



EUROPEAN ASSOCIATION OF HEARING AID PROFESSIONALS

AEA Feedback on the European Commission's "Smart Wearables: Reflection and Orientation Paper"

The European Association of Hearing Aid Professionals, AEA, welcomes the initiative of the European Commissions' request for public feedback on the Smart Wearables – Reflection and Orientation Paper. AEA sees Smart Wearables as a great opportunity to improve quality of life and healthy ageing. In fact Smart Wearables are already integrated and connected to modern digital hearing aids today. Wireless microphones, wireless connection to telephone, smartphone, smart devices, television, alert systems, car navigation systems, demotics and many more applications are currently already available and very actively used in professional hearing care. These solutions clearly help to increase end-user satisfaction, improve quality of life, lower resistance again using hearing aids, allow communication in challenging environments and integrate people with hearing loss and the dynamic society. But this is clearly only the beginning.

Hearables: Smart Wearables intended to be used by people with normal hearing should not cause hearing damage.

Since many Smart Wearables will deliver sound in the ears of the user (also called Hearables), they need to be safe, so there is no risk of noise induced hearing loss. Hearing Aid/Care Professionals play an important role in hearing protection and prevention of hearing loss.

Therefore the "COMMISSION DECISION of 23 June 2009 on the safety requirements to be met by European standards for personal music players pursuant to Directive 2001/95/EC of the European Parliament and of the Council" can certainly be the basis for a safety regulation on Smart Wearables.

The requirements stated in Article 3 should at least be met:

1. For the purpose of Article 4(1)(a) of Directive 2001/95/EC, the safety requirement for personal music players shall be the following:
 - Personal music players shall be designed and manufactured in a manner that ensures that, under reasonably foreseeable conditions of use, they are inherently safe and do not cause hearing damage.
2. The requirement set out in paragraph 1 shall include in particular the following:
 1. Exposure to sound levels shall be time limited to avoid hearing damage. At 80 dB(A) exposure time shall be limited to 40 hours/week, whereas at 89 dB(A) exposure time shall be limited to 5 hours/week. For other exposure levels a linear intra- and extrapolation applies. Account shall be taken of the dynamic range of sound and the reasonably foreseeable use of the products.
 2. Personal music players shall provide adequate warnings on the risks involved in using the device and to the ways of avoiding them and information to users

Hearables: Smart Wearables intended to be used by people with hearing loss should or be connected to hearing aids (medical device class IIa) fitted and provided by a recognised hearing aid professional or shall be classified and regulated as hearing aid (medical device class IIa) when directly providing amplified sound.



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Hearing aids are medical devices and lie therefore within the scope of the directives 90/385/EC and 93/42/EC resp. the future Medical Device Regulation. The later provides for strict stipulations with respect to their production, placing them on the market and putting them into service.

Fitting hearing aids lies within the only responsibility of hearing aid professionals who exercise a recognized health care profession in line with the directive 2005/36/EC about the recognition of professional qualifications.

Fitting and application of hearing aids must be in line with European and national laws with respect to the safety of consumers in general, for instance Directive 2001/95/EC.

Hearing aid professionals shall be informed and trained to:

- Help people with hearing loss to use Smart Wearables in connection with hearing aids.
- Select, connect and fit Smart Wearables to function in combination with hearing aids.
- Integrate the use of Smart Wearables in Professional Hearing Care.

Hearables: Smart Wearables and Data Protection.

In case hearing aids collect personal data, their use must be in line with the national data laws resp. with the General Data Protection Regulation EU/2016/679. The same kind of safety guidance should be used for Smart Wearables.

AEA is willing to play a very constructive role

Since we see a great opportunity to actively use and recommend Smart Wearables in professional hearing care and in ensuring safe use of Smart Wearables, the AEA is willing to play a very constructive role to unleash the full potential of Smart Wearable in the interest of the user.

The **European Association of Hearing Aid Professionals (AEA)** was founded in 1970 as the European umbrella organisation for "Hearing Aid Professionals". AEA membership is open to all national associations of hearing aid professionals in Europe that have been officially recognised by their relevant national authorities. We currently represent the interests of more than 8,000 small and medium-sized enterprises (SMEs) and more than 20,000 practitioners in the following 13 European countries: Austria, Belgium, France, Germany, Greece, Italy, the Netherlands, Romania, Poland, Portugal, Spain, Switzerland and the United Kingdom.

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