Federal Government Position on OTC Devices Shared by Brian O'Riordan, Registrar CASLPO

Health Canada is committed to enabling access to safe and effective medical devices in Canada. Health Canada regulates the sale, advertising for sale and importation for sale of medical devices through the *Medical Devices Regulations* (the Regulations) of the *Food and Drugs Act*. Under the Regulations, Health Canada ensures that medical devices sold in Canada meet regulatory requirements with respect to safety, effectiveness, and quality. Under the *Regulations*, medical devices are classified into one of four classes where Class I represents the lowest risk and Class IV the highest. Hearing aids are classified as Class II medical devices, and they require a medical device licence for import or sale in Canada.
The use of and access to medical devices licensed for sale by Health Canada, including hearing aids, fall under the practice of medicine, which is outside of Health Canada's mandate. While the federal government plays a role in supporting health care by providing funding to the provinces and territories, the provincial and territorial governments have primary jurisdiction in the administration and delivery of health care services. …

Health Canada is aware of the US Food and Drug Administration's (FDA) regulatory approach regarding OTC hearing aids. However, the Department does not have specific regulatory requirements or plans to introduce new ones in relation to OTC hearing aid access similar to those implemented by US FDA, as access to medical devices is overseen by the provinces and territories in Canada.