



Changes in the Procedural guidance for validation in DCP and MRP - Input from the public consultation

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On behalf of CMDh

Background

- **A proposal to clarify the technical validation in the CP, DCP and MRP was raised from industry through a Change Request to TIGes**
- **Also, the need to simplify the technical validation for DCP and MRP was raised from the authorities with a proposal to leave the technical validation for RMS to handle**
- **This was encouraged by CMDh and HMA.**
- **The Procedural Advice for Automatic Validation needs to be updated and a proposal was published at the CMDh website for public consultation**

The proposed update was published at the CMDh website for Public Consultation

CMDh
Co-ordination Group for Mutual Recognition
and Decentralised Procedures – Human

**PROCEDURAL ADVICE
AUTOMATIC VALIDATION
OF MR/REPEAT-USE/DC PROCEDURES**

PUBLIC CONSULTATION
This draft revision is for public consultation until 9 November 2011. Comments should be sent to h-CMDhSecretariat@ema.europa.eu.

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All days mentioned in this document should be regarded as calendar days.

Technical validation of electronic submissions
Applications in electronic format (eCTD or NeeS) should be checked for technical validity by the RMS as a pre-step before the application is submitted to the CMS and the administrative.

Answers were received from:

- EGA
- AESGP
- EFPIA
- some pharmaceutical companies and consultants

The CMDh really welcome and thank you for the comments.

Issues raised by industry are presented as well as reflections from the CMDh

Main issues raised from industry

The principle of RMS to technically validate is well supported

Technical validation problems seem to declined

Still issues are seen regarding corrupt CDs due to burning mistakes which will still remain

It is emphasised that the CMSs have to really rely on the technical validation done by the RMS (even if different tools) and never re-test and request updates

The CMDh appreciate that eSubmission quality seems to improve. For burning problems, applicants are requested to check each CD/DVD for readability prior to submission to NCAs

It is clear to all NCAs that CMSs should rely on the RMS so this should not be a problem when implemented. Small differences, if any, should be accepted. (These are currently not many and an improvement is foreseen in future updates of the tools.)

Main issues raised from industry

The clarified timeline for technical validation is seen as prolonging the total validation time, which is not welcomed. It would not promote electronic submissions instead of paper.

The technical validation acceptance by RMS is proposed to be communicated by CTS instead of via e-mail to be printed by applicants and attached to the CMSs submission

The regulatory ("content") validation normally starts after the submission is found technically valid and is loaded into the document management systems. The time needed if only the RMS will do this step will be further discussed in the CMDh.

The use of CTS will be further discussed.

Main issues raised from industry and clarification from CMDh

The technical validation made by the RMS should only apply to the eCTD format, since NeeS submissions are not exact copies in all MSs, as the national documents are mainly included by the local affiliates

For agencies, the changed procedure would only be really beneficial if it applies to both eCTD and NeeS. Also, since to dossiers should be exactly the same in different MSs, the CMDh see this raised issue as a major problem. Further discussions are needed on what differences there are and how we can solve this to end up in ONE common dossier also for NeeS.

Main issues raised from industry and clarification from CMDh

The statement that technical validation cannot be done before the Data Exclusivity expiry is arguable since the generic applicant does not at that stage refer to the preclinical and clinical data of the reference product

For now there is a strong position of many NCAs concerning the Data Exclusivity expiry as stated in the current proposal

The inclusion of a "pre-step" is not encouraged as it will give problems around the critical finalisation of a dossier

The procedure will be further discussed in the CMDh to see if other solutions might be possible. Anyhow, the applicants are advised to technically validate with the appropriate validation tools

Main issues raised from industry and clarification from CMDh

Proposed that the technical validation should only be performed by the applicant and a report and the MD5 checksum be provided

This might be appropriate in the future, but for now this would not be accepted by the CMDh

Main issues raised from industry and clarification from CMDh

Will the RMS technical validation procedure be extended also to other submission types (renewals, variations...)?

Yes, the plan is that this will be applicable to all submission types. However, we have to first implement for new MAA and see how it works. Specific issues/questions raised by industry will be taken into account as appropriate if/when other submission types are concerned.