AEA and OTC-hearing aids – for the AEA board meeting on the 3rd of February 2022

In order to prepare for this meeting, we kindly request you to send us your risk evaluation for OTC-hearing aids (or PSAPs) coming to your country.

1. Is the risk high that this will have a negative impact on professional hearing aid fitting in your country?
2. Are your local regulations ready to handle this risk? If so, can you give us more details?
3. What do you expect from AEA to support you in this challenge?
4. Do you have enough information on the FDA OTC-Hearing Aids draft proposed rule?

Can you send us this information as soon as possible? Thank you.

Austria:

Is the risk high that this will have a negative impact on professional hearing aid fitting in your country?

NO.

Probably not, as long as the social security system for hearing aid provision is not changed.
HAP/HCP is a recognized and regulated profession in Austria (see below).
Almost every person is covered by social security. And social security pays roughly € 800 for a monaural fitting and roughly € 1.500 for a binaural fitting with "standard" HI, including five years of service and repair. So why buy and pay for a hearing aid yourself?
Opportunities with OTC/PSAPs: we think that there are still many people who would need a hearing aid but are not fitted (maybe 40%?). Barriers: the path to the ENT, HAP, stigma, etc.
If clients with mild or moderate hearing loss and no additional diseases provide themselves with OTC or PSAPs (like iPods or Bose), these products could serve as appetizer and could have positive effects for a later classical provision: *clients are used to having something in their ear, *clients know the difference of hearing better with a device, *clients might realise that these devices are no longer sufficient.
Risks with OTC/PSAPs: negative would be if OTC and PSAPs are used where only a hearing aid would be indicated.

Are your local regulations ready to handle this risk? If so, can you give us more details?

YES.

As mentioned above, HAP/HCP is a recognized and by law regulated profession in Austria.
If the intended use of these products is medical - correction of hearing loss – the fitting is only allowed by a HAP/HCP.
If the intended use of these products is medical - correction of hearing loss - and no fitting is intended/possible, then they may also be sold by medical device traders.
Also medical device trader is a recognized and by law regulated profession in Austria.
As we understand, the FDA also sees the medical purpose (correction of hearing loss), so only to sell in Austria by HAP/HCP (and other medical device traders).

What do you expect from AEA to support you in this challenge?

We need an European awareness campaign to bring the understanding of differences between OTC/PSAPs and classical (fitted) hearing aids to the population!
If OTC should also come to Europe, we propose a European regulation for safe use:
OTC should have a maximum OSPL90 output level of 105 dBSPL as a general rule, contrary to the 115 dBSPL FDA proposal.
However, for OTC with input-controlled compression and a user-adjustable volume setting, we propose a limit of 110 dB SPL, contrary to the 120 dBSPL FDA proposal.

Further the suggestion not to use these devices more than 8 hours a day. Possibly, the maximum output power could also be further reduced automatically after 8 hours of wearing time per day.

Do you have enough information on the FDA OTC-Hearing Aids draft proposed rule?

YES.

Please keep the flow of information about FDA OTC-Hearing Aids draft proposed rule!

Belgium:

Is the risk high that this will have a negative impact on professional hearing aid fitting in your country?

We don't think so. So far, PSAPs haven't had any success in Belgium and due our regulations stating that "*hearing aids can only be delivered by a regulated hearing aid professional*" , we managed to stop publicity and the distribution of these devices in supermarkets and even pharmacies.

Further, in Belgium, if you meet the criteria (40 dBHL average hearing loss or a 3 dBSNR loss for people younger than 65 years), you can already obtain a hearing aid including the professionals services and follow up for at least 5 years, by a Hearing Aid Professionals from a starting price of €37, the rest is paid by the social security.

But you never know. Regulations can change, so we need to stay attentive.

Are your local regulations ready to handle this risk? If so, can you give us more details?

