

European Federation of Hard of Hearing People

13 January 2017

## **EFHOH Feedback on the European Commission's "Smart Wearables: Reflection and Orientation Paper"**

The European Federation of Hard of Hearing People (**EFHOH**) is a non-profit European non-governmental organisation consisting of/for hard of hearing, late deafened people, those living with tinnitus, hyperacusis, Menière's disease and CI as well as parent organisations and professional organisations. EFHOH has been founded and registered as a charitable organisation in 1993. EFHOH's aim is a Europe where hard of hearing people can live without barriers, and can participate on all levels in society. EFHOH membership currently represents 21 different countries and over 52 million hard of hearing people across European Union.

EFHOH welcomes the initiative of the European Commissions' request for public feedback on the Smart Wearables – Reflection and Orientation Paper. Some of our members have already experienced the benefit of smart technology used with the hearing aids and cochlear implants, enabling them greater independence and to hear well. We believe that this is beneficial to the improved end-user satisfaction as well as improved quality of life.

### **Hearables: Safe listening guidance and protection.**

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. EFHOH has worked in past on introduction of the Directive 2001/95/EC of the European Parliament and of the European Council, which relates to safety standards for personal music players. We propose that those safety requirements should be used as a basis for a safety regulation on Smart Wearables.

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

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### **Hearables: Smart Wearables and role of hearing care professionals.**

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. Furthermore fitting hearing aids lies within 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.

Similar approach should be adapted to Hearable also in respect of the Directive 2001/95/EC.

Taking into consideration EFHOH Essen Declaration

[http://media.wix.com/ugd/c2e099\\_13e3b120ba6b4518a5567ce2287cc593.pdf](http://media.wix.com/ugd/c2e099_13e3b120ba6b4518a5567ce2287cc593.pdf)

it is important that hearing care professionals are part of the solution as they will be able 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.

### **Smart hearing technology and hard of hearing people.**

Another aspect of wireless technology is potential interference. The challenge is quite simply that hearing aids are already using Bluetooth technology for audio communication with mobile phones, personal audio, TV, schoolteachers and many other daily interactions and hearing aid users will be more and more dependent on Bluetooth technology in the future. The interference between the different Bluetooth bands used for different purposes may disturb or block Bluetooth applications utilized by hearing aids. A special challenge is that small Bluetooth devices like hearing aids or cochlear implant processors have limited possibilities to protect themselves against such interference because effective filters are impossible to apply in hearing aids due to size and power supply constraints. We welcome further discussions on this topic.

Further thought and actions are needed to ensure that hard of hearing people who are part of protected characteristic under UN Convention of the Rights of Persons with Disabilities ( UNCRPD) are able to use technology essential to their ability to hear well.

We recommend that a small fraction of available Bluetooth bandwidth is reserved and protected to ensure millions of hard of hearing citizens a better quality of life and the ability to function in society instead of making them exclusive property of large companies or specific commercial technologies.

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### **Smart Wearables and Data Protection.**

There is a general universal concern that the increase in connectivity of everyday objects has outpaced security at the same time, there is also concern over data being collected and lack of any regulations in this respect.

In case of hearing technology which 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. It is therefore important that hard of hearing person consent for data collection is obtained specifically in relation to smart technology use.

### **Smart wearables and traditional technology.**

Currently we observe across EU a discrepancy in hearing aids procurement whatever it is via universal health service or a reimbursement system as traditionally governments focus on cost effectiveness rather than quality and there is little to no indication that they would be willing to switch to more expensive hearing technologies that can enhance hard of hearing people life and help them hear better. Significant awareness rising and investment will be required to reverse the trend with proven investment on return.

However it is also clear that our purchasing and personal habits have not yet adapted and complete reliance on smart technology by discarding traditional technology can provide unnecessary barriers to those who are unable to benefit for different reasons such as cost, ease of technology use by the end-user.

EFHOH argues that those two are not excluding each other and can be used in combination depending of circumstances. We are concerned with possibility of having only smart enabled hearing device which potentially exclude the possibility of using hearing loops which require telecoil fitting in hearing technology. The hearing loops are used widely in Europe and despite being around for a long time, they still provide the right listening conditions in many public buildings. Our members use both technologies with great success and having both technologies available we can ensure that everyone is benefiting from assistive technology should it be old or new.

EFHOH welcomes the debate on the use of smart wearables and their true potential for hard of hearing people and wishes to be involved in the further discussions.

Yours sincerely,



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