Pharma Newsletter

Export of Medicinal Products and Other Amendments to the Medicinal Products for Human Use Act

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Bill Amending the Medicinal Products for Human Use Act

A Bill Amending the Medicinal Products for Human Use Act ("MPHUA") was promulgated on March 4, 2014. The bill regulates the export of medicinal products (including the so-called "parallel export"), sets forth further obligations of marketing authorisation holders in relation to suspension of the marketing of medicinal products, provides for a new regulatory body – Expert Council on Retail Sale of Medicinal Products, and contains detailed rules on the Urgent Union Procedure, implementing Directive 2012/26/EC.

The new rules concern pharmaceutical companies, distributors of medicinal products and pharmacy owners.

Here, we present the major amendments introduced by the Bill, as promulgated in the State Journal, without commenting in detail on their implications. Please note that a group of members of Parliament has filed a request for declaring the unconstitutionality of Art. 217c MPHUA regarding parallel export of medicinal products before the Constitutional Court.

Export of Medicinal Products

How is "export" defined in MPHUA?

Export of medicinal products under MHHUA encompasses export to third countries as well as intra-community supply, i.e., supply of medicinal products to another European Union ("EU") country.

Holders of licenses permitting sale or manufacture of medicinal products may export medicinal products from the territory of Bulgaria. Specifically, a manufacturer is allowed to export only the medicinal products manufactured by it.

What are the obligations of wholesale distributors of drugs, which are included in the List of Reimbursed Medicinal Products?

MPHUA introduces specific rules on export of drugs included in the List of Reimbursed Medicinal Products.

A distributor who intends to export drugs included in the List of Reimbursed Medicinal Products has to file a notification to the executive director of the Bulgarian Executive Drugs Agency ("EDA") on a case-by-case basis.

EDA keeps a register of all submitted notifications.

Under what conditions may EDA executive director object to the export of medicinal products?

Upon receipt of an export notification, EDA requests information:

a) from the National Health Insurance Fund and/or the Ministry of Health regarding the use of the medicinal product intended for export for the preceding 6 months;

b) from the marketing authorisation holder(s) regarding the medicinal products quantities supplied on the territory of Bulgaria. Marketing authorisation holders are obliged to provide the requested information within 15 days from receipt of EDA's letter.

EDA analyses the information obtained and compares the volumes of the medicinal product supplied on the territory of Bulgaria and those used.

The executive director may object to the export (by issuing a decree

specifying the grounds for the refusal) if:

(i) The quantities of the medicinal product, which is subject to export, available as of the date of the notification to EDA, are not sufficient for satisfying the Bulgarian market needs;

(ii) A temporary shortage of the medicinal product may arise as a result of its export;

(iii) The shortage of the medicinal product may endanger patients' life and health.

When may a wholesale distributor export medicinal products?

If EDA executive director does not object to the export of medicinal products within 30 days after filing a notification of their export, the director is deemed to have consented to the export and the medicinal product may be exported.

The export shall be carried out within three months from expiration of the 30-day period, during which the EDA executive director may object to the export.

What is the penalty for not submitting an export notification?

A distributor, who has not filed an export notification with EDA in compliance with the procedure above, is subject to fine/ financial sanction in the amount of EUR 25,000 and EUR 50,000. In case of a repeated violation, the fine increases from EUR 50,000 to EUR 100,000.

Suspension the Marketing of a Medicinal Product

Who must a marketing authorisation holder/ holder of a registration certificate ("Pharmaceutical company") notify?

a) Notification to EDA

A pharmaceutical company has to notify EDA in writing at least two months before suspension of the marketing of a medicinal product, irrespective whether the suspension will be temporary or permanent. If the suspension is due to unforeseeable circumstances, the notification has to be filed within 7 days from finding about the relevant circumstance.

The pharmaceutical company must specify the reasons for suspending the marketing of the medicinal product and declare whether the suspension is due on any of the grounds set out in Art. 276 and Art. 277 MPHUA (adverse drug event, lack of therapeutic efficacy, the risk-benefit balance is not favourable, etc.).

b) Notification to MH and NCRMP

A pharmaceutical company suspending the marketing of a medicinal product must notify not only the Ministry of Health ("MH"), as it was the case before the entry into force of the discussed Bill, but also the National Council on Reimbursement of Medicinal Products ("NCRMP"), provided that:

(i) the medicinal product, which will be suspended, is on the List of Reimbursed Medicinal Products, and

(ii) no medicinal product with the same international non-

proprietary name (INN) has been authorized for use, or the price of the medicinal product serves as reference price for the respective INN and pharmaceutical form.

Other obligations of pharmaceutical companies

a) Notification obligations

Similarly, pharmaceutical companies must notify EDA of any action taken in connection with withdrawal of a medicinal product from the market, withdrawal of a marketing authorisation or intention not to renew a marketing authorisation, together with the reasons for such action. The obligation to submit a notification to EDA is also triggered if any of those actions is taken in a third country on any of the grounds set out in Art. 276 or Art. 277 MPHUA. In the latter case, i.e., an action taken on the grounds of Art. 276 or Art. 277, the marketing authorisation holder must notify the European Medicines Agency.

Further, when requested by EDA, pharmaceutical companies are obliged to provide information of the sales volumes of a particular medicinal product and any other information regarding prescriptions of that medicinal product by health professionals.

b) Obligation to ensure sufficient quantities of medicinal products

Pharmaceutical companies have to ensure market availability of medicinal products in such quantities to satisfy the necessities of the Bulgarian population.

c) Clear and understandable leaflet

The package leaflet must be written and designed in such a way as to be clear and understandable, enabling users to act appropriately, when necessary with the help of health professionals

Expert Council on Retail Sale of Medicinal Products

Under the Bill amending MPHUA an Expert Council on Retail Sale of Medicinal Products will be set up (the "Council").

Composition

The Council consists of three representatives of the Bulgarian Pharmaceutical Association, one representative of the pharmaceutical departments of each medical university and four representatives of EDA.

The Council's members are appointed by EDA executive director, who issues a decree after consultation with the Minister of Health.

Functions

The Council has consultation functions. It gives opinion on the applications for permits for retail sale of medicinal products.

Urgent Union Procedure

Under MPHUA EDA may initiate the Urgent Union Procedure

before the European Medicines Agency if:

(i) EDA is informed by the marketing authorisation holder that, on the basis of safety concerns, the holder has interrupted the placing on the market of a medicinal product or has taken action to have a marketing authorisation withdrawn, or intends to take such action or has not applied for the renewal of a marketing authorisation.

(ii) EDA considers that a new contraindication, a reduction in the recommended dose or a restriction to the indications of a medicinal product is necessary.

The amendments discussed above entered into force on March 8, 2014.

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