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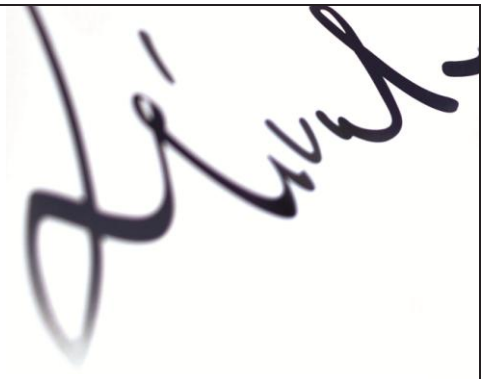
EU and Competition

June 15th 2016

EUROPEAN COMMISSION: PORTUGAL SHALL REMOVE THE RESTRICTIONS ON EXPORT OF MEDICINAL PRODUCTS

Recently, the European Commission rendered a reasoned opinion in an infringement procedure nr. 20144166 against Portugal, urging Portugal to amend the Medicines Act (*Decreto-Lei* nr. 176/2006, of August 30th) based on the argument that it created obstacles to the free movement of goods within the Union's single market (articles 34 to 36 of the TFEU). Failure to comply with a European Commission's reasoned opinion in such a procedure may lead the European Commission to refer Portugal to the EU Court of Justice (ECJ).

It should be recalled that the Medicines Act imposes public service obligations on wholesale distributors regarding the marketing supply, namely having a minimum amount in stock. It also imposes obligations on marketing authorization holders. However, that is not the issue. Recently, the Medicines Act was amended by Decreto-Lei nr. 128/2013, which henceforth stipulates that «INFARMED, I.P., may establish, by means of a Regulation: «(...) a list of medicinal products the export or distribution of which to other Member States of the European Union, and the respective quantities depend on prior notice by the wholesale distributor to INFARMED, I.P.» (article 100, nr. 2, subparagraph b)) (free translation). As a result, INFARMED, I.P. approved the



Regulation on prior notice of medicinal products transactions for outside the country (Resolution nr. 022/CD/2014 of INFARMED, I.P. Governing Board, subsequently amended and republished by Resolution nr. 1157/2015, of June 22nd), containing a list of those medicinal products, which has been successively updated (last amended by Resolution nr. 661/2016, of March 26th, published in the Official Gazette, 2nd Series, on April 13th 2016).

According to article 100(3) of the Medicines Act that notice shall occur within a period of **5 to 20 days in advance**, allowing INFARMED, I.P. to decide within a period of three working days, on the prohibition of the export or distribution notified or on part of it, based on public health protection or on the right of patients to have access to such medicinal products, in light of the principles of necessity, adequacy and proportionality.

For the European Commission, this obligation of prior notice of exports of medicinal products to other Member States of the European Union constitutes an obstacle to the free movement of goods and, in particular, a measure of equivalent effect to a quantitative restriction on exports of medicinal products. In order to actuate the procedure and its development, the Commission further considered it as disproportionate and not justified in light of both imperative reasons of general interest recognized in the jurisprudence of the European Court of Justice and article 36 of the Treaty.

In the European Commission's opinion, Portugal shall consider the application of restrictive measures concerning intra-EU trade. In the words of the Commission, «*Parallel imports and exports of a medicinal product is a lawful form of trade within the single market*»; however, «*these notification procedures do not set out clear and transparent criteria for determining the*



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medicinal products that may be at risk of a potential shortage due to parallel trade. Furthermore, the procedures impose disproportionate reporting obligations on wholesalers».

Even though Member States have some range to determine which public health reasons justify restriction measures on the movement of goods, it does not follow that they have the right to establish any such measures that do not comply with the principle of proportionality, and that are not absolutely necessary to achieve the legitimate goals pursued, even though they are presented as (legal or *de facto*) non discriminatory. All provisions contrary to European Union law must remain unapplied by the Administration and national courts and their inapplicability does not depend on any condemnation of the State in an infringement procedure. The Medicines Act has not been altered yet to accommodate the Commission's reasoned opinion. However, there is also no news of an infringement procedure against Portugal having been initiated.

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