

HAMADAA submission to ACCC Button Battery Consultation



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Hearing Aid Manufacturers and Distributors Association of Australia (HAMADAA) submission to ACCC Button Battery Consultation

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Submitted via email to nationalprojects@accc.gov.au.

The Hearing Aid Manufacturers and Distributors Association of Australia (HAMADAA) welcomes the opportunity to provide input into the Australian Competition and Consumer Commission's (ACCC) Button Battery Safety consultation.

HAMADAA recognises that the ACCC is *not* conducting this consultation with reference to medical devices such as hearing aids, as these devices fall under the remit of the specialist regulator, the Therapeutic Goods Administration (TGA). However, HAMADAA will use this consultative process to provide the ACCC with contextual information around; hearing impairment and treatment; the hearing aid market; and the regulation of medical devices (specifically hearing aids) through the specialist regulator. Additionally, this submission expresses HAMADAA members' commitment to continue working productively with the TGA over risk benefit regulation of hearing aids.

GLOSSARY OF TERMS

BTE – BEHIND THE EAR

CIC – COMPLETELY IN CANAL

FDA – FOOD AND DRUG ADMINISTRATION

HAMADAA – HEARING AID MANUFACTURERS AND DISTRIBUTERS ASSOCIATION OF AUSTRALIA

HSP – HEARING SERVICES PROGRAM

ITC – IN THE CANAL

ITE – IN THE EAR

RITE – RECEIVER IN THE EAR

TGA – THERAPEUTIC GOODS ADMINISTRATION

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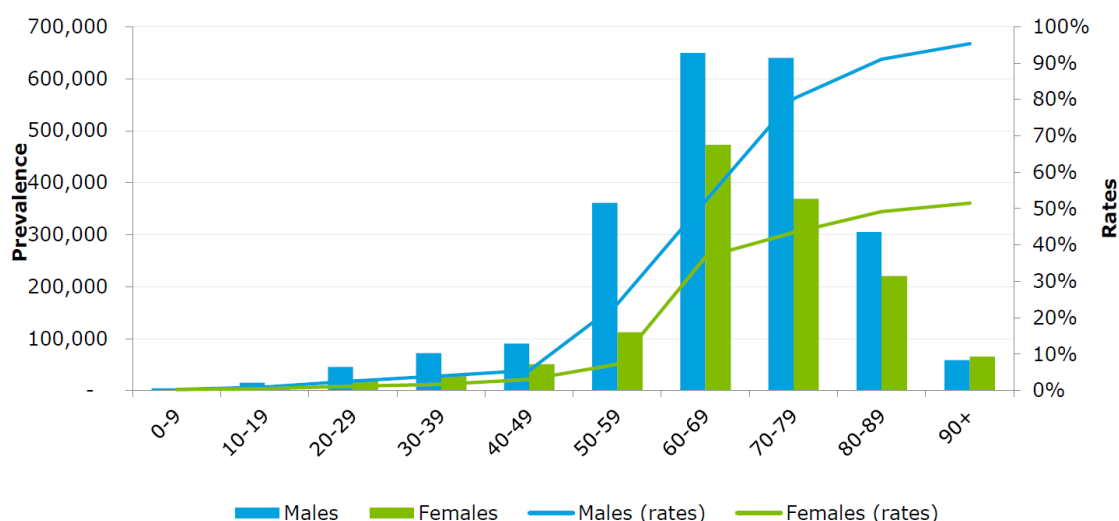
1. HEARING HEALTH BACKGROUND

1.1 Prevalence and Impact of Hearing Impairment

Hearing is intrinsic to the lives of most Australians; it underpins the conversations that form the basis of our relationships and social lives, it gives us access to the beauty of music, and it can warn us of approaching danger. Hearing seems so natural that is not until it is gone or affected in some way that we realise how much we have taken it for granted. In Australia, 3.6 million people (14.5% of population) are affected by some form of hearing impairment and, by 2060, it is estimated that this will increase to 7.8 million of the population (an increase to 18.9%)¹.

Hearing impairment is particularly prevalent among older people, affecting 2.7 million people (11% of population) over the age of 60 and by the age of 70 years, 3 out of 4 Australians will be expected to have developed a hearing loss².

