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Therapeutic Products Bill Consultation

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Submission of the New Zealand Audiological Society (NZAS)

Summary

The NZAS supports the purpose of the Bill which is to protect personal health by ensuring acceptable safety, quality and efficacy or performance of therapeutic products across their life cycle and regulating the import and supply or use of therapeutic products.

The New Zealand Audiological Society

The New Zealand Audiological Society (NZAS) was incorporated in 1976 and is a self-governing body representing over 620 Audiologist, Audiometrist and provisional members in New Zealand. NZAS members work in public and private sector audiology, as well as in University programmes, Deaf Education Centres, Cochlear Implant Trusts, and undertake research in the field of Audiology.

NZAS has a vision for people with hearing loss fully participating in their communities and supports this by promoting excellence in hearing care through leadership, advocacy and setting professional standards of practice for all members.

NZAS members adhere to agreed Standards of Practice issued by the NZAS and are required to maintain their proficiency through continuing education and regular peer reviews. Members are also required to uphold the NZAS Code of Ethics. NZAS has an independent Complaints Board who investigate complaints from consumers, the public and NZAS members themselves regarding possible breaches of the Code of Ethics.

Definition of therapeutic purpose

The NZAS supports the Bill's inclusive and broad definition of a therapeutic purpose. Of particular relevance to the NZAS is section 15(1) (a):

Preventing, diagnosing, monitoring, alleviating, treating, curing or compensating for a disease, ailment, defect, or injury.

And section 15(1) (f):

Investigating, replacing, modifying, or supporting part of a human's anatomy.

Members of the NZAS, when providing audiological services, do so for a therapeutic purpose. These services include diagnosing, monitoring, treating and compensating for an injury or defect i.e. hearing loss, tinnitus, hyperacusis, auditory processing and balance disorders.

Definition of therapeutic products

The NZAS supports the definition of therapeutic product which includes medical devices. Members of the NZAS when providing audiological services use therapeutic products.

Section 16 (1) states:

A product is a therapeutic product if it is intended for use in, on, or in relation to humans for therapeutic purpose.

Section 21(1) (a) – meaning of therapeutic product.

A therapeutic product is a medical device if it is a therapeutic product under section 16(1) (a).

The NZAS agrees that there should be a category for Type 4 products for future therapeutic products that are not known about yet.

Definition and Regulation of medical devices - a wider range of products

The NZAS supports the definition of medical devices which covers a wide range of products used in primary and secondary health care. Of relevance to NZAS members would be:

- implants; such as CI (cochlear implants) and BAHS (bone-anchored hearing systems)
- diagnostic equipment; such as audiometers, acoustic immittance meters (tympanometry and acoustic reflex measurement), oto-acoustic emissions (OAEs) measurement devices
- hearing aid verification equipment; such as real ear measurement equipment, sound field measurement
- hearing aids
- hearing aid accessories; such as ear moulds.

It agrees that the span ought to range from low risk products to higher risk products. The NZAS will address the risk assessment of hearing aids later in the submission.

Hearing Aids

Hearing aids are currently regarded as medical devices so the Bill, as proposed, will incorporate hearing aids within its ambit. This is welcomed.

Hearing aids are complex medical devices that provide amplification and incorporate many unique and complicated signal processing features for the purpose of alleviating hearing impairment. The NZAS welcomes the decision to further regulate therapeutic products which would include hearing aids.

The Ministry of Health has issued a Gazette Notice: the Section 88 Hearing Aid Services Notice 2018. In particular it defines hearing aids in its schedule.

The Section 88 Notice issued by the Ministry of Health defines a hearing aid.

"It means a personal electronic amplification device that is used wholly or principally by a person to

alleviate the impact of their hearing loss. A hearing aid must be capable of being adjusted (through manual control or computer, have its acoustic output tuned in a frequency specific manner) and verified in situ by a hearing care professional in order to meet the unique hearing needs of an individual with hearing loss; and

(a) includes:

(i) hearing aid accessories; but

(b) excludes:

(i) cochlear implants;

(ii) devices that have microphones and amplification systems that are designed primarily for other uses, such as stereos and mobile phones;

(iii) consumable items (for example, batteries); and

(iv) second-hand hearing aids."

