Canadian Academy of Audiology
Academie Canadienne d'audiologie

Canadian Academy of Audiology Position Statement on Over-The-Counter devices and Sound Amplifying Products

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This position statement represents the Canadian Academy of Audiology's (CAA) position on a particular topic or area of practice. It provides a time-limited viewpoint that will be reviewed and revised as necessary when and if new information becomes available. This document represents an update from a previous Position Statement from the CAA on a similar topic and it can be found at: https://canadianaudiology.ca/professional-resources/guidelines-and-position-statements/

Position:

In the past several years, the US Food and Drug Administration (FDA) finalized legislation creating a category of Over-The-Counter (OTC) devices (Federal Register, 2022). These medically regulated devices are subject to regulations designed to address safety and reasonable quality, and to address the communication issues arising for those people with mild to moderate sensorineural hearing loss in adults. (Federal Register, 2022).

(1) It is the position of the CAA that OTC devices may improve access to amplification for some adults with mild to moderate hearing loss and acknowledges that accessibility in Canada varies substantially between provinces.
(2) The CAA calls for additional safety protocols which includes labelling of all sound producing products with a warning to consumers of the possibility of the generation of high sound levels that may compromise hearing status. (e.g., "This product will contribute to an increase sound exposure that may add to future hearing deterioration"). We acknowledge and applaud those manufacturers that have already voluntarily added this information in their consumer materials.
(3) It is the position of the CAA that this labelling and caution be extended to all devices that are sound producing products that may contribute to hearing loss risk, such as consumer earphones

Background regarding OTC devices:

In the United States, the FDA considered input from the President's Council of Advisors on Science and Technology (PCAST), and the National Academies of Sciences, Engineering and Medicine (NAS) reports, which led to the development of legislation that passed through both the House and the Senate. It was signed into law in August of 2017. The FDA was given time to create a proposed rule defining access to an OTC class of amplification products for adults in the US, concurrently with final guidance to clarify their differences from traditional hearing aids. The guidance came into effect on October 17, 2022 and was reported in the Federal Register (2022). https://www.fda.gove/medical-devices/sonsumer-products/hearing-aids

Some Highlights of the Guidance:

- For people 18 years and older
- For those with perceived mild to moderate hearing loss

Conditions for sale:

- Purchaser must be 18 years or older
- No medical exam
- No prescription
- No fitting by an audiologist
- No need for licensed seller

Background regarding Canadian federal regulations and oversight:

Canada does not have this level of government regulatory guidance at the federal level. Health Canada historically has required a Class II medical license for hearing aids and more recently has begun approving non-hearing aid devices such as what may be described as OTC devices under Class II licensing. (See definitions in this document for a description of what is included in Class II licensing.) An example is the Apple AirPods Pro 2 with approval for both hardware and software elements and an iOS app where a consumer can avail themselves of a built-in four threshold-based test of hearing acuity (CTA-2118 Standard, August 2023), or upload data from a previously performed audiogram. (License #112368 and Licence #112369, Health Canada, Dec. 11, 2024)

OTC devices:

OTC devices must meet the Consumer Technology Association (CTA) standard ANSI/CTA-2051, 2017) which like, ANSI S3.22 specifies how certain electro-acoustic features are measured and reported, and in addition, specifies several performance-related measures such as the smoothness of the frequency response.

Non-OTC sound producing products:

Canadian consumers may avail themselves of similar amplification products such as Personal Sound Amplification Products (PSAPs) (ANSI/CTA-2051 Standard, January 2017) which were not intended for the hard of hearing consumer but do nevertheless provide amplification. Unlike the OTC devices, PSAPs do not need to adhere to any standards such as CTA (ANSI/CTA-2051, 2017).

Other sound producing devices such as earphones and earbuds that are used for communication and music listening purposes also provide unregulated amplification and are a significant part of a Smartphone or computer system that may be capable of generating high sound levels in an occluded ear.

Sound producing products, in addition to other noise sources that Canadians may experience on a daily level, may contribute to an individual's noise or music "dose" reaching unacceptable levels.

Audiologists:

In Canada, Audiologists are hearing health care professionals with graduate-level university degrees who abide by provincial legal statutes that describe their regulations, scope of practice, and provincially defined authorized acts. Audiologists use multiple tests to assess the degree, type, and configuration of an individual's hearing, balance, and neural disorders and develop specialized management and follow-up plans for each individual. They are knowledgeable in the assessment of candidacy, and fitting and recommendations of assistive listening devices, computer apps, and accessories, including hearing aids and cochlear implants, and are skilled in identifying when to refer to other health professionals as necessary.

There are several types of hearing loss that Audiologists are trained to identify and manage. A common type among adults is sensorineural hearing loss that is typically acquired later in life and can be associated with the aging process, or music and noise exposure. Depending on the degree of hearing loss, most can be managed by the use of properly fitted hearing aids. If left untreated, adults with hearing loss can become depressed, isolated, and/or frustrated which could impact other areas of their lives such as their work and personal relationships. The use of hearing aids alone will not entirely mitigate the negative impacts of hearing loss and an audiologist can offer further rehabilitative strategies and technical accessories to assist in improving the individual's overall quality of life.

