19 July 2016: Hearing aids

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As part of its investigation on the hearing aids sector, the Autorité de la concurrence launches a public consultation on its mid-point assessment today.

The Autorité encourages the sector's players to express their opinion on the competition issues identified.

Interested actors are invited to submit their observations until 20 September.

> Version française

In brief

Having observed low level of use of hearing aids among the French population and the expensive costs of devices, the Autorité de la concurrence has decided, in February, to begin an investigation at its own initiative in order to evaluate the state of competition within the sector and to identify any obstacles to competition.

After having conducted around thirty hearings among manufacturers, patient associations, consumer protection associations, purchasing and listing offices, hearing aid providers, unions, ENTs, experts, and a field investigation carried out among sixty hearing aid centers in France, the Autorité de la concurrence publishes today a mid-point assessment to be submitted to public consultation. It encourages the sector's players to issue their opinion on issues identified by the Autorité, especially regarding the downstream market of dispensing, which notably deals with the sale of hearing aid coupled with the provision of accommodation and follow-up services for the patient, of possible price regulation, on numerus clausus and on care networks.

The Autorité calls on the sector's players (manufacturers, hearing aid providers, consumer associations, patient associations, trade associations...) to answer before 20 September to the 37 questions. Received contributions will provide more clarity to the Autorité in its analysis, for the purpose of its future recommendations to be issued in its final opinion by the end of the year.

High prices, low financial coverage and an under-equipped population

Several million of French people are suffering from hearing impairment. Only 2 out of 3 million people eligible to hearing aids are equipped. Their profile? A person suffering from medium to severe hearing impairment, in 80% of the cases binaural, aged 69 on average. It should be pointed out that untreated hearing impairment leads to numerous physical and behavioural problems, which bear significant human and financial costs.

If psychological deterrent still exists and revolves around the patient's fear of being stigmatised –deafness still being perceived in France as a disability that is hard to admit-, economic brakes can also explain this low level of use. The devices' cost is significant: 1500€ per ear on average. The National Health Provider's (Assurance Maladie) coverage of these expenses being too low (120€ per device for 785€ in Germany, 666 € in Belgium and 600€ in Italy), despite an additional reimbursement provided by the OCAM (complementary health insurance organisations), the remaining cost to be borne by the patient is important (around 1000€ per ear) knowing that most of the time both ears have to be equipped.

In spite of the high cost of hearing aids, demand, linked to the ageing of the population, has been strongly progressing over the last twenty years. Hearing aids sales have raised by 6.18% a year on average between 1994 and 2014 and by 8.98% in 2015. They represent a one-billion-euro market. Considering the demographic increase and the ageing of population –hearing impairment being naturally due to age- the sector's growth should remain constant in the future.

An oligopolistic upstream market however caracterised by a competitionbased innovation

Six manufacturers share 90% of the French market without any of them being in a dominant position. The three main suppliers Siyantos (Siemens, Audioservice and Biotone brands), Sonova (Phonak, Unitron, Hansaton) and William Demant (Oticon, Bernafon) hold 70% of market shares.

Although manufacturers' prices are close, from 250€ for the entry-level range to 450€ on average, it seems that competition is based on innovation. The releasing pace of new products is sustained (every 2 years) and investments in research and development (R&D) are important, around 5 to 12% of production costs. Considering the investments needed for the quick development of technology, the devices do not appear to be overpriced. Their price has in fact been reduced by 30% in ten years. Besides, net margins recorded by these companies, of around 5% to more than 15%, seem to validate the existence of a certain degree of competition.

Nonetheless, manufacturers tend to integrate themselves vertically by investing in retailing stores, such as William Demant which took over Audika in 2015 or Sonova which announced in 2016 its plan to acquire AudioNova. If vertical integration can induce positive effects (rationalization of distribution), it could also lead to foreclosure of a market. The manufacturer who would not have its retail network could see its access to clients restrained if integrated centers supplied themselves essentially from their own networks. In a similar way, independent hearing aid providers could have a restrained access to the devices' market if integrated suppliers refused to sell them at least favourable conditions.

If transactions of vertical integration are to be newly submitted to the Autorité, it will make sure that competition, upstream between manufacturers as well as downstream between retailers, remains sufficient.

An intermediate level which does not seem to significantly elevate the devices' costs

Intermediate structures consist of purchasing or listing offices (the Centrale des audioprothésistes, Luz Audio, Rev Audio, Audiocentrale, Dyapason). But their intervention is not mandatory, some hearing aid providers negotiating directly with manufacturers.

The cost in services from these intermediate actors is low since it represents on average 1.35% of the price including taxes, which represents in numerical value some twenty euros on a 1500€ device. The impact of the margin taken by purchasing or listing offices on the devices' cost appears to be minor.

