20 July 2012: Distribution of medicinal products

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The *Autorité de la concurrence* issues an opinion on a draft decree relative to the supply of medicinal products for human use

It asks public authorities not to restrict parallel trade of medicinal products between EU Member States more than required to achieve the public health objective of the draft decree

> Version française

The *Autorité de la concurrence* has published today an opinion issued to the French Minister of social affairs and health on a draft decree relative to the supply of medicinal products for human use.

Preventing supply shortages of medicinal products

Article 47 of Law no. 2011-2012 of 29 December 2011 relative to the reinforcement of safety of medicinal and health products provides for a *Conseil d'Etat* decree (*Décret en Conseil d'Etat*). The decree introduces a set of measures to respond to supply shortages of medicinal products for human use. The French medicine distribution channel is regularly affected by problems that generate supply shortages, particularly of medicinal products regarded as essential for patients. Such shortages primarily affect the 22,500 pharmacies in France, insofar as the urban medicinal supply chain works constantly to a "tight flow".

Several factors cause the shortages

Shortages can arise as a result of the behaviour of various players in the distribution channel: pharmaceutical companies (quota systems, manufacturing problems and exports), wholesale distributors (who are bound by public service

obligations but may nonetheless export), and export wholesalers (*cf. pages 11 to 17 of the opinion for further details about the cause of shortages*).

Export wholesalers mainly procure their supplies from wholesale distributors. Although the latter must primarily fulfil a public service supply mission in France, they may also export their medicinal products, which can be economically advantageous for them (due to the potential difference between the regulated price in France and the non-controlled export price): this is known as "parallel export". It can contribute to supply shortages by taking medicinal products subject to quotas out of the national distribution system.

Recommendations of the Autorité: safeguard the public health objective without disproportionately restricting exports of medicinal products

The *Autorité* considers that the shortage management plan provided for by the decree, which only concerns medicinal products of major therapeutic interest[1], does not contain any difficulties with regard to competition law. It is fully justified by public health objectives and the need to supply the national territory with medicinal products of major therapeutic interest that are particularly important. Moreover, reinforcing the obligations incumbent upon wholesale distributors does not appear to raise any problems.

The draft decree also contains provisions seeking to restrict or effectively restricting parallel exports (in principle, any medicinal product as the current draft stands), particularly to avoid shortages occurring as a result of exports by wholesale distributors. In this respect, the draft decree stipulates that when a medicinal product cannot be delivered within 72 hours, it would be deemed in short supply and may no longer be exported. It further organizes a monitoring system, in which pharmaceutical companies play a key role, thus raising questions of neutrality.

The *Autorité* recalls that such provisions must be justified in principle and be proportionate in practice having regard to the public health objective pursued. Regarding the principles of competition law, particularly the Treaty on the Functioning of the European Union, provisions effectively preventing all exports (both direct and indirect) of medicinal products by wholesale distributors and

export wholesalers could be deemed disproportionate.

Relax conditions relative to parallel exports, so they are justified and proportionate to the public health objective

Accordingly, the *Autorité de la concurrence* proposes several adjustments to the decree with the aim of ensuring that it does not lead to unjustified restrictions on competition, while safeguarding the public health aim it pursues. In particular, the *Autorité* proposes:

- limiting restrictions on parallel exports solely to medicinal products of major therapeutic interest;
- relaxing the conditions governing the list of medicinal products in short supply and thus prohibited for export;
- restricting the obligations incumbent upon wholesale distributors to inform pharmaceutical companies of medicinal product exports.

Lastly, regarding the centralization of information about shortages, and particularly the mission assigned to emergency call centres[2], the *Autorité* recommends that this be fulfilled directly by the public authorities – which will pass on the information to the pharmaceutical companies –, rather than by the companies themselves. Out of concern for greater neutrality, the Autorité would like to see the central role of public authorities reinforced compared to that of pharmaceutical companies.

1I.e. medicinal products a shortage of which could be life-threatening for patients.
2Permanent emergency call centres are accessible to pharmacies and wholesale distributors and handle shortages of medicinal products of major therapeutic interest whenever necessary.

> Full text of Opinion 12-A-18 on a draft decree relative to the supply of medicinal products for human use

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