Chart i: Number of cases of hearing loss and prevalence rates (better ear), by age and gender, 2017



Source: Deloitte Access Economics calculations

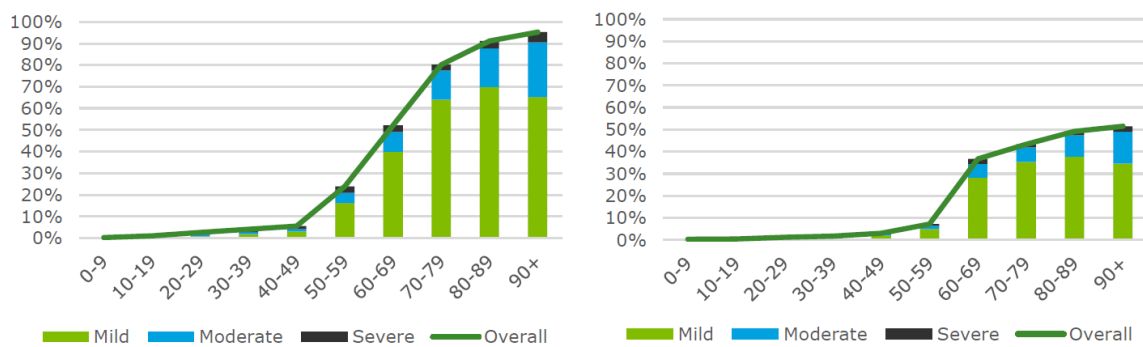
Chart i (above) shows the number of cases of hearing loss and the prevalence rates of hearing loss (better ear) by age and gender. Prevalence rates increase with age, with most men expected to have at least mild hearing loss by the age of 65, and most women by age 90. Chart i shows that the number of cases of hearing loss peaks in the 60-69 age range, then decreases for both males and females. This is primarily driven by the decreasing underlying population³.

¹ PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA: Still waiting to be heard... *Report on the Inquiry into the Hearing Health and Wellbeing of Australia*. Sept 2017.

² Deloitte Access Economics: *An Update of the Social and Economic Cost of Hearing Loss and Hearing Health Conditions in Australia*, July 2017, pp 3-4.

³ Ibid

Chart 3.4: Prevalence rates of hearing loss (better ear) by severity and age, males (left) and females (right)



Source: Deloitte Access Economics calculations

Chart 3.4 shows the prevalence rates by severity and age for males and females. For males, 18.2% had hearing loss in 2017, with 13.2% mild, 3.4% moderate and 1.5% severe. Hearing loss prevalence increases with age and as males age, they are highly likely to develop hearing loss. For females, 10.9% had hearing loss in 2017, with 8.1% mild, 2.0% moderate and 1.1% severe.

The key point to note is that as a person gets older, both the *prevalence and severity* of hearing impairment increases. This means they are more dependent on the various forms of hearing support such as hearing devices, that are available to assist them to live their lives normally in an equitable manner.

1.2 Economic Impact of Hearing Impairment

Hearing impairment does not just impact those immediately affected. On a broad scale, it has been estimated that hearing loss costs the Australian economy \$33.3 billion, comprised of \$15.9 billion in financial costs and \$17.4 billion in lost wellbeing for individuals⁴.

1.3 Social and Health Impact of Hearing Impairment

Hearing impairment has a negative impact on overall health and is associated with an increased use of healthcare. A report by Lamb, et al. (2016)⁵ on hearing loss as well as the benefits to society of investing in hearing technologies, showed the overall cost of not providing hearing technologies is greater than providing them.

Hearing care has a positive effect on both physical and mental health, as well as employment and social engagement. Conversely, the consequences of not providing hearing care for the hearing impaired have negative effects. Elderly people with hearing loss have a higher risk of mental health issues such as depression and dementia. Studies also show that hearing loss is associated with increased mortality rates.⁶ Furthermore, hearing loss also influences communication and interaction, and often leads to isolation and higher unemployment rates⁷.

Implementation of hearing healthcare results in large social and economic benefits for societies. Current estimates indicate that the prevalence of hearing loss at birth is between 2 and 7 per 1000 newborns. Although there are very few economic evaluations of universal newborn hearing

⁴ Ibid

⁵ Lamb, Archbold, O'Neill. *Spend to save: Investing in hearing technology improves lives and saves society money*. The Ear Foundation October 2016.

⁶ Deloitte Access Economics: *An Update of the Social and Economic Cost of Hearing Loss and Hearing Health Conditions in Australia*, July 2017

⁷ Barnett, C., Veran, D. & Huijnen, J. 2016. *Hearing Care across the Life Span*. Whitepaper, OticonFonden.

screening, the consensus is that screening programs reduce costs related to lifetime healthcare needs and education and increase lifetime productivity⁸.