Main issues have been identified on the downstream market

The downstream market is very fragmented since 3250 hearing aid providers share the market. The latter are divided in two types of stores: those specialized in audition such as Amplifon, Audika, Audition mutualiste, Audition Santé, Audition Conseil or Entendre and optical stores which have diversified by opening corners or dedicated centers (Audio 2000, Optical Center, Krys Audition, Afflelou). Taking this fragmentation into account, the market does not appear a priori subject to collusive or abusive behaviours.

Concerning the formation of a hearing aid's price taken one by one, the inspection shows that 66% of the value is created by hearing aid providers. This important share can be explained by the fact that hearing aid providers do not solely retail the goods but provide health services as well. Their activity cannot be compared to these of a merchant who buys products to sell them back while applying a margin. It is more to be compared to the activity of a nurse or of a masseur-physiotherapist for the share relating to the services linked to the device's sale, by providing long-term healthcare services to the patient. The price of a hearing aid reflects both the device's value and the time spent for related services, 12 to 15 hours on average spread onto 5 to 6 years.

If the retail's organisation induces a certain level of competition between actors, the Autorité has identified, during its pre-diagnosis, several issues linked particularly to legal or regulatory constraints which can prevent an optimal functioning of the market.

1 – Does the pairing of the device with follow-up services curb price reductions?

No matter which store is chosen by the patient, each of them practice the pairing of the device's purchase with follow-up services which are staggered on 5 to 6 years, of which the price is set in advance and the payment often immediate. If the Macron Law of 6 August 2015 provides that the price inquiry submitted to the patient must henceforth differentiate the price of purchase of the device and the price of accommodation and follow-up services, the reimbursement by social security is still based on the global price. The global fixed rate rate remains thus the only method for setting prices practiced by professionals.

This pairing has several downsides: it raises the immediate cost of the device and can lead patients who are more sensitive to the price to give up on equipping themselves. Moreover, considering that the payment is a fixed rate and concerns a period of 5 to 6 years (« prospective payments »), some patients pay for services they won't use in their entirety, for example if they pass away, if they move or if their audition center closes. Besides, some patients who need

less important follow-up pay the same price as those who need a more important one. But this mutualisation of costs holds its own advantages, patients being able to ignore ex ante the amount of following-up they are going to need.

An alternative would be to differentiate the device's purchase from the patient's follow-up services. It would have the advantage of enhancing price transparency by allowing the price estimate to play a real part and by enabling patients to set up competition between hearing aid providers on follow-up services. But such a division also presents several risks.

First of all, the one for the patient to pay a double margin if he were to use the services from different hearing aid providers for the equipping and the follow-up. Then, patients could be tempted to underestimate their follow-up needs and to limit it to a few sessions, affecting quality of the care. Finally, the end of pairing could also encourage hearing aid providers fearing that the follow-up would not be booked with them to raise the price of their devices or to encourage patients to go for the most expensive of them.

Besides, it is possible that reinforcing competition concerning the follow-up services won't be of any help in reducing the remaining cost to pay for the patients, reimbursement of hearing aids by the Assurance maladie still being very low. Question is whether to rethink a raise of reimbursement fees by the Assurance maladie providing that, for example, a ceiling price was set for entry-level range hearing aid devices.

Thus, the differentiation of device/services calls for a nuanced response and leads in particular to the following interrogations:

- What would be the optimal sale/accommodation combination of the device?
- In case of differentiation, what would be the appropriate payment for the follow-up: fee-for-service or fixed rate?
- What would be a reasonable remaining cost to be settled by patients sensitive to prices?
- To which level could these limited sale prices be set?

2 – Towards a price regulation?

To explain economic barriers to the market access and the foreclosure of a part of the population from prosthesis care, hearing aid providers and their trade organisations have insisted on the importance of the remaining price for patients, resulting from the low levels of reimbursement from the Assurance maladie, and have called for an improvement of coverage by mean of national solidarity.

If this option deserves to be explored, the raise in the reimbursement, in particular for entry and medium-level range hearing aids, legitimately leads to interrogations on price regulation practiced by hearing aid providers in order for the reduction of prices to benefit to the patients.

On this point, several approaches could be taken under consideration.

A first lead could concern hearing aids manufacturers. The Assurance maladie could issue a call for tenders for manufacturers which would allow to list them for the purpose of reimbursement of maximum prices. This option should be strengthened by a downstream control.

A second lead could concern the framing of the sale of hearing aids by hearing

aid providers. The Assurance maladie could offer to reimburse part of the ceiling rates offers, in particular for entry and medium-level range hearing aids: for example, a ceiling rate offer of follow-up comprising two visits a year on 4 or 5 years, paid and reimbursed every year.

