REG-84 version 3 Electronically submitted applications regarding marketing authorisation

This guideline supersedes guideline REG – 84 version 2, as of July 1, 2014.

1. INTRODUCTION

Abbreviations

eCTD	Electronic Common Technical Document
NeeS	Non-eCTD Electronic Submissions
MRP	Mutual Recognition Procedure
DCP	Decentralized Procedure
CESP	Common European Submission Platform
ASMF	Active Substance Master File
RMP	Risk Management Plan
PSUR	Periodic Safety Update Report

Decree No 228/2008 Coll., on the marketing authorisation of medicinal products, as amended, 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 or NeeS 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."

In compliance with the foregoing, it is no longer possible to submit applications and other documents associated with newly submitted applications regarding marketing authorization in other than the valid eCTD or NeeS format as of January 1, 2014.

2. TYPES OF APPLICATIONS AND RELATED DOCUMENTATION

With respect to the aforementioned facts, from January 1, 2014, all newly submitted applications and related documentation, incl. additions and supplements thereto, shall be submitted to the Institute in the valid eCTD or NeeS 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 of marketing authorisation, applications for transfer of marketing authorization and applications for take-over of marketing authorisation.

Failure to submit the application and dossier in electronic format in the valid eCTD or NeeS format shall mean that the submission does not comply with the particulars specified by Act No. 378/2007 Coll., on Pharmaceuticals and on Amendments to Some Related Acts (Act on Pharmaceuticals), as amended, and its implementing regulation with all of the consequences (e.g. in case of Type IA variations of national marketing authorisations it will not be possible to accept the notifications; in the case of Type IB or II variations of national marketing authorisations it will not be possible to acknowledge the receipt of the valid notification or application; where the proceedings require approval, e.g. submission of the application for marketing authorisation or renewal of marketing authorization, it will imply an invitation to amend and eliminate these shortcomings).

3. PROCEDURE TO SUBMIT APPLICATIONS AND DOCUMENTATION

The format applicable to the marketing authorisation documentation shall be the eCTD and the NeeS.

For more information on the eCTD format, please visit the following websites[1]:

- http://esubmission.ema.europa.eu/tiges/docs/eCTD%20Guidance%20v3.0%20final%20Aug13.pdf
- http://esubmission.ema.europa.eu/eumodule1/index.htm
- http://estri.ich.org/eCTD/eCTD_Specification_v3_2_2.pdf

When transitioning to the eCTD format, it is highly recommended to present a "baseline", most commonly as a 0000 sequence containing no less than Module 3. The baseline constitutes the submission of the existing state of the documentation, i.e. the repeated submission of the approved documentation that has already been submitted to the State Institute for Drug Control, only this time in another format. This submission does not constitute a change in or addition to the documentation. Therefore, it is most convenient to submit it when no registration proceedings are pending.

It is impossible to revert back from the eCTD format to the NeeS format. When transitioning from the NeeS format to the eCTD format, it is also necessary to present a baseline.

For more information on the NeeS format and its particulars, please visit the following website[1]:

- http://esubmission.ema.europa.eu/tiges/docs/NeeS%20eGuidance%20Document%20v4%200_final%20for%20publication%20Nov%202013.pdf

The "baseline" is not required when making the move to the NeeS format.

In terms of technical validation, the documentation in the eCTD and NeeS formats must be submitted in line with the applicable validation criteria. The applicable validation criteria for the eCTD and NeeS formats are available here[1]:

- http://esubmission.ema.europa.eu/tiges/tigesdocuments.html

The national requirements of the individual member states of the European Economic Area on submissions are available on HMA's website[1]:

- http://www.hma.eu/277.html

Product information (summary of product characteristics, package leaflet and labelling) must be, in addition to the PDF format in module 1.3.1, submitted also in MS WORD and placed in the "working documents" section outside the appropriate sequence.

It is required to deliver powers of attorney (unless delivered earlier) with the original signature by post or courier, so that the original power of attorney is ideally delivered on the same day as the submission via CESP or close to this date. If an authorisation is granted for an unspecified number of a particular subject - related proceedings that will be initiated in future, the grantor's signature must be officially certified.

It is possible to submit applications and documentation regarding medicinal products authorised via national procedure or DCP or MRP on electronic data carriers, via the electronic mail room, the data box or the CESP portal.

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)*

[1] *Links to websites are valid as of the date of publication of this information.*

Name of the applicant for marketing authorisation (marketing authorisation holder [2])
Marketing authorisation number[2]
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 and the electronic format used.

Apart from their electronic format, application forms shall be also submitted in the printed version with original signature of the authorized representative.

B) Submission via the electronic mail room

The documentation in the eCTD or NeeS format submitted via the e-mail room shall be provided in a one compressed ZIP file, without any password. No other compressed files may be placed in this ZIP file. For the eCTD or NeeS 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 15 MB.** Documentation with attached certified electronic signature of the authorized representative is to be sent to posta@sukl.cz.

C) Submission via the data box

The documentation in the eCTD or NeeS format submitted via the data box shall be provided in one compressed ZIP file, without any password. No other compressed files may be placed in this ZIP file. For the eCTD or NeeS directory it is necessary to be compressed, incl. the root directory. It is possible to use the data box only for the submission of documentation which **in its compressed form does not exceed 10 MB.**

D) Submission via the CESP portal

The documentation in the eCTD or NeeS format submitted via the CESP portal shall be provided in one compressed ZIP file. No other compressed files may be placed in this ZIP file. For the eCTD or NeeS directory it is necessary to be compressed, incl. the root directory. Through the CESP portal, it is possible to send any type of marketing authorisation applications and related documentation, except documentation on centralized procedures, ASMF and PSUR **without size restrictions.** More information on submission of documentation through the CESP portal can be found at: http://cesp.hma.eu/GeneralInformation.

[2] *Applies to authorised medicinal products.*