1.4 Treatment Options for Hearing Impairment

The continuous growth of Australia's proportionately ageing population will increase the need for hearing services. Other health issues that are often associated with ageing (e.g. prolonged exposure to industrial noise in the workplace) are also likely to lead to increased demand for hearing services and hearing devices.

There are various treatment options available for hearing impairment, but this depends of the cause of the impairment, for example middle ear disease in children may require surgical intervention. However, surgical treatment is not available for a vast majority of people with hearing impairment as this is due to damage inside the inner ear from hereditary causes, noise exposure, ototoxicity or age-related hearing impairment (which are the most prevalent causes of hearing impairment). In fact, hearing devices are the most commonly used form of treatment.

Hearing aids can help individuals with hearing loss by amplifying sound and facilitating improved communication. Hearing aids can differ in model, completely in the ear canal (CIC), in the canal (ITC), in the ear (ITE) and behind the ear (BTE), and are prescribed depending on the individual's listening goals, severity of one's hearing loss, and other individual specific medical and social circumstances.

Not all form factors or styles are suitable for an individual for anatomical, physiological, audiological and aesthetic reasons. In other words, each hearing-impaired person's individual needs should be evaluated and accounted for to decide which style will be the best to meet their needs.

We note that the vast majority of hearing aid users in Australia are elderly, and many factors come into play (section 2.2.2) when assessing appropriate provision of hearing devices to this cohort to lessen the negative impacts, as above, of hearing impairment on a person's life. Please also see Attachment A for personal excerpts of the impact of hearing loss or impairment.

2. 'BUTTON BATTERIES' AND THE REGULATION OF MEDICAL DEVICES

Goods manufactured and distributed by members of HAMADAA are subject to regulatory control by the specialist regulator the Therapeutic Goods Administration (TGA), as has been noted in the Button Battery Safety Issues Paper;

*This Issues Paper does not consider, or seek response regarding, goods that are subject to regulatory control by specialist regulators such as electrical safety regulators, the Therapeutic Goods Administration (TGA) or the National Industrial Chemicals Notification and Assessment Scheme who regulate products including medical devices and devices for industrial and scientific use. The ACCC will continue to liaise with these and other specialist safety regulators, such as the TGA, about the safety of button batteries more broadly.*⁹

This submission however, is intended to provide further contextual information to the ACCC to assist in their consultation on button battery safety. This includes information around: the risk profiles of different battery types; the regulatory processes that exist for medical devices (specifically hearing

⁸ Ibid

⁹ Australian Competition and Consumer Commission. August 2019. *Button Battery Safety Issues Paper* p.4

aids); and some of the cost benefit considerations that go into the design, and provision of a hearing aid to someone with hearing impairment.

2.1 Risk Profiles of Battery Types

In the Issues Paper, we note for convenience, that button batteries are taken to mean all flat, disc-shaped cells or batteries, regardless of their size or chemistry. This includes coin, disc and button cells or batteries, which operate under alkaline, lithium, silver oxide or zinc-air chemistries. HAMADDA submits that disaggregation of both size and chemistry is absolutely necessary in relation to the battery types used in hearing aids. This is due to the highly variable risk profile across size and chemistry.

Unlike the use of batteries in a *consumer* goods context, the use of batteries in hearing aids must be considered and situated within the *public health* context that hearing impairment and loss belongs (see section 1, section 2.2.2 & 2.2.3). The different risk profiles of batteries explored below demonstrates that the disposable battery type used in hearing aids is relatively safe and, and we stress that this low risk profile must be weighed against clinical and therapeutic benefit in a medical device like a hearing aid.

All of HAMADAA Members' disposable hearing aid batteries are Zinc-Air (ZnO) type. The Issues Paper highlighted data from both the U.S and Australia indicating that where there are battery exposures, the source of the battery is unknown in the majority of cases.¹⁰ However, in cases where the source of the battery is known, and zinc-air batteries are represented, they 'are not implicated in significant injuries'.¹¹

The Issues Paper also identified that it is the 'combination of larger battery diameter, higher (and residual) voltage and exposure via swallowing that results in the most catastrophic injuries and death' and that lithium batteries, particularly those with a larger diameter size, account for the overwhelming majority of battery related injuries.¹²

ZnO type hearing aid batteries pose a significantly lower risk of harm when ingested than other battery types (e.g. lithium, silver oxide etc) for a number of reasons. ZnO batteries only produce a current if there is free access to oxygen. This means that the battery will stop producing current shortly after ingestion due to the lack of oxygen. Combined with the relatively low voltage of the battery, the risk of electrical tissue damage if these batteries are ingested is low. This is in contrast to other battery types (such as lithium chemistries) which continue to produce a current after ingestion. Additionally, the small size of the batteries means that, if ingested, they are unlikely to get caught in the esophagus, with the Issues Paper noting that;

