Products used for and by people with disabilities

Submission to the TGA from the Hearing Aid Manufacturers and Distributors Association of Australia (HAMADAA)

November 7, 2019

TGA Consultation: Products used for and by people with disabilities

Options for amendment to the Therapeutic Goods (Excluded Goods) Determination 2018

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The Hearing Aid Manufacturers and Distributors Association of Australia (HAMADAA) welcomes the opportunity to provide input into the TGA's consultation on **options for amendment to the Therapeutic Goods (Excluded Goods) Determination 2018.**

Introductory remarks

HAMADAA's members understand the foundation for the TGA's periodic review of regulatory requirements for therapeutic goods – to ensure that regulations continue to be appropriate, and that that the level of regulation for therapeutic goods is commensurate with the potential risk these products pose to public health and safety.

HAMADAA also notes the importance of the *scientific and clinical expertise* that the TGA applies in its assessments and ongoing regulation of products and how critical this expertise is in measuring product risks and benefits, in a regulatory framework that is distinct from the Australian Consumer Law framework.

Hearing aids supplied by HAMADAA members are sophisticated medical devices that have made significant advancements in digital signal processing to remove unwanted noise, enhance speech clarity, and provide 2.4GHz Bluetooth connectivity to a large variety of everyday devices such as TV's, smart phones and tablets, and music players. These, and other improvements have been made in order to meet the complex needs of hearing-impaired patients, and are founded on years of investment in research and development (R&D).

In terms of the regulatory amendments proposed in the consultation document, HAMADAA submits that hearing devices, as well as accessories/software that are either used by patients in conjunction with the device and/or that are necessary to their functioning, remain regulated under the medical device regulatory framework. The rationale for this proposal is that the medical device regulatory framework ensures the best possible outcomes for users of these devices in terms of manufacturing quality, safety and compliance with international standards. Excluding hearing devices from the operation of the medical device framework carries with it the risks that poor quality devices, which may be ineffective and unsafe, will be supplied to Australian patients.

Background

As noted in the consultation document, the Australian Government has been proceeding with significant reforms to further strengthen medicines and medical device regulation in Australia. This program of reform came about as a result of endorsed recommendations from the 2015 Review of Medicines and Medical Devices Regulation (MMDR). This consultation focuses specifically on Recommendations fourteen (14) and twenty-three (23) as below;

Recommendation Fourteen

The Panel recommends that the Australian Government undertake a review of the range of products currently listed in the ARTG (not including complementary medicines) and subject to regulation under the medicines framework, with a view to ensuring that:

1. Products that might best be regulated under other regulatory frameworks, without undermining public health and safety, are removed from the auspices of the Act; and

2. Goods remaining under the auspices of the Act are subject to regulatory requirements that are commensurate with the risk posed by the regulated products.

Recommendation Twenty-Three

The Panel recommends that the Australian Government undertake a review of the range of products currently classified as Class I medical devices, with a view to reclassifying products as consumer goods in circumstances where the product poses little or no risk to consumers should it not perform as specified or malfunctions.

Assistive Technology

The proposal options in the consultation document aim to provide increased clarity around items, products and equipment intended for use for, or by people with disabilities that are *excluded goods* and therefore regulated as consumer rather than therapeutic goods.

Schedule 1, Item 9 of the Therapeutic Goods (Excluded Goods) Determination currently provides that the "household and personal aids, or furniture and utensils, for people with disabilities" are not regulated as therapeutic goods. Although these items, products and equipment are broadly known as 'assistive technology' there is not currently a definition for 'assistive technology' used in Australian regulation.

Options 1a and 1b of this consultation propose to draw on the World Health Organisation's (WHO) definition of assistive technology for amendment to the Determination. This is proposal is intended to inform to differing levels – which goods may be able to be reclassified as *excluded goods* in line with MMDR recommendation fourteen and twenty-three. It is important to note that these recommendations only propose a reclassifying of goods in circumstances not 'undermining public health and safety' (14) and 'where the product poses little or no risk to consumers should it not perform as specified or malfunctions' (23), which specifically relates to Class 1 medical devices.

