Information for sponsors on the import of pharmaceuticals containing narcotic drugs and psychotropic substances

INTRODUCTION:
The handling of dependency producing substances, i.e., narcotic drugs and psychotropic substances is governed by Act No. 167/1998 Coll., on Dependency Producing Substances and on the Amendments of some other Acts, as amended (hereinafter "Act No. 167/1998 Coll."). The obligations stipulated therein also apply to products (preparations) containing dependency producing substances (hereinafter referred to as the "products") to be imported into the Czech Republic for the purposes of performing clinical trials at selected and approved special workplaces.

The import or export of dependency producing substances (or products) means their physical relocation from one country to another (including within the EU).

Contact point for queries:
Ministerstvo zdravotnictví České republiky– Inspektorát omamných a psychotropních látek
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IMPORT CONDITIONS PURSUANT TO ACT No. 167/1998 Coll.:

The following possibilities exist for the import of products for the purposes of clinical trials:

An import authorization can be applied for and obtained by:

1. **A subject with a valid authorization to handle narcotic drugs and psychotropic substances** (Section 4 of Act No. 167/1998 Coll.)

   Import can be realised through a wholesaler that already has a valid authorization to handle the respective medicinal product (or products). The wholesaler will then apply for the import authorization in its own name.

2. **A subject that does not yet have an authorization to handle narcotic drugs and psychotropic substances and intends to apply for it**

   It is the contact person himself - a representative (based in the Czech Republic) authorised by a foreign sponsor that applies for the handling authorization. Appropriate import authorization will then be issued to this contact person. Before the handling authorization is issued, the contact person must meet particularly the requirements of Sections 8, 9, 10, 17, 18 and 19 of Act No. 167/1998 Coll.

   For issuance of the import (or export) authorization a fee of **CZK 1000** is charged [Act No. 634/2004 Coll., on Administrative Fees, Part VI of the Table of Fares, Item 100(b)].

   Administrative procedures apply to the application for issuance of the import authorization (or export authorization) [Section 44 (1) of Act No. 167/1998 Coll.].

ADMINISTRATIVE PROCEDURE (IMPORT APPLICATION)

Application for issuance of Official import authorisation (hereinafter "import authorization")

All required forms, e.g. "Application for issuance of handling authorization" and "Application for issuance of import authorization" (or export authorization), as well as the respective legal regulations, can be found on the web pages of the Ministry of Health (www.mzcr.cz / odborník zdravotník / zdravotní služby / návykové látky a prekursory drog).

The submitted application for issuance of import authorization must contain the following information **related to the name** of the investigational product:

- Pharmaceutical form
- Strength
- Package size,
  (If the package size is not stated in the name, it is necessary to state the number of tablets, capsules, patches, vials, bottles, etc., to be imported for the clinical trial.)
- Full name of the narcotic or psychotropic substance;
  (e.g., morphine sulphate 5 H_2O, morphine hydrochloride 3 H_2O; as a water-free morphine hydrochloride also exists, it is necessary to clearly state the type of salt)

The information should be filled in the table, with accompanying text if necessary. This table will form an integral part of the application for issuance of the import authorization. In case it is necessary to import a "placebo pharmaceutical", state the number of packages in this case as well.

EXAMPLE OF TABLE:

A	**B**	**C**	**d**	**e**	**f**
No.	**Name of product**	**Number of packages/kits/ tablets/ capsules/ patches/ vials**	**Name of Narcotic Drug/ Psychotropic Substance**	**Total amount of Narcotic Drug/ Psychotropic Substance (in grams)**	**Total amount of Narcotic Drug/ Psychotropic Substance base (in grams)**
1.					
2.					
3.					
4.					
5.					
	TOTAL				

Copies of the documents issued by the State Institute for Drug Control ("Státní ústav pro kontrolu léčiv") (e.g., positive opinion on the "Notification of a Clinical Trial" or "Approval of a Clinical Trial " or "Confirmation of the Approval/Notification of a Clinical Trial for the Customs Clearance" etc.) and the list of trial sites form part of the application.

Documents for the application for issuance of import authorization are provided to the importer by the sponsor of the Clinical Trial.

Similar procedure should be followed in the case of a Clinical Trial with veterinary medicinal products.

A properly filled in application (stating the reason for import and listing the trial sites) is filed with the Inspectorate of Narcotic Drugs and Psychotropic Substances pursuant to Section 22(2) of Act No. 167/1998 Coll.

The import authorization is issued for a six-month period. Upon the importer's request, this period can be even shorter. During the course of one clinical study a number of separate imports can take place.

Import in partial deliveries is not allowed, i.e., it is possible to perform only one delivery per import authorization.

The imported amount stated on the import authorization cannot be exceeded, but a smaller amount can be imported.

FOLLOW UP OBLIGATIONS IMPOSED ON THE IMPORTER PURSUANT TO ACT No. 167/1998 Coll.

1. **Monthly report of importation**
   (Section 26(1)(c) of Act No. 167/1998 Coll.)

   After realising the import, the importer is obliged to send the respective monthly import report to the Ministry of Health – Inspectorate of Narcotic Drugs and Psychotropic Substances (Appropriate Form No. 18 can also be found on the web pages of the Ministry of Health).

2. **Return of unused product**
   (Section 22(2) of Act No. 167/1998 Coll.).

   In the event that the foreign sponsor requests that the products be returned to the foreign sponsor of the clinical trial this is considered as export of product and an export authorization is required.

3. **Redistribution of product**

   If the clinical study takes place concurrently also in foreign trial sites (e.g., in Slovakia), to which the product would be distributed from the Czech Republic, this is also considered as export, which means it can only be carried out on the basis of an import authorization issued by the competent authority of the foreign partner. The Ministry of Health will only issue the export authorization after it receives the import authorization (it will be an appendix to the application for the export of product). Without these documents, the narcotic drugs and psychotropic substances cannot move between countries, even within the EU. The free movement of goods and services does not apply to narcotic drugs and psychotropic substances and products. EU legislation regulates only so-called scheduled substances in Category 1, 2 and 3 (precursors and essential chemicals the regime for narcotic drugs and psychotropic substances remains without change, i.e., as before accession to the EU).

   The obligation to submit monthly reports applies to exports as well.

4. **Note**

If it is planned to perform a Clinical Trial of a product containing narcotic drugs and psychotropic substances for which the Czech Republic has not had an assessed estimate, the Ministry of Health – Inspectorate of Narcotic Drugs and Psychotropic Substances must first apply to the International Narcotics Control Board (hereinafter the "INCB") in Vienna for approval of the estimate of the amount of this substance for the Czech Republic. Without this confirmation of data, published in the INCB periodical, the foreign supplier will not issue an export authorization. In such case, it will be necessary to take into account a certain delay when planning the study.

Inspectorate of Narcotic Drugs and Psychotropic Substances
8th July 2008