

November 2016

How the legislator restricted the export of medicinal products

New restrictions on the export of certain medicinal products abroad, their resale to wholesalers and manufacturers, and related obligations

Background

In recent years, the Slovak Republic experienced **an increase in the export of medicinal products**. This increase in the export of medicinal products was caused by regulating the prices for medicinal products as an average of the three lowest prices in other Member States of the European Union, i.e. the so-called “European reference price”. This measure has led to a situation where the price for medicinal products in Slovakia is relatively low in comparison with the price for medicinal products in other Member States, making medicinal products from the Slovak market attractive for export to other Member States. **In some cases, this increase in the export of medicinal products caused a subsequent lack of medicinal products for Slovak patients.**

According to the Slovak government, after implementing the European reference price for medicinal products, Slovakia saw an **increase in the registration of wholesalers of medicinal products** with the single intention of buying cheaper medicinal products in Slovakia and exporting them to other Member States where distributors can sell them with higher margins.

To ensure the availability of medicinal products, certain pharmaceutical companies have considered implementing measures to limit exports, e.g. by including contractual clauses restricting the sale of medicinal products in other Member States or differentiating the prices for medicinal products intended for the local market and for export. However, the majority of these measures are prohibited under competition law.

Last week, the president countersigned an amendment of the Slovak Act on Medicinal Products¹ implementing measures restricting the export of medicinal products to ensure their availability on the Slovak market.

¹ Act amending and supplementing Act No. 362/2011 Coll. on Medicinal Products and Medical Instruments and on amendments and supplements of certain acts, as amended

Restrictions on the export of certain medicinal products

As of 1 January 2017, the restrictions on the export of certain medicinal products for human use will affect the whole distribution chain, i.e. pharmaceutical companies, wholesalers, and pharmacies.

Wholesalers shall distribute the medicinal products for human use, listed in the list of categorized medicinal products maintained by the Ministry of Healthcare of the Slovak Republic, only to (i) pharmacies, (ii) outpatient medical facilities, (iii) providers of emergency medical service, (iv) military forces, and (v) **other wholesalers only for the purpose of their final delivery to pharmacies**. In other words, the wholesalers will not be able to deliver medicinal products for the purpose of export abroad.

According to certain information, the pharmacies were also involved in parallel exports by re-selling medicinal products to wholesalers for export. According to the amendment, the pharmacies will only be allowed to provide medicinal products to the patients and other pharmacies for the purpose of their final delivery to patients. **The pharmacies will only be able to resell the medicinal products to wholesaler(s) from whom they received the medicinal products in the first place.**

A breach of the above obligations may even lead to a revocation of their licences and fines of up to EUR 1,000,000. The right to export these medicinal products will be granted only to the pharmaceutical companies manufacturing the products, holders of the registration of these medicinal products, and wholesalers authorized by the pharmaceutical companies to do so.

Right to export this category of medicinal products will remain only for manufacturers, marketing authorization holders or wholesalers authorized in writing by the marketing authorization holder.

Exports of medicinal products will no longer have to be notified to the State Institute for Drug Control within 30 days before the actual export takes place. However, this obligation only shifts to an obligation to notify such export seven days thereafter. This means that the State Institute for Drug Control will no longer have the right to prohibit the export of medicinal products, however their export will be prohibited directly by the law.

Information system and emergency delivery of medicinal products in 24 hours

To ensure that the relevant medicines reach patients in need, **as of 1 April 2017**, new legislation will enter into force with a system of “24-hour drug deliveries” concerning the delivery of medicinal products for human-use included in the list of categorized medicinal products. Naturally, this system will burden the marketing authorization holders the most since they will need to be prepared for almost immediate delivery of these medicinal products to pharmacies or wholesalers.

The most important obligation for the marketing authorization holders of these medicinal products is the implementation of an information system for orders of medicinal products registered for such marketing authorization holders. This system shall provide a list of the pharmacies and wholesalers to which the marketing authorization holder delivered the medicinal products and information on the availability of these medicinal products. This system must be operational for 24 hours a day, 7 days a week. Marketing authorization holders will be obliged to deliver medicinal products for human use to

wholesalers (they can only deliver these products to pharmacies) within 24 hour after an order is made by such pharmacy or wholesaler via the information system.

