REG-84 version 1 Electronically submitted applications regarding marketing authorisation.

This guideline supersedes guideline REG – 84, as of October 1. 2008.

1. INTRODUCTION

Abbreviations

eCTD Electronic Common Technical Document
ICH International Conference on Harmonisation
TIGes Telematics Implementation Group on Electronic Submission

Decree No 228/2008 Coll., on the marketing authorisation of medicinal products in its Section 3, paragraph 1 stipulates as follows: “Applications and other documentation submitted to the Institute, where products for human use are concerned, or to the Veterinary Institute, where products for veterinary use are concerned, must be submitted in electronic format, unless in special cases agreed otherwise with the Institute where products for human use are concerned or with the Veterinary Institute where products for veterinary use are concerned. Where products for human use are concerned, the applications and other documentation shall be processed in the eCTD electronic format as advised by the Institute; this format shall be also used for information and reports to be submitted in compliance with this Decree in electronic format to the Institute.”

The following shall be considered special cases:

- Situations when, should the application remain pending due to the failure to submit source materials in the eCTD electronic format, the health of the patient would be jeopardised due to unavailability or shortage of the concerned medicinal product on the market (E.g. the conduct of safety-related variations to marketing authorisation, marketing authorisation renewals for medicinal products which cannot be therapeutically interchanged, applications for marketing authorisation of products containing new active substances in the Czech Republic, applications for marketing authorisation of products containing a new combination of active substances, applications for marketing authorisation containing a new indication, new strength and new pharmaceutical form, applications for marketing authorisation, MA renewals or variations to MA of a product intended for paediatric use, applications for marketing authorisation of a product submitted as “line extension“);
- Situations when, should the application remain pending due to the failure to submit source materials in the eCTD electronic format, unjustified higher costs to be covered by the public health insurance would arise (e.g. delayed marketing of a cheaper generic product);
- European MA procedures (MRP and decentralised procedure), where the Czech Republic is the Concerned or Reference Member State;
- Inclusion of a previously authorised medicinal product in a Mutual Recognition Procedure (REG-80);
- Any applications for variations to or renewals of marketing authorisation of products which have been authorised via so called national procedure where documentation in the NTA format has been submitted with the original application for marketing authorisation (the application for marketing authorisation has been submitted before 11 May 2004); the submission of the application must include a proper justification that the products concerned are medicinal products the marketing authorisation of which was applied for before the coming into force of Decree No 288/2004 Coll. (Marketing Authorisation Decree);
- Amendments to marketing authorisation dossiers within the scope of pending administrative procedures;
- Other cases where the applicant provides an adequate rationale of why the application cannot be declined due to the failure to submit documentation in electronic format with a view to the public interest, public health and/or availability of an effective therapy.

Any special case must be properly documented by the applicant, i.e. the applicant shall be obliged to provide a written rationale for submitting the application and dossier in a format other than the eCTD.

2. TYPES OF APPLICATIONS AND RELATED DOCUMENTATION

With respect to the above mentioned facts, from July 1 2008, any application and related documentation shall be submitted to the Institute in electronic format. The submissions apply to new applications for marketing authorisation regardless of the type of procedure (national, MRP, DCP), applications for variations, applications for renewal and revocation of marketing authorisation, applications for transfer of marketing authorisation, applications for parallel import and applications for take-over of marketing authorisation. Failure to submit the application and dossier in electronic format in other than the above specified special cases shall mean that the submission does not comply with the particulars specified by the Act on Pharmaceuticals and its implementing regulation with all of the consequences (e.g. in the case of Type IA variations it will not be possible to confirm the notified changes; in the case of Type IB variations which require approval it will imply an invitation to amend and eliminate these shortcomings, like in the case of submitting an application for marketing authorisation or renewal of marketing authorisation). The submission in electronic format applies not only to the application but also to the documentation to be provided in order to supplement a pending administrative procedure initiated by an application in the course of 2008.

3. PROCEDURE TO SUBMIT APPLICATIONS AND DOCUMENTATION

The format applicable to the marketing authorisation documentation shall be the eCTD (Electronic Common Technical Document). It is defined as an interface for the exchange of information between applicants/marketing authorisation holders and the regulatory authority. It reflects the standard 5-module structure of the dossier. The format of Modules 2 – 5 is stipulated by the requirements of ICH (International Conference on Harmonisation) which are uniform for the EU, USA, and Japan and their current version is available from the ICH website*):

- http://estri.ich.org/

The format of Module 1 is governed by regional requirements; i.e. for the EU by the requirements drafted by TIGes (Telematics Implementation Group on Electronic Submission); their current version is available from the website of the European Commission *):

- http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/homev2.htm

For the time being it is possible to submit documentation on electronic data carriers or via the electronic mail room.

A) Submission using an electronic data carrier

The electronic data carrier (a CD or DVD) must be labelled with the following information:

- Name of the product, pharmaceutical form, strength;
- Application type (new marketing authorisation, renewal, variation; where a MRP and DCP application is concerned, also the procedure number);
- Name of the applicant for marketing authorisation (marketing authorisation holder **);
- Marketing authorisation number **);
- A numeric identification of the data carrier/total number of data carriers (e.g. 1/3, 2/3 and 3/3).

The data carriers shall be submitted together with a cover letter which will contain an overview of information contained on all carriers submitted within the scope of the concerned application, incl. information on the total number of electronic data carriers enclosed. For the time being, product information (SPC, PIL, labelling) shall be submitted in text editor format (MS WORD 97-2007). Apart from their electronic format, application forms shall be also submitted in two printed copies.

B) Submission via the electronic mail room

The documentation in the eCTD format submitted via the e-mail room shall be provided in a compressed ZIP format, without any password. For the eCTD directory it is necessary to be

compressed, incl. the root directory. For the time being it is possible to use the e-mail room only for the submission of documentation which in **its compressed form does not exceed 10MB.** Documentation with attached certified electronic signature is to be sent to posta@sukl.cz .

*) Links to websites are valid as of the date of publication of this information.
**) Applies to authorised medicinal products.