Regulation of second-hand hearing aids

The Bill provides an opportunity to consider new products and products which are currently not regulated such as second-hand hearing aids.

Hearing aids parts are inserted into the ear canal with some hearing aids having the device sitting on the back of the ear. Without appropriate regulatory controls of second-hand hearing aids, personal health may be compromised by the introduction of bacteria, blood products, dust and dirt, some of which is difficult to see with the naked eye. The Ministry of Health has already indicated in the Section 88 notice that they are not prepared to support the provision of second-hand hearing aids.

Outline of regulatory scheme

The NZAS welcomes the well-constructed regulatory scheme to protect the health of people, which is made up of 2 broad components: a product approval requirement and controlled activity restrictions.

That medical devices will be regulated throughout their life cycle is welcomed. In this submission we will speak to the new requirement in the Bill for pre-market approval.

The NZAS also welcomes the provision for mandatory adverse event reports by product sponsors. The NZAS submits that in the context of audiology, there ought to be mandatory adverse event reporting when a person suffers an allergic reaction from the chemicals embedded in the lacquer applied to some hearing aids, and/or to ear mould and hearing aid shell materials.

The regulation of therapeutic products, the Bill says, will be proportionate to the risks posed by the products. As we will state later in this submission, care must be taken in calculating risks from products such as hearing aids.

Product approval requirements

The NZAS supports the purpose of the Bill which is to regulate products to ensure the safety, quality, efficacy and performance of products over their life cycle. It agrees that standards may be specified

in rules and these may relate to the manufacturer's quality management system; packaging and labelling and product or consumer information (see section 96).

The NZAS notes that preparing a medical device for use following the manufacturer's instructions e.g. for calibration, is not manufacture of a device (see section s 34(4)).

If hearing aids are appropriately assessed for risk it will ensure that they are traceable, appropriately used, accompanied by good information, and avoid diversion from the licit supply chain. (See section 95).

Approval pathway

The NZAS supports the enhanced approval pathway which includes approval based on scrutiny of evidence of conformity assessment/overseas approval of devices; approval without scrutiny if devices are under a Mutual Recognition Agreement.

Controlled activity requirements

A controlled activity regulates who is allowed to carry on certain activities involving therapeutic products. Audiologists and audiometrists use and fit medical devices on and in patients and are involved in non-wholesale supply of medical devices.

NZAS notes that what constitutes a controlled activity varies depending on the type and category of product and the circumstances in which the activity is carried out.

NZAS submits that audiology/audiometry work ought to be a controlled activity.

Ability to restrict the supply and/or use of specified medical devices/authorizing activity

The NZAS agrees that the Regulator ought to have the power to place restrictions on the supply and/or use of specified devices (such as hearing aids) via regulations. The regulator ought to have the power to require a person who is purchasing a hearing aid to have an evaluation by a specified hearing care professional, before the purchase of the aid. The purpose for this professional evaluation is to assure that all treatable conditions that may affect hearing rehabilitation are identified. An individual's hearing needs assessment must be undertaken to take into account the individual's impairment and unique characteristics to inform the individual treatment plan and appropriate selection of the hearing devices. The NZAS welcomes the extra protection that the legislation provides to consumers.

Currently the route to hearing aids is generally through a professional. The most common route of entry to treatment is through discussion of hearing loss with an audiologist or audiometrist. 56% of the hearing-impaired also discussed hearing loss with an ENT or general practitioner.[1]

The NZAS perceives this legislation as supporting and maintaining the professional pathway to hearing aids. This submission will set out its concerns about the personal importation or fitting of

[1] Anovum, 2018 NZ Trak 2018 page 3

hearing aids by non-professionals as this will circumvent the protection and oversight provided by professionals.