The WHO definition for assistive technology is:

> *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.*

In addition, WHO provides that:

> *Assistive devices and technologies are those whose primary purpose is to maintain or improve an individual's functioning and independence to facilitate participation and to enhance overall well-being. They can also help prevent impairments and secondary health conditions. Examples of assistive devices and technologies include wheelchairs, prostheses,* ***hearing aids****, visual aids, and* ***specialised computer software and hardware that increase*** *mobility,* ***hearing****, vision, or communication capacities.* (emphasis added)

As highlighted above – the WHO definition cites hearing aids, and likely, the accessories/software that are either used by patients in conjunction with the device and/or that are necessary to their functioning as assistive technology. Although as a normative term this may be suitable, this

classification would be unsuitable in regulatory terms for these products in Australia as it would result in their exclusion from the Determination and therefore the ARTG. As outlined in this submission, an exclusion of these goods from the ARTG would go against the public health and safety, and risk to consumer measures outlined in the MMDR recommendations.

It is important to note the context of the development of the WHO definition, and the citing of examples such as hearing aids and specialised computer software that increases hearing capacities in that definition. This was developed as part of a policy aimed at improving access to high quality and affordable assistive technology, particularly for low to middle-income countries where there are high levels of unmet need for these devices and other technologies.

The Australian context is fortunate to not experience similarly high levels of unmet need, due to the policy and funding of the Commonwealth Hearing Services Program (HSP), which provides broad access to many in-need cohorts across Australia.

The Essential Principles and Conformity Assessment

The Essential Principles

All medical devices supplied in Australia are required to comply with the Essential Principles, including the following 6 general principles:

1. Use of medical devices not to compromise health and safety
2. Design and construction of medical devices to conform with safety principles
3. Medical devices to be suitable for intended purpose
4. Long‑term safety
5. Medical devices not to be adversely affected by transport or storage
6. Benefits of medical devices to outweigh any undesirable effects

Conformity Assessment and Quality Management

To demonstrate compliance with the Essential Principles, medical devices are required to undergo a conformity assessment process. For hearing devices, this includes a requirement for manufacturers of the device to implement a Quality Management System, including audit requirements by regulators or recognized certification bodies. Conformity assessment evidence is required to be submitted to the TGA as part of the process of including a hearing device in the Australian Register of Therapeutic Goods (ARTG).

ISO 13485 is a harmonized standard for medical device quality management systems, and certification with ISO 13485 ensures continual effectiveness, safety and quality of the devices

developed under the system. HAMADAA members' products are manufactured in accordance with ISO 13485.

Safety Standards Specifically Applicable to Medical Devices

In addition to ISO 13485 (which relates to Quality Management Systems), there are safety and performance standards that are applicable to medical devices generally, and hearing devices specifically, that HAMADAA members' products are assessed against as part of the conformity assessment process to further demonstrate compliance with the Essential Principles. These standards are:

- IEC 60601-1 Medical electrical equipment – Part 1- General requirements for basic safety and essential performance
- IEC 60601-1-2 Medical electrical equipment – Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-2-66 Medical electrical equipment – Part 2-66: Particular requirements for the basic safety and essential performance of hearing instruments and hearing instrument systems. IEC 60601-2-66 is an annex to IEC 60601-1 and specifically relates to hearing devices

If hearing aids were excluded from the TGA regulation, this would create a standards gap. It is likely that some manufacturers of poorer quality devices would disregard the series of safety and performance standards specifically applicable for Medical Devices (IEC 60601-series) and may instead rely on the safety standard for consumer electronics IEC 62368, if they assess against a standard at all (noting that, with the exception of electromagnetic compatibility/radiocommunications regulatory requirements, and electrical safety requirements which could potentially apply to a charger, hearing devices/accessories would not be subject to any product regulatory regimes that require assessment against any standards prior to being placed on the market).

As opposed to IEC 60601-1, IEC 60601-1-2 and the safety standard specific for hearing aids IEC 60601-2-66, IEC 62368 does not have a holistic view on patient safety and does not require the manufacturer to have e.g. risk management, usability, material safety (Registration, Evaluation and Authorisation of Chemicals - REACH/ Restriction of Hazardous Substances - ROHS) and Software control.

All of these factors make hearing aids, fitting software and other hearing device accessories safer, more user friendly and more secure from cybercrime.

Furthermore, IEC 60601-2-66 specifically outlines requirements for maximum sound pressure level in hearing instruments which is not comparable with the requirements of other safety standards, like IEC 62368.

Further, under current regulatory arrangements for general consumer products it is not illegal to sell goods that are unsafe. While there is discussion regarding the introduction of a general safety provision in Australia, it is not law yet. In addition, even if a general safety provision were introduced, this is unlikely to require manufacturers to implement an audited Quality Management System, or assess products against specific safety and performance standards.