'Button batteries with alkaline or other non-lithium chemistries have an electrical output of 1.5 volts or less and are generally less than 16 mm in diameter. Ingested alkaline button batteries are more likely to pass the oesophagus and travel through the gastrointestinal tract without causing significant problems.'¹³

¹⁰ Ibid, p. 23

¹¹ Ibid, p.9

¹² Ibid, p. 8

¹³ Ibid, p.9

In addition to highlighting the low-risk profile of ZnO type (hearing aid) batteries, we have also conducted research into the adverse events databases of the medical device regulators in both the U.S (FDA-MAUDE) and Australia (Australia-DAEN) with the results as follows;

- MAUDE (Manufacturer and User Facility Device Experience) – in the period 1 January 2015 to 30 September 2018, we were not able to identify any hearing aid battery related incidents in the MAUDE
- DAEN (Database of Adverse Event Notifications) – in the period 1 January 2015 to 1 August 2018, there was 1 report of a child ingesting a hearing aid battery (report number 42271). There is insufficient information on the public record to determine the battery type involved, and the nature/severity of any injury suffered.

To put into context, there were 3.65 million hearing aids dispensed in the U.S in 2016¹⁴, and 450,000-550,000 hearing aids supplied in Australia in 2017.¹⁵

HAMADAA notes that as an *aggregated* class, ‘button batteries’ are implicated in a significant number of injuries to children, and commends the ACCC’s work to remove the risks posed in consumer goods by those batteries that do cause harm, however, in the case of ZnO type (such as disposable hearing aid batteries), it is critical to understand their low risk profile, and situate this within a public health context, and the framework for regulation of medical devices.

2.2 Regulation of Medical Devices and Safety Considerations for Hearing Aid Batteries

The TGA is Australia’s regulatory authority for therapeutic goods including medicines and medical devices, such as hearing aids. Distinct from the regulation of consumer goods, therapeutic goods regulation has a particular focus on applying clinical and scientific expertise to its decision-making to ensure the benefits of a product outweigh any risk, noting that ‘all therapeutic goods have some level of risk.’¹⁶ This risk-benefit approach is taken to ensure products are safe for their intended use, while still providing access to products that are essential to their health needs.¹⁷

The overarching legislative instrument for hearing aids, is the *Therapeutic Goods Act 1989* (the Act), with hearing aids being classed as a medical device (see Table 1). The regulatory mechanisms used by the TGA are;

- pre-market assessment;
- post-market monitoring and enforcement of standards; and
- licensing of Australian manufacturers and verifying overseas manufacturers’ compliance with the same standards as their Australian counterparts¹⁸

¹⁴ “US Hearing Aid Unit Sales Increased by 8.7% in 2016.” *the Hearing Review* Last modified February 9, 2017 <http://www.hearingreview.com/2017/01/us-hearing-aid-unit-sales-increased-8-7-2016/>

¹⁵ “Annual Program Statistics 2017-2018.” *Australian Government Department of Health* Last modified July 5, 2018 https://www.hearingservices.gov.au/wps/portal/hso/site/about/program_stats/

¹⁶ “Benefits versus risks approach to regulating therapeutic goods.” *Australian Government Department of Health, Therapeutic Goods Administration* <https://www.tga.gov.au/benefits-versus-risks-approach-regulating-therapeutic-goods>

¹⁷ “How the TGA regulates.” *Australian Government Department of Health, Therapeutic Goods Administration* <https://www.tga.gov.au/how-tga-regulates>

¹⁸ Ibid

Table 1. Definition of ‘medical device’, *Therapeutic Goods Act (1989)*

Division 2—Interpretation

41BD What is a *medical device*

(1) A *medical device* is:

- (a) any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following:
 - (i) diagnosis, prevention, monitoring, treatment or alleviation of disease;
 - (ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability;
 - (iii) investigation, replacement or modification of the anatomy or of a physiological process;
 - (iv) control of conception;
 and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means; or
- (aa) any instrument, apparatus, appliance, material or other article specified under subsection (2A); or
- (ab) any instrument, apparatus, appliance, material or other article that is included in a class of instruments, apparatus, appliances, materials or other articles specified under subsection (2B); or
- (b) an accessory to an instrument, apparatus, appliance, material or other article covered by paragraph (a), (aa) or (ab).

