After several months of investigation and a large public consultation, the Autorité de la concurrence releases the findings of its healthcare sector inquiry

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The medicinal product distribution sector is undergoing deep transformations. In order to maintain the high level of protection of public health guaranteed in France, by the good network and the quality of the pharmacy network, the Autorité issues proposals.

Their goal is to consolidate the pharmacist profession: pharmacists must have strengthened and diversified means to finance the development of their activity, to seize the opportunities offered by the digital technologies, and to be able to develop new missions (vaccination, advice on monitoring of treatments, telediagnosis and e-health ...).

Biomedical laboratories also need more flexibility to continue to modernize and enhance their effectiveness.

Finally, a greater variety of distribution modes of the optional medical prescription product, implemented in strict compliance with the pharmacist's monopoly, will offer patients an increased access to medicines.

In short

In November 2017, the Autorité de la concurrence decided at its own initiative to issue an opinion in order to lead an extensive investigation in the sector of medicinal products distribution and chemical pathology field. These sectors are particularly important to the French economy and are facing deep and rapid

evolutions: development of telemedicine driven by digital technologies and Artificial Intelligence, will of public authorities and of professionals to develop new missions for pharmacists, announce by the Government of an ambitious project to reorganize a care pathway in the city, development of online medical product sale led by Europe, reform of the chemical pathology field with successive amendments to the legislative framework and continuous innovations in the analytical techniques requiring regular investments.

These reasons led the Autorité to analyze the competitive dynamics of the sector. To this end, it relied on fifty hearings, associating actors and representatives of the profession, as well as the results of a successful large public consultation launched a few months ago (1600 pharmacists and nearly 900 biologists participed). The Autorité also received around fifteen comments from actors of this industry, deepening its reflection.

At the end of its investigation, the Autorité notes that the legislative and regulatory framework applying to pharmacists, biologists and intermediaries in the medicinal products distribution chain is excessively restrictive, on certain clearly identified points, of their modernization. Therefore, the Autorité issues in its opinion proposals to accompany the modernization of pharmacists and biomedical laboratories and thus, to enable them to seize all the available development opportunities. These recommendations take into account the legitimate public health requirements and observations made by healthcare professionals and public authorities, including the Ministry of Health.

MODERNIZING THE BUSINESS MODEL OF PHARMACISTS TO EASE THE FINANCING OF THEIR ACTIVITY AND GROWTH

For several years, pharmacies have been experiencing a relative erosion of their financial profitability. Several reasons can explain it. First of all, the sales revenue of pharmacies is largely based on their reimbursable medicine dispensing activity: it accounts for about 72% of the pharmacy's sales revenue on average. However, the will of public authorities to control health expenditure has led to a

relative fall in the price of medicines and thus affected the economic situation of some pharmacists. In addition, out of the pharmacy's monopoly, pharmacists are faced with increased competition notably from parapharmacies and mass retail, who have better purchasing costs and lower labor costs.

Therefore, the Autorité believes that the French pharmacies in order to proceed with the necessary modernization of its business and safeguard its model both by exploiting the opportunities offered by new technologies and the new missions entrusted by French law.

- **Easing the constraints on online medicinal product sale to allow French pharmacies to compete on a level playing field with European websites**

Although online sales have been authorized in France since the end of 2012, its very restrictive framework does not allow pharmacies - the only ones allowed to open a website - to develop and compete effectively with their European counterparts. The possibility of buying optional prescription medicinal product online is also unknown, as many patients are unaware that this method of purchasing medicinal products exists in France and complies with the legal framework.

The choice of a very restrictive French model, especially on the communication methods around the website's activity, leads to an underdevelopment of the online sales of medicines in France, compared to the situation in neighboring countries (Germany, Belgium): 1% of non-prescription medicines are sold online in France, compared to 14% in Germany for example. The online sales websites, and particularly the Belgian sites, take advantage of the rigid French framework to significantly expand their business with French patients, while the sites of pharmacies operating in France are restrained by multiple constraints that the more than legitimate protection of public health, does not always justify.

Thus, French pharmacies are allowed to have storage rooms only if they are close to the pharmacy, which constitutes a considerable financial and logistic constraint. They must comply with very strict rules to communicate on their websites (constraints on the character font size used on the site, forbidden

website referencing...).

Moreover, the regulation does not provide pharmacies the possibility to consolidate their offer of online medicinal products sale within a common website and thus to mutualize their resources. Finally, pharmacies, unlike parapharmacies, must recruit a deputy pharmacist for each new turnover range of € 1.3 million, even though the sales would not relate to medicinal products but to cosmetics, hygiene or parapharmacy products.

