Sector Inquiry into the distribution of medicinal products

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After gathering market players' insight, and having carried out an in-depth analysis of how the sector operates,
the Autorité de la concurrence publishes its opinion. It calls for the stimulation of competition throughout the distribution chain, and in particular supports the supervised opening up of the retail distribution of medicinal products that are not reimbursed.

In February 2013, the Autorité de la concurrence took the initiative of launching a vast sector inquiry in order to examine the distribution of medicinal products for human use in private practices.

A number of factors have led the Autorité to study this area more closely, including the magnitude of the healthcare sector in the national economy, the decision-making practices of competition authorities worldwide and recent developments in the sector (innovation and a new direction in research towards biotechnology, the development of generic and biosimilar medicinal products, and particularly new challenges for dispensing chemists).

Following several months of consultation with all of the parties involved, it is today publishing an opinion (the full 168-page text is available on the website) in which it formulates a certain number of observations and proposals, forming part of a coherent process to stimulate competition in a heavily regulated business sector.

Far from calling for a complete overhaul of the distribution of medicinal products in private practices, which could harm public health policy, the Autorité de la concurrence is calling for the gradual and limited adaptation of the sector to

new types of sales, and to consumer expectations as regards pricing and services.

The opinion therefore proposes an overall and coherent framework for reflection for the parties involved in the relevant sector, as well as the public authorities responsible for these issues. The Autorité would like to instil a little more competition in the distribution in private practices of medicinal products for human use, in order to boost innovation upstream, to enable intermediaries to play a role of a counter purchasing power, and to give dispensing chemists the opportunity to become more robust players who are better equipped to deal with new competitors in the sector of medicinal products for self-medication. The stimulation of competition throughout the value chain should eventually benefit consumers of medicinal products, namely both the state health insurance fund and patients.

A fruitful public consultation and a changing legislative and regulatory context

The Autorité de la concurrence has carried out an initial phase of talks with all of the parties involved in the sector (pharmaceutical laboratories, wholesalers and importers, professional unions, administrations, French Council of Pharmacists and National Medical Council, consumer associations, and representatives of the supermarket distribution sector).

This initial phase was followed by the publication of a public consultation document (see the press release of 10 July 2013), which aroused considerable interest from the parties involved in the sector: in total there were 105 written contributions to enhance the reflection process of the Autorité de la concurrence.

In addition, the Autorité would like to highlight the fact that current events have played a part in the formulation of the opinion given that in 2013, the legislator and the public authorities favoured changes that moved towards proposals or guidance from the consultation document, including: the extension of the Register of generic products to include certain forms of paracetamol, the

supervision of rebates taking the form of 'disguised' back margins on generic medicinal products in the framework of the social security finance act [loi relative au financement de la sécurité sociale] (hereinafter called "LFSS") for 2014, the ministerial order of 20 June 2013 on good practice for the electronic dispensing of medicinal products, and also the authorisation of the sale of ovulation and pregnancy tests as well as cleaning and application products for contact lenses outside dispensing chemists, as set out by the consumer bill. The Autorité de la concurrence welcomes the fact that these changes, which are wholly positive for competition, have emerged at the time at which it has published its opinion.

SUPPORTING INNOVATION AND PROTECTING COMPETITION

The Autorité de la concurrence reiterates the need to ensure that the competition policy serves innovation and the production of value, particularly upstream in the sector. Indeed innovation is at the heart of competitiveness in the pharmaceutical industry, a sector which has undergone rapid development, including the obsolescence of a business model focusing on blockbusters, and a new direction in research and development towards in particular the treatment of rare diseases, as well as biotechnology, the outsourcing of research, and the boom in cooperation between laboratories. This movement should be supported as it is a powerful driver of progress, competition, competitiveness and employment.

Some fear that the intervention of the competition authorities in this business sector will unsettle the pharmaceutical laboratories, particularly those producing innovative originator medicinal products. The Autorité de la concurrence does not share this opinion. On the contrary, the Autorité believes that the stimulation of competition will promote the innovation and competitiveness of pharmaceutical companies.

