10 July 2013: Sector enquiry in the area of prescription medicine distribution in private practices

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The Autorité de la concurrence is submitting to public consultation an initial assessment in which it has identified several potential sticking points

> Version française

Medicinal products are the second-largest health-expenditure item in France, totalling around 35 billion euros in 2011, putting France fifth in the world in terms of average individual consumption. This is why, given the economic weight of this sector of activity, and acknowledging several contentious medicine-related issues as well as the increase in requests for opinions from public authorities on the development of the legislative and regulatory framework for the distribution of medicines, in February 2013 the Autorité de la concurrence decided to embark on a sector enquiry to investigate competitive operation within the sector and to identify any possible obstacles.

The Autorité would first note that in its decision-making practice in the area of healthcare, it wants to maintain competition in the sector, namely via innovation, but it is also mindful of patient safety and of preserving a good-quality medicine distribution system. Its approach in the area of healthcare therefore relies upon a balanced view, taking account of all these legitimate objectives.

Prior to adopting its final conclusions at the end of this year, the Autorité is today publishing an initial assessment that it is submitting to public consultation. The various interested parties will consequently have the opportunity to put forward

their observations and make new suggestions that will help to ensure that competition in this sector of activity develops favourably and benefits both the sector as a whole and consumers. This document sets out the details of the sticking points that the Autorité de la concurrence has detected at each level of the distribution chain and explores ways in which they could be remedied. The first phase of this sector enquiry seems to indicate that at least for generic medicinal products and medicines that cannot be reimbursed, strengthening of competition could lead to lower prices which would benefit both the state health-insurance fund and households.

1/CERTAIN PRACTICES BY PHARMACEUTICAL LABORATORIES ARE LIABLE TO CURB ANY DECREASE IN THE PRICE OF MEDICINAL PRODUCTS

1) Medicinal products that are reimbursed

Barriers to the development of generic medicinal products

The stimulation of competition with regard to reimbursed medicinal products is largely generated by generic medicinal products, direct competitors of originator medicines ; their entrance into the market has the direct effect of reducing the price of the medicine by around 60%. Generic medicines therefore need to be protected from various unilateral practices by the originator laboratories and concerted practices between the originator and generic laboratories.

These practices include, for example:

- denigration, a practice for which the Autorité recently issued a fine in its decision 13-D-11 of 14 May 2013 (Plavix case)
- the practices of withdrawal of clearance for the release into the market of originator medicinal products and the communication of erroneous information to patent offices with a view to preventing the entry of generic medicinal products (for which fines were imposed at a European level in the AstraZeneca case).
- “pay-for-delay” practices which, for a generic laboratory, consist of agreeing to

delay the entry of its generic product into the market in exchange for payment from the originator laboratory, for which fines were recently imposed by the European Commission in its decision of 17 June 2013 (Lundbeck).

Significant risks of anticompetitive agreements

-> through price negotiations with the *Comité économique des produits de santé* (Economic Committee for Healthcare Products – CEPS)

In its report, the Autorité highlights the risk that certain parameters for price negotiations with the CEPS could, at the top of the supply chain, be the subject of agreements between pharmaceutical laboratories. In particular, it is within the bounds of possibility that certain originator laboratories may reach agreement before going before the CEPS, for example by submitting artificially inflated costs so as to obtain higher prices on their medicinal products or to avoid too great reductions in price being applied to them within a single therapeutic class. Likewise, certain generic laboratories could, with a view to retaining a higher margin on certain proprietary medicines, be encouraged to coordinate their negotiation efforts so as, for example, to claim jointly very high manufacturing or development costs. The generic laboratories could furthermore share out the markets for certain proprietary medicines (by sharing out by Register group).

-> through not applying for marketing authorisation (AMM)

There may be a risk that generic laboratories would agree not to ask the ***Agence nationale de sécurité du médicament et des produits de santé*** (ANSM) to grant a generic status to their proprietary medicines and the latter will then not create a group in the Register. In such a case, the price of the proprietary medicines concerned will be negotiated individually by each laboratory with the CEPS, which could not apply the automatic discount of 60%. The prices of these medicinal products are therefore mechanically maintained at an artificially high level.

The Autorité also highlights the specific situation of paracetamol and acetylsalicylic acid, for which no group has yet been established within the

Register of generic products, even though the patents for these proprietary medicines passed into the public domain a long time ago. At this stage, no justification has been given to the Autorité to justify this state of affairs. Paracetamol is legally substituted everywhere in Europe, with the exception of France. This is no trivial matter, given that Doliprane® (a proprietary paracetamol manufactured by Sanofi-Aventis), was the fifth most reimbursed medicine in France in 2012, with the sum of reimbursement totalling 276 million euros.

