UST-28 version 1

Authorisation of parallel import of medicinal products

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This Guideline supersedes UST-28 (June 1 2004), effective to date.

INTRODUCTION

The purpose of this Guideline is to explain those aspects of parallel import of medicinal products to the Czech Republic which are associated with the activities of the State Institute for Drug Control (hereinafter referred to as the "Institute") pursuant to Act No 378/2007 Coll., on Pharmaceuticals and on Amendments to Some Related Acts (Act on Pharmaceuticals), as amended (hereinafter referred to as the "Act"). The provisions stipulated by Section 45 of the Act imply that a parallel import means the distribution of such medicinal product into the Czech Republic, which is concurrently authorised in the Czech Republic and in a Community Member State, and this distribution is not provided for by the marketing authorisation holder for the Czech Republic or in cooperation therewith.
A parallel import shall not mean the distribution of a medicinal product authorised by the centralised procedure from another Member State to the Czech Republic. This distribution is labelled as "parallel distribution" and it may be conducted after a notification submitted to the European Medicines Agency (EMEA). For more details on the notification procedure please refer to the following website:
http://www.emea.europa.eu/pdfs/human/parallel/1339704en.pdf

Parallel import may be conducted only by the holder of an authorisation for the distribution of medicinal products (Sections 75, 76 and 77 of the Act refer), on the basis of a parallel import authorisation issued by the Institute for individual medicinal products imported from the selected EEA Member States. Where conditions stipulated by this Act are met, the Institute shall grant the parallel import authorisation applied for. The holder of the parallel import authorisation shall be responsible for the activities provided for thereby without prejudice to the responsibility of the marketing authorisation holder of the reference product.

The European Commission has issued a detailed Communication on parallel import (Commission Communication on parallel imports of proprietary medicinal products for which marketing authorisation have already been granted C0M(2003) 839), which is based upon a number of court rulings related to parallel import. The Communication contains also specifying information on parallel distribution of medicinal products authorised by the centralised procedure. This communication, published on December 30 2003, may be found at the following website: http://eur-lex.europa.eu/LexUriServ/site/en/com/2003/com2003_0839en01.pdf

CONDITIONS WHICH HAVE TO BE MET BY THE MEDICINAL PRODUCT FOR THE PURPOSES OF PARALLEL IMPORT

A medicinal product placed on the market in the Czech Republic within the scope of parallel import must be legally authorised in any of the Member States and imported from the given State. **The product, therefore, cannot be imported from a third country.**
At the same time, an alternative medicinal product must be authorised in the Czech Republic.

The alternative product in the Czech Republic is hereinafter referred to as a “reference product”.
Pursuant to the Act, in comparison with the reference product the parallely imported product must have:

a) qualitatively and quantitatively identical composition in terms of active substances;
b) an identical pharmaceutical form;
c) identical therapeutic effects.

The parallely imported product, furthermore:
a) must not pose a risk to the public health;
b) must be used in compliance with the conditions of the marketing authorisation of the reference product (e.g. compliance with the same indications, contraindications, special precautions).

Labelling of the parallely imported medicinal product, package leaflet, and conditions governing re-packaging

- The outer packaging of the product which is the subject of parallel import, or the immediate packaging, where necessary, shall provide, in a suitable manner, particularly by means of additional print or a self-adhesive sticker, essential information consistent with the conditions of marketing authorisation of the product in the Czech Republic, which cannot be easily derived from the foreign-language text, and all details which are not provided in the Latin alphabet. Essential information shall mean, in particular, the name of the product, strength, pharmaceutical form, active substance, marketing authorisation holder, storage method, and expiry date. The name of the product in Braille on the outer packaging shall be presented in a manner avoiding any confusion, if the name in the country from which the product is being imported is a different one.
- The European Article Number (EAN code) shall be presented in the form of a bar code, different from the code of the reference product; the marketing authorisation number of the parallely imported product stated in the parallel import authorisation, and the holder of the parallel import authorisation shall be specified.
- The package leaflet and the labelling shall show changes to excipients or other changes.
- If the outer packaging of the parallely imported product is replaced, data as per the relevant Annex to the Marketing Authorisation Decree shall be shown so as to be consistent with the conditions of the marketing authorisation of the reference product in the Czech Republic, except for the marketing authorisation number of the reference product and the name of the marketing authorisation holder for this product. The EAN code different from the reference product code shall be added as well as the marketing authorisation number of the parallely imported product specified in the parallel import authorisation, and the parallel import authorisation holder.
- Re-packaging, re-labelling or other manufacturing operations involving the parallely imported product may be conducted only by a holder of a manufacturing authorisation for medicinal products under the conditions of Good Manufacturing Practice, and afterwards, the batch must be again released. For these manufacturers, the applicant shall evidence the manufacturing authorisations for medicinal products or the certificates of GMP compliance (post-inspection certificates issued in compliance with “Compilation of Community Procedures on Inspections and Exchange of Information”

available from
http://www.emea.europa.eu/Inspections/docs/CoCP/CoCP_CoverNote.pdf).
The qualified person of the manufacturer who within the scope of parallel import re-packages the medicinal product shall evidence, in compliance with Section 66, paragraph 3 of the Act, that each batch of the re-packaged medicinal product has been manufactured in compliance with GMP principles, and is consistent with the marketing authorisation dossier of the parallely imported medicinal product. The manufacturer re-packaging medicinal products containing highly effective active substances such as cytostatic agents, penicillin or hormones, must have decontamination procedures drafted to be applied should the primary packaging be compromised during re-packaging and a risk of contamination of the manufacturing premises and processed materials arise.

