

UPDATE: Bulgaria's new Pharmaceuticals Act and the importation of active substances into Bulgaria

Introduction

The production of medicinal products and active substances in Bulgaria and their import are governed by the Bulgarian Pharmaceuticals in Human Medicine Act (PHMA).

PHMA came in force on 13/04/2007, just weeks after its hurried adoption and is as yet untested in the courts and lacking in crucial in the Bulgarian legal system subordinate legislation as explained further below.

This article reviews the impact of the new piece of legislation on undertakings which sell to producers only - both within the EEA, and outside it. As such, it is outside its remit to consider the impact of the new Act on aspects of the law connected with marketing/sale to consumers and/or processing and production.

Executive Summary

The Bulgarian Pharmaceuticals in Human Medicine Act (PHMA) 2007 is designed to align Bulgarian pharmaceutical law with the EC *acquis*. A number of documents are required in connection with importation of active substances. The Act has been implemented so far inadequately and this detracts from its intended effect of modernising Bulgarian law in this field.

The key achievement of the legislation is to remove obstacles at the legislative level to intra-EU medicinal trade. If imported from outside EEA and Switzerland a specific Import Permit need to be obtained in advance.

Definitions

For the purposes of PHMA, an "**active substance**" is every substance or ingredient intended for use as a pharmacologically active ingredient of a medication.

A "**pharmaceutical**" is every substance or combination of substances used for the medical treatment of human disease or diseases or administered for the recovery, correction or change of physiological human functions.

Accordingly, a substance can be both a pharmaceutical and an active substance at the same time.

A "**lot**" is such a definite amount of a substance, manufactured in compliance with a reproducible technological scheme that is designed to ensure the necessary homogeneity in relation to the controlled values. This legal definition transposes into Bulgarian law an understanding on which a lot is the lot as batched and numbered by the producer.

The "**BDA**" is the Bulgarian Medicines Executive Agency, officially known in English as the Bulgarian Drug Agency.

Importation of "active substances":

a) A special regime applies to the importation of ASs into Bulgaria from outside the EEA. If the active substance is imported from a 3rd country (meaning a country outside the EEA), the following documents are required:

- (i) an Import permit and
- (ii) a Certificate for Release of each and every lot.

Following their import to Bulgaria, the ASs are available for free circulation within the customs territory of the EEA. Each EEA state may require the Bulgarian-issued Import Certificate as proof of valid importation.

b) If the AS is imported from an EEA country instead, Analyses' Certificates and a Certificate for Release or equivalent (by the equivalent authority of the EEA state) of the respective lot there are substituted as the documentary requirements.

c) All importers should submit to the BDA a Questionnaire on a form, approved by the BDA for the active substances imported to Bulgaria. The information should be submitted to the BDA in 10 days after the delivery. Copies of all Certificates for the Release and Protocols for analyses should be submitted together with the Information. The copies should be marked as originals, signed and stamped.

Procedure for obtaining an Import Permit

1. Conditions for obtaining an Import Permit.

The Import Permit is issued by/on behalf of the Director of the BDA.

Any person (whether it is a natural person or a company) registered* as undertaking in a EU member-state can obtain an Import Permit provided that they meet the following requirements:

(a) At any given time, the undertaking has access to at least one "qualified" (in the meaning of the Act) person.

Such a qualified person is left undefined in the relevant section but it appears on reading the Act more widely that an employer-employee relationship between the undertaking and the qualified person is envisaged, when the importing undertaking is not the qualified person him- or herself.

The qualified person should meet the following requirements (as specified directly in the PHMA):

He or she should:

(1) have a master's degree in one of: medicine, pharmacy, chemistry, biotechnology or biology;

(2) have at least two years of practical experience in the area of pharmaceutical production and/or performance of the quality and quantitative analyses of pharmaceuticals and active substances;

(Further requirements and clarifications of requirements are envisaged to be imposed by a statutory instrument (an Order, to be adopted no later than 13/10/2007 and as yet unadopted)).