A restriction requiring, from a safety perspective, that a level of clinical oversight is provided by appropriately qualified audiologists and audiometrists when supplying hearing aids is especially important as audiologists and audiometrists are not registered health practitioners. If they are members of NZAS, their practice is regulated by the NZAS. The NZAS is accountable for ensuring the standards, safety and fitness to practice of qualified health practitioners within their remit. Audiologists and audiometrists who are members of NZAS are accountable for their professional practice to the NZAS. Those who are not members of NZAS are not accountable to a professional body. All patients have recourse to the Health and Disability Commission; but non-member audiologists/audiometrists are not bound by the standards of training, competence, practice, and continuing education requirements of the NZAS nor its code of ethics.

Hearing loss is a medical condition best addressed by a hearing healthcare professional. Such work includes examining the ear canal; quantifying and classifying the hearing loss, identifying "red flags" including sudden, quickly worsening or fluctuating hearing loss; hearing loss in only one ear or a large difference in hearing between ears; identifying tinnitus in one or both ears; and onward referring to other professionals for treatment outside their scope of practice.

Currently hearing is tested by one or more professionals:

- 46% by audiologists/audiometrists (who will also undertake a hearing assessment, proper fitting, verification and adjustment of a device, counselling and follow up care).
- 21% by GP (who will generally screen and refer on to an audiologist/audiometrist for treatment).
- 13% by an ENT.[2]

At present only 2% of hearing tests are carried out online. The NZAS welcomes greater oversight and controls to ensure that hearing tests are administered by professionals.

A member of NZAS assists by improving the listening experience and sound quality for the patient. The NZAS submits that fitting hearing aids ought to be an authorised activity. NZAS says that a condition of sale for a hearing aid must be through an authorised hearing health care professional, and that only members of the NZAS are suitably qualified to be so authorised. The legislation allows for this extra protection for the consumer. The Bill would enable this authorization to apply by regulation.

Anovum 2018 NZ Trak found that the professionalism of the audiologist was rated at 90%. [3] This is backed up by ACC data. A 2015 survey undertaken by Research NZ for ACC also found 90% satisfaction with the audiologist. [4]

[2] Anovum 2018 – NZ Trak 2018 page 19.
[3] Anovum 2018 NZ Trak page 52
[4] Research NZ Audiology Client Satisfaction Survey 2015 – undertaken for ACC. Page 5.

Setting the level of risk

The NZAS submits that care must be taken when determining the lowest risk class, as for this class self-declaration and notification for devices is sufficient. The NZAS submits that hearing aids cannot fit into the lowest or low risk classes for the reasons set out in this submission.

One of the many reasons the NZAS welcomes this legislation and the increased surveillance and control of medical devices such as hearing aids, is because an individual can be harmed if there is an error in fitting a hearing aid. The more severe the hearing loss, the more likely the patient is to have hearing aids, and the greater the risks of harm if there is an error. [5]

Harm can be controlled through the regulatory regime proposed by the Bill. This includes:

1/ Loss of hearing: if the hearing aid is improperly tuned and causes acoustic trauma leading to further loss of hearing. Over amplification can harm hearing. [6] Users find it difficult to self-determine when a prolonged over exposure can cause further damage.

2/ Discomfort, annoyance, and reduced ability to hear: if the hearing aid is improperly tuned and causes acoustic feedback, e.g. leading to loudness discomfort, sound annoyance, reduced sound quality and eventually reduced speech understanding.[7]

3/ Lack of hearing aid efficacy because of poor or inaccurate fitting, tuning and real ear verification.

4/ Inappropriate or unnecessary treatment.

5/ Testing and hearing aid fitting equipment are capable of producing sound at intensities which will damage hearing.

6/ Inappropriate use of these devises can misdiagnose hearing loss.

Register – the extension of approval to pre-market controls

The NZAS welcomes the extension of the powers of the regulator to impose pre-market controls on therapeutic products, along with the therapeutic products register which will be maintained by the regulator (see section 113).

Under the existing system the Ministry of Health keeps a list of hearing aids. All products available for funding by the MOH (either via a subsidy or through the funding scheme) must be on the list. Accessories available for funding must also be named on the list.

