CAPSULAS
Boletín de información jurídica

Number 199 | Faus & Moliner Abogados | February 2019

Enforcement of competition law in the pharmaceutical sector. Second generation issues

The Report of the European Commission COM(2019)17, of 28 January, and the Press Release of the Spanish Competition Authority talk much about access and little about parallel trade

Access to medicinal products as primary concern

The enforcement of competition law to companies operating in the pharmaceutical sector has gained great importance in recent years. We observe a shift in the traditional approach of the Commission and national authorities. In the 80's, the time of the 'blockbusters', the main concern was assuring that companies did not establish artificial barriers to intra-community trade of medicinal products.

The Commission's major concern was that the efforts that were being made to build a single market were not frustrated by anti-competitive agreements. At that time, in Brussels, they had many difficulties understanding the licensing or co-marketing agreements; and the obsession to favor parallel trade was almost ridiculous.

Currently, these issues are still a trending topic; but both the Commission and the national authorities concentrate their efforts on pursuing behaviors that may endanger access by patients to medicinal products, especially to essential medicinal products.

Approach by the Commission and the national authorities

According to the Commission, since 2009, more than 100 cases have been investigated and 29 antitrust decisions have been taken against pharmaceutical companies, with fines totaling over 1,000 Million Euros.

Among the cases analyzed by the Commission, we would highlight the cases in which manufacturers of reference medicinal products intend to extend the commercial life of their products through illicit commercial strategies.

Sometimes these cases concern unilateral actions taken by the company holder the reference product, such as in case of disrepute practices to hinder market access of some generic medicinal products in relation to which the French authorities have been particularly active; or of companies that have abused regulatory procedures to hinder the market entrance of generic products.

There are other cases, such as the so-called 'pay for delay', in which the company that has developed a generic medicinal product agrees to restrict or delay its independent entrance to the market in exchange for benefits transferred from the originator.

Other anti-competitive practices that have been pursued by the competition authorities include boycotts by pharmacists to the products chosen by a particular company. We refer to the Dávur case in Spain, where the Spanish authorities found the existence of an infringement. Also, pursued anti-competitive practices include market sharing agreements. In Spain, action was taken against the agreements promoted by the Healthcare Service of Castilla-La Macha as they contemplated a market share between pharmacies for the supply of medicinal products to healthcare centers.

The Commission and the national authorities have also pursued cases in which they have understood that companies have abused their dominant position either by imposing excessive prices for their products; or by trying to exclude competitors from the market by means of offering predatory discounts in public tender procedures.

Specificities of the sector and relevant market

In the Report, the Commission highlights its interest in considering the specificities and competitive dynamics of the pharmaceutical sector, and there are some interesting ideas.

On the one hand, the Commission assumes the important role played by national administrations, which can have an impact on the application of competition rules. On this point, the Commission, acknowledges that national administrations are competent in all matters related to public funding of medicinal products.

On the other hand, about how to define the relevant market, the Commission considers the possibility that each molecule constitutes a market when the main competitive threat comes from generic versions of the same molecule. In this regard, we can interpret that the Commission supports the analysis of the demand substitution not only from the point of view of the prescriber but also from the point of view of the pharmacist. This is because both the prescriber and the pharmacist play very relevant roles in case of products having generic competition.

In case of hospital tenders, everything points to the fact that the relevant market must be defined in relation to the molecule, given that the need that the contracting authority must cover when calling a tender is the availability of medicinal products containing certain molecule to meet the physician's prescriptions.

The offers presented to hospitals, especially in cases of tying and multi-product discounts (bundling) must be carefully analyzed from this point of view.

Right to compensation for damages

To conclude, it is interesting to note that the Commission devotes a part of its Report to remember that the victims of anti-competitive behaviours have the right to claim damages according to Directive 2014/104/EU, on certain rules governing actions for damages under national law for infringements of the competition law provisions of the Member States and of the European Union.

In Spain, this Directive was incorporated into domestic law through Royal Decree-Law 9/2017.

In accordance with these rules, any person who suffers damages caused by an infringement of competition law, has the right to claim full compensation before the ordinary civil jurisdiction.

Full compensation is understood as returning the person who suffered the damage to the situation in which such person would have been if the infringement of competition law had not been committed. Also, the ones responsible for the infringement of competition law will be responsible in a joint and several manner.