Our regulations stating that "*hearing aids, defined as (google translate from Dutch: a hearing aid in our Belgian regulation) "any device intended to receive, amplify, process and adapt acoustic signals in such a way that people with hearing impairment can receive the information they contain within the limits of their perception and tolerance capacity", can only be delivered by a regulated hearing aid professional*" , we managed to stop publicity and the distribution of these devices in supermarkets and even pharmacies.

What do you expect from AEA to support you in this challenge?

Exchanging with all our AEA member associations on this point is essential. See and learn what works in other countries, and joining forces to inform each other and influence policy making and regulations.

Do you have enough information on the FDA OTC-Hearing Aids draft proposed rule?

There is a lot of fake news and incorrect information on OTC-hearing aids. Our local associations need to be very well informed and prepared.

France:

Is the risk high that this will have a negative impact on professional hearing aid fitting in your country?

The French Ministry of Health has just made public a 388-page long report with its annexes, entitled "Assessment of the auditory sector" and carried out by the Inspectors of Social Affairs (IGAS) and the Ministry of Higher Education.

It can be downloaded here: https://igas.gouv.fr/spip.php?article843

OTCs are mentioned only once in the report's conclusion: "the development of over-the-counter (OTC) sales which is being set up on a large scale in the United States and which could, come day, inspire some of our European neighbours".

This sentence confirms the impression of the SDA. A priori, there is no short-term danger for two reasons:

1. "Listening assistants", basic OTCs, were authorized for sale in pharmacies in 2014 and, two years later, pharmacists themselves confirmed that it did not work without personalized follow-up...
2. It was then that the public authorities reassessed the reimbursement. This is a success claimed by the Ministry.

So, unless there is a successful deployment in another European country, there does not seem to be any short-term concern in France.

For other countries, to avoid OTC they can rely in particular on the excellent Lancet article that we also quoted in our press release of January 25:
https://www.sdaudio.org/doc/CP_SDA_Rapports_IGAS-IGESR_HCFiPS-25.01.2022.pdf

Are your local regulations ready to handle this risk? If so, can you give us more details?

The implementation of 100% health with reimbursed hearing aids does not leave room for OTCs in France at present.

Members of the National Federation of French Mutual Funds (FNMF) reimburse more than half of audio expenses (the rest is reimbursed by health insurance and by insurers for a small part).
Here is what the FNMF wrote recently on the subject:

New ways of selling hearing aids: “over the counter”, via the internet
The practice of the Hearing Aid Professional consists in ensuring "the choice, the adaptation, the delivery, the immediate and permanent control of the effectiveness of the hearing aid and the prosthetic education of the hearing impaired hearing aid".
This practice can only take place in the room reserved for this purpose and arranged according to the conditions set by L. 4361-6, D. 4361-19 and D. 4361-20 of the Public Health Code (art. 13 of the new agreement of
hearing aid professionals).
In addition, the delivery of a hearing aid and its reimbursement by Health Insurance and by the OCAM are subject to medical prescription. The efficiency of the device for a hearing impaired person is conditioned by the choice of a device adapted to the patient's hearing correction needs and expectations.

The purchase of a device over the counter (OTC) or on the internet would therefore prevent the patient from benefiting from a personalized device adapted to his hearing loss.

It seems to us that the public authorities are on the same line.

What do you expect from AEA to support you in this challenge?
Not applicable

Do you have enough information on the FDA OTC-Hearing Aids draft proposed rule?
Not applicable

Germany:
Question1: Is the risk high that this will have a negative impact on professional hearing aid fitting in your country?
Answer 1: No risk

Question 2: Are your local regulations ready to handle this risk? If so, can you give us more details?
Answer 2: According to the German Handicraft Law, the dispensing and fitting of hearing aids is only permitted to hearing aid acousticians. The German MDR also provides exclusively for the hearing care professional as the profession legitimised for this purpose.