The *Therapeutic Goods (Medical Devices) Regulations 2002* contains ‘Essential Principles’ of quality and safety which apply to medical devices (such as hearing aids) and are monitored by the TGA. Of most relevance here are the 6 “general principles” below, with an excerpt from the corresponding legislation found in [Attachment B](#).

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 effects¹⁹

¹⁹ Schedule 1 *Therapeutic Goods (Medical Devices) Regulations 2002*

While acknowledging that the Essential Principles impose stringent requirements regarding the safety of medical devices, they do not require that medical devices be completely free of risks. This is consistent with the TGAs remit to weigh risks and benefits of medical devices and medicines (e.g. pacemakers, EpiPen's, chemotherapy etc.). For example, Essential Principle 1.1(b) provides:

(b) any risks associated with the use of the device are:

- (i) acceptable risks when weighted against the intended benefit to the patient; and
- (ii) compatible with a high level of protection of health and safety

Similarly, Essential Principle 6 is in the following terms:

The benefits to be gained from the use of a medical device for the performance intended by the manufacturer must outweigh any undesirable effects arising from its use.

Accordingly, when assessing the safety of a device, due regard must be had to both the risks and expected benefits.

2.2.1 Safety Considerations and the Industry Code

Under the medical devices regulatory framework administered by TGA, one method by which manufacturers can demonstrate compliance with the 'Essential Principles' above is the use of standards.

All HAMADAA Members hearing aids are assessed against and meet requirements of IEC 60601-1 Medical electrical equipment – Part 1 – General requirements for basic safety and essential performance (or equivalent or better) *and* IEC 60601-1-2 Medical electrical equipment – Standard: Electromagnetic disturbances – Requirements and tests. These standards are recognised by the TGA as an acceptable means of demonstrating compliance with those parts of the Essential Principles to which the standards relate.

In addition to these general standards, HAMADAA Members' hearing aids are assessed against (and meet) 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 aids.

Also, the Instructions for Use for HAMADAA Members hearing aid products include the following regarding batteries

- Warnings to only use hearing aid batteries recommended by the hearing professional. This will help to minimise the risk of different, higher risk battery types.
- Warnings regarding battery ingestion risks and to consult a doctor if swallowed.
 - o Although, for reasons explained in section 2.2 Risk Profiles of Battery Types, a ZnO battery should not pose a significant risk of injury if swallowed. HAMADAA nonetheless considers this to be prudent advice, on the basis that even if it is suspected that it is a hearing aid battery, it could be something else (for example, a higher risk battery type).

One of the standards HAMADAA Members hearing aids are assessed against (IEC 60601-2-66) notably includes requirements regarding battery doors for products intended for use by children under the age of 36 months. Clause 201.15.3.1 provides:

Mechanical design requirements for instruments intended for use by infants under 36 months:

(a) Battery doors shall be constructed to:

- Require a tool to remove the battery;
- Require a force of at least 10 N in the least favourable direction to be able to remove the battery

In compliance with this requirement, paediatric products supplied by HAMADAA members who offer products for paediatric use, incorporate a tamper-resistant battery compartment.

That IEC 60601-2-66 does include requirements for battery doors for paediatric products demonstrates that this issue was considered by the standards committee, and that this was assessed as being the most appropriate risk control measure for hearing aid products.

We note that one of the efforts in pursuing button battery safety in **consumer** goods was the development of an 'Industry Code for Consumer Goods that Contain Button Batteries' in July 2016 [Industry Code]. The Industry Code expressly states 'The requirements [of the Voluntary Industry Code] do not apply to professionally prescribed and fitted medical devices such as hearing aids'²⁰, making apparent that issues specific to hearing devices were not considered when formulating the Industry Code.

IEC 60601-2-66 does not include any requirements that are equivalent to the ACCC's Industry Code for non paediatric products. Secondly, as far as HAMADAA is aware, there are no requirements that are equivalent to the Industry Code for non-paediatric hearing devices anywhere in the world

HAMADAA would submit that for the reasons above, the application of the Industry Code is not appropriate for hearing devices, and that this issue should continue to be examined and managed by the specialist regulator, the TGA, having regard to the specific risks and benefits applicable to hearing devices.

As it is within their area of regulatory responsibility, the TGA commenced a post-market review of medical devices containing button batteries in 2017.²¹ Since this time a series of self-assessments have been required of HAMADAA members on their registered medical devices, of which members have complied.

