EUROPEAN ASSOCIATION OF HEARING AID PROFESSIONALS

AEA Board Meeting
Thursday the 3rd of February 2022 from 17.00h till 19.00h
Video/Phone conference call

Agenda

1. Welcome
2. Welcome Luxemburg, our new AEA member
3. The FDA OTC-Hearing Aids draft ruling
    a) Status – reactions to the FDA so far
    b) What is the risk in your country, that OTC-hearing aids and PSAP's will have impact and can be sold to people with hearing loss? (please send this information before the meeting)
4. Updates on the Medical Device Regulation
5. ECAT report and topics
    a) Status of the development of the ISO standard on "Tele-services, as part of hearing aid fitting management (tHAFM)"
    b) Other ECAT topics
6. World Hearing Day – 3rd of March 2022
    a) Suggested materials for AEA members
    b) Events by AEA member organisations
    c) Lunch Debate from the European Parliament
7. Planning the next AEA board meeting and AEA general assembly
8. Round table on other topics from AEA members
9. Conclusion and end of the meeting.

Participants:

Austria:	Herdis Menhardt
France:	Benoît Roy
Germany:	Marianne Frickel & Stephan Baschab (invited)
Greece:	Athanasios Tsigos
Greece & ECAT President:	Dimitris Chrysikos
Italy & AEA Operative Secretary:	Dario Ruggeri
Luxembourg	Guy Lejeune (invited)
Malta:	Andrew Sciberras
Poland:	Anna Cierpicka
Portugal:	Melissa Cravo
Romania:	Ramona Nicolae
Spain:	Francesc Carreño
Switzerland:	Christoph Schönenberger & René Bürgin (invited)
The Netherlands:	Carmen de Jonge & Hein Greven
AEA General Secretary	Fritz Zajicek
AEA President	Mark Laureyns

Excused:

Belgium:	Patrick Verheyden & Pol Coulonval

EUROPEAN ASSOCIATION OF HEARING AID PROFESSIONALS

1. Welcome

Mr. President declares the Meeting open at 17.00 and thanks all the participants.
Given the presence of some new members in the Board, **Mr. President** proposes to make a quick tour of introduction by all the participants. After that, the Board welcomes **Mrs. Anna Cierpicka**, new Member of the Polish delegation.

2. Welcome Luxemburg, our new AEA member

The Board welcomes the Luxembourg delegation, in the person of **Guy Lejeune**.

3. The FDA OTC-Hearing Aids draft ruling

Mr. President begins the discussion of point 3 on the agenda by thanking all the members of the Board who participated in the survey, sent in the previous days, regarding a risk evaluation of the impact of the entry of OTC hearing aids on the European market. [*the summary of the comments received can be seen in figure 1 and the full document with all your comments will be attached as Annex 5 to this report*]. In general, what emerges is that such devices could create greater problems in those countries where the profession of hearing care professional is not sufficiently recognised and regulated as a health care profession.

Country	OTC-hearing aids a risk?	Regulations ready?	Expect from AEA?	Enough information?
Austria	No	Yes	awareness campaign	Yes
Belgium	No	Yes	exchange	Yes, but more usefull
France	No	Yes		
Germany	No	Yes	argumentation	Yes
Greece	Yes	No	influence legal framework	Yes, more is usefull
Italy	No now, but maybe later	Not for PSAPs	Defend the right for clients	Yes
Luxemburg	Yes	No	Give regulatory support	Definitively not
Malta	Yes, it could	No	Common way forward	maybe
Netherlands	Could be (not yet)	No sure OTC <> PSAP	Counter jointly	Onepager
Poland	Yes	No	Propose regulations	No … please send more
Portugal	Yes	No	regulatory position & recom	No
Romania	Not more, than it PSAPs	Not sure	info and good practices	No
Spain	Controlled risk	Not, if OTC's are no Med Devices	influence legal framework	need AEA documentary
Switzerland	Yes and No	No	support to regulate prof	Yes

[Figure 1]

In any case, according to **Mr. President**, it is not appropriate to give excessive attention to OTCs, to avoid that they acquire excessive importance in the eyes of the institutions.