- The above-mentioned specifying Communication of the European Commission stipulates that the presentation and method of presentation and placement of the re-packaged product on the market must not harm the goodwill of the trademark or its owner.
  The packaging therefore must not be imperfect, defective, compromised, of low-quality, carelessly prepared, etc. (see the ruling of the European Court of Justice of June 11 1996, re MPA Pharma GmbH at Rhône-Poulenc Pharma GmbH. C-232/94). Unless, however, the issues concern the quality, safety and efficacy of the medicinal product, they are not covered by the activities of the Institute.

APPLICATION FOR PARALLEL IMPORT AUTHORISATION

For each product, a separate application shall be submitted; separately for each pharmaceutical form, strength, and country from which the product is imported.

The application shall be submitted on the "Application for parallel import authorisation" form (Annex 1 to this Guideline). Pursuant to Section 3 of Decree No 228/2008 Coll. on Marketing Authorisation of Medicinal Products, coming into force on July 1 2008, applications and other documentation submitted to the Institute have to be provided in electronic format. When processing the application and other documentation in electronic format, the eCTD electronic format shall be used in compliance with SÚKL guideline REG-84.

Before the application is submitted, the applicant shall pay the administrative fee and reimburse the costs associated with the handling of the application using the procedure set forth in the effective version of guideline UST-29.

Specific mechanism:
The treaty of accession of the Czech Republic to the EU governs the cases of parallel imports of products from Estonia, Lithuania, Latvia, Hungary, Poland, Slovakia or Slovenia for which patent-based protection or additional proprietary certification based protection has been provided in the Czech Republic at the time when in the country from which the product has been imported such protection could not be provided. Pursuant to this provision, in these cases the applicant has to specify in the application or attach to the application a document to evidence whether the applicant has informed on the intention to import the product to the Czech Republic the owner of the patent or additional proprietary protection or the person authorised on the basis of such protection regarding the imported product at least one month in advance of the submission of the application. Where the applicant fails to do so, the applications shall be regarded incomplete. Informing the owner of the patent of additional

proprietary protection or person authorised by such protection does not prejudice the parallel importer's duty to notify the marketing authorisation holder of the reference product in the Czech Republic of the commencement of parallel import thereafter (Section 45, paragraph 7, letter d) of the Act).

The following shall be attached to the application:

- Original package leaflet of the product from the Member State and its translation to the Czech or Slovak language where other than English version is concerned, incl. the applicant's declaration of consistency of the contents of the texts;
- Draft Czech text of the package leaflet, summary of product characteristics, labelling, and colour graphic package presentation in the Czech language, sized 1:1 (so called mock-up);
- A sample of the product in the form in which it is marketed in the Member State;
- A sample of the medicinal product in the form in which it is intended for marketing in the Czech Republic;
- Where an applicant who is the holder of a distribution authorisation granted by an EU Member State is concerned, a copy of this authorisation, incl. any variations thereto as may be applicable (where GMP certificates have been granted in a language other than the Czech, Slovak or English, it is necessary to attach the English translation to the GMP certificates);
- Where a manufacturer involved in re-packaging, re-labelling or other manufacturing operations conducted in the parallely imported product who is the holder of an authorisation granted by an EU Member State is concerned, a copy of the manufacturing authorisation, incl. any variations thereto as may be applicable;
- Proof of payment of the administrative fee and reimbursement of costs (see above).

PARALLEL IMPORT AUTHORISATION PROCEDURE CONDUCT ·

- On the day of delivery of the application to the Institute the administrative procedure commences and the statutory 45-day period for the issue of the decision starts.
- Where the application does not contain the mandatory particulars, the Institute shall ask the applicant to provide the missing information and the procedure shall be suspended. For the period when the procedure is suspended, the administrative period shall be suspended as well. Where the suspension lasts for more than 180 days the procedure may be stopped.
- If the Institute does not receive the required additional information for the application within the period of time established in the decision on the suspension of the administrative procedure, the application shall be declined.
- The Institute may, moreover, request additional information on the conditions of marketing authorisation of the parallely imported medicinal product from the concerned regulatory authority of the country from which the product is to be imported. The period of 45 days is then extended to 90 days, and is suspended for the time from the request to the delivery of the information. Where the Institute fails to obtain the necessary data, the application shall be declined.
- Where other information is needed, the Institute may also address the marketing authorisation holder of the reference product, who is, pursuant to Section 45 , paragraph 6 of the Act, obliged to provide upon request of the Institute information on the conditions of marketing authorisation in the Member States and on differences

between the marketing authorisation of the reference product in the Czech Republic and in the Member States, incl. information on manufacturing sites.