2) Medicinal products that are not reimbursed

Over-the-counter medicinal products in France represent a third of household expenditure on medicinal products[1]. 4/5 of self-medication expenditure by French people, namely around 1.65 billion euros in 2011, was on medicinal products that cannot be reimbursed, and which are sold at free prices by dispensing chemists.

Direct sale in dispensing chemists: a means of maintaining higher margins for laboratories

Pharmaceutical laboratories that sell non-reimbursable medicinal products are largely biased towards the direct sales channel of dispensing chemists, with some of them going as far as refusing to sell to wholesalers and intermediaries. The larger chemists, which have more storage space and order greater volumes, enjoy discounts that can sometimes amount to as much as a 50% reduction in the pre-tax price.

This form of distribution does, however, raise a certain number of questions. It could be a means for the laboratory to keep its margins high and retain control of retail sale prices. In fact, were buyers and wholesalers also to benefit from advantageous conditions, they would be able to pass them on to all their customers, particularly smaller dispensing chemists that do not enjoy the commercial advantages linked to direct sale. Therefore, by refusing to grant more significant advantages to intermediaries, the laboratories are ensuring that the smaller chemists continue to pay a high price for these medicinal products.

Non-discriminatory distribution with regard to wholesale intermediaries could, therefore, lead to a reduction in the average price of numerous medicinal products for which there is no reimbursement.

The practice of disguised back margins: an indicator that prices are too high?

The Autorité has established that certain generic laboratories carry out tied selling of generic medicines and medicines that cannot be reimbursed. Specifically these 'disguised' rebates or back margins take the form of payment for commercial cooperation in relation to the generic laboratory's range of medicinal products for which there is no reimbursement. But in reality, these commercial cooperation agreements are only entered into on the condition that the chemist references this same laboratory's range of generic medicines. Furthermore, it is even possible that these commercial services may be completely fictitious, namely that the dispensing chemist does not fulfil the agreed service at all.

In addition to the fact that these tied-selling practices could, under certain circumstances, be classified as anticompetitive, this capacity of the generic laboratories to grant major levels of rebates could suggest that the price of generic medicines could be globally revised downwards by the CEPS, thus benefitting the state health-insurance fund and consumers. Nor can it be ruled out that these downwardly revised prices could also have an influence on the prices of originator medicinal products, when they are generic products for them.

2/ DISTRIBUTION AT THE WHOLESALE STAGE DOES NOT PLAY A SUFFICIENT ROLE IN STIMULATING COMPETITION

As regards medicinal products that are reimbursed, distribution at the wholesale stage is mainly performed by wholesale distributors. These play an instrumental role in the fast and regular supply to chemists across the whole territory. On this basis, they are fulfilling public service obligations that impose on them significant logistical constraints and sizeable investments.

The lack of purchasing power vis-à-vis the pharmaceutical laboratories

All medicine distribution intermediaries of to private practices suffer from a lack of compensatory purchasing power and consideration should therefore be given to strengthening this purchasing power, so that chemists and end users can benefit from the sizeable generalised reductions in the range of products that is not reimbursed.

In addition, the wholesale margin on reimbursed medicinal products is set by law at a principal rate of 6.68% on the pre-tax manufacturer's price. This rate is not, however, obligatory and it has been found that on generic medicine sales, their margin is virtually nil. As explained above, it is difficult for them to sell medicinal products for which there is no reimbursement as generally the laboratories choose a direct-sales channel which allows them to deal with the dispensing chemist directly without going through an intermediary.
In addition, the ways in which pharmacists group themselves together to buy medicinal products that are not reimbursed likewise do not manage to obtain equivalent conditions to those offered to certain dispensing chemists. On this matter, the Autorité finds that the practice of grouped purchases by a pharmacist leading to rebates, a practice which is in fact illegal, has developed with a view to offsetting the imbalance with the ***structures de regroupement à l'achat*** (purchasing grouping structures – SRA) and the ***centrales d'achat pharmaceutique*** (pharmaceutical purchasing organisations – CAP).

The development of parallel trade could lead to a reduction in prices

In addition to strengthening the involvement of wholesale distributors in medicinal products that are not reimbursed, the Autorité suggests considering opportunities for development of the parallel medicinal-product trade within the European Union. Indeed, wholesale distributors should be able to be supplied more easily from the pharmaceutical laboratories within Union Member States where the price of proprietary medicines is lowest, developing their competition activity and ensuring that the state health insurance fund and consumers benefit from it.

As a result, a reduction in the price of identical or similar products in France could be expected. At the same time, they should be in a position, subject to compliance with their obligations in terms of supplying national territory, to develop their sales to European Union Member States where medicinal products are more expensive.

