

NEW OBLIGATIONS IMPOSED ON PHARMACEUTICAL COMPANIES: THE BEST WAY TO ENSURE SAFE MEDICINE SUPPLY?

A recent amendment to the Medicines Act imposed new obligations on marketing authorization holders to ensure the safe supply of medicines in Hungary. In parallel, the power of the Hungarian medicine agency (GYEMSZI-OGYI) to investigate potential breaches has also been significantly increased.



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Marketing authorization holders (MAHs) have been required to notify GYEMSZI-OGYI if they do not wish to further distribute their products in Hungary or if they cannot ensure the continued supply of their products, which may be detrimental to patients' health or quality of life (product shortage). The amended Medicines Act, which entered into force on July 6, 2013, imposes new obligations on pharmaceutical companies in addition to the above-mentioned notification obligation.

GENERAL SUPPLY OBLIGATION

The amended Medicines Act imposes a general obligation on MAHs to supply wholesalers with their products if the wholesaler claims that the medicinal product ordered is needed to satisfy local patient demand. Wholesalers purchasing products under this provision may only sell the products to Hungarian healthcare service providers (including pharmacies) and cannot export them through wholesale trade. Additionally, wholesalers are required to keep records of the medicinal products purchased under this provision.

It is obvious that the above provision restricts one of the key elements of the freedom to contract principle (i.e. the freedom of persons to enter into contracts), as it obliges MAHs to enter into contracts with distributors simply on the basis of the distributor's claim that it needs the product to satisfy local demand in Hungary. However, it is important to note that the freedom to contract principle can be overruled by law, and legislation may make it compulsory for certain persons to conclude a contract.

What happens if the MAH refuses to supply the product to a distributor? Besides the potential administrative proceeding for failure to comply with the general supply obligation, according to the Civil Code, if the parties who are obliged to enter into a contractual relationship on the basis of legislation do not comply with their obligation, the court may establish the contractual relationship and determine the contractual terms, except if a party can prove that it is unable to perform the contract. This exception may be applicable to the MAH under certain circumstances; however, the burden of proof shall lie with the MAH that it was unable to perform.

As well as the restrictions, the practical application of the above supply obligation raises several questions. To date, no guidelines have been issued that would help with the interpretation and application of the new obligation.

SPECIFIC SUPPLY OBLIGATION

According to the amended Medicines Act, the MAH must supply wholesalers with a sufficient amount of certain medicinal products containing active ingredients that are to be specified by a separate ministerial decree. The minimum level of stock that wholesalers must possess collectively shall also be determined in a separate ministerial decree. Such a decree has not been adopted to date.

EXPORT BAN

According to the amended Medicines Act, GYEMSZI-OGYI may – based on a notification – prohibit the export of a particular medicinal product for as long as there is a risk to safe supply in Hungary. This prohibition shall last no longer than one year.

Is the above provision compatible with the EU principle of the free movement of goods? On the basis of the reasoning of the amended Medicines Act, GYEMSZI-OGYI will assess on a case-by-case basis whether the export ban is needed to ensure the safe supply of medicinal products in Hungary (i.e. the ban does not apply automatically and there should be a public health objective to prohibit the export), which suggests that the new provision qualifies as a proportionate restriction to the free movement principle. However, the new provision's compatibility with the free movement of goods principle can only be assessed on the basis of its practical application, which is yet to come.

At the moment, it is hard to predict whether the new provisions will indeed make medicine supply safer. However, MAHs should be aware of the new legislative framework and adapt their operation and distribution scheme to take it into account accordingly. It is important to highlight that the amended Medicines Act authorizes GYEMSZI-OGYI to conduct dawn raids in any regulatory inspection, including the investigation of pharmaceutical companies' compliance with the new obligations detailed above. In case GYEMSZI-OGYI establishes any infringement, it may impose a fine of up to HUF 500 million on the MAH.

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