Rationale:

Non-regulated sound producing products have been available in Canada for decades and little research is available regarding their safety and sound quality aspects. While individual manufacturers may have performed their own research, there are few independently published data on this overall category of products. Specifications may need to be sought directly from the manufacturer. Possessing a medical Class II license does not in itself assure sound safety nor optimal sound quality. While it might be possible to achieve safe hearing improvements, depending on the design of the manufacturer, there is no Canadian regulatory licensing that has been given to guarantee this. These devices have been designed to be used by the consumer. Should a consumer want to ensure the quality of a device, they can seek assistance from an Audiologist. Sound quality from a device can be verified in a clinical setting using advanced measurements on an individual basis by an Audiologist. The CAA supports hearing access for all Canadians but cautions that not all people will benefit from using sound producing products such as OTC devices without the support of an Audiologist.

Availability of OTC devices in Canada:

The Canadian Academy of Audiology welcomes any device, Smartphone app, or software that improves accessibility for Canadians. There are a number of regulatory steps that must be taken both at the Federal and Provincial levels prior to having a product being available for sale to Canadians. The Canadian Academy of Audiology encourages a speedy, but thorough approval so that Canadians can avail themselves of these products in a timely manner.

Recommendations:

(1) Proper labelling to protect the consumer from damaging sound levels is required for all sound-producing consumer products in order to educate the public of the potential for the generation of overly high sound levels that may contribute to further hearing loss.
(2) Health Canada's medical Class II licensing requirement should be a minimum for OTC devices but it should be clearly indicated that such licensing does not guarantee hearing safety nor optimal sound quality.
(3) It is recommended that a person who is considering purchasing an OTC device is advised to consult an Audiologist for advice and assessment if they are not able to benefit from self-assessment and/or self-fitting and are concerned about the risks of exposure to excessive volumes with OTCs and other sound amplifying products. Consumers are advised to be aware of risks of exposure to excessive volume and can seek advice from an Audiologist. An Audiologist is a professional trained to assess candidacy for, prescribe, and fit hearing aids to individuals with a wide range of hearing loss conditions, as well as to provide the necessary counselling and rehabilitation supports to incorporate the devices into daily life.

Definitions:

Hearing aids are ear-level devices that amplify sound in an individualized manner for each person's hearing loss. They use signal processing to automatically adjust the sound level and relative balance of the bass and treble along with sophisticated limiting of the output of the amplified sound. They are designed to mitigate the impact of permanent hearing loss and are available for most types, degrees, and configurations of hearing loss. They are distinguishable from OTC devices because they are prescribed and verified by a hearing health care professional such as an audiologist along with counselling, aural rehabilitation, and when necessary, associated accessories. In most Canadian provinces and territories, obtaining hearing aids is a controlled act and therefore requires a prescription by an audiologist or physician. This is because hearing aids that are set too loud or too soft in relation to measured hearing levels poses a significant risk of harm to the individual. (Regulated Health Professions Act, 1991).

Over-The-Counter devices are only now becoming available in Canada with the approval of Health Canada medical Class II licenses. It is possible that Canadians are also purchasing OTC devices from the United States or other countries through online channels. According to the US FDA OTC guidance document, OTCs are medical devices that can be obtained by adults

over the age of 18 years with a perceived mild to moderate hearing loss, (even without a formal audiometric evaluation). Unlike traditional hearing aids, OTC devices can be obtained without input from an Audiologist or other hearing health care professional for an assessment, recommendation, fitting, or verification of the fitting. The quality and efficacy of the signal processing of these devices compared to hearing aids obtained through the professional route is currently the topic of much investigation in the hearing health care field. (Federal Register, 2022).

An application for a Medical Class II License from Health Canada (FRM-0292) does not require information on safety and optimal sound quality, but only quality control in the manufacturing process (ISO 13485 Certification), and if manufactured outside of Canada, another associated application will be required (Medical Device Establishment License) which allows non-Canadian products to be distributed in Canada. Issues surrounding safety and effectiveness are required for Class III and Class IV Medical Devices in Canada, but not Class II (which includes hearing aids and new OTC devices that are aimed at the consumer market.) The Health Canada Medical Device Class II license only requires that such information exist in a pre-market condition, but there is no requirement to supply it. This License does have certain labelling requirements: name, intended use, instructions for use, and warnings and precautions.

References:

United States Food and Drug Administration, Department of Health and Human Services. (2022). Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids, Federalregister.gov, Document: 87 FR 50698 https://www.Federalregister.gov/documents/2022/08/17/2022-17230/medical-devices-ear-nose-and-throat-devices-establishing-over-the-counter-hearing-aids

Ontario Regulated Health Professions Act. (1991). S.O. 1991, Chapter 18 https://www.Ontario.ca/laws/statute/91r18/v43

American National Standards Institute/Consumer Technology Association (ANSI/CTA-2051 Standard, 2017). Personal Sound Amplification Performance, January 2017.

Consumer Technology Association (CTA-2118 Standard), Four Frequency Pure Tone Average Testing Methodology and Reporting Metrics for Consumer Facing Hearing Solutions, August 2023.

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