La Kanzlei

New restrictions for French mail order pharmacies

Wettbewerbsrecht
Vertragsrecht / AGB



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Stricter regulations concerning the mail order sale of pharmaceuticals weaken the competitiveness of French retailers compared to their European competitors

In November 2016, the French legislator issued two decrees that came into force at the beginning of February 2017 and change the legal framework for the mail order sale of pharmaceuticals. The European Court of Justice had already ruled in 20031 that pharmacists who lawfully carry out their activities in the member states of the European Union may offer prescription-free medicaments for online sale.

This principle was taken up and given legal form by the subsequently adopted Directive 2001/83/EC on the Community code relating to medicinal products for human purpose. The member states had to implement the directive into their national law by 2 January 2013. France, with its Decree No. 2012-1427 of December 19, 2012, created the legal framework for the mail order sale of medicines and established the conditions under which mail order sales were permitted.

However, as this regulation was incomplete and raised numerous detailed questions, two decrees (arrêtés) followed in November 2016, which have been in force since 1 February 2017 and which extensively regulate the rights and obligations of mail order pharmacies.

1 ECJ, judgment of 11 December 2003, German Pharmacists' Association (C-322/03). New restrictions for French mail order pharmacies.

Requirements for the sale of medicines by mail order

The decree of 28 November 2016 (NOR No. AFSP1633476A) specifies the requirements that "best practices" (bonnes pratiques) concerning the sale of medicines by mail order have to meet and thus supplements Art. L. 5121-5 of the French Public Health Code. The text begins by referring to the rules of conduct applicable to all French pharmacists. These include in particular the

verification of the prescription and the pharmaceutical advice related to it. The decree stipulates that for every €1,300,000 increase in annual turnover, an additional pharmacist must be employed.

The decree makes no distinction between established pharmacies and mail-order pharmacies. The French antitrust authority (Autorité de la Concurrence) had already criticised this regulation in the draft phase of the decree in its statement of 10 April 2013 (Avis No. 13-A-12), pointing out that mail-order pharmacies are limited to non-prescription drugs anyway and that the need for advice is therefore much lower compared to stationary pharmacies selling prescription drugs.

In addition, in its paragraph 7, the Decree provides, inter alia, for the following special rules for mail-order trade:

- Obligation to collect personal data on the purchaser and his state of health before the conclusion of the first order of each customer (in particular: age, weight, height, sex, current medication, allergies, contraindications, and if necessary the existence of a pregnancy);
- obligation to offer individual advice during the entire ordering process;
- limitation of order quantities per order taking into account the expected duration of taking the medication.

In the decree of 28 November 2016 (NOR no. AFSP1633477A), which came into force at the same time as the aforementioned decree, the French legislator specifies the technical requirements to be met by the operation of a mail-order pharmacy website in accordance with article L. 5125-39 of the Public Health Code.

In particular, it is now prohibited to provide discussion forums on the website and to use paid advertising services of search engines or price comparison portals when selling medicines online.

National discrimination Overall, the two decrees severely restrict the entrepreneurial freedom of mail-order pharmaceutical companies based in France compared to their European competitors. According to ECJ case law, pharmacies established in the EU may sell over-the-counter medicines and other over-the-counter pharmaceutical products to France via online shops aimed at French customers.

Due to the fact that each pharmacy is subject to the national regulations of its country of domicile with regard to its online presence, the strict French rules lead to discrimination against the French mail-order pharmacies, which are still relatively few in number anyway. Even though foreign mail-order pharmacies are only allowed to offer on the French market those medicines that are available without a prescription in France, large mail-order pharmacies, e.g. from Great Britain and Germany, which have more freedom in terms of their online design and presence and are subject to fewer formal restrictions, thus have a certain advantage over French mail-order pharmacies.

In the medium term this could lead to French suppliers being squeezed out of the French market. The question of the legality and constitutionality of the obligation of mail-order pharmacies to store their goods in the immediate vicinity ("proximité immédiate") of their establishment is currently being clarified in court. This poses logistical problems, especially for pharmacies in densely populated, urban areas, which must have large storage areas to expand and develop the mail order

business.

Despite recognition of the legality by the court of appeal before which the case was rose, the French antitrust authority declared the requirement of immediate proximity to be completely unsuitable in its opinion of 26 April 2016 (Avis 16-A-09), arguing that the obligation of proximity between a (mail-order) pharmacy and its warehouse for online sales cannot be founded on the requirements of the public interest. On the contrary, that obligation constitutes an obstacle to the development of pharmacies' activities in the French mail-order trade.

It remains to be seen how the French supreme administrative court, the "Conseil d'État", will decide this question. The current legal situation of French mail-order pharmacies and the associated restrained development of the French mail-order business for pharmaceuticals for human use offer opportunities for mail-order pharmacies from other European countries which are subject to less restrictive laws and can therefore better serve demand in the French market.

However, as it is to be expected that French suppliers will soon be able to defend themselves against their disadvantage, legislative corrections can be expected in the medium term.

2017-03-29

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