The institution of the Qualified Person is novel to the PHMA and as such there are no analogues under previous legislation. It is therefore difficult to advise how, if at all, the BDA will interpret the law to impose further more detailed requirements on who can act as a Qualified Person. Such guidance can be requested in writing from the BDA, but an answer may be slower than the publication of a statutory instrument.

* In this context "registered" may include "recognised" or "recognisable" under the law of the respective EEA country as an undertaking, without the need for a registration

(b) The undertaking has access to a (i) laboratory for quality control and (ii) a premises for the storage of the substances that are equipped “with the necessary technical equipment”. The detailed requirements including requirements as to the necessary technical equipment are to be given in secondary legislation under the PHMA (as yet unadopted). It is likely that the access requirement (unlike the qualified person requirement) applies only to a given moment in time (at least in relation to access to the lab if not access to the storage facility).

2. Application for obtaining an Import Permit

The application (for the moment not on a standard form) is submitted to the Director of the BDA. The following documents should accompany the application:

- Certificate of Good Standing of the undertaking;
- List of the active substances applied for;
- Copy of the Production Permit issued by the competent authority of the export country;
- Address of a laboratory on the territory of Bulgaria to which the applicant has access and which has the capacity for conducting qualitative and quantitative analyses of the active substances (perhaps derived from Good Production Practice);
- Address of the storage premises where the active substances will be stored following importation;
- Copy of documents proving the qualification and the experience of the Qualified Person;
- Contract(s) specifying the responsibilities of each party in relation to compliance with the principles of good production practice (to be determined by an Ordinance as yet unissued) and the ways by which the qualified person will carry out its obligations if the applicant does not have its own laboratory;
- Evidence of paid state fees for the issue of the Import Permit, to be determined by a future Tariff. There is no analogue in previous law or practice to this fee (various other fees range between BGN 800 and 10,000)

If the production premises are located in a third country, such a third country can be one with which the EU has an Agreement on Good Production Practice. In this event, the additional information required to be submitted is as follows:

- (1) the name and registered address of the person who has the production permit and
- (2) all addresses of production facilities for the active substance;
- (3) certificates for correspondence with the conditions for production, control and storage equivalent to the respective standards of the Ordinance of good production practice;
- (4) the name of the Qualified Person, where such a Qualified Person is equivalent to the Qualified Person envisaged in the case of an import from the EEA

In the event that the third country does not have a Good Production Practice Agreement with the EU, the BDA may perform checks at the relevant production facilities addresses and the addresses of the companies involved. All costs of such checks are at the expense of the applicant.

3. Timing

The Director of BDA must issue a decision within 30 days of the submission of the application in all of the above cases. We expect that where a check of the production facilities needs to be conducted it will be in practice impossible to issue a decision within 30 days. Where for one or another reason a decision is late, the applicant is entitled to assume a silent refusal. In those cases, it can bring an action in the Administrative Court, which can, if desired be combined with a civil action for compensation. If the Administrative Court rules that the silent refusal was unlawful, it will remit the matter back to the BDA and may in the

event of a civil action, order a compensation in addition. Legal costs are borne by the losing party.

The Import Permit is not limited by a term. It covers only the substances and the premises in relation to the quality control and storage conditions described in the application but different batches can be imported using the services of the same lab and stores.

4. Secondary Legislation

Secondary legislation must be issued within 6 months of the entry into force of the PHMA (ie by October 13, 2007). But for the moment the secondary legislation under the previous relevant Act will presumptively apply as long as it does not contradict the Act.

In the absence of this subordinate legislation, there is unfortunately a risk that the issue of the Import Permit will be hampered and delayed. Given Bulgarian bureaucratic tradition, BDA officials may be expected to uncertain how to proceed and it is possible that they would either set the application to the side and not process it or, that they would issue conflicting/confused demands for documentation.

In a best case scenario, the officials will already have internal know-how on how they are going to process applications under the new statute, or will seek internal legal and policy advice and will not hesitate.

Procedure for obtaining a Certificate for Release

This is a document signed by the Qualified Person, for whose veracity the Qualified Person bears responsibility. There is no prescribed form.

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