More specifically, competition linked to the launching on the market of generic medicinal products leads to cost savings for the state health insurance fund, which, in a difficult budgetary context, releases resources to fund the most innovative medicinal products at a fair value.

- ***The rules on competition authorise, under certain conditions, laboratories to enter into cooperation agreements for research and development***

Competition law fully takes into account the dynamics of markets and innovation: European Commission regulation No. 1217/2010 of 14 December 2010 provides in particular a secure legal framework for pharmaceutical companies that choose to cooperate as regards innovation.

- ***Originator laboratories may legitimately defend their intellectual property rights together with the quality of their standard drugs, but they must refrain from abusing this right for the purposes of preventing generic medicinal products from entering the market***

The Autorité de la concurrence in no way contests the legitimacy of originator laboratories to defend the intellectual property rights that they hold for their medicinal products in court. Indeed, this is an essential right in order to uphold the results of research and to ensure innovation is maintained. However, proceedings should be brought against some laboratories which, in specific circumstances, have been able to abuse such a right for the sole purpose of preventing a generic medicinal product from entering the market and creating a certain type of competition. Indeed, this is an abuse of a dominant position.

Similarly, originator laboratories may legitimately defend the quality of their standard drugs when generics are introduced. However a small number of laboratories have confused defence and attack. The Autorité de la concurrence has therefore developed a decision-making practice against the disparagement of generics. By disparagement, it does not mean an objective defence of the qualities of the originator medicinal products or alerting the health authorities of true problems linked to the generic. It refers solely to the conveying of incorrect or unverified information on competing products for the sole purpose of harming their sales.

In this respect, it notes that disparagement practices against generics unfortunately have a certain resonance in France, and as the Plavix® decision[1] has demonstrated, this is undoubtedly linked to specific national factors including an insufficient knowledge of the pharmacopeia of medicinal products,

the misunderstanding by the parties involved in substitution and by pharmacists of complex legal rules, and even the irrational sensitivities of patients.
The opinion, which assesses the decision-making practice of European and American Authorities in cases related to laboratory practices, therefore proposes guidelines for companies in the pharmaceutical sector when carrying out their business activity.

- ***Measures to combat the disparagement of generics enable us not only to combat the deepening of the social security deficit, but also to indirectly defend the incentive to innovate***

Savings resulting from the sale of generic medicinal products (for which a price reduction of 60% is applied in comparison with the price of the originator medicinal product) are not solely aimed at reducing the social security deficit. They also enable new resources to be freed up, which are rare in a difficult budgetary context, to fund the most innovative medicinal products at a fair value .

The Economic Committee for Healthcare Products (Comité économique des produits de santé), aware of the need to preserve innovative companies, will be more inclined to award high prices to innovative medicinal products if the deficit of the state health insurance fund is contained. The withdrawal of "comfort" medicinal products from the reimbursement list and the development of generics are tools that can be used to achieve this. The disparagement of a generic therefore serves the very short-term interests of an originator laboratory, but, in the long term, it greatly hinders innovation for the whole medicinal products sector. If we combat the disparagement of generics therefore, we also indirectly defend the incentive to innovate.

- ***Inflated prices of some ranges of medicinal products***

in its public consultation document, the Autorité, highlighted the apparently inflated price of generic medicinal products through its observation of the existence of considerable 'disguised' rebates. The LFSS for 2014 revised the system of rebates granted on medicinal products, and imposed an obligation to declare rebate amounts to the Economic Committee for Healthcare Products – CEPS. Although these measures are likely to control the price of generics more

effectively, their true medium-term impact should be assessed.

For medicinal products that are not reimbursed, the Autorité deems that the strengthening of intermediaries' counter purchasing power for the distribution of medicinal products in private practices may enable greater rebates to be obtained, particularly on generics and medicinal products that are not reimbursed, which would also benefit all dispensing chemists as well as wholly or partially benefitting consumers.

