



Speech-Language & Audiology Canada
Orthophonie et Audiologie Canada
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Speech-Language & Audiology Canada
1000- 1 Nicholas Street
Ottawa, ON, K1N-7B7

April 17, 2025

Subject: Submission to Health Canada Consultation – Draft Guidance on Managing Applications for Medical Device Licences

Dear Health Canada, Medical Devices Directorate,

On behalf of Speech-Language & Audiology Canada (SAC), the national body representing speech-language pathologists and audiologists, we appreciate the opportunity to provide feedback on the *Draft guidance on managing applications for medical device licences*. We commend Health Canada for revisiting this important guidance and wish to offer the following feedback on two key areas identified for consultation: *Overall, Clarity and Content of the Guidance Document* and *Revamped Reconsideration Process*. Our submission focuses primarily on the implications for over the counter (OTC) hearing aids, which are of critical interest to our members and the Canadians they serve.

We recommend that the revised guidance:

- Strengthen regulatory oversight for OTC hearing aids as they become increasingly available direct-to-consumer. Given their classification as Class II medical devices, it is essential that labeling, adverse event reporting, and safe output limits are clearly defined and enforced. Without robust safeguards, there is significant risk to the hearing health of Canadians, including potential cochlear damage from excessive sound levels.
- Clarify the roles of federal and provincial/territorial authorities regarding the regulation and dispensing of hearing devices. Given that audiologists are provincially regulated professionals with specific mandates around hearing aid dispensing, consumers and practitioners alike would benefit from clearer distinctions between federal approval and local standards of care.
- Highlight the responsibilities of professional support in the safe and effective use of OTC hearing aids. The guidance should encourage collaborative care, where professionals like audiologist's support consumers in optimizing device use and in recognizing concerning symptoms that may require clinical intervention.

We support a transparent and efficient reconsideration process for medical device licensing decisions and recommend the following:

- Consultation with audiology professionals when reconsideration requests involve hearing devices as they can provide essential insight into device functionality, patient safety, and evidence-based clinical outcomes.
- Responsive and clear timelines that reflect the pace of technological change in hearing devices, to avoid delays in bringing safe and effective technologies to Canadians.

Ensuring the well-being, safety, and satisfaction of hearing aid users is a top priority for audiologists. As OTC hearing aids continue to gain traction as a pathway to improve access to hearing health care, SAC supports the reinforcement of stringent regulations and careful attention to quality standards for these direct-to-consumer devices.

We appreciate the opportunity to provide feedback and remain available for any further consultation or collaboration as you finalize this important document.

Sincerely,

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

Luciana Nechita
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