The Autorité therefore calls for a review of the regulations to define a new balance, more favorable to the development of online sales of medicines business. To this end it proposes:

- to allow pharmacies to have storage facilities further away from the pharmacy, if necessary, so that they have the necessary space to efficiently develop their online medicinal product sales;
- to allow pharmacists to consolidate, if they wish to, their offer via a common website, which will allow more pharmacies to access this activity and will make possible efficiency gains;
- to review the rule of recruiting deputy pharmacists, so that the rule is based on the sole criterion of medicinal product sales made by the pharmacy, thus excluding sales of parapharmacy products (parapharmacy, hygiene, cosmetics)

- **Enable the effective development of the new missions that have been entrusted to pharmacists by public authorities, which are struggling to materialize, when they will make it possible to sustain the pharmacy model, while meeting the needs for strengthening the care network and access to health**

The French law "hospital, patients, health and territories" of 2009 has given pharmacists new missions. However, these provisions have long remained unheeded, for lack of support for these new missions by a suitable framework. These new missions are slowly starting to take hold, as exemplified by the

successful testing of influenza vaccination by pharmacists.

The Autorité has identified a certain number of blockages that have severely limited the concrete development of these new missions, even though they respond to clearly identified needs (eg to ensure a better immunization coverage, to promote a better treatment of patients, develop new telediagnostic services ...).

The Autorité therefore invites public authorities to remove the identified blockages (linked, for example, to the lack of pricing of some of the new missions or the need for a specific framework). It encourages, moreover, a broader reflection on the development of new complementary missions that could further enrich the role of pharmacists, while responding to issues identified for the network of care. These developments could allow the pharmacy to move towards a role of "clinical pharmacy".

- Completing the supervision of new pharmacy missions to ensure their effective development by removing the identified barriers.
- Inviting public authorities to examine the extension of the benefit of pharmacists of these new missions which could for example include:

- the testing for non-communicable or infectious diseases;
- the delivery, with supervision, of certain medicinal products subject to medical prescription for benign pathologies, in an emergency or preventive situation which does not require a medical diagnosis, etc.

Such a reform will require an in-depth debate and a legislative framework defining sufficient guarantees for the patient's interest, and aimed at improving the care pathway.

Such diversification, on which it will be for the legislator to decide, will strengthen both the competitiveness of the pharmacy and the access to care for the patient.

- **Clarifying and easing the advertising provisions to allow pharmacists to communicate on their parapharmacy offers and services**

Medicinal products are subject to specific rules of advertising aiming at guaranteeing the preservation of public health. The public health code (Code de la santé publique) therefore prohibits any advertising for prescription-only medical products (PMO) and regulates the optional medical prescription products (PMF). The Autorité does not proposes any modification of these rules, which respond to obvious justifications.

The Autorité notes, however, that the rules on pharmacies' advertising are much more restrictive than those imposed on their competitors, such as mass retail, as regards the sale of parapharmacy products without a public health ground justifying such a limitation. Some ethical provisions broad and poorly defined - such as "prohibiting the solicitation of customers by processes contrary to the dignity of the profession" – sometimes lead, in practice, to prohibit pharmacists to rely on some forms of advertising, including when it does not concern medicinal products but cosmetic or parapharmaceutical products, which do not present a risk to public health;

Thus, while inviting to maintain the principle of strictly regulating medicinal products' advertising, the Autorité issues several concrete proposals for revising the advertising applicable regulations by pharmacies, and in particular the pharmacists' code of ethics, with a two-fold objective:

- to ease the advertising of products other than medicinal products (parapharmacy, cosmetics);
- to ease the rules of advertising in favor of the pharmacy, in particular to allow pharmacists to better highlight the services offered to the patients.

- **Diversifying, with supervision, the possibilities of financing pharmacies to allow their development while guaranteeing public health and the independence of the pharmacist**

The legal framework applicable to capital ownership of French pharmacies strongly constrains their funding possibilities. Thus, a pharmacist can only own one pharmacy and can only hold minority stakes in a limited number of pharmacies.

In addition, some pharmacists find it difficult to fund their installation or development project, and are forced to resort to very expensive processes.

The consolidation of the pharmacy model and the development of new missions of the pharmacist as a health player (telemedicine, telediagnosis) require access to adapted funding sources. This is why, like other European countries that have already implemented this[1], the Autorité considers that France could explore the trail of a controlled opening of the capital of pharmacies, while ensuring the strict respect of the professional independence of the pharmacist.
To this end, the Autorité identifies several graduated scenarios for changing the regulations (from increasing the number of minority interests of pharmacists to opening up to outside investors). It accompanies these easing scenarios with a range of collateral to preserve public health (guarantees ensuring the independence of the pharmacist, supervision of the holding of voting rights, supervision of conflicts of interest).

