



Speech-Language & Audiology Canada
Orthophonie et Audiologie Canada
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May 2, 2025

Mr. Greg Orencsak, Deputy Minister, Health Canada
Deputy Minister's Office, Health Canada, Brooke Claxton Building, Tunney's Pasture
Ottawa, ON, K1A 0K9

Subject: *Ensuring public safety in OTC hearing aid regulations*

Dear Mr. Greg Orencsak,

On behalf of Speech-Language & Audiology Canada (SAC), we appreciate Health Canada's commitment to expanding access to hearing health solutions. We would like to highlight some key considerations regarding the recent licensing of Class II medical devices marketed as over-the-counter (OTC) hearing aids in Canada.

We support increasing access to hearing health solutions for Canadians. However, we need to emphasize the importance of ensuring **public safety, consumer education, and product efficacy** through appropriate regulatory oversight. Given that many individuals purchasing these devices may not undergo a professional hearing assessment, it is critical that robust licensing criteria and consumer safeguards are in place. Without these measures, potential risks to public health include:

- **Permanent hearing damage:** lack of gain limitations may result in excessive amplification, potentially leading to further irreversible hearing loss or conditions such as tinnitus.
- **Harm to vulnerable populations:** children and older adults may be at higher risk of misusing these devices, which could negatively affect speech, language, and cognitive development.
- **Unreliable and unsafe products:** without consistent monitoring, consumers may be exposed to devices that are ineffective and even harmful.
- **Consumer misinformation:** consumers may not receive adequate guidance on appropriate device use, leading to misinformation, improper expectations regarding their effectiveness and potential health consequences.

The current regulatory framework does not provide provincial regulatory bodies with the authority to assess the safety and effectiveness of OTC hearing aids. Without enhanced federal oversight, consumers may be left without adequate safeguards, potentially exposing them to products that do not meet appropriate safety and efficacy standards.

To ensure both accessibility and safety, we offer to work with Health Canada in developing an enhanced oversight structure for OTC hearing aids in Canada. We are committed to contributing our expertise to help

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establish a framework that upholds evidence-based quality standards and provides clear consumer guidance on the safe and effective use of these devices. By working together to define stringent criteria for device performance, labeling, and public education, we can ensure that Canadians have access to hearing solutions that are both innovative and safe.

We welcome the opportunity to collaborate with Health Canada and provide our professional expertise in shaping policies that balance innovation, accessibility, and patient safety. Please let us know a convenient time for a discussion on this important matter.

Sincerely,

A handwritten signature in black ink, appearing to read 'Luciana', followed by a long, sweeping horizontal stroke.

Luciana Nechita
CEO, Speech-Language & Audiology Canada