All importers / wholesale suppliers of hearing aids must have contracts with the Ministry of Health and agree to comply with mandatory requirements.

[5] Anovum 2018 NZ Trak 2018. Slide 16.
[6] Johnson (2017) Safety limit warning levels for the avoidance of excessive sound amplification to protect against further hearing loss. International Journal of Audiology 2017; 56:829-836.
[7] Mueller, Ricketts, Bentler (2014) Modern Hearing Aids: Pre-fitting, testing and selection considerations, as reported by Herbig and Lueken (2018) A comparison of feedback cancellation systems in premier hearing aids, published in the Hearing Review.

However, the existing WAND Database is not an approval system for medical devices. There is no approval system for medical devices under the Medicines Act 1981. There is no mandatory requirement for medical devices to be approved by any medical device regulator prior to being supplied in New Zealand. Notification to the WAND database does not mean or imply that a medical device has been assessed by Medsafe in terms of quality, safety, efficacy, or performance. It is, though, a mandatory requirement for importers, exporters and New Zealand manufacturers to advise the Director-General of Health, via the WAND database, of the devices that are supplied here.[8]

Medsafe has a role to monitor post-market activity in relation to medical devices and to take action when required to ensure devices continue to meet legislative requirements with respect to safety. Medsafe used the information in WAND to identify sponsors of products when necessary in order to make contact when post market issues have been raised through international or local reports.

Personal importation of hearing aids

The NZAS supports the ability of the regulator to regulate pre and post market controls. The proposed scheme envisages that some devices should have either access or supply restrictions for safety reasons. A regulation could place a restriction on use or supply. (See section 22).

The Bill provides that a person may import a medical device for personal use unless there is a specific restriction on the device.

Personal importation of medical devices is not currently regulated. However, agencies such as the ACC and the MOH have agreed that they do **not** provide any funding for hearing aids that have been purchased over the internet and will only fund hearing aids purchased and fitted by a member of the NZAS.

The ACC further restricts the activities of hearing testing and fitting of hearing aids to Full Members of NZAS. ACC issued the following statement: "ACC's contribution towards hearing aids for clients with hearing loss cover and entitlement can currently only be used for hearing aids purchased through and fitted by an audiologist who is a full member of the New Zealand Audiological Society"

The Section 88 Notice 2018 stipulates that only authorised persons can fit hearing aids; authorised persons are audiologist and audiometrists who are members of NZAS. In only those circumstances will the subsidy or funding be provided to the consumer.

In 2014, the National Foundation for the Deaf issued the following policy statement:

1. Hearing Aids are a medical device that must be prescribed by a health professional.
2. The Foundation supports the sale of hearing instruments to people with hearing impairment, exclusively through face-to-face, in-person consultations.
3. Internet sales of hearing instruments is a practise that is in no way supported by the Foundation and is to be actively dissuaded.

[8] https://medsafe.govt.nz/regulatory/DevicesNew/3-2Explanation.asp - accessed 8.04pm 22 March 2019.

Regulatory Orders and announcements

The NZAS welcomes the powers of the regulator to issue recall orders; advertising remediation orders, directive orders, product prohibitions, and can make public safety announcements.

Advertising

The NZAS welcomes the potential for greater regulatory oversight of advertising for hearing aids. While the NZAS has promoted advertising standards, which it enforces on members, it would be fair to say oversight and monitoring of advertising of hearing aids by importers, by on line sellers and some retail suppliers are not subject to sufficient regulatory oversight and scrutiny. The NZAS has taken up its concerns with Trade Me in the past when hearing aids have been advertised for sale on their site.

