

## **“Global Regulatory Update on OTC Hearing Aids: Experience from US and Abroad”**

A Sponsored Talk Hosted by

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The U.S. Food and Drug Administration (FDA) authorized the sale of over-the-counter (OTC) hearing aids after a lengthy regulatory process. The market for OTC hearing aids is open and consumers with perceived mild to moderate hearing loss now can purchase a hearing aid without involvement of a hearing care professional. This has created new opportunities and challenges for professionals, consumers, and hearing healthcare industry as a whole, across the world.

One of the intended benefits of creating the new OTC hearing aid category was to increase accessibility and affordability of hearing aids in the United States. As such, OTC hearing aids can be purchased without a prescription, allowing consumers to bypass the traditional process of consulting with a hearing care professional. While this could have the potential benefit for many people, the lack of involvement of a professional has also caused an uptick of ill-intended opportunists to bring potentially harmful products to market. This creates additional challenges among professionals and consumers. As such, the role of the professional becomes more important than ever.

The impact of OTC hearing aids on the hearing healthcare industry world-wide is now unfolding. While these devices have the potential to improve accessibility and affordability, it is important to consider their impact on consumers and the broader hearing healthcare ecosystem.

This presentation will explore the evolution of the hearing care policy landscape, regulatory requirements governing OTC hearing aids, and lessons learned from the United States, and the impact of OTC hearing aids world-wide.

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