²⁰ "Australian Competition and Consumer Commission. *Industry Code for Consumer Goods that Contain Button Batteries*. July 2016 <https://www.productsafety.gov.au/system/files/INDUSTRY%20CODE%20on%20Consumer%20Goods%20that%20contain%20BUTTON%20BATTERIES%20VERSION%201%20....pdf>

²¹ "Medical devices post-market vigilance – statistics for 2017." *Australian Government Department of Health, therapeutic Goods Administration*. August 10, 2018 <https://www.tga.gov.au/medical-devices-post-market-vigilance-statistics-2017#post>

The discussion over ‘button batteries’ in hearing aids is an evolving one with the TGA, and both HAMADAA and its Members will continue to engage with the TGA productively and in a structured, consultative manner.

2.2.2 Hearing Aid Users and Risk Benefit Analysis

A safety analysis of the risks and benefits of medical devices, must be made within a public health context. Section 1 provides a background to hearing health, and this section highlights factors key in assessing the risks associated with hearing aid batteries:

The vast majority of hearing aid users are elderly, with the average age when an Australian gets their first hearing aids around 79 years old. Due to their age, many hearing aid users have dexterity issues (see below), which would make operating a battery compartment that requires a tool or two or more simultaneous actions to access impractical for that cohort. Given that hearing aid batteries (disposable type) need to be changed approximately once a week, the likely result of implementing a requirement that all hearing aid battery compartments be tamper-resistant would be that many people will stop using their hearing aids due to difficulties in changing the batteries. The social and health impacts of hearing impairment have been well documented, including in Section 1.3.

A typical example of where this applies would be with an elderly man aged 79 (the average age of hearing aids being fitted in Australia) who has a severe hearing impairment, large hands, and poor fine motor skills (research shows that declining fine motor skills is a common problem as people age and in fact starts in middle age)²². He will require high power behind-the-ear (BTE) hearing aids, or high power in-the-ear (ITE) hearing aids because these need to have a high level of sound amplification.

To operate the hearing aids, he needs to be able to manage the controls, remove a battery from its packet, and open the battery compartment. The battery compartment for this age group will not have a tamper-resistant battery door as using a tool to open and close this would be a very difficult task for adults with poor finger dexterity (note the battery of each device will need to be replaced approx. once per week). He then needs to place the battery in the compartment, close it, adjust the volume and be able to put this into his ears.

Hearing care professionals would be aware of the availability of hearing devices that can be supplied with tamper-resistant battery compartments for patients for whom that is an appropriate solution. However, it is important to note that this does not apply to the majority of cases or patients.

Although the ACCC’s Industry Code **does not** apply to hearing aids and medical devices, HAMADAA stresses that the impact of any change to non-tamper-resistant battery door requirements would be enormous for both consumers and industry. This is in the context of the Australian hearing aid market (section 2.3 below), and in the context of the social, health and economic impacts of hearing impairment; the low-risk profile of hearing aid (ZnO) batteries; global standards and existing compliance and average age of the cohort to be negatively affected by any change.

HAMADAA also notes that any regulatory requirement that disposable ZnO hearing aid batteries be supplied in child-proof packaging could also have a negative impact on hearing aid users with

²² Yoo Young Hoogendam et al. 2016. *Older Age Relates to Worsening of Fine Motor Skills: A Population-Based Study of Middle-Aged and Elderly Persons*. Front Aging Neurosci. 2014; 6: 259; Lawrence., E et al. *Quantification of dexterity as the dynamical regulation of instabilities: comparisons across gender, age, and disease*. Front. Neurol., 15 April 2014 <https://doi.org/10.3389/fneur.2014.00053>

dexterity issues as this could also potentially create a barrier to users changing their hearing aid batteries.

2.3 The Australian Hearing Aid Market

In 2017, approximately between 450, 000 – 550, 000 hearing aids were supplied in the hearing aid market for Australians of all ages. A majority of those (395, 000) were through the Australian Government Hearing Services Program (HSP), which were fitted mostly to adults over the age of 65. It is estimated that over 1 million hearing impaired Australians have hearing aids, with 800, 000 clients provided services under the HSP in 2017/18²³.

According to 2017 statistics from HAMADAA²⁴, which is the hearing aid manufacturer peak body, approx. 85% of hearing aids supplied were behind the ear (BTE, RITE) and the remaining 15% were in the ear (ITE, ITC, CIC), which also correlates with HSP statistics. Importantly, a majority of **rechargeable hearing aid technology** supplied by HAMADAA members comes in receiver in the ear style (RITE) and rechargeable technology is currently **not available** in the Free to Client (i.e., fully subsidised by the HSP) segment of the market, which constitutes over 60% of the Australian Market. The fully subsidized segment is comprised only of **non-rechargeable** BTE and ITE/ITC styles. In fact, only 36% of total sales within the HSP were receiver-in-the-ear style (RITE) and all of these were in the partially subsidised segment of the HSP, in which consumers need to pay an additional co-payment on top of the government subsidy. Rechargeable technology is not currently available in in the ear (ITE, ITC, CIC) styles.

