26 April 2016: Draft orders/on-line sales of medicinal products

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> Version française

In brief

The *Autorité de la concurrence* today publishes the opinion it has issued to the government[1] on two draft orders related to the on-line sales of medicinal products (good practices in the dispensing of medicine by electronic means and technical regulations applicable to e-commerce websites selling medicinal products on-line).

The *Autorité* has issued an unfavourable opinion on these draft bills, which contain provisions of a restrictive nature that had already been highlighted in previous opinions. Furthermore, **these draft bills introduce new provisions that create additionnal disproportionate constraints in terms of the aim of protecting public health**. In addition, they establish a discriminatory regime in comparison with the conditions required for over-the-counter sales, removing all interest in the sale medicinal products on the Internet, for both the patient and the pharmacists.

This mechanism seems aimed at restricting the scope of the already limited freedom granted under the ordinance of 19 December 2012 to French pharmacists wishing to establish an an on-line sales website and makes more onerous the regime established under the previous order of 20 June 2013, which only allowed very restricted development of on-line sales in France.

The *Autorité* reiterates its support for the wider use by dispensing chemists of this new form of sale, which would allow for revitalization, modernisation and greater visibility of their professional activity. At the same time, **patients would benefit from the greater flexibility of on-line sales (extended working hours, lower travel costs, etc.), lower prices and better information on prices**. The *Autorité* reiterates that while it is important to counter the risks that on-line sales can pose to patients if not carefully delimited, any restriction of competition must be justified by public health considerations that are proportionate to this objective.

CONTEXT

Directive 2011/62/EU of 8 June 2011 requires Member States to allow distance selling of medicinal products to the public by means of electronic services (namely the internet). The distance selling of medicinal products subject to prescription may however be prohibited if justified on the grounds of protection of public health.

This Directive was transposed into French law by Ordinance 2012-1427 of 19 December 2012, opening the way to on-line sales of medicinal products exclusively for non-prescription products. An initial draft bill regarding good practice for the electronic dispensing of medicinal products was submitted to the *Autorité* in 2013 for its opinion. In its opinion 13-A-12[1], the *Autorité* had identified a significant set of prohibitions and restrictions not justified by public health considerations. The *Autorité* had, therefore, issued numerous recommendations (see press release of 15 May 2013), which the government had only partially followed (order of 20 June 2013). In March 2015, the French State Council (Conseil d'Etat) finally annulled this order[2], on the basis that it contained regulations that exceeded the scope of authority granted to the Minister under Article L.5121-5 of the Public Health Code (code de la santé publique) and had not been notified to the European Commission.

THE ON-LINE SALES OF MEDICINAL PRODUCTS IN FRANCE

Since the publication of the order of 20 June 2013, development of on-line sales of medicinal products has remained very limited in France: of 22,401 dispensing pharmacists surveyed in 1 January 2015, only 301 had developed a website for on-line sales of medicinal products[3], namely a rate of only 1.34%, ten times lower than in Germany.
Furthermore, the rate of refusal of authorisation for the creation of sites for on-line sales of medicinal products is high. In 2013, of 259 applications, 80 were refused by regional health agencies (ARS - agences régionales de santé), namely a refusal rate of almost one third.

THE TWO NEW DRAFT ORDERS PERPETUATE A NUMBER OF RESTRICTIVE PROVISIONS ON WHICH THE *AUTORITÉ* HAS ALREADY EXPRESSED ITS VIEWS IN ITS OPINIONS 13-A-12 AND 13-A-24.

French websites are subject to a set of technical rules and good practice requirements that effectively prohibit them from carrying out a wide range of commercial practices linked to on-line sales, such as:
- free use, subject to respect of ethical rules, of tools such as hypertext links and newsletters;
- sub-contracting all or part of internet sales activity to a third party;
- pay-for referencing in search engines or on price comparison websites;
- promotion of their prices by advertising display.

In addition, the obligation to provide an information leaflet for the medicinal product concerned in PDF format, which increases wait time on the site (a factor in early abandonment of orders), and quantitative limits on delivery (not more than one month's treatment at the usual dose), do not seem suited to on-line sales.

Finally, internet pharmacies are also subject to two major financial and technical constraints:
- first, the obligation to factor on-line turnover into the application of rules regarding the number of assistant pharmacists who must be employed. This leads to an excessive burden in terms of the service's operating costs.
- secondly, the obligation for on-line chemists to prepare and store orders within their dispensary or in premises in the "immediate proximity" may become an insurmountable obstacle for a fast-growing website, which will soon require large premises for logistical purposes. It is difficult for pharmacies located in cities and towns to find such premises. This restriction does not appear to be justified by any public health imperative, because the presence of assistant pharmacists on the premises, assigned to the on-line sales activity, ensures the control, safety and quality of this means of dispensing.

IN ADDITION, THE ORDERS INTRODUCE ADDITIONNAL CONSTRAINTS THAT ARE HIGHLY DISSUASIVE FOR INTERNET PHARMACISTS

In comparison with the previous version, the new draft order regarding good practice for dispensing medicinal products by means of electronic services introduces a large number of formalities and constraints that are not imposed on "bricks and mortar" pharmacies.

Very exacting requirements in terms of pharmaceutical analysis

It was already a requirement for patients to fill out a full health questionnaire prior to making an initial order. The new draft bill now envisages that the pharmacist may have to request a great deal of information from the patient, some of which is covered by medical confidentiality. The information may include the results of biological analyses, disease history or a doctor's diagnosis. The order also "invites" internet pharmacists to draw up a "pharmaceutical intervention" for each order, namely a written report that sets out the basis and the details of the pharmaceutical analysis. Finally, for each new order of the same medicinal product, the pharmacist must collect information from the patient (i.e. whether there have been any undesirable effects) and assess the risk/benefit ratio of continuing the treatment.
The level of detail of the information to be requested from the patient does not seem relevant in terms, first, of the limit of on-line sales to solely non-prescription medicinal products, and secondly, the information usually requested in the context of over-the-counter sale of these products.

The implementation of a quality management system

The new draft provides a very detailed description of numerous formalities to be carried out in order to dispense medicinal products by electronic means. This level of requirement is comparable to the requirements that have to be met in order to obtain ISO 9001 certification. For example, internet pharmacists must establish a quality review system with a "periodic performance review of the quality management system", a "self-assessment of dispensing practices" as well as "external assessment" and "the implementation of quality indicators".
This set of formalities creates numerous administrative constraints and additional management costs, thus discriminating against this means of dispensation in comparison with over-the-counter sales, which are not subject to

"quality system" obligations.
These conditions seem even more restrictive given that they render licensed pharmacists liable: consequently, were legal action to be taken against them, they could be charged with not having done all they could to guarantee the quality of the dispensing of the medicinal product.

In any event, this set of obligations appears disproportionate. In fact, this "good practice" seems much more justified for medicinal products subject to prescription which are only sold over-the-counter at the pharmacy.

[1]Opinion 13-A-12 of 10 avril 2013 on a draft resolution regarding good practice in the dispensation of medicinal products by electronic means
[2]Décision of 16 march 2015 (n° 370072, 370721 et 370820)
[3]See the list as of 8 october 2015 available on the website www.medicaments.social-sante.gouv.fr

> Full text of Opinion 16-A-29 of 26 April regarding two draft orders on the dispensation of medicinal products by electronic means

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