Question 3: What do you expect from AEA to support you in this challenge?
Answer 3: Medical/professional argumentation

Question 4: Do you have enough information on the FDA OTC-Hearing Aids draft proposed rule?
Answer 4: Yes

Greece:

1. Is the risk high that this will have a negative impact on professional hearing aid fitting in your country?
In Greece the number of OTC hearing aids - PSAP is still high and cause confusión to the hearing impaired persons and therefore affect the market having a negative impact on the professional fitting Most of them are sold through arvertistmets and unauthorize shops despite the activities of our association with legal action in many causes as well
2. Are your local regulations ready to handle this risk? If so, can you give us more details?
There is no any legal regulation to handle this risk since our profession is not recognized by the Greek State
The only ‘’positive” fact is that these products are not approved by the Social Security Organization and sold only in the free market

3. What do you expect from AEA to support you in this challenge?
We expect from AEA, the influence on the legal framework of OTC/PSAP devices in EU and also all the communication information forward to the Ministries of Health and Commerce
4. Do you have enough information on the FDA OTC-Hearing Aids draft proposed rule?

Up to the point yes we do, but a collection of the official documents and articles indicating also the high risk of using these devices will be very useful

Italy:

Is the risk high that this will have a negative impact on professional hearing aid fitting in your country?

In Italy, PSAP’s are available on the market for approx. fifteen years. They are not, obviously, fitted by a hearing care professional, and are sold mainly via web (a small portion of them are sold in pharmacies). As long as they are not sold as “apparecchi acustici” or “protesi acustiche” (the proper names of the hearing aids in Italian) their sell is perfectly legitimate out of any healthcare path. For this reason, their negative impact should have already been felt and measurable: as far as we know, PSAP’s are not damaging our branch in an extremely worrying way, but it has to be said, also, that we FIA ANA ANAP have always taken this issue into very serious account whenever it could become dangerous (we initiated, in the past, various legal actions against any incorrect sale of such products).

To come to OTC’s, as proposed by FDA, it would surely have a bad impact on our branch if a law as such would be published in Italy since they could be named “hearing aids”, they could be sold to hearing impaired people and, in general, they will be just as traditional hearing aids without… hearing care. Anyway, it would be a huge revolution that, honestly, we don’t think could be likely in the near future (our profession is well recognized, hearing aids are reimbursed by the National Healthcare System, etc…)

Are your local regulations ready to handle this risk? If so, can you give us more details?

Our local legislation links tightly hearing aids and hearing care professionals: such devices must be fitted by a “Tecnico Audioprotesista”, a recognized profession (recently part of the National Register of Healthcare Professions, created in 2018) that, in order to be exercised, requires a Degree in

“Tecniche Audioprotesiche”. As regards PSAP’s in particular, there is no specific legislation. Anyway, they are class I medical devices not meant for long-term use, and so not suited for hearing impaired people (MDR 2017/745): this is a natural impediment to a reckless sale of such products.

What do you expect from AEA to support you in this challenge?

As Italian association, we think the support must be mutual: FIA ANA ANAP can support AEA in any action it will undertake in the interest of the patients/clients and of our profession. As for our expectations, we think the best way to handle this issue is to clearly state the nature of the hearing impaired person (whether named patient or client) and of the hearing care he needs to overcome his/her problems. Briefly, the concept is that all hearing impaired persons (and not just a bunch of them on the basis of a do-it-yourself evaluation of their hearing loss) must undertake a healthcare path not only in order to compensate his/her hearing loss but, maybe more important, to be correctly evaluated before any action.

Do you have enough information on the FDA OTC-Hearing Aids draft proposed rule?

Yes, we already handled this topic when the FDA proposal was published last October.

Luxemburg:

Is the risk high that this will have a negative impact on professional hearing aid fitting in your country?

Yes if it is allowed, it will kill the actual business plans.
It will disturb also the PHI Concept

Are your local regulations ready to handle this risk? If so, can you give us more details?

We are not ready, those items are not "yet" on the Luxembourg market. we have to plan this project.
Commercial regulation base: there is a big risk, because we don't have any rules, neither for hearing devices. We just have a regulation based on people certification, but not on devices.
PHI regulation base: we are up to date protected by the B3 files (homologation)

What do you expect from AEA to support you in this challenge?