We do not have data on how many rechargeable hearing aids are supplied in the market, but based on the above statistics we estimate the combined Silver-Zinc and emerging Lithium-Ion rechargeable technology would be approximately 15%-25% of total hearing aids supplied by HAMADAA members. Currently, for a majority of HAMADAA members, Lithium-Ion hearing technology is also comparatively more expensive to manufacture and supply into the Australian market.

These market-based factors provide a very significant challenge to supply all Australian hearing-impaired consumers with a tamper-resistant (which might include rechargeable) hearing aid solution. Further, were such a requirement to be imposed suddenly, then this would likely result in significant supply disruptions in the Australian hearing aid market (and consequent flow on effects for hearing-impaired individuals). This is because the vast majority of hearing aids currently supplied in Australia do not incorporate a tamper-resistant battery compartment, and the supply chain is simply not set up to only supply tamper-resistant product.

²³ "Annual Program Statistics 2017-2018." *Australian Government Department of Health* Last modified July 5, 2018 https://www.hearingservices.gov.au/wps/portal/hso/site/about/program_stats/

²⁴ Hearing Aid Manufacturers and Distributors Association of Australia. 2017 Market Statistics.

3. CONCLUDING REMARKS

The Australian Government is committed to raising awareness of hearing impairment and its consequences, and to improve access to hearing services and hearing technology for those who most need it. To facilitate this objective, **Hon Ken Wyatt AM MP**, the then **Minister for Indigenous Health and Minister for Senior Australians and Aged Care** commissioned the **Roadmap for Hearing Health**, which was completed in February of this year.²⁵

It is well established that hearing technology such as hearing aids play a vital role in the hearing healthcare journey, treatment and rehabilitation of the 3.6 million hearing impaired Australian consumers. However, it is estimated that only approximately 30-40% of those hearing-impaired Australians seek help and receive hearing aids, with the remaining 60-70% not taking action often due to the stigma associated with hearing aids and ageing²⁶. We know that on average it takes 7 years for a person with a hearing impairment to seek assistance, and the average age when an Australian gets their first hearing aids is around 79 years old. Therefore, the typical hearing aid user in Australia is in the older cohort and on a pension.

Fortunately, at the present time, these Australian consumers enjoy access to a wide variety of world class hearing aid technologies, styles and price points to cover their hearing needs, with a majority opting for the fully subsidised devices available under the HSP.

Any changes made that reduce this choice will potentially lead to a significantly lower uptake of hearing aids and may increase the likelihood of some of the well documented negative impacts of untreated hearing impairment, such as social isolation, depression, higher rates of under/unemployment, increased risk of cognitive decline²⁷.

Please contact James Battersby (President, HAMADAA), if you have any questions regarding this submission or require further information. jbat@oticon.com.

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Sonova Australia, Oticon Australia, Evertone Australia, Bernafon Australia, Sonic Australia, GN Hearing Australia, Starkey Australia, Widex Australia.

²⁵ Department of Health. *Roadmap for Hearing Health – Supporting all Australians who are deaf or hard of hearing to live well in the community*. February 2019

²⁶ Deloitte Access Economics: *An Update of the Social and Economic Cost of Hearing Loss and Hearing Health Conditions in Australia*, July 2017

²⁷ Livingston G., et al. *Dementia prevention, intervention, and care*. Lancet. 2017;390(10113):2673; Deal JA, Reed NS, Kravetz AD, Weinreich H, Yeh C, Lin FR1,2,3, Altan A. *Incident Hearing Loss and Comorbidity: A Longitudinal Administrative Claims Study*. JAMA Otolaryngol Head Neck Surg. 2018 Nov 8. doi: 10.1001/jamaoto.2018.2876. [Epub ahead of print]

About HAMADAA

The Hearing Aid Manufacturers and Distributors Association of Australia (HAMADAA) membership comprises eight of the nine major global hearing aid manufacturer brands. The Association operates to promote the advancement of research into and development of hearing aid technology, increase public awareness of available hearing aid technology for the hearing impaired and, promote the importance and high standing of the hearing aid manufacturing and distribution industry to government and the public.