> For further details, refer to pages 102 to 126 of the opinion

STRENGTHENING THE PURCHASING POWER OF INTERMEDIAIRES

The operation of the intermediary stage, characterised by the involvement of a host of very diverse parties, has been closely examined by the Autorité.

- Wholesale distributors and purchasing group networks (SRAs and pharmaceutical purchasing organisations - CAPs) should be able to fully occupy the role of a counter power in respect of the pharmaceutical laboratories, which is not currently the case

It is important that the wholesale stage is able to provide a base for a market counter power vis-à-vis suppliers (the pharmaceutical laboratories).

Under the current conditions of the distribution of medicinal products (including reimbursable medicinal products), the role of wholesale distributors seems necessary to ensure the regular and speedy provision of the dispensing chemist network, in the framework of public service obligations. However, the Autorité de la concurrence, noting the key role of wholesale distributors, emphasises the relative low level of their remuneration, largely due to the difficulties they encounter in distributing medicinal products for self-medication at competitive prices, given that the laboratories favour direct sales through the major dispensing chemists.

Moreover, the Autorité has also highlighted the inability of purchasing group networks (hereinafter called 'SRAs') and pharmaceutical purchasing

organisations (hereinafter called 'CAPs') to develop. SRAs and CAPs would promote group purchases by small and isolated pharmacies who do not benefit, in the area of medicinal products for self-medication, from the commercial advantages that laboratories grant to large dispensing chemists through direct sales. Any barriers to the development of these new networks should therefore be removed.

- Parallel imports may constitute a means for dispensing chemists to obtain the best prices, whether directly or indirectly

Importers of medicinal products which carry out parallel imports within the European Union can also contribute to the stimulation of competition, insofar as dispensing chemists can use the argument of lower prices that they obtain from importers in order to negotiate better commercial conditions from their usual suppliers. Importers of medicinal products must therefore continue to occupy their role as a driving force, while ensuring that such movements of medicinal products within Europe does not compromise the security of supply for the Member States, particularly France.

> *For further details, refer to pages 126 to 134 of the opinion*

ADAPTING AND CONSOLIDATING THE OPERATIONS OF THE LATTER STAGES OF THE MARKET

The retail sale of medicinal products, particularly self-medication, is currently undergoing major changes that are causing upheaval in the competitive landscape.

Firstly, the self-medication market is experiencing strong growth. In the light of medicinal products being withdrawn from the reimbursement list, patients are increasingly turning to self-medication. And yet when a medicinal product is removed from the reimbursement list, it moves from fixed pricing to free pricing. In this context, patients can legitimately demand a varied and more transparent range of products and services, competitive prices and new services.

Secondly, the authorisation of online sales of medicinal products and the

creation of new duties for pharmacists constitute real changes which offer dispensing chemists the opportunity to play a comprehensive role vis-à-vis competition, both in terms of pricing and the quality of service delivered to the patient.

In this context, the Autorité is convinced that maintaining the status quo is not an effective option, either for consumers or for dispensing chemists. Restrictions should therefore now be relaxed, and we must look at how the conditions for the distribution of medicinal products in private practices in France might be opened up.

The Autorité de la concurrence has noted the opposition of organisations representing dispensing chemists and of the Ministry of Social Affairs and Health to this reform. It has closely studied the arguments put forward, but most of them are not sufficiently convincing to postpone a reform that many other European countries have already implemented, with no adverse effects on public health.

> For further details, refer to pages 138 to 142 of the opinion

A restricted and supervised opening up of the distribution of medicinal products in private practices

The Autorité de la concurrence has noted that the intensity of competition between dispensing chemists is relatively low, as demonstrated by major differences in pricing (from 1 to 4) observed for medicinal products that are not reimbursed. This situation is unfavourable for consumers, especially as it involves a lack of information and publication of prices, thereby preventing them from making comparisons.

Following its public consultation, the Autorité de la concurrence is still in favour of the sale of medicinal products for self-medication and certain "borderline" products (such as pregnancy tests and cleaning products for contact lenses) in parapharmacies or supermarkets as well as pharmacies, as it is convinced, particularly in the light of foreign examples, that these types of stores, with their strong abilities to negotiate with suppliers, could offer benefits to consumers

both in terms of pricing and services.

