Legal Alert

11/2016

NEW LAW AGAINST RE-EXPORT OF DRUGS

On 19 October 2016 deputies of the National Council of the Slovak Republic approved amendment that amends and supplements Act no. 362/2011 Coll., on Drugs and Medical Devices and on Amendment and Supplement of Certain Acts, as amended, and that amends the Act on the Extent and Conditions of Payment for Drugs, Medical Devices and Dietetic Food on the basis of Public Health Insurance (hereinafter the "Amendment"). The Amendment will take effect on 1 January 2017. The aim of the Amendment is to prohibit the reverse sale of drugs and to eliminate the inconsistencies in current legislation with EU law.

What is the main reason for the change in legislation?

The main reason for the change in legislation is the deficit of some drugs for serious illnesses included in the list of classified drugs, which were partly or fully reimbursed from public health insurance, (hereinafter the "Classified drug" or the "Classified drugs") in Slovak pharmacies. The low price of drugs on the Slovak market has led to their export to other EU member states where trade still continues.

What will be the new requirements for exporting drugs?

Only a producer of a Classified drug who has permission to produce drugs, a registration holder and a distribution company, upon written power of attorney, granted by the relevant registration holder, will be able to export the Classified drug abroad.

The registration holder will be obliged to notify the State Institute for Drug Control on the export of the Classified drug abroad in electronic form within seven days from its realisation. The State Institute for Drug Control will immediately publish such notification on its website.

What will be the new obligations of distribution companies?

The amendment specifies an exhaustive list of subjects to which the distribution companies will have to supply the Classified drugs. The Ministry of Health of the Slovak Republic (hereinafter the "Ministry of Health") will cancel the distribution company´s permission for manipulation with drugs and medical devices in the case of repeated attempts to violate this obligation and will be authorized to request the distribution company's individual supply records.

Those permitted to distribute drugs wholesale (hereinafter the "Distribution company") will be obliged to supply the Classified drug only to:

- those permitted to provide pharmaceutical care in public or hospital pharmacies (hereinafter the "Pharmacy" or the "Pharmacies");
- ambulatory care facilities to the extent permitted by law;
- providers of emergency medical services;
- the armed forces and the armed security forces; and
- another Distribution company exclusively for the purpose of its final delivery to the Pharmacy.

In case the Distribution company is unable to ensure the delivery of the Classified drugs to the Pharmacy within 24 hours of receipt of order, the Distribution company will be obliged to take over the relevant Classified drug from the registered holder of human drugs (hereinafter the "Registration holder"), on the basis of the Pharmacy´s order with the Registration holder carried out by means of the information system for the emergency ordering of drugs (hereinafter the "Information system") along with the attached prescription in anonymous form, and deliver it to the Pharmacy within 48 hours of receipt of such order. The Pharmacy will be obliged to take over the relevant Classified drug from the Distribution company within the stated time period. If, however, the Distribution company will have a claim against the Pharmacy for drugs already supplied after a double period of contractual maturity, the Distribution company will be obliged to supply such Classified drug to the Pharmacy only under condition that the Pharmacy will pay the price for such Classified drug at the time of its delivery at the latest. If the Pharmacy fails to pay for the Classified drug, the Distribution company will be obliged to return it to the relevant Registration holder.

The Distribution company will be punished by a fine of up to EUR 1,000,000 for violations of the above stated obligations.

What will be the new obligations of Pharmacies?

The Pharmacy will be obliged to dispense the Classified drugs only in a public or hospital pharmacy under threat of having its permission for manipulation with drugs and medical devices cancelled. In addition, the Pharmacy will be obliged to keep records of those Distribution companies and Registration holders that have provided the Pharmacy with Classified drugs for the calendar year. These records will have to be kept for at least five years and submitted to the Ministry of Health upon request.

In case the Distribution company is unable to ensure the delivery of the Classified drugs to the Pharmacy within the stipulated time period the Pharmacy will be obliged to ensure the delivery of such drugs from the relevant Registration holder via order carried out by means of the Information system.

The Pharmacy will be punished by a fine of up to EUR 100,000 for violation of the above stated obligations.

The Pharmacy will not be able to dispense prescription human drugs that amount to more than three months of necessary treatment. This is intended help to ensure the accessibility of the drugs.

What will be the new obligations of Holders of registration?

Registration holders will be obliged to create and continuously operate the Information system that must provide him/her with an overview of those Pharmacies and Distribution companies to which the Classified drugs have been provided and to keep such records and retain them for at least five years and submit them to the Ministry of Health upon request.

The Information system will be used by Pharmacies to order the Classified drugs only in case the Distribution companies fail to provide them. The total costs for creating and operating the information system should not exceed EUR 10,000 to EUR 15,000 in any particular case. Adding data to the information system and any changes will require notifying the Ministry of Health, which will publish such data on its website. Neither the Amendment nor the implementing decree specifies the Information system´s content and format requirements yet.

The Registration holder will be obliged to deliver the ordered Classified drugs via the Information system to the Pharmacies and Distribution companies within the stated period of time. This does not apply in case of the existence of claims against the relevant Pharmacy or the existence of a procedure for disposing of such drugs. The Registration holder will be able to deliver the Classified drug to the Distribution company only for the purpose of its final delivery to the Pharmacy.

The upper limit of fines for violating the above stated obligations is EUR 1,000,000.

Contacts:
In case you need help with setting up access to the electronic mail box, please do not hesitate to contact your contact person in our office, or approach JUDr. Marek Olekšák (marek.oleksak@bapol.sk) or Mgr. Marek Orosz (marek.orosz@bapol.sk).

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