risks include having inappropriate or poor fitting coupling of the hearing aid to the ear, which could cause permanent damage in the case of occluding ear wax and/or infection in the outer or middle ear, presence of a perforated tympanic membrane or active middle ear pathology. Coupling of hearing aids to ears requires expert otoscopic examination of the ear, assessment of function beyond the ear drum, and the taking of an ear impression that is suitable for the condition of the ear. Hearing aids are usually coupled to ears with custom made earmolds – which may sit deeply in the ear canal, require specialised signal routing in in the case of CROS aids, or require effective ventilation to avoid repeated infections. Coupling hearing devices to ears inappropriately can exacerbate conditions and lead to complications such as cholesteatoma, a condition resulting from repeated ear infections that can cause bone erosion and spread of infection to surrounding areas, including the inner ear and brain. Hearing aids with Bluetooth capabilities pose further risk for those using pace makers. Direct to smartphone technology built into many hearing aids can interfere with the functioning of brain stimulation devices used to treat Parkinson's Disease in selected patients.
Hearing aid neck induction loop, active	A portable, battery-powered device worn around the neck intended to receive sound from an audio source [e.g., mp3 player] via a wire (e.g., 3.5mm Jack plug) and transfer it via an audio frequency magnetic field to a hearing aid	Exclude unconditionally	Neck induction loops are typically used when paired with paired with a hearing aid, which if regulated as a Class 11a medical device (as recommended above). The neck induction loop itself serves as a transmitter, not an amplifier and is safe to be used by anyone.

	with an induction coil (i.e., bypassing the hearing aids microphone) when it is switched to the "T" or "M"' position, in order for the hearing aid user to hear (e.g., music) more clearly. It typically consists of an input cable leading to a small active amplifier with a wire loop worn around the neck.		
Hearing aid enhanced audio attachment	A passive device intended to enable a wired audio transmission from a multimedia device (e.g., computer, phone, mp3 player) to a behind-the-ear (BTE) hearing aid, to enhance the sound quality received by the wearer of the hearing aid. Also known as an audioshoe, it consists of a hearing aid attachment which attaches/plugs directly into the hearing aid, making an electrical connection [e.g., direct audio input (DAI)], to receive power from and	Exclude when used, advertised or presented in a particular way	DAI to a hearing aid via a show only affects the input, not the amplification or the use of the device in the ear. Accessories to hearing aids for the most part pose no risk to the public because they do not amplify sound themselves or couple directly to the ear. Provided the air conduction hearing aid they are coupled to is regulated, and fit to the appropriate person, audio shoes can be excluded from regulation. However, DAI audio attachments attached to FM systems are used by very vulnerable children such as those with autism or auditory processing disorder associated with a myriad of complex developmental conditions. Without careful monitoring of hearing and use of these devices, they could potentially, when coupled with hearing aids, cause substantial damage to hearing and/or auditory processing. We consider that direct to consumer marketing and lack of oversight by the TGA would introduce risk, that would be minimised if these devices were coupled to hearing aids that were regulated (as discussed above) and with limitations so that FM systems that rely on audioshoes are TGA regulated.

	transmit the signal to the active hearing aid. A wire is used to connect the device to the multimedia device.		
Hearing aid remote control	A battery-powered device designed to be operated by the wearer of a hearing aid to enable discreet wireless (remote) adjustments to the hearing aid (e.g., volume and program changes). It is designed to be conveniently portable (e.g., carried in a pocket, handbag, or attached to a key ring).	Exclude unconditionally	Remote controls are not amplifying devices, but are accessories to hearing aids. Accessories to hearing aids pose little risk to the public because they do not amplify sound themselves. Provided the air conduction hearing aid they are coupled to is regulated, and fit to the appropriate person, remote controls can be excluded from regulation.