However, such sales must be governed by strict rules to ensure the quality and safety of the sale of the medicinal product, including in particular the presence of a qualified pharmacist, the creation of a dedicated sales area and the obligation to provide advice. These measures will ensure that medicinal products do not become commoditised in new sales outlets.

> For further details, refer to pages 143 to 146 of the opinion

The Italian example

In relation to the various models existing in other countries, this restricted and supervised opening up corresponds to a "mixed" model, namely a middle road between the ultra-liberalised US/UK model and the heavily regulated French model. This is the model chosen by Italy in the 2000s, where medicinal products which have been liberalised must still be sold by a qualified pharmacist, whether in a pharmacy, parapharmacy or dedicated area of a supermarket. The dispensing chemist monopoly has been revised, while the pharmaceutical monopoly has been maintained.

The study of the impact on competition of generalising the distribution of medicinal products for self-medication in Italy shows that it has had a positive effect on pricing, without however affecting the economic sustainability of pharmacies:

-> In 2008, 87.6% of medicinal products for self-medication, the distribution of which had been liberalised in 2006, were still sold by dispensing chemists.
-> In 2008, according to the Italian competition authority, the average reduction of the retail price inclusive of tax observed in Italian supermarkets (compared to the maximum ex-tax manufacturer price) was 25% (reductions of between 20% and 30-35%).

However, opening up must be implemented while reinforcing the pharmacist's role in the healthcare system and consolidating their income sources

At the same time, the restricted and supervised opening up of medicinal product distribution should be teamed with measures that aim to consolidate the role and income of pharmacists, and give them the means to be dynamic and competitive in the self-medication sector.

- Firstly, support should be provided for increasing number of new duties performed by dispensing chemists so that they can strengthen their position as fully-fledged stakeholders in the healthcare sector. In addition to their crucial role in the structure of the national healthcare system, these new services offer pharmacists new income streams that will enable them to reduce their dependency on the sale of medicinal products.

- Secondly, the Autorité de la concurrence supports the online sale of medicinal products for self-medication, within the secure framework provided by the law. This new sales medium will drive competition in the sector, and will indeed improve the distribution service and generate lower prices. As the law states that only dispensing chemists can sell medicinal products online, they should use this new tool to boost their business activity. However, it is necessary to limit - as far as possible - the regulatory restrictions on the development of online sales.

- Thirdly, dispensing chemists must have unrestricted access to the commercial benefits gained from group purchases, in order to pass on all or part of these benefits to their clients, and to be in a position to compete with new market players. Therefore, legal group structures should be strengthened, not only such as pharmacist groups, but also SRAs and CAPs whose growth has been sluggish to the point that should the SRAs and CAPs fail, the legalisation of retrocession between dispensing chemists should be favoured, enabling some of them to benefit from commercial advantages granted by the laboratories.
- Finally, it seems necessary to relax some of the provisions on the publication of prices imposed on pharmacists in order to promote more transparent sales methods for the consumer.

[1] *Decision Nr 13-D-11 of 14 May 2013.*

> For further details, refer to pages 146 to 160 of the opinion

- Sheet Nr 1: Recommendations of the Autorité de la Concurrence
- Sheet Nr 2: The French and Healthcare
- Sheet Nr 3: Generic Medicinal Products
- Sheet Nr 4: Self-Medication Products
- Sheet Nr 5: The Prominent Pharmaceutical Laboratories in France
- Sheet Nr 6: A Very Dense Pharmaceutical Network
- Sheet Nr 7: The Medicinal Products Supply Chain
- Sheet Nr 8: The Price Setting of Medicinal Products
- Sheet Nr 9: Margins of Parties Involved in the Pharmaceutical Sector

> Consult the full text of Opinion Nr 13-A-24 of 19 December 2013 regarding the functioning of competition in the sector for the distribution of medicinal products for human use in private practices.