Conclusion

1. The NZAS is a self-governing body representing over 620 Audiologist, Audiometrist and provisional members in New Zealand.
2. The NZAS supports the purpose of the Bill which is to regulate products to ensure the safety, quality, efficacy and performance of products over their life cycle.
3. The NZAS supports the Bill's inclusive and broad definition of a therapeutic purpose.
4. The NZAS supports the definition of medical devices which covers a wide range of products used in primary and secondary health care, and will include hearing aids within its ambit.
5. The NZAS supports the opportunity that the Bill provides for the regulator to consider regulating new products and products which are currently not regulated such as second-hand hearing aids.
6. The NZAS supports the enhanced approval pathway which includes approval based on scrutiny of evidence.
7. The NZAS welcomes the provision in the Bill requiring mandatory adverse event reports by product sponsors.
8. The NZAS submits that the Bill ought to give powers to the regulator to require a person who is purchasing a hearing aid to have an evaluation by a specified hearing care professional, before the purchase of the aid.
9. The NZAS submits that care must be taken when determining the lowest risk classes. The process of determining the level of risk must involve those working in the profession who are using or supplying the therapeutic product.
10. The NZAS welcomes the powers of the regulator to issue recall orders, advertising remediation orders, directive orders, product prohibitions, and can make public safety announcements.
11. The NZAS welcomes the potential for greater regulatory oversight of advertising for hearing aids.

Lucy **Cochrane**
President, NZAS

Appendix: providing background to hearing loss.

Does hearing loss fall within the Category of a defect or injury?

Yes.

In the case of noise induced hearing loss, when the level of noise exposure is very high, the recovery of hearing thresholds can be incomplete, and when exposure is repeated over time, it can lead to a permanent and irreversible hearing threshold shift (Bohne and Clark 1982). The classic histologic description of the effects of permanent hearing threshold shifts shows destruction at the top of the hair cells; a reduction in the number of hair cells and destruction of the auditory nerve (Nordmann, Bohne and Harding 2000).

This leads to a permanent reduction in the ability of workers to detect high frequency sounds at low amplitudes, compared to the normal population. The combined effect of exposure to noise and aging on the hearing thresholds of an otologically normal population of men and women is predicted. Aging, like noise exposure is associated with progressive degradation of hearing thresholds. This is associated with changes in the functioning of the sensory cells in the inner ear, the nerve fibres of the auditory nerve, and structures of the central auditory system (Yamasoba el al 2013). Findings from studies show (Wong and Ryan 2015) that exposure to noise accelerates the process of age-related hearing loss.

Does a hearing aid have a therapeutic purpose?

Yes.

Hearing aids augment hearing to improve communication effectiveness, and ability to participate in group activities.

- Communicate more effectively in most situations
- Sense of safety
- Sense of independence
- Mental/emotional health
- Physical health [9]

It improves confidence in moving in a city e.g. traffic signals, vehicles approaching.

WorkSafe NZ: resources obtained from their website on 4th February 2019

Workplace noise can be harmful to hearing

If workers are exposed to hazardous noise over a long period of time, the hairs or nerve cells in the inner ear become damaged, and eventually stop responding to sound. This is called noise induced hearing loss

[9] Anovum 2018 NZ Trak 2018 page 57 www.anovum.com

(NIHL). Hearing damage can also occur from a sudden loud noise, extended exposure to vibrations from noisy machinery or ototoxic chemicals (chemicals that damage your hearing) found in substances such as paints, thinners, and glues.

Hearing loss is irreversible. Exposure to hazardous noise levels can cause temporary or permanent hearing loss, or tinnitus (a ringing in the ears). Damaged hearing reduces a person's ability to hear high frequency sounds, and some common consonant sounds such as t, k, s, sh and p. This type of damage can't ever be repaired.

NOISE INDUCED HEARING LOSS (NIHL)
NIHL resulting from workplace noise affects as many as 100,000 New Zealanders. Noise-related injuries are most common in the manufacturing and construction sectors, and in male-dominated industries. Around 30% of all workers in New Zealand are exposed to hazardous noise at work at least a quarter of the time.

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Eng, A., 'T Mannetje, A., Cheng, S., Douwes, J. Ellison-Loschmann, L., Mclean, D., gander, P., Laird, I., Legg, S. & Pearce, N. (2010).
The New Zealand Workforce Survey I: Self-Reported Occupational Exposures.
Annals of Occupational Hygiene, 54 (2), 144-153.

WorkSafe has estimated the Quality Adjusted Life Years (QALY's) for those suffering hearing loss.