We will need support (regulation lines from other countries)

Do you have enough information on the FDA OTC-Hearing Aids draft proposed rule?

Definitively not.

Malta:

• Is the risk high that this will have a negative impact on professional hearing aid fitting in your country?

It could have an impact depending on who sells the devices however the cost will definitely impact sales of hearing aids considering the price.

• Are your local regulations ready to handle this risk? If so, can you give us more details?

Not really they cannot even handle controlling people who are not registered from continuing to practice

• What do you expect from AEA to support you in this challenge?

Need a common way forward or stand.

• Do you have enough information on the FDA OTC-Hearing Aids draft proposed rule?
I had a read but not in depth
My personal opinion
OTC devices have advantages and disadvantages.
If OTC devices had to come in i would definitely revise my pricing and go for the unbundling model to push the value of the professional.

Portugal:

• Is the risk high that this will have a negative impact on professional hearing aid fitting in your country?

I Believe the risk is high. Hearing aids are expensive considering average income. Although funding through health insurance, health or social services is available for hearing aids, the bureaucracy involved and the time it takes is discouraging and may lead people to opt for OTCs. Also, the difference between HA and OTC may be difficult for people to fully understand and create an image that we are trying to sell the same thing but at a higher price.

• Are your local regulations ready to handle this risk? If so, can you give us more details?

I would say no. Even though in the regulations for MD a prescription from a "person authorized by national law" (which unfortunately was translated as "medical prescription"), HA are still sold without any prescription and there is no national institute that takes responsibility for monitoring the MD market. I do not predict any difference for OTC if they are considered MD. If they are not, I believe there will be no control.

• What do you expect from AEA to support you in this challenge?

Position statement on regulation in Europe.
Recommendation for hearing care professionals on how to manage OTC

• Do you have enough information on the FDA OTC-Hearing Aids draft proposed rule?

No, need more information on US regulation and any studies, position statements, etc relevant.

Romania:

Here in Romania we are right now on the 5th wave of COVID and personally I didn't managed to read a lot about new OTC-hearing aids rules.
1) As you already know PSAPs are a part of the market here in Romania and I don't think they will impact professional hearing aid fitting more than they are already doing.
2) I'm not sure if the regulations are ready to handle the risk since it takes a lot of time to adopt new rules here.
3) AEA could support us with more information regarding this and good case practices.
4) We do not have enough information regarding FDA OTC-Hearing Aids draft, so if you could provide more information, I would be grateful.

Spain:

Is the risk high that this will have a negative impact on professional hearing aid fitting in your country?

Although Spain is a country with strong regulations in all sectors, it is also a country where it is easy for the rules to be disregarded and the courts have to be used very frequently.

After this comment, I think that Hearing Care Professionals need to be able to segment OTC users and hearing aid users. I think A.N.A. and A.E.A. we must contribute to help them with criteria for this segmentation.
Despite this, we believe that it's a controlled risk if we work from the services of professionals associated with hearing aids versus the specific sale of a product.

Are your local regulations ready to handle this risk? If so, can you give us more details?
If OTCs are classified as medical devices in Spain/Europe, it is easy to control because they must be dispensed by a hearing care professional and must be dispensed from a hearing care shop. But if the OTC is not classified as a medical device, then we will not be able to control the dispensing process of the product and we will only be left with the training of society and professionals and communication campaigns.

What do you expect from AEA to support you in this challenge?
Esperamos de AEA, la influencia en el marco legal de los OTC dentro de la UE

- We expect from AEA, the influence on the legal framework of OTC/PSAP in EU
- Support for professionals, in the dichotomy between fitting hearing aids with products and services versus simply selling the product in the two ways provided, without adjustments and with adjustments by the consumer
- Communication campaigns that help us spread these ideas in society.

Do you have enough information on the FDA OTC-Hearing Aids draft proposed rule?
Although they are published and available to users and professionals, I believe that we should have a documentary collection in AEA site, with documents and articles on this subject and others that affect us, available to the different countries.

