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/20.html

Question 1.6

Deleted in June 2015

2. How to deal with the numbering of eCTD sequences

Question 2.1

If a submission is found to be technically invalid, how should the corrected sequence be submitted?

Answer:

When submitting an eCTD in DCP or MRP, the so called 'comprehensive' model should be used, since it ensures that the same sequence number is used for all mutual submissions and therefore minimises any potential confusion between NCAs.

a. Technical validation: If a submission is found to be technically invalid, a corrected sequence should always be submitted immediately to RMS and all CMSs, re-using the same sequence number.
b. Content validation: If the content (regulatory) validation concludes that not all documents have been submitted in a technically valid application or any other

corrections are needed, the following submission including the corrections on the content should have the next unused sequence number and so keep a continuous numbering system. This eCTD sequence could be submitted at the end of the validation period to all RMS/CMSs.

For further information see CMDh Best Practice Guide on the use of the electronic Common Technical Document (eCTD) in the Mutual Recognition and Decentralised Procedures Doc. Ref.: CMDh/084/2008
http://www.hma.eu/277.html