3/ LIBERALISATION OF THE RETAIL DISTRIBUTION OF SELF-MEDICATION AND "BORDERLINE PRODUCTS" WOULD ALLOW CONSUMERS TO CHOOSE THEIR DISTRIBUTION CHANNEL FREELY AND ENJOY MORE COMPETITIVE PRICES

In France, the retail distribution of medicines is characterised by the double pharmaceutical/dispensing chemist's monopoly. In other words, all medicines and a certain number of products covered by the French Public Health Code can only be sold by a pharmacist (pharmaceutical monopoly) and exclusively in a dispensing chemist's (dispensing chemist's monopoly).

A deeply marked disparity between dispensing chemists in the prices of medicinal products that are not reimbursed and a lack of consumer information in this area

The public authorities have been trying for several years to develop stronger competition between pharmacists with regard to self-medication medicinal products, for which prices can be set freely. Since 2008, pharmacists have been encouraged to sell medicinal products known as "chemist's medication" over the counter. In the course of its enquiry[2], the Autorité has found that the prices for medicinal products that are not reimbursed are extremely disparate and may vary from one to four from one chemist's to another, without the consumer being properly informed since advertising for these medicinal product prices is very limited, notably due to ethical rules.

Very recently, the on-line sale of medicines subject to optional medical prescription has been authorised in France. This new means of selling should provide new opportunities in terms of lowering retail prices and providing consumers with information on prices. It is therefore necessary to be particularly vigilant in ensuring that the cyber-chemists can develop without artificial

obstacles being placed in their path.

Stimulation of competition, in particular with regard to price, and most particularly with regard to medicinal products that are not reimbursed, can include measures other than on-line sales.

The partial opening up of the dispensing chemist's monopoly would allow consumers to benefit from more attractive prices in their purchasing of medicinal products for self-medication and "borderline" products.

There are grounds, first of all, for considering the opportunity of partially opening up the dispensing chemist's monopoly, without calling into question the pharmaceutical monopoly, in order to allow distribution networks other than chemists to sell medicinal products subject to optional medical prescription known as "self-medication" (such as for example cold and cough and analgesic medicine) or products listed in Article L.4211-1 of the Public Health Code (such as for example contact lens care products, pregnancy and glucose tests).

This opening up should be accompanied by a relaxation of pharmacist's ethical rules as regards commercial freedom, in order to foster price-based competition. Some large-scale retailers have expressed their interest in distributing certain medicinal products in their stores, in dedicated spaces ran by pharmacists.

The study of the impact on competition of the liberalisation of the distribution of self-medication products in Italy shows that it had favourable repercussions on price. The UFC Que Choisir indicates in a report dated March 2012[3] that in Portugal and Italy, "*pharmacists' market share in self-medication products has remained high (around 90%) at the price of reduced margins in order to remain competitive*". Overall, the average decrease in prices recorded in Italian supermarkets was 25%, with prices in parapharmacies experiencing less of a price decrease.

This opening up of the sector of medicines that are not reimbursed with a view to lowering prices should also be very easily accepted by dispensing chemists

given that the share of medicines that are not reimbursed in a chemist's turnover remains limited (less than 10%) and where, under legal provisions on pharmacists' new roles, the latter may now offer paid services to their patients and, consequently, increase their income. In addition, the situation of small chemists could be globally improved if they too were offered good terms by bulk buyers and wholesalers on medicinal products that are not reimbursed.

See Background Notes in the Presskit (in French):

Background Note 1: The French and Healthcare
Background Note 2: Generic Medicinal Products
Background Note 3: Self-Medication Products
Background Note 4: The Prominent Pharmaceutical Laboratories in France
Background Note 5: A Very Dense Pharmaceutical Network
Background Note 6: The Medicinal Products Distribution Channel
Background Note 7: The Price Setting of Medicinal Products
Background Note 8: Questions Asked Within the Framework of the Public Consultation

(1) UFC Que Choisir, "Self-Medication: against bad diagnoses, UFC Que Choisir suggests its antidotes", March 2012.
(2) The Autorité de la concurrence did a survey of 177 chemists in Paris and certain other towns and cities in metropolitan France, in May 2013. The cities and towns in question are: Paris (75010, 75009, 75006, 75001, 75018, 75020, 75003, 75008, 75011, 75016), Evreux, Lille, Chartres, Orleans, Amiens, Le Mans, Drancy, Rouen, Reims, Saint Mandé, Vincennes and Boulogne Billancourt. This is a snapshot of the reality at a given moment, without any scientific claims. Within this framework, the Autorité de la concurrence made 2097 price records.
(3) UFC Que Choisir, "Self-Medication: against bad diagnoses, UFC Que Choisir suggests its antidotes", March 2012.

> The Autorité de la concurrence invites any interested party to react to the developments and conclusions laid out in this public consultation document before 16 September 2013: E-mail

> Full text of the document submitted for public consultation on the Autorité

***de la concurrence website** (in French)*

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