Switzerland: Risk evaluation for OTC-hearing-aids
1. Question: Is the risk high that this will have a negative impact on professional hearing aid fitting in your country?
It can go both ways!
It may have a positive effect because some of those who would not see a professional could bye OTC and realize that amplification could help.
Another positive scenario could be that they find out that the OTC are not good enough for them and they decide to make an appointment with a professional.
It would be very negative, when those who buy such an OTC-device would be completely disappointed and conclude that hearing instruments in general are not worse the effort and money.
It would also be rather negative, when people buying an OTC-device are not happy with the solution but settle with it not knowing what professionally fitted hearing instruments could do for them
The worst case would be if people with a mild to moderate hearing loss would damage their hearing not knowing that an OTC-device can also harm your hearing when turned on to loud too often.

2. Question: Are your local regulations ready to handle this risk? If so, can you give us more details?
No – we just recently had a very constructive meeting with our federal office for metrology regarding rules and regulations around audiometry and audiometer calibration etc. They told us that they have not been aware of the ongoing development with the OTC instruments. The y thanked us for the input and promised to investigate that matter more closely in the future.

3. Question: What do you expect from AEA to support you in this challenge?
As we here in Switzerland are not yet a acknowledged health care profession, the only way to make sure that hearing impaired have to see professional hearing instrument and fitting specialist is by establishing contracts with the federal insurance companies. Sadly since 2011 this is not any longer

the case with the federal insurance for Invalidity and for the elderly. We are very happy, that we could renew such a contract with the federal insurance concerning professional and military accidents.
It would be highly appreciated if the AEA can provide us with Ideas and support on how to become an acknowledged health car profession in Switzerland. This would make sure that people with moderate to severe hearing loss an above have to see a professional hearing care or hearing instrument specialist.

4. Question: Do you have enough information on the FDA OTC-Hearing Aids draft proposed rule?
Yes – we were able to download the first proposal of the FDA. Now that the 90 days comment period is over, we are looking forward to the summery. We are also aware that BOSE as well as Starkey as two of the key players have both commented with quite detailed comments. It is not surprising that BOSE is in favour of more gain and output and that Starke is strictly for limiting the gain to 20dB and the max. Output to 110dB. The second interesting comment is on the labelling of the packaging and it's also clear that both companies want a explanation on how the FDA differentiates in between OTC-instruments and self-fitting OTC-Instruments.
For those who are not aware of this we propose the VLOGs of Cliff Olsen also known as Dr. Cliff AuD.
https://www.youtube.com/watch?v=mE79fSwTZPg&t=1092s

The Netherlands
Please find our reply regarding the Dutch view on the OTC issue underneath
- Is the risk high that this will have a negative impact on professional hearing aid fitting in your country?
In principle this is a development with a negative impact on quality of care and professional hearing aid fitting. At the moment this is not a significant part of the market.

- Are your local regulations ready to handle this risk? If so, can you give us more details?
We need a deeper assessment for this, however Dutch law makes a distinction between medical products on prescription, medical products that can be sold through drugstores without prescription and general OTC. It could be that PSAP's fall in the second category which would make it easier to distribute them.

- What do you expect from AEA to support you in this challenge?
Counter it as much as possible with cloes cooperation with members (as AEA is doing)

- Do you have enough information on the FDA OTC-Hearing Aids draft proposed rule?
A one pager with an overview would be welcome. , as well as facts, examples and figures that show actual and/or potential damage due to OTC PSAP's.

Poland:

1. Is the risk that high that this will have a negative impact on professional hearing aid fitting in your country?
In our opinion- yes. The OTC-hearing aids can have negative influence on the market in our country.

2. Are your local regulations ready to handle this risk? If so, can you give us more details?
In Poland there are no regulations what so ever. We do not have our profession regulated and also there are no regulations about this type of "hearing aids".

3. What do you expect from AEA to support you in this challenge?
Can AEA with the members prepare some regulation related to OTC-hearing aids?

4. Do you have enough information on the FDA OTC-hearing aids draft proposed rule? Could you send us this information as soon as possible? Thank you