Mr. President points out that this proposal has given rise to numerous discussions, essentially regarding the definition of candidates for this new category of hearing aids and the acoustic characteristics of these devices, for which a maximum output of 120 dB is identified without any indication on maximum gain: this is of particular concern, according to **Mr. President**, as these hearing aids would be aimed at people without any medical assistance or official audiograms. There were comments from the Make Listening Safe Workgroup, EFHOH and ITU. On this point, concludes **Mr. President**, there are some movements to introduce OTC-hearing aids in the UK and Australia: for this reason the AEA must be well prepared on the subject.

Subsequently, **Mr. Laureyns** gives the floor to **Mr. Baschab** for an examination of the legal aspects of the subject, with particular reference to the MDR which came into force last year.

4. Updates on the Medical Device Regulation

Mr. Baschab continues with an analysis of the possible impact of the new MDR on OTC hearing aids. According to **Mr. Baschab**, the key to protecting the profession of hearing care professional can only be its recognition by the national laws. The category of "fitter" was included in the implementation of the MDR in Germany in order to enhance this protection in the interest of the end-user. Given that hearing aids are not custom-made devices (for which the MDR provides that they must be applied by persons authorized by national laws), nor can they be defined in this way, the market is therefore open to OTCs, concludes **Mr. Baschab**.

Mr. President intervenes by agreeing with Mr. Baschab and adding that the MDR clearly establishes that: "*This Regulation shall not affect national law concerning the organization, delivery or financing of health services and medical care, such as the requirement that certain devices may only be supplied on a medical prescription, the requirement that only certain health professionals or healthcare institutions may dispense or use certain devices or that their use be accompanied by specific professional counselling"* The MDR therefore, concludes **Mr. President**, is not in itself capable of protecting any profession.

This is followed by a discussion on the implementation of the MDR in the various European countries. **Mrs. Cierpicka** intervenes informing the members that, in Poland, there is no specific regulation of the profession. A legislation draft was recently introduced, but its effective publication and implementation has been slowed by the ongoing pandemic.

Subsequently **Mrs. Cravo** takes the floor emphasizing the fact that, in Portugal, despite the recognition of the hearing care professional, there are some problems in the implementation of the new MDR. The translation of the Regulation, continues **Mrs. Cravo**, presents indeed a substantial difference compared to the English, French and German versions: the "written prescription" mentioned in the description of custom-made devices becomes "medical prescription", which would highlight a centrality of the medical profession which, in fact, is not provided in the original version.

Mr. Bürgin underlines that, in Switzerland, the new MDR has not yet been implemented and considers an excellent choice to include the category of "fitter" as was done in Germany.

Mr. President concluded by informing Members that an information one-pager on OTC hearing aids and their possible impact on the various European countries will soon be produced and the Q&A document (MDCG 2021-3 Questions and Answers on Custom-Made Devices & considerations on Adaptable medical devices and Patient-matched medical devices), which can be very helpful to discuss with your regulators on the local implementation of the MDR and how Hearing Aid Professionals should be seen.

5. ECAT report and topics

Mr. ECAT President gives the floor to Mr. AEA President to address point 5 in the Agenda.

Mr. Laureyns takes the floor and updates the Members on the progress of the work related to the drafting of the ISO standard on teleaudiology. After thanking everyone who attended the latest ISO meeting on the 5th of January, **Mr. Laureyns** explains that, for timing reasons, this document will not be an annex to the ISO standard on hearing aid fitting management but will be a separate document. On 7 April 2022, the date of the next ECAT meeting, “we will go into the details of the document”.

