

Q&A ON THE USE OF eCTD IN MRP/DCP

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1. How to deal with National Translations of the Product Information

Question 1.1

In the future, should the final versions of the national translations be submitted in an eCTD sequence?

Answer:

No, in the BPG on the use of the eCTD in MRP and DCP it has been clarified that national translations should be handled outside the eCTD. There is no requirement to submit *any* version of the national translations in the eCTD format. Only the final English version should be handled within the eCTD.

Question 1.2

As national translations are now to be handled outside the eCTD, how should an applicant proceed with existing eCTDs that already contain national translations? Should the national translations be deleted from the eCTD, and in this case when should it be done?

Answer:

We recommend applicants delete the national translations in the eCTD with the next submitted sequence or, at the latest, when the translations become obsolete. Preferably, this should be clarified in the cover letter.

Question 1.3

How should the national translations be submitted to the relevant NCA?

Answer:

They can be submitted via Eudralink or e-mail in accordance with the national requirements in the same way as for non-eCTDs. Please follow national guidance.

Question 1.4

At the NCAs, are the national translations handled separately within its own life cycle?

Answer:

It is up to each NCA how the national translations are stored, e.g. in a separate folder beside the eCTD or in a totally different system.

Question 1.5

Is the recommendation to handle national translations outside the eCTD only applicable to new applications or also for variations and other procedures?

Answer:

The recommendation is applicable throughout the whole life cycle of a medicinal product. This means that national translations are never submitted within an eCTD sequence. When the national translations are submitted at the start of a procedure (e.g. Type IA and IB) they should be submitted together with the application but outside the eCTD structure. Section 2.9.6 of the “Guidance for Industry on Providing Regulatory Information in Electronic Format: eCTD electronic Submissions” (<http://esubmission.ema.europa.eu/doc/index.html>) illustrates how to organise and submit these files on the submission medium with an eCTD sequence.

Please also refer to Variations Q&A

http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/Variations/CMDh_132_2009_Rev3-Clean.pdf