



Speech-Language & Audiology Canada
Orthophonie et Audiologie Canada
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OFFICIAL STATEMENT FROM SPEECH-LANGUAGE & AUDIOLOGY CANADA (SAC)

FDA Releases Final Rule for OTC Hearing Aids

On August 16, 2022, the United States Food and Drug Administration (FDA) released its [final rule for over-the-counter \(OTC\) hearing aids](#). This historic rule established a new regulatory category for OTC hearing aids. This action is intended to increase the availability and affordability of hearing aids for adults aged 18 years and older with perceived mild to moderate hearing loss by allowing direct purchase from stores and online retailers without the need for a medical exam or audiological evaluation, prescription, or verification by an audiologist.

Compared to the proposed rule issued on October 20, 2021, the finalized FDA rule incorporates several changes and provides performance and design specifications, including lowering the maximum output limits, revising the insertion depth limit in the ear canal, and requiring that all OTC hearing aids have a user-adjustable volume control. The FDA has also simplified the phrasing throughout the required labeling. A separate gain limit was not specified.

Speech-Language & Audiology Canada (SAC) recognizes that the FDA OTC rule will have an impact on the demand and availability of OTC hearing aids in the United States. To date, the Canadian government has not instigated a proposal to follow suit with its own regulated class of OTC hearing aids. SAC will monitor guidance from Health Canada and provincial/territorial regulatory bodies related to OTC developments in Canada. SAC will also continue to support its audiology members and advocate on their behalf regarding OTC hearing aids, particularly should regulatory changes occur in Canada.

SAC advocates for equitable access to hearing health care that is individualized, safe, and effective. This requires the expertise audiologists provide at the highest level of training and quality of care. SAC upholds the importance of using evidence-based hearing aid selection, verification, and validation best practices for optimal aided benefits and as a standard of care (Mueller et al., 2021; Palmer, 2018). SAC emphasizes the necessity for a comprehensive audiological assessment which includes diagnosis of the type, degree, configuration and potential asymmetry of the hearing loss prior to and in conjunction with hearing aid fitting and aural rehabilitation. This is especially concerning for audiological findings that present with the need for further medical review which is well within the audiologist's scope of practice to direct. Additionally, SAC advocates that hearing loss and auditory system deficits are best managed through the development of a customized, person-centered treatment plan that audiologists are uniquely qualified to provide.

This SAC Official Statement has been developed in the context of an emergent ruling in the US and is subject to change as additional information becomes available.

References

Mueller, H.G., Coverstone, J., Galster, J., Jorgensen, L., & Picou, E. (2021, September 13). *20Q: The New Hearing Aid Fitting Standard - A Roundtable Discussion*. AudiologyOnline. <https://www.audiologyonline.com/articles/20q-new-hearing-aid-fitting-27938>

Palmer, C. (2018, January 22). *Signia Expert Series: Over-the-counter Hearing Aids - Opportunity or Disaster?* AudiologyOnline. <https://www.audiologyonline.com/articles/signia-expert-series-over-counter-21066>

About SAC

Speech-Language & Audiology Canada (SAC) is a member-driven organization that supports and promotes the professions of more than 6,500 members and associates including over 800 audiologists. We are the only national organization passionately supporting and representing speech-language pathologists, audiologists and communication health assistants inclusively. Through this support, we champion the needs of people with communication disorders.

Visit www.sac-oac.ca to learn more.

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