15 May 2013: On-line sales of medicinal products not subject to prescription

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Following a referral from the government, the Autorité de la concurrence has delivered an opinion that does not support the draft resolution on "good practice" in the dispensing of medicinal products by electronic means

> Version française

Following information that appeared in several newspapers, echoing the statements of pharmacists' unions with regard to the opinion it delivered on 10 April, the Autorité de la concurrence has today, in the interest of transparency, published the opinion that it delivered to the government on a draft resolution of the Minister of Social Affairs and Health regarding good practice in the dispensing of medicine by electronic means, made in application of Article L.5121-5 of the Public Health Code (amended by the Order of 19 December 2012), which states inter alia that *"dispensation, including online sales, of medicinal products must be done in accordance with good practices, the principles of which are defined by the ruling of the Minister of Health".*

Overall, the Autorité has delivered an unfavourable opinion on the draft resolution, on the basis that it contains a significant set of prohibitions and restrictions – and notably some particularly restrictive provisions on competition - , not justified by public health considerations, which aim to limit the development of on-line sales of medicinal products by French pharmacists, and indeed to dissuade the latter from using this sales channel. Furthermore, some

of these measures make sales on-line particularly unattractive to patients.

It would be regrettable to marginalise French pharmacies, by depriving them of new opportunities for development, while their competitors in other Member States would be benefitting from them, and even meeting French demand.

In this opinion, the Autorité sets out several recommendations as to how the text could be improved, some of which were already set out in its Opinion no.12-A-23 of 13 December 2012 *(see table below for the legislative and regulatory context).*

The extent of on-line sales must be expanded to all medicinal products not subject to prescription

The Autorité has reaffirmed its recommendation[1] that on-line sales should not be restricted to those medicinal products that are available in self-service counters, but should be expanded to cover all medicinal products that are not subject to prescription[2], including those that are not available in self-service counters, but delivered by the pharmacist (such as aspirins, paracetamol and cough medicine).

This regulatory limit would bring in an additional restriction in comparison with European law, which only makes a single distinction: medicinal products which are subject to prescription and those which are not.

Pharmacists should be able to offer medicinal products and parapharmaceutical products on the same Internet site

By prohibiting the creation of Internet sites offering both medicinal products not subject to prescription and cosmetic and hygiene products (also known as "parapharmacy"), the draft resolution would significantly limit the appeal of the sites created by French pharmacists for their customers. The latter would not be able to order products on a single site that they would, however, find in a single place at a pharmacy.

There appears even less justification for this restriction given that pharmacists'

sites in other Member States aimed at French customers would not be subject to this same separation requirement and could, therefore, offer a broad range of products that would be more attractive than that offered by French pharmacists. Belgian pharmacists' sites are already offering, from a single Internet site, medicinal and parapharmaceutical products which can be delivered to France.

The separation requirement would therefore put French pharmacists in an unfavourable position in comparison with their European competitors.

The obligatory alignment of Internet sales prices with pharmacist shop prices would be contrary to operators' freedom to establish their own commercial strategy

While the prices of most medicinal products not subject to prescription are not covered by any regulations, the draft resolution would severely limit the freedom of pharmacists to set prices, by obliging them to charge the same prices on the Internet and in their pharmacy and making it compulsory to invoice the customer for delivery costs "at cost price". This would lead to an increase in the price of medicinal products bought on the internet and then delivered, to the detriment of the consumer.

The Autorité points out that the free and full exercise of competition supposes that each operator independently establishes their own commercial strategy, and decides whether it is appropriate to offer uniform on-line and in-shop prices, or whether a policy of price differentiation seems more profitable.

Furthermore, online sales are a source of price competition, which must benefit the purchasing power of the consumer or patient, while allowing pharmacists to increase their sales. The Autorité therefore proposes that these provisions set out in the draft resolution are removed as they are too restrictive and would curb an activity that is only just emerging.

Other regulatory restrictions must also be lifted

Given that logistical organisation constitutes a determining factor in on-line sales

activities, the Autorité recommends that pharmacists should be able to set up specific premises which would allow them to deal efficiently with product orders placed via the Internet. The obligation to use the same storage premises for medicinal products sold in the pharmacy store and those sold on the Internet would constitute an artificial obstacle that would limit the development of on-line sales.

While on the whole justified on public health grounds, rules regarding health questionnaires may seem excessively restrictive. Indeed, once patients have registered on an on-line medicinal products site, and already filled out a health questionnaire, the obligation to fill out this questionnaire again each time they place a new order appears particularly tedious, such that it might deter customers from using French medicinal-product sales sites.

Reverse discrimination to the detriment of French pharmacists

The adoption of a draft resolution containing a set of particularly restrictive provisions, which cumulatively lead to the creation of an extremely restrictive and limiting framework, would restrict any commercial initiative in terms of price, ranges of new goods and services and deprive the patient/consumer of the advantages linked to e-sales.

Since operators in other European Union countries are obviously not subject to the "good practice" drawn up by the French Ministry of Social Affairs and Health, the set of restrictions in the draft resolution that are not justified by public health considerations, could consequently favour the development on the French market of sites located in other Member States (since they would be in a position to offer more attractive prices, ranges and services) and marginalise the Internet sites run by French pharmacies.

The future development of on-line sales activity must allow French pharmacists to grasp new opportunities, increase their sales figures and encourage the emergence of new ways of selling.

Lastly, excessive regulation of the activity of on-line sales of medicinal goods

could result in putting France into a position of non-compliance with European Union law *(see sections 108-110 of the opinion).*

Legislative and regulatory context: transposition of a European directive that authorises the on-line sale of medicinal products not subject to prescription throughout the Union

The order of 19 December 2012 (which amends Article L.5121-5 of the Public Health Code) and the decree of 31 December 2012[3] have transposed into the French Public Health Code the provisions of Directive 2011/62/EU of 8 June 2011. This directive aims to strengthen the whole supply chain, in order to avoid diversions. Its aim is also to harmonise national regimes on the on-line sale of medicinal products not subject to prescription.

The Directive, which should have been transposed by 2 January 2013 at the latest, requires Member States to allow distance selling of medicinal products to the public by means of electronic services (namely the Internet). Member States may however prohibit distance selling of medicinal products subject to prescription. The on-line sale of medicinal products not subject to prescription must consequently be authorised in all Member States.

The majority of European Union Member States have already authorised the on-line sale of medicinal products. For example, in Germany, Denmark, Finland, Sweden, The Netherlands and the UK, all medicinal products may be sold on-line, whether or not they are subject to prescription (and may also be sold by *pure players* in the latter two countries, namely by Internet sites not linked to a pharmacy). In other countries (such as Belgium, Greece, Ireland, Poland and Portugal), only the on-line sale of medicinal products not subject to prescription is authorised.

Certain Internet sites established outside of France have already started selling medicinal products to French residents.

(1) Recommendation made in Opinion no. 12-A-23 of 13 December 2012, but so far not followed by the Minister of Health in the new Article L. 5125-34 of the Public Health Code
(2) While allowing health authorities the possibility of prohibiting on-line sales of certain specifically designated medicinal products, on objective public health grounds
(3) The Autorité delivered an opinion to the government on these two texts, before they were adopted: Opinion no. 12-A-23 of 13 December 2012 regarding a draft order and a draft decree transposing Directive no. 2011/62/EU of the European Parliament and Council of 8 June 2011 amending Directive no. 2011/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products.

> Full text of Opinion no. 13-A-12 of 10 April 2013 on a draft resolution regarding good practice in the dispensation of medicinal products by electronic means (in French)

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