Canadian Audiologist
The Official Publication of the Canadian Academy of Audiology

Canadian Academy of Audiology Position Statement on Over-the-Counter Hearing Aids

Published January 18th, 2023

The Canadian Academy of Audiology

Date: November 15, 2022

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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 new information arises.

Position

Recently, the U.S. Food and Drug Administration (FDA) finalized legislation creating a category of over- the-counter (OTC) hearing aids (FDA, 2022). These medical devices are subject to regulations designed to ensure safety and reasonable quality, while aiming to relieve the negative impact of perceived mild- to-moderate hearing loss in adults.

It is the position of the Canadian Academy of Audiology (CAA) that OTC devices may improve hearing access for some adults with mild-to-moderate hearing loss. However, the lack of similar legislation in Canada may allow underperforming and hazardous technology to enter the market, with significant risks for Canadians with hearing loss. Importantly, OTC devices will not address the hearing health care needs of many adults with hearing loss and are not a replacement for the professional hearing care services provided by Audiologists. The specialty services that Audiologists provide, such as real ear verification and counselling, optimize hearing aid and hearing health outcomes.

Background

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 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 hearing aids for adults in the U.S., concurrently with final guidance to clarify their difference from traditional hearing aids. The guidance came into effect on October 17, 2022: https://www.fda.gov/medical-devices/consumer-products/hearing-aids

Some Highlights of the Guidance

Intended users:

- people 18 years and older
- 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 audiologist
- no need for licensed seller

At present, Canada does not have this type of government or regulatory guidance. Consequently, adults in Canada who purchase OTC devices from abroad do not have the same protections that are in place for adults in the U.S. purchasing OTC devices. Unregulated OTC devices may be both inadequate to alleviate hearing difficulties and may further damage hearing.

Audiologists

In Canada, Audiologists are hearing health care professionals with graduate-level university degrees who abide by professional statutes that describe their regulations, scopes of practice, and 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 of assistive listening devices, including hearing aids and cochlear implants, and are skilled in identifying when to refer to other medical professionals when issues beyond their scope of practice arise.

Hearing Loss

There are several types of hearing loss that Audiologists are skilled to identify and manage. A common type among adults is sensorineural hearing loss that is acquired later in life. Depending on the degree of the hearing loss, most can be managed by the use of properly fitting 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 to help improve the individual's overall quality of life.

Rationale

Although OTC devices are not directly available in Canada, they may be obtained from online U.S. sources without the need for the individual to see an audiologist. The CAA supports hearing access for individuals but cautions that not all will benefit from using OTC devices without the support of an audiologist.

Recommendations

Regulation of OTC devices in Canada is vital to ensuring safe and effective hearing device technologies for Canadians with Hearing Loss.

Until that time, when considering an OTC device, Canadians should be aware that FDA-approved devices are safe and of reasonable quality but may be limited in their ability to alleviate all the listening challenges that accompany a perceived hearing loss. An Audiologist is the 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 way for each person's hearing loss. They use signal processing to automatically adjust the level and relative levels of bass and treble along with limiting the output levels of loud sounds. They are designed to mitigate the impact of permanent hearing loss and are available for most types, degrees, and configurations of hearing loss. In some 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 set too loud or too soft in relation to their measured hearing levels poses a significant risk of harm to the individual (Regulated Health Professions Act, 1991).

Over-the-counter hearing aids are not available legally within Canada at this time, and Health Canada has not approved their use. It is possible, however, for Canadians to obtain OTC hearing aids from the

U.S. through online channels. According to the U.S. FDA OTC guidance, OTC hearing aids are medical devices that can be obtained by adults over the age of 18 years with a perceived mild-to-moderate hearing loss. Unlike traditional hearing aids, OTC devices can be obtained without seeing an audiologist or other hearing care practitioner for an assessment, recommendation, or fitting. The quality and efficacy of the signal processing of these devices compared to hearing aids obtained through traditional channels is currently the topic of much investigation in the hearing industry.

References

1. United States Food and Drug Administration, Department of Health and Human Services. (2022).

2. 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

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