BEATOW PARTNERS

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HEALTH CARE SECTOR UPDATE

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INTRODUCTION TO THE AMENDMENT TO THE MEDICINAL PRODUCTS ACT

On October 19, 2016 the National Council of the Slovak Republic adopted an amendment to the Act No. 362/2011 Coll. on Medicinal Products and Medical Devices, as amended (the "**Medicinal Products Act**") (the "**Amendment**"). The Amendment primarily focuses on the prevention of the export of human drugs as well as on the maintenance of the availability of the human drugs registered in the list of categorized human drugs (in Slovak: *humaný liek zaradený v zozname kategorizovaných liekov"*) (the "**Registered Human Drug**") on the market. The Amendment has been signed by the President of the Slovak Republic and shall soon be published in the Collection of Laws of the Slovak Republic. The Amendment shall become effective on January 1, 2017, with certain provisions specified in the Amendment becoming effective on April 1, 2017.

NEW OBLIGATIONS ARISING FROM THE AMENDMENT - WHOLESALE DISTRIBUTORS

The Amendment introduces, *inter alia*, the following obligations with respect to the holder of the license for the wholesale distribution of human drugs (in Slovak: *držiteľ povolenia na veľkodistribúciu humánnych liekov*) (the "**Distributor**"):

a) to supply the Registered Human Drug only to:

   i.) pharmacies;

   ii.) ambulant healthcare providers;

   iii.) providers of emergency medical services;

   iv.) armed forces and armed corps; and

   v.) other Distributors solely for the exclusive supply to a pharmacy.

b) submit to the Ministry of Healthcare of the Slovak Republic (the "**Ministry**"), upon request, in electronic form that allows automatic data processing, within the time period specified by the Ministry, which shall not be less than five business days:

   i.) the record on the receipt of the Registered Human Drugs and the record on the supply of the Registered Human Drugs to pharmacies;

   ii.) the record on the supply of the Registered Human Drugs to other Distributors solely for the exclusive supply to pharmacies;

   iii.) the record on the resale or the record on the return of the Registered Human Drugs to a holder of the registration of a human drug (in Slovak: *držiteľ povolenia na registráciu*

humánnych liekov) (the "**MAH**") holding the marketing authorization of the respective Registered Human Drugs as a result of claiming defects of the supplied Registered Human Drugs or withdrawal of the Registered Human Drugs from the market; or

iv.) data from the record stated in the above points;

c) to accept the Registered Human Drugs from the MAH ordered pursuant to the provisions of the Amendment for the purpose of supply to pharmacies;

d) to supply the Registered Human Drugs obtained from the MAH for the purpose of their supply to pharmacies within 48 hours from placing an order.

NEW OBLIGATIONS ARISING FROM THE AMENDMENT – MARKETING AUTHORIZATION HOLDERS

The Amendment introduces, *inter alia*, the following obligations with respect to the MAHs:

a) to secure the implementation and permanent operation of an information system for emergency ordering of medicinal products, which the MAH holds the registration of (details of the information system are set forth in the Amendment);

b) to secure the acceptance and confirmation of orders of the Registered Human Drugs, which the MAH holds the registration of, via the information system described in letter a) and, in the event of a breakdown of the system, via any other form;

c) to supply the Registered Human Drugs, which the MAH holds the registration of, ordered in the manner prescribed in the Amendment with an attached anonymized medical prescription pursuant to the Amendment, to a pharmacy or a Distributor within 24 hours from receipt of the order;

d) to notify the Distributor of the time of the acceptance of the order of the pharmacy with an attached anonymized medical prescription pursuant to the Amendment in the event of the supply of the Registered Human Drugs to the Distributor pursuant to letter c) above;

e) to notify the Ministry of the data on the information system and notify the Ministry, without undue delay, of any changes of this data; please be informed that the data on the information system shall be made publically available on the website of the Ministry;

f) to keep a record (for a period of at least 5 years) of the pharmacies and Distributors to whom the MAH supplied the Registered Human Drugs during a calendar year and, upon request, submit this record to the Ministry in electronic form that allows automatic data processing within the time period specified by the Ministry.

Please also note that the MAH, who holds a registration with respect to a Registered Human Drug, is obliged to fulfill the obligations as set forth in the Amendment not later than 14 days following the enforceability of the Decision on the registration of the human

drug into the list of categorized human drugs.

The new obligations of the MAH as set forth in the letters a) – e) above shall become effective on April 1, 2017.

EXPORT OF HUMAN DRUGS

Pursuant to the Amendment, the export of the human drugs shall be limited only to the Registered Human Drugs, whereas such export shall only be permitted to the following entities:

a) holder of the license for the manufacturing of medicinal products, who manufactured the exported Registered Human Drug;

b) MAH holding the registration of the exported Registered Human Drug; or

c) Distributor if granted a written authorization to export the Registered Human Drug by the MAH holding the registration of the respective Registered Human Drug.

With this respect, the MAH shall be required to notify, by electronic means, the export of the Registered Human Drug to the State Institute for Drug Control (in Slovak: *Štátny ústav pre kontrolu liečiv)* (the "**State Institute**") no later than 7 days following the export.

SANCTIONS

The Amendment also sets forth new sanctions ranging up to 1,000,000 EUR for breach of the new obligations set forth in the Amendment.

One of the most important changes brought about by the Amendment in terms of sanctions is the removal of financial sanctions of up to 30,000 EUR for the MAH that failed to secure the availability of its medicinal product on the market in a sufficient amount for 60 consecutive days pursuant to Act No. 363/2011 Coll. on the Scope and Conditions of Payments for Medicinal Products, Medical Devices and Dietary Food, as amended.