In summary, by excluding all assistive devices from TGA regulation, there would be no requirements for hearing devices to comply with the Essential Principles, and nor would manufacturers of hearing devices be required to have a certified quality management system. This could directly affect the safety and quality of hearing devices in Australia.

Supply chain considerations – Australian context

The regulation of hearing devices, their fitting software, and functional accessories as medical devices forms part of the quality and safety control of the supply chain responsible for reducing the impacts of hearing loss for patients.

Major audiology associations have published documents on Best Practices within hearing aid assessment and fittings. These require hearing aids to be fit by highly qualified professionals and they require conducting real-ear measurements to verify the sound pressure level in the ear canal is correct and appropriate for a specific hearing loss, and the user's individual listening preference. Hearing aids are meant to be fitted through extensive customization to the individual patient and good counseling is required before, during and after fitting, in order for rehabilitation with hearing aids to be successful.

The requirements for fitting hearing aids are typically standardised in Australia under the Australian Government Hearing Services Program (HSP), however the needs of each hearing-impaired individual must be assessed by an appropriately trained and qualified hearing care professional so that they can provide an individualised audiological service to match the hearing aid provided to meet the wearers hearing needs. They are not simply a fit and go solution and cannot be compared to fitting a person with corrective eye wear.

While acknowledging that if hearing devices were to be excluded from the medical device regulatory system that this would not necessarily preclude professional fitting, it is HAMADAA's submission that manufacturers of poorer quality devices would be more likely to target patients directly (as hearing care professionals will be reluctant to fit poor-quality devices). This could result in clients foregoing to see a hearing care professional, delaying access to timely and effective treatment for their hearing loss. Poor outcomes with these low-quality hearing devices may also put patients off continuing with treatment of their hearing impairment i.e. by NOT wearing them regularly or at all, leading to the well-known adverse effects of untreated hearing impairment.

In addition, most hearing devices supplied in Australia are funded through the Australian Government Hearing Services Program (HSP), which is a world-class program providing Australians with access to affordable, quality devices. It is a requirement of the Hearing Services Program that devices be included in the Australian Register of Therapeutic Goods, which provides a quality control mechanism for hearing devices supplied under the program. Should hearing devices be deregulated, the Commonwealth would need to carefully consider how it would propose that quality standards for devices supplied under the Hearing Services Program be maintained.

Supply chain traceability and recalls

Under general consumer laws, there is no regulatory obligation to have in place a traceability system through the supply chain.
For goods classed as medical devices under the remit of the TGA, manufacturers are required to keep extensive records, and conduct medical device risk analysis.

As noted on the TGA website – medical device manufacturers must keep records for at least 5 years from the last date of manufacture, or for the lifetime of the device, *whichever is longer.*

In terms of risk analysis – as part of the Quality Management Systems requirements (ISO 13485) that apply to medical devices, manufacturers are responsible for analyzing the potential risks associated with an adverse event, goods failure or complaint. This requires manufacturers must have in place;

- A system to recall any batch of goods by notifying sponsors or distributors
- A system to investigate any issue, including identification of root cause and implementation of corrective and preventative actions (CAPAS)

All of these existing measures go to the importance of maintaining quality and safety across the supply chain, and in this case, the TGA offers stronger protections than the Australian Consumer Law for patients with hearing impairment.

Consequences of poor quality/unsafe devices for patients

IEC 60601-2-66, one of the safety standards specifically applicable to hearing instruments specifically outlines requirements for maximum sound pressure level, providing safety measures for vulnerable patients to ensure that devices do not worsen hearing impairment.

Given that manufacturers of poorer quality devices would be more likely to target patients directly if their products were removed from the remit of the medical device regulatory framework, this would expose patients to considerable risk. Hearing damage can result from excessive exposure to high sound pressure levels (dBSPL) and these risks are currently mitigated through the standards required for hearing instruments under IEC 60601-2-66, and with hearing aids being fitted by suitably qualified hearing care professionals.

Additionally, a key feature of the Australian supply chain context (including the HSP) is heavily weighted on the regulation of hearing devices and accessories/software that are either used by patients in conjunction with the device and/or that are necessary to their functioning as medical devices. This provides a quality control mechanism in Australia.