- **Partially easing and strictly supervising the pharmacy monopoly to authorize the dispensing of medicinal products in parapharmacies and mass retail**

The public health code reserves the sale of medicinal products and some categories of products (certain medicinal plants, certain essential oils, etc.) to pharmacists only (pharmaceutical monopoly) and to pharmacies only (pharmacy monopoly). But for patients to benefit from some of the gains produced by the modernizing of the profession, a partial and strictly regulated ease could be considered.

Without calling into question the pharmaceutical monopoly, to which the Autorité is committed to the strict maintenance, it proposes a limited

diversification and strictly supervised of medicinal products distribution places in order to improve access to the concerned products and to provide greater competition for prices when it is allowed, to the benefit of the patient's purchasing power. This supervised diversification would thus complete the official network, without replacing it.

Such an easing would only cover a limited number of products and would exclude prescription-only medicines. Would only be concerned:

- Medicinal products with optional medical prescription (treatments for sore throats, colds, superficial wounds ...);
- in vitro diagnostic medical devices (HIV self-tests, blood glucose monitors, cholesterol tests, diagnostic tests for Lyme disease, etc.);
- certain medicinal plants (listed in the pharmacopoeia)
- some essential oils reserved until now for sale in pharmacies.

In order to guarantee the public health imperatives, a qualified pharmacist would obligatorily be present to deliver medicines and products and give advice on the whole range of opening hours of the sales point (on the model of reforms introduced in Italy and Portugal).

The sale of these products could only be done in a dedicated space, benefiting from a separate cash register.

Complementary requirements could be considered, such as the prohibition of sales targets or the setting up of a co-responsibility mechanism for the company manager and the employed pharmacist.

INTERMEDIARIES IN THE MEDICINAL PRODUCTS DISTRIBUTION CHAIN: REVIEWING THE BUSINESS MODEL OF WHOLESALE REDISTRIBUTORS, IN PARTICULAR THE BALANCE BETWEEN THEIR PUBLIC SERVICE MISSIONS AND THEIR METHOD OF REMUNERATION

Although intermediaries in the medicinal products distribution chain are required to order large volumes of medicinal products, the commercial conditions they obtain from laboratories often remain less advantageous than those obtained directly by the pharmacies, which yet order significantly less important volumes.

The development of these direct sales, between laboratories and pharmacies, and the generalization, for certain categories of medicines, of the retrocession of the margin originally allocated to wholesalers redistributors are likely to affect, in the long term, their economic sustainability if the wholesalers redistributors are not able to meet the cost of their public service obligations (which aim to ensure a continuous and homogeneous supply of the territory with medicines).

Like the Court of Auditors (Cour des comptes) and the General Inspectorate of Social Affairs (IGAS), the Autorité invites public authorities to re-examine the overall model of wholesaler redistributors, and in particular their remuneration conditions, which are now based only on the price of medicines, in order to be proportionate to their public service obligations. A remuneration according to the volumes distributed could thus be envisaged.

MEDICAL BIOLOGY: REVISING THE RULES ON CAPITAL DETENTION AND TERRITORIAL NETWORK

In regards to the private chemical pathology field, the work carried out by the Autorité shows that the successive changes in the framework for holding capital of laboratories have led to the functioning of this two-tier market. Indeed, the texts initially allowed a temporary opening of the capital of the biomedical laboratories of which some benefitted, before prohibiting soon after. Some laboratories have had the opportunity to restructure by external growth while others are no longer allowed to do what was allowed to their competitors, who were been able to acquire a "critical mass".

The legislative framework thus generates today a deep inequality between laboratories as to their ability to develop and appears both unjustified and ineffective.

The Autorité is therefore in favor of revising the conditions for capital ownership of these laboratories in order to put an end to such asymmetry and to allow all players in the sector to benefit from the same opportunities for external growth.

Moreover, the rules relating to the geographical location of laboratories or the regulation of their activity appear, in certain well-identified points, too heavy and costly for laboratories.

The Autorité therefore invites public authorities to check whether such rules are always justified by public health considerations or if, on the contrary, their revision must be initiated. It could thus be envisaged:

- to allow laboratories to extend their establishment over a larger area than at present (extension to the region);
- to authorize price discounts between laboratories or laboratories to hospitals.

[1] Of 33 countries on the European continent, 18 (or 55%), including Sweden, Norway, Italy, Belgium and the United Kingdom, have partially liberalized the access to capital to investors other than pharmacists.

> For more information, read the full text of the opinion 19-A-08 regarding the sector of medicinal products distribution and chemical pathology field

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