Pharmacies must first order the medicinal products from the wholesalers and only when the wholesalers are not able to deliver the respective medicinal product will the pharmacies carry out the order directly with the marketing authorization holder via the above described information system. Wholesalers will be obliged to deliver these medicinal products to the pharmacy within 48 hours after the delivery.

A violation of the obligations related to the operation of the information system on the side of the marketing authorization holder and the wholesalers may lead to a fine of up to EUR 100,000, and the continuous violation of the obligation to deliver the medicinal products to the pharmacy or the wholesaler within 24 hours for three consecutive months may lead to a fine of up to EUR 1,000,000 for the marketing authorization holder.

What does it mean for the Slovak medicinal product market?

The parallel export of medicinal products on the Slovak market has long been perceived as serious problem. Publicly known cases of unavailability of important medicinal products also contributed to greater awareness of this issue. Hence, the legislator can be commended for addressing the problem.

That being said, a big question is the compliance of the new legislation with European Union law. The explanatory memorandum to the amendment states that the aim was to remove the European Commission's objections to the existing legislation concerning the obligation to notify the planned export of medicinal products to the State Institute for Drug Control. However, the amended wording may be even more restrictive and the European Commission may not consider it to be proportional.

A second question is how the new regulations will interact with competition law. For instance, the amendment obliges marketing authorisation holders to supply medicinal products to wholesalers only for the purpose of deliveries to pharmacies. It is questionable whether such restriction in an agreement between a marketing authorisation holder and a wholesaler would not represent a prohibited vertical agreement under competition law. It is also questionable whether a marketing authorisation holder which refuses to authorise a wholesaler to export medicinal products could be liable for abuse of dominance under competition law. There have been cases in the past where the competition authorities found infringements despite the conduct in question being allowed under special sector regulations. This question will probably have to be analysed on an ad-hoc basis in specific cases.

From the point of view of the pharmaceutical sector, it is crucial to align all processes with the new restrictions. Marketing authorisation holders, wholesalers and pharmacies should revisit their business models in light of the new legislation.

Marketing authorization holders will be obliged to further establish processes securing compliance with the provisions on the information system and emergency delivery which appears to require considerable costs. Some aspects of the new legislation are, however, completely clear (e.g. the right to refuse deliveries if the medicinal product is otherwise available in the distribution chain) while substantial fines are in place for respective violations.

If you have any questions about the new legislation, we would be happy to answer them.

Contact



Juraj Gyárfáš
Senior associate

Contact

Tel +421 2 5920 2406
juraj.gyarfas@allenoverly.com

Allen & Overy Bratislava, s.r.o

Eurovea Central 1, Pribinova 4, 811 09 Bratislava Slovak Republic | Tel +421 (0)2 5920 2400 | Fax +421 (0)2 5920 2424 | www.allenoverly.com

In this document, Allen & Overy means Allen & Overy LLP and/or its affiliated undertakings. The term partner is used to refer to a member of Allen & Overy LLP or an employee or consultant with equivalent standing and qualifications or an individual with equivalent status in one of Allen & Overy LLP's affiliated undertakings.

Allen & Overy LLP or an affiliated undertaking has an office in each of: Abu Dhabi, Amsterdam, Antwerp, Bangkok, Barcelona, Beijing, Belfast, Bratislava, Brussels, Bucharest (associated office), Budapest, Casablanca, Doha, Dubai, Düsseldorf, Frankfurt, Hamburg, Hanoi, Ho Chi Minh City, Hong Kong, Istanbul, Jakarta (associated office), Johannesburg, London, Luxembourg, Madrid, Milan, Moscow, Munich, New York, Paris, Perth, Prague, Riyadh (cooperative office), Rome, Sao Paulo, Seoul, Shanghai, Singapore, Sydney, Tokyo, Warsaw, Washington, D.C. and Yangon.

© Allen & Overy Bratislava, s.r.o 2016 This legal update is provided by Allen & Overy Bratislava, s.r.o and is for information purposes only. It does not constitute legal advice or an offer for legal services. The distribution of this document does not create an advocate–client relationship.