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Over-the-counter (OTC) devices: One year later

The final FDA regulations for over-the-counter (OTC) regulations were implemented on Oct 17, 2022, and products in this class of devices are now on the market. By October 2023, we will have almost one year of OTC availability. The questions we will address in the lecture are:

- did this help to solve the access issue?
- or the affordability issue?
- or spur innovation from outside the industry?
- or change consumer behaviour regarding OTC/Prescription devices

Regarding access, we have seen retailers, including Amazon and other online outlets, as well as pharmacies and consumer electronics stores enter the market with OTC devices. However, the process has been slower than anticipated and with limited success at this early stage. Consumers continue to be slow to adapt to hearing devices despite the additional channels. The general lack of awareness about hearing health and hearing technology coupled with misleading advertising by some OTC companies could be responsible for both consumer confusion and low uptake. The professional segment is gradually adding OTC devices to their practice portfolio. We will examine the potential interest from countries outside the US to add the OTC segment to their private markets and/or government funded health programmes for hearing care.