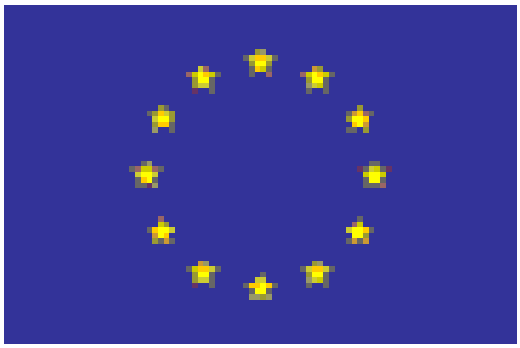
Revised Implementation guide for

EU Module 1 Specification, version 2.0

and

EU eCTD Validation Criteria, version 5.0

EU NeeS Validation Criteria, version 4.0



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EU eCTD M1 Specification v2.0

A new version of the EU eCTD M1 Specification, version 2.0, was published on 1 March 2013 on the EMA eSubmission website. The version 2.0 enables marketing authorisation applications in Croatia and can be used from 1 July 2013.

The EU eCTD M1 