REG-84 version 6
Electronically submitted applications regarding marketing authorisation

This guideline supersedes guideline REG – 84 version 5, as of November 21, 2018.

The guideline is being issued on the basis and in compliance with the Decree No 228/2008 Coll., on the marketing authorisation of medicinal products, as amended.
The guideline is legally binding.

1. INTRODUCTION

Abbreviations

eCTD	Electronic Common Technical Document
NeeS	Non-eCTD Electronic Submissions
MRP	Mutual Recognition Procedure
DCP	Decentralized Procedure
MA	Marketing authorisation
eAF	Electronic Application Form
RUP	Repeat-Use Procedure
CESP	Common European Submission Platform
ASMF	Active Substance Master File
RMP	Risk Management Plan
PSUR	Periodic Safety Update Report
HMA	Heads of Medicines Agencies
EMA	European Medicines Agency

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, the Institute started to accept applications and other documentation associated with newly submitted applications regarding marketing authorization only in the valid eCTD or NeeS format, the use of which is further specified below in chapter Obligation to use eCTD format and electronic Application Form (eAF).

2. OBLIGATION TO USE eCTD FORMAT AND ELECTRONIC APPLICATION FORM (eAF)

With regard to the development of a uniform system for the submission of applications for marketing authorisation and related documentation across the European Medicines Regulatory Network, HMA and EMA approved and in November 2014 published so called eSubmission

Roadmap, which, *inter alia*, imposes the below specified obligations upon applicants for marketing authorisation and marketing authorisation holders in the sphere of use of the eCTD format and the eAF type application forms.

Binding data for the submission of documentation in the eCTD format:

- **As of 1 July 2015, the applications for marketing authorisation** newly **submitted via decentralised procedure (DCP)**, including applications for marketing authorisation of so called duplicates, are **accepted solely in the eCTD format**
- **As of 1 January 2017, the applications for marketing authorisation newly submitted via mutual recognition procedures (MRP, including RUP, and extensions of marketing authorisation within the scope of both DCP and MRP)** are **accepted solely in the eCTD format**
- **As of 1 January 2018,** any **other MRP and DCP applications** (e.g. for MA variations and renewals) **shall be accepted solely in the eCTD format**
- **As of 1 July 2018, the applications for marketing authorisation** newly **submitted via national procedure** shall be **accepted solely in the eCTD format**
- **As of 1 January 2019,** any **other national applications** (e.g. for MA variations and renewals) **shall be accepted solely in the eCTD format**

- **ASMF:** The format should be in accordance with the format of the dossier according to the above mentioned rules.

Obligations to submit the application form of the eAF type:

- **As of 1 January 2016** sole use of the **eAF electronic application form for all newly submitted applications for new marketing authorisations, MA variations and renewals submitted through national procedures, DCP as well as MRP**

Possibility to submit an application form which is not of the eAF type:

- **As of 1 January 2016, use of other types of AF permissible only for application forms which have been issued by the Institute and are available from** http://www.sukl.cz/leciva/pokyny-a-formulare (e.g. application for parallel import authorisation, variations thereto and renewals thereof; application for MA revocation; application for MA transfer; application for variation to labelling or package leaflet which is not associated with the summary of the product characteristics; application for CZ outgoing Mutual Recognition Procedure)

The eSubmission Roadmap is available from the eSubmission[1] website:

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

The aforementioned rules governing the use of the eCTD form and the eAF electronic Application Form shall be applicable to all of the aforementioned types of applications and related documentation, including amendments thereto, newly submitted as of the aforementioned timelines.

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

Failure to submit the application and dossier in compliance with the aforementioned rules 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 it will not be possible to accept the notifications; in the case of Type IB or II it will not be possible to acknowledge the receipt of the valid notification or application; where the submission of the application for marketing authorisation or renewal of marketing authorization is concerned, an invitation to amend and eliminate these shortcomings shall be issued).

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:

- http://esubmission.ema.europa.eu/tiges/docs/eCTD%20Guidance%20v4%200-20160422-final.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, it is necessary to submit the documentation in the eCTD and NeeS formats 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/cmbdocumentation.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

Information on electronic application form (eAF) is available from[1]:

- http://esubmission.ema.europa.eu/eaf/index.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.

Powers of attorney containing an authorisation for an unspecified number of a particular subject - related proceedings that will be initiated in future, must be delivered with the original signature by post or courier, 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)*
Name of the applicant for marketing authorisation (marketing authorisation holder [2])
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 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. 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.

[2] *Applies to authorised medicinal products.*

C) Submission via the data box

The documentation in the eCTD or NeeS format submitted via the data box shall be provided in a non-compressed form. It is possible to use the data box only for the submission of documentation which **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, **without size restrictions.** More information on submission of documentation through the CESP portal can be found at: https://cespportal.hma.eu.