Another lead could consist for the Assurance maladie in setting a ceiling reimboursement for the entire sale (device, accommodation, follow-up), in particular for entry and medium-price hearing aids, and to submit the standardised price estimate to prior validation before reimbursement.

On this basis, the Autorité notably raises the following questions:

- Providing that an improvement of the level of reimbursement by the Assurance maladie is undertaken, does a better framing of the prices by the latter, notably for entry and medium-level range prosthesis, seem desirable?
- If so, what framing modalities would appear to be the most efficient to you?

3- Is the numerus clausus legitimate or must it be raised?

The setting of quotas for the access to regulated health professions is a tool for regulating the health care supply. Supply creating demand, a framing can be necessary to avoid social expenses to go adrift. It also ensures students to benefit from a quality curriculum that befits the training capacity of the colleges.

However, free pricing for hearing aid providers, and the low level of reimbursement of hearing aids by the Assurance maladie (120€ per device) raise the issue of justifying such a quota in this case.

The fact remains that any reconsideration of the quota or of its raising would imply an increase of the present training capacity of hearing aid providers.

Public authorities have set for the first time a quota of 199 students allowed in freshmen year for the year 2015/2016 (they used to be less than 150).

Professional organisations deem this quota to be sufficient to answer the

foreseeable progression of hearing-impaired persons. On the contrary, consumers and patients associations, as well as and healthcare networks consider that the offer of hearing aid providers is too weak. The salaries (4500€ a month on average), higher than those of paramedical professions with an equivalent level of training (opticians, masseur-physiotherapist, nurses) and the tension on the employment market would tend to prove this lack of professionals.

An additional supply of professionals could have a positive effect on the retail market of hearing aids. On the one hand, by balancing the supply and demand of work, this measure could result into a downward revision of hearing aid providers' salaries and therefore of the cost of accommodation and follow-up services. On the other hand, it would allow new entrants who have recruitment issues to develop more easily and to stimulate the market's supply. Yet, a more dynamic competition should foster a decrease in prices. This reduction of the hearing aids' cost could then again induce the demand to be stronger, and favour the equipping of patients, notably those of them who are not equipped for financial reasons. To answer this rise of demand, a raise in the number of hearing aid providers appears necessary.

Nevertheless, students are believed to already have issues finding internships in hospital ENT wards, internships which are a core part of their training. This major difficulty is explained by the shortage of ENT doctors and specialised hospital wards.

Thus, the Autorité reflects on the necessity to raise the actual quota of students allowed to integrate the training curriculum. More widely, the Autorité asks itself if it is necessary to maintain a numerus clausus when the coverage of the Assurance maladie is weak.

On this basis, the Autorité asks the following questions:

- Is the numerus clausus justified in the hearing aids sector to regulate health care supply?
- If it is so, to which level must the student quota be set for the next five years to ensure a quality training?
- Is the raising of the quota likely to favour a virtuous circle regarding competition: increase of the service supply and decrease of prices? In the case that it does, what are the best conditions? In the event of a downward reconsideration of hearing aid providers' salaries, matching them with equivalent professions', what could be the impact on the price of hearing aids to the final consumer?

4- Should the development of health care networks be fostered?

Observing the insufficient financing of hearing aids by social security, complementary health insurance organisations (OCAM) have set since 2009 healthcare networks in order to better regulate health care expenses while improving support for insured persons as well as the level of their reimbursement. These healthcare networks rely on conventional agreements with health care professionals selected on candidacy.

The Autorité has always supported healthcare networks in their capacity to enhance competition. The beneficial effects of these networks' supply are indeed important for both affiliated health professionals (inflow of customers, visibility) and for adherent patients (lower price and better coverage, reestablishment of a certain symmetry of information in favour of the patient).

Still, some of the sector's players criticize the constitution of these networks arguing that the particularly low prices would impair the quality of services and that patients would give up on equipping themselves from affiliated hearing aid providers and go back to non-affiliated hearing aid providers. Nonetheless, some examples seem to show that professionals (VivaSon or Unisson networks, for

example) which rely on a more limited follow-up period and lower prices are believed to have high satisfaction rates.

In order to objectify these allegations, the Autorité raises the following questions:

- -Do impartial data exist that can support the allegations according to which time spent by affiliated hearing aid providers would not be adequate?
- -Would the price level of some networks be objectively incompatible with maintaining the quality of care?
- > The entirety of the questions raised by the Autorité are available on the public consultation document.
- > Answer should be sent by email by 20 September by clicking on this link.
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