The working document that was used was entirely based on the one modified after the ECAT inputs. During the meeting the following agreements were made:

- OTC hearing aids, self fitting hearing aids and assisted teleaudiology were excluded, in this way only hearing aid fitting management performed by a hearing care professional was included;
- the term "telehealth" will not be used in the title (conflict with Korean legislation) but, in any case, the document must be fully compliant with the ISO 13131: 2021 standard "Health informatics - Telehealth Services - Quality planning guidelines";
- the risk- assessment has been removed and will be the responsibility of producers and developers of IT platforms (hearing care professionals will have the task of providing quality services and using systems compliant with ISO 13131);
- the "traditional service" has been defined as the services provided in the facilities of and by the hearing care professional;
- an important safety aspect has been included: if the hearing care professional encounters quality issues that do not allow quality telehealth care, he / she shall stop the telehealth-service;
- a specific focus group will soon be activated (with the presence of Mr. Bürgin) on educational requirements;

- tele services must be understood as a part of hearing aid fitting management and not as a complete separated service;
- verification and validation is better defined, so that specific aspects mentioned in the original standard can only be done by "traditional service".

Mr. Laureyns concludes by saying that in any case, the AEA's objective is to arrive at a drafting of the standard that ensures the highest quality of service for the end user. **Mr. Baschab** intervenes by thanking the ECAT team.

Still with respect to the work of the ECAT, **Mr. Sciberras** takes the floor illustrating the aims and contents of the questionnaire on the application of cochlear implants recently distributed to all AEA Members. **Mr. Sciberras** specifies that the main objective of the questionnaire is to obtain a survey on the legislation relating to cochlear implants with particular reference to which professional is entitled to carry out the application phases (programming, switch on, etc ...). The results of the survey will be presented during the next ECAT Meeting. **Mr. President**, concludes point 5 by congratulating the ECAT team for the work done in the last period.

6. World Hearing Day – 3rd of March 2022

Mr. President takes the floor by illustrating the progress of the organization of the next World Hearing Day.
The translations of the Manifesto are now available. The AEA website, continues **Mr. President**, will shortly be updated with all promotional materials for all countries. The day, which will be hosted by MEP Agius Saliba, will be organized in the same way as last year. [*the program of the day is visible in figure 2*].
Mr. President hopes for a massive participation to the event.

- **Welcome & Introduction** – MEP Alex Agius Saliba (Malta, S&D)
- **"To hear for life, listen with care"** - Shelly Chadha WHO
- **The WHO Global Standard for Safe Listening Entertainment Venues** – Mark Laureyns - AEA
- **Why hard of hearing people care for safe listening** – Lidia Best– EFHOH
- **Young Ambassadors going to schools** – Laia Zamora - EURO-CIU
- **"The importance of Adult Hearing Screening"** - Patrick D'Haese - Hear-it
- **"The importance of Access to Ear and Hearing Care in Europe"** - Satish Mishra – WHO-Europe
- **Debate** - All
- **Conclusion** – MEP Agius Saliba

[Figure 2]

7. Planning the next AEA board meeting and AEA general assembly

As for whether to hold the next AEA General Assembly in videoconference or face-to-face mode, any decision on the matter is postponed due to the unpredictable evolution of the ongoing pandemic.

8. Round table on other topics from AEA members

The discussion focuses on the non-recognition of the hearing care professional as a regulated health care profession in some European countries, in particular Switzerland, Luxembourg, and the Netherlands. In conclusion, the need to obtain the recognition throughout Europe is emphasized in order to guarantee the highest quality of service for the end-user.

9. Conclusion and end of the meeting

Mr. President declares the Meeting closed at 19.00 and thanks all the participants. The next AEA (short) board meeting, is planned for Thursday the 21st of April from 18 till 19h CET.

Date: February, 22th 2022

Mr. President
Mark Laureyns

The General Secretary
Fritz Zajicek

Dario Ruggeri

Annexes:

1- *Hearing Review on OTC – nov 2021*
2- *OTC for Australia*

4- *MDCG 2021-3 Questions and Answers on Custom-Made Devices & considerations on Adaptable medical devices and Patient-matched medical devices*
5- *AEA and OTC-hearing aids – for the AEA board meeting on the 3rd of February 2022*