Untreated/poorly treated hearing loss could result from the proliferation of poorer quality devices, and limited restrictions on advertising to the public and labelling. Hearing aids supplied by HAMADAA members have the benefit of many years of investment in R&D into the causes of hearing impairment, it's varied impact on different hearing-impaired groups (e.g. children, severe/profound hearing impairment, and new versus experienced users of hearing aids). Hearing aids developed by HAMADAA members are not just simple amplifiers of sound, but in fact are highly customisable to meet individual needs as they utilise sophisticated signal processing algorithms to reduce the unwanted effects of background noise, enhance speech clarity, and also enable connectivity to a large range of Bluetooth enabled consumer devices such as TVs, smart phones and tablets, computers and other audio-visual devices. All of these capabilities allow Australian hearing-impaired patients to have the best opportunity to live their lives in the same way as the hearing community does.

Australian hearing-impaired patients greatly benefit from the hearing aids supplied into the Australian market being designed to meet their needs and being "fit for purpose", which results in very a low level of complaints about these medical devices as reported by the HSP each year.

As noted in the 2017 Deloitte report into the social and economic costs of hearing loss, 'hearing loss can have a significant impact on an individual's ability to work. This may include a reduced chance of employment, premature retirement, a greater number of sick days than average, or a diminished capacity to be productive at work due to impaired ability or psychological stresses.'[1]

In Australia, these productivity losses from hearing loss were estimated to reach $12.8 billion in 2017 – primary through reduced employment. This cost is borne heavily by both individual consumers (47%) and the government (32%) primarily through lost tax revenue.

Any increase in poor quality/unsafe devices that would likely result from exclusion of hearing devices, software and accessories could risk an increase in these social and economic costs to patients, the wider community and government.

Advertising restrictions and information requirements for Medical Devices

Therapeutic goods are distinct from consumer goods, with patients relying on the former for their health. The therapeutic goods advertising regulatory framework recognises this unique role of therapeutic goods for patients in the marketplace, and as such, requires a higher ethical standard than may apply for ordinary consumer goods.[2] The Therapeutic Goods Advertising Code (No.2) 2018 (the Code) is the main pillar of this regulation, and the various restrictions on advertising ARTG listed goods to the public reflects the importance of patients having access to information that is truthful, balanced and not misleading.

The object of this specific legislation that goes over and above requirements set out in Australian Consumer Law is to ensure the maintenance of the principle that patients are properly informed if and when they are selecting treatment options for their own and their family's healthcare.

In addition to advertising restrictions to the public that apply to therapeutic goods, the Code mandates that medical devices and other therapeutic goods must include in their labelling or instructions for use (IFU), health warnings as required by the Act, Regulations or Medical Devices Regulations. The Therapeutic Goods (Medical Devices) regulations 2002 – specifically sets out in Essential Principle 13 – Information to be provided with medical device, the extensive requirements around information pertaining to devices.

These advertising restrictions and labelling/IFU requirements work in tandem to mitigate public health and safety risks of therapeutic goods for patients. As noted, these restrictions and requirements go above and beyond the Australian Consumer Law, and ensure that hearing devices as well as accessories/software that are either used by patients in conjunction with the device and/or that are necessary to their functioning are, as is appropriate, compliant with the risk/benefit regulatory requirements of the TGA.

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[1] Deloitte Access Economics: *An Update of the Social and Economic Cost of Hearing Loss and Hearing Health Conditions in Australia,* July 2017

[2] 'Advertising to the public – complying with the Therapeutic Goods Advertising Code (No. 2) 2018'. *Department of Health, Therapeutic Goods Administration.* January 2019. https://www.tga.gov.au/sites/default/files/advertising-public.pdf?fbclid=IwAR1dYgsAG_piESs5UcUzAwGz2gurN_pG4uLvEt9e2CCh6N0r0QVOEgHX07g

Global alignment and conformity with equivalent regulatory systems

Worldwide, and indeed throughout the review of Medicines and Medical Device Regulation (MMDR) there are moves towards aligning classifications and requirements of medical devices, as is seen with the Medical Device Single Audit Program (MDSAP). If the TGA decided to de-regulate hearing devices and their associated software and accessories, this would place Australia's regulatory system out-of-step with other equivalent regulatory systems, and would make Australia one of the only countries in the world (with a medical device legislation) that regards hearing devices and associated software and accessories as consumer products.

