REG-84 version 8 Electronically submitted applications regarding marketing authorisation

This guideline supersedes guideline REG–84 version 7 with the effect from July 1 2024.

The Guideline is issued in accordance with the provision of Section 3 paragraph 1 of Decree no. 228/2008 Coll.

The Guideline is for recommendation.

Its content is based on legal requirements and EMA and CMDh recommendations which are legally binding.

1. INTRODUCTION

Abbreviations

eCTD	Electronic Common Technical Document
NeeS	Non-eCTD Electronic Submissions
MRP	Mutual Recognition Procedure
DCP	Decentralized Procedure
eAF	Electronic Application Form
CESP	Common European Submission Platform
ASMF	Active Substance Master File
PIL	Package leaflet
SmPC	Summary of the product characteristics
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 accepts applications and other documentation regarding marketing authorisation only in the valid eCTD or NeeS format, the use of which is further specified below.

2. OBLIGATION TO USE eCTD FORMAT, ELECTRONIC APPLICATION FORM (eAF), AND THE CESP PORTAL

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, the eAF type application forms, and the CESP portal**.

Submission of applications and related documentation in the eCTD format:

- **As of 1 January 2019, all applications for marketing authorisation, variations to and renewals of marketing authorisation via the national, DCP or MRP procedures shall be submitted solely in the eCTD format** *(in respect of applications for marketing authorisation transfers and revocations and national applications for changes to labelling or PIL that are not associated with the SmPC, it is strongly recommended to use the eCTD format; the NeeS format submitted in compliance with effective validation criteria shall be also acceptable)*
- Furthermore, **as of 1 May 2020, amendments to all applications for marketing authorisation, variations to and renewals of marketing authorisation via the national, DCP or MRP procedures** shall be submitted **exclusively in the eCTD format**
- **Parallel import, variation and renewal of parallel import authorisation:** dossier shall be submitted in eCTD or NeeS format, unless an exemption has been agreed with the Institute
- **ASMF:** The format should be in accordance with the format of the dossier

Submission of applications via the CESP portal:

- As of 1 July 2019, **common documentation for all applications for marketing authorisation**, variations to and renewals of marketing authorisation via the DCP or MRP **procedures shall be submitted exclusively via the CESP portal** (the CESP portal is strongly recommended for submissions within the scope of the national phase of the DCP and MRP procedures and within national procedures; other below listed methods of submission are also acceptable)

Submission of the application form of the eAF type:

- **As of 1 January 2016** sole use of the **eAF electronic application form for all applications for marketing authorisations, variations to and renewals of marketing authorisation submitted via national, DCP and MRP procedures**

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 – REG-87, variations thereto – REG-88 and renewals thereof – REG-95; application for marketing authorisation revocation – REG-72; application for marketing authorisation transfer – REG-69; application for changes to labelling or PIL that are not associated with the SmPC – REG-90)

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

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

Failure to submit the application and related documentation 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 authorisation is concerned, an invitation to amend and eliminate these shortcomings shall be issued).

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

3. INFORMATION ON THE eCTD AND NeeS FORMAT AND ON TRANSITION TO THE eCTD FORMAT

The obligatory format applicable to the marketing authorisation documentation shall be the **eCTD and the NeeS** (NeeS only for applications for marketing authorisation transfers and revocations and national applications for changes to the labelling or PIL not associated with the SmPC).

For more information on the eCTD and NeeS format and on effective validation criteria that have to be complied with, please visit the following website:

- http://esubmission.ema.europa.eu/ectd/index.html

When transitioning to the eCTD format, it is strongly 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 Institute, 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.

The mandatory eCTD format shall be also applicable to amendments to all applications for marketing authorisation, variations to and renewals of marketing authorisation via the national, DCP or MRP procedures.

The course of action to be taken when transitioning to the eCTD format in ongoing procedures, strong recommendation to use the tracking table also for national procedures, and the obligation to use the unique UUID identifier are available from the Q&A section of the following website[1]:

- http://esubmission.ema.europa.eu/ectd/index.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 (SmPC, PIL, 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 before, or at the latest on the date of submission of the application.

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.

4. METHODS OF SUBMISSION OF APPLICATIONS AND RELATED DOCUMENTATION

Via the CESP portal:

- **Mandatory** for the submission of **common documentation for all applications for marketing authorisation, variations to and renewals of marketing authorisation via the DCP and MRP procedures**.
- The documentation shall be submitted in the form of a single compressed file in the ZIP format. This ZIP file must not contain any other compressed file. It is necessary to compress the eCTD (or NeeS) directory including the root directory.
- The CESP portal may be used for the sending of all types of marketing authorisation applications and related documentation, except for documentation for centralised procedures,

without any size restrictions. For more information on the submission of documentation via the CESP portal, please refer to the following website: https://cespportal.hma.eu.

Via e-mailroom:

- The documentation shall be submitted in the form of a single compressed file in the ZIP format, without the use of a password. This ZIP file must not contain any other compressed file. It is necessary to compress the eCTD (or NeeS) directory including the root directory.
- The e-mailroom may be used only for the sending of documentation the **compressed size of which is less than 15 MB. The documentation, signed by a certified electronic signature of the authorised person, shall be sent to posta@sukl.cz**.

Via data mailbox:

- Documentation in the eCTD or NeeS format submitted via the data mailbox shall not be compressed.
- The data mailbox may be used only for the sending of documentation the size of which is **less than 20 MB**.

On 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 and the electronic format used.

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