DECISION ON PARALLEL IMPORT AUTHORISATION

Where all statutory conditions are met, the Institute shall issue a decision granting parallel import authorisation, which shall contain the following data:

- Identification of the holder of parallel import authorisation;
- Name, strength, pharmaceutical form, and pack size of the parallely imported medicinal product;
- Name of the country from which the product is to be imported;
- Marketing authorisation number of the product to be parallely imported which shall be generated from the marketing authorisation number of the reference product in the Czech Republic by adding the "PI" code (standing for "parallel import"), a sequence number of the authorisation issued for the given medicinal product (regardless of the pharmaceutical form, strength, pack size, country from which it is imported, etc.), and year of the parallel import authorisation (e.g. 59/001/95-C/PI/001/08);
- Code of the Institute for each pack size and type of immediate packaging of the parallely imported product;
- Special conditions which have to be fulfilled by the holder of the parallel import authorisation, e.g. to submit samples of each batch of the medicinal product for retesting by the Institute prior to the release onto the market where this duty has been imposed upon the marketing authorisation holder of the reference product.

A parallel import authorisation shall be valid for the period of 5 years, and on the basis of an application may be (repeatedly) renewed for further five years.

PUBLISHING OF INFORMATION ON PARALLEL IMPORT AUTHORISATIONS

Information on parallel import authorisations shall be published by the Institute on a monthly basis in SÚKL Bulletin and on the website of the Institute www.sukl.cz.
The published information shall include the name, strength, pharmaceutical form, and pack size of the medicinal product, marketing authorisation number of the parallely imported product, name of the holder of the parallel import authorisation, and a notice of any differences significant for healthcare professionals and patients as may be applicable. These data shall be published for newly issued authorisations as well as for revoked or expired authorisations.

Medicinal products, for which parallel import authorisations have been granted, shall be entered in the List of authorised medicinal products which is available from the website www.sukl.cz.

DUTIES OF THE HOLDER OF PARALLEL IMPORT AUTHORISATION

Pursuant to Section 45, paragraph 7 of the Act, the holder of the parallel import authorisation shall be obliged to:

a) maintain records of the origin, number of packages, and batch numbers of the parallely imported product for the minimum period of 5 years;

b) ensure that the supply or marketing of the parallely imported medicinal product is suspended in the same scope as that of the reference product in the Czech Republic or that of the product in the Member State from which it is imported, if the supply or marketing of the reference product has been suspended due to a quality defect or decreased safety or efficacy of the product or if the marketing authorisation of the reference product in the Czech Republic or in the Member State has been revoked for public health protection reasons;
c) monitor variations to the marketing authorisation of the reference product and reflect in the parallely imported product such changes which may affect the efficacy and safety of the medicinal product; where a change requiring a variation to the parallel import authorisation is concerned (i.e. where data submitted with the original application for parallel import authorisation are changed; this does not apply to data necessary for cooperation with the holder of the parallel import authorisation) implement such variation by means of an application for variation to parallel import authorisation (Annex 2 to this Guideline refers);
d) use for re-packaging, re-labelling and any other operation involving the parallely imported product only the services of holders of manufacturing authorisations for pharmaceuticals, and notify any possible changes to these manufacturers to the Institute in advance;
e) label the re-packaged medicinal product in a manner stipulated by the Decree on Marketing Authorisation and in compliance with the decision granting the parallel import authorisation (see above);
f) cooperate with the Institute as outlined in Section 33 , paragraph 3, letters d) and e) of the Act – to provide to the Institute samples of the product upon request for the purposes of laboratory control and to forthwith inform the Institute on changes to the data of the holder of the parallel import authorisation;
g) notify the marketing authorisation holder of the reference product in the Czech Republic of the intention to commence parallel import of the product at least one month in advance, taking into consideration the provision of the Treaty of Accession of the Czech Republic to the EU (see above), and, upon request, provide a sample of the parallely imported product to the reference product marketing authorisation holder in the form marketed in the Czech Republic;
h) ensure pharmacovigilance by means of collecting, recording, and notifying adverse reactions to the marketing authorisation holder and to the Institute, applying the rules specified in guideline PHV-1, particularly as regards the minimum scope of the data to be notified.

SUSPENSION OR REVOCATION OF A PARALLEL IMPORT AUTHORISATION

The Institute shall suspend or revoke a parallel import authorisation, if:

- The validity of the parallel import authorisation of the product poses a risk to public health (i.e. especially in those cases where the marketing authorisation of the reference product for the parallel import in the Czech Republic or of the parallely imported product in the Member State has been revoked and the Institute has evaluated reasons for suspension or revocation of the marketing authorisation in terms of the risk-benefit ratio and the product poses a risk to public health);
- The holder of the parallel import authorisation fails to comply with the conditions stipulated by the authorisation;
- The holder of the parallel import authorisation has seriously breached the conditions laid down by the Act.

The Institute shall revoke a parallel import authorisation of a medicinal product upon request.