In terms of the specific options provided in the TGA consultation – the responses below highlight the mechanisms through which the TGA can maintain regulation of hearing devices and their associated fitting software and accessories as medical devices. This will ensure the TGA can continue to apply their scientific and clinical expertise to the risks and benefits of devices used by Australians with hearing loss and impairment.

Accessories and Software

This submission, notably refers not only to hearing devices (which are often Class IIa medical devices), but also to accessories/software that are either used by patients in conjunction with the device and/or that are necessary to their functioning.

Accessories and software used in conjunction with devices, or that are necessary to the functioning of devices may on their own, be a lower classification than the principal device. However, HAMADAA submits that it is appropriate to continue to regulate these accessories and software under the medical device regulatory framework as such regulation is essential to continuing to ensure the quality standards of the principal device. For example – for software integral to the operation of a device (such as fitting software), if this does not work as intended it may impact on the principal device's compliance with quality and safety standards and increase risk to patients.

Again, where accessories and software need to integrate with the principal device for operational purposes – poor patient outcomes could result if they are not properly integrated. Measures including, but not limited to, the labelling and IFU requirements (Essential Principal 13) set out in the Regulations, and the quality and safety standards, help to ensure accessories and software operate as intended with the principal device, for patient benefit.

HAMADAA RECOMMENDATIONS

Option 1(a) is unsuitable for adoption.

Applying the exclusion to all WHO defined assistive technologies without consideration of the level of risk of the product would consequently expose vulnerable patients to unnecessary risk. The exclusion would result in regulation of many moderate risk products falling under the remit of consumer law as noted on page 12 of the consultation paper;

> 'If not drafted to limit the scope to low risk products, the definition of "assistive technology" may also include with the exclusion a range of moderate risk technologies (e.g. hearing aids are typically moderate risk Class IIa device).'

HAMADAA submits that consumer law is an insufficient regulatory mechanism with regard to Class IIa medical devices such as hearing aids, and their associated accessories and software.

Option 1(b) may be suitable for adoption pending the definition of 'low risk' device.

Option 1(b) proposes that that the exclusion could apply to 'a subset of the WHO definition of assistive technology, limited to low risk products i.e. those which would otherwise be Class I medical devices (without a measuring function or not supplied sterile).

If this approach is selected, what is meant by "low risk" will need to be clearly and appropriately defined.

Only Class I devices should be considered low risk for the purposes of this definition, and Class I devices that are low risk on their own, but comprise accessories/software that are either used by patients in conjunction with and/or that are necessary for the proper functioning of higher risk (e.g. Class II) devices, should for these purposes also be regulated as a medical device. This approach takes into account the TGA's consideration of products in the context of their *intended use*.

Option 2 may be suitable pending the content of the excluded goods list.

The table in **Attachment A** shows HAMADAA's feedback on appropriate classification of hearing aids and associated attachments. Given that hearing aids are moderate risk as a Class IIa medical device, for the reasons outlines in this submission they should remain regulated as a medical device. Additionally the software and accessories/software that are either used by patients in conjunction with and/or that are necessary for the proper functioning of the Class IIa hearing devices should be considered in light of their intended use – which of course is closely linked to the operation of the higher risk principal device. Therefore, HAMADAA submits for the four categories of therapeutic goods listed in Attachment A, the TGA should '3. Regulate as a medical device'.

The TGA consultation paper, and the MMDR Review recommendations, note that the chosen amendment option 'should also ensure that the specified products pose little or no risk to consumers, should these products not perform as specified, and that removing these products from the auspices of the TG Act will not undermine public health and safety' (p. 10). HAMADAA submits that public health and safety will not be undermined *as long as* hearing aids and associated

accessories/software remain classed as medical devices – this will be ensured by the clarification suggested by HAMADAA in regards to Option 1(b), and this may also be achieved through Option 2, under the conditions outlined above and in Attachment A. However, given the desire to reduce regulatory burden, Option 1(b) may provide a more efficient mechanism.

Attachment A – Products for stakeholder feedback

Therapeutic good	Description	Choose:
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 in a case behind-the-ear (BTE) connected, via a wire, to a receiver (speaker) in the ear canal [receiver-incanal (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.	Regulate as a medical device
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 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.	Regulate as a medical device
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 transmit the signal to the active hearing aid. A wire is used to connect the device to the multimedia device.	Regulate as a medical 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).	Regulate as a medical device