Attachment A – Experiences with hearing loss from the Inquiry into Hearing Health and Wellbeing in Australia (Still waiting to be heard)

Report excerpts –

A number of submissions from people with hearing impairment described the impact of their hearing loss on their everyday lives:

- ‘I’ve stopped going to public spoken-word occasions such as drama and talks and many community events because I too often can’t hear the speakers. I often can’t hear when I try to listen to podcasts or YouTube videos online. I want to be able to participate in and contribute to community organisations. I do not feel confident that I would any longer be able to take on voluntary or paid work.’
- ‘I find it distressing that I am often treated as being ‘daft’ when I am just deaf.’
- ‘I am at a point where my hearing loss is affecting my work life and my personal relationships so I plan to purchase a hearing aid for my affected ear. There is still a social stigma associated with hearing aids, however, so I plan to purchase one that will be largely invisible to others. This, of course, is a more expensive option but important to my self-confidence.’
- ‘I had lots of instances when I was in meetings and I gave the wrong answer to a question because I misheard, and I sometimes felt that people thought I was a little bit mentally deficient because of that.’
- ‘In my experience, hearing loss still cannot be openly discussed amongst the corporate and social communities and many people still refuse to wear hearing aids because of the stigma attached.’
- ‘As a young teenager in secondary school, he [my son] began to feel conscious of wearing the hearing aids in term of his appearance. He wanted to feel what he perceived as being “normal” and he subsequently refused to continue to wear the hearing aids. I observed that without the hearing aids, he could not hear conversations properly.’
- ‘I know of many older men who have worked in the building industry (my husband is a plumber) who by 60 years old are not yet able to retire but have such poor hearing and often other associated mental health issues that they cannot effectively work.’⁷³

Source: House Standing Committee on Health, Aged Care and Sport, Parliament of Australia, *Still waiting to be heard: Inquiry into the Hearing Health and Wellbeing of Australia* (2017)

Schedule 1—Essential principles

(regulation 2.1)

Part 1—General principles

1 Use of medical devices not to compromise health and safety

A medical device is to be designed and produced in a way that ensures that:

- (a) the device will not compromise the clinical condition or safety of a patient, or the safety and health of the user or any other person, when the device is used on a patient under the conditions and for the purposes for which the device was intended and, if applicable, by a user with appropriate technical knowledge, experience, education or training; and
- (b) any risks associated with the use of the device are:
 - (i) acceptable risks when weighed against the intended benefit to the patient; and
 - (ii) compatible with a high level of protection of health and safety.

2 Design and construction of medical devices to conform with safety principles

- (1) The solutions adopted by the manufacturer for the design and construction of a medical device must conform with safety principles, having regard to the generally acknowledged state of the art.
- (2) Without limiting subclause (1), in selecting appropriate solutions for the design and construction of a medical device so as to minimise any risks associated with the use of the device, the manufacturer must:
 - (a) first, identify hazards and associated risks arising from the use of the device for its intended purpose, and foreseeable misuse of the device; and
 - (b) second, eliminate, or reduce, these risks as far as possible by adopting a policy of inherently safe design and construction; and
 - (c) third, if appropriate, ensure that adequate protection measures are taken, including alarms if necessary, in relation to any risks that cannot be eliminated; and
 - (d) fourth, inform users of any residual risks that may arise due to any shortcomings of the protection measures adopted.
- (3) In paragraph (2)(d):
residual risk, for a medical device, means the risk remaining after the measures described in paragraphs (2)(a), (b) and (c) have been applied.

3 Medical devices to be suitable for intended purpose

A medical device must:

- (a) perform in the way intended by the manufacturer; and
- (b) be designed, produced and packaged in a way that ensures that it is suitable for one or more of the purposes mentioned in the definition of **medical device** in subsection 41BD(1) of the Act.

4 Long-term safety

A medical device must be designed and produced in a way that ensures that if:

- (a) the device is used within the period, indicated by the manufacturer, in which the device can be safely used; and
- (b) the device is not subjected to stresses that are outside the stresses that can occur during normal conditions of use; and
- (c) the device is regularly maintained and calibrated in accordance with the manufacturer's instructions;

the characteristics and performances mentioned in clauses 1, 2 and 3 are not adversely affected.

5 Medical devices not to be adversely affected by transport or storage

A medical device must be designed, produced and packed in a way that ensures that the characteristics and performance of the device when it is being used for its intended purpose will not be adversely affected during transport and storage that is carried out taking account of the instructions and information provided by the manufacturer.

6 Benefits of medical devices to outweigh any undesirable effects

The benefits to be gained from the use of a medical device for the performance intended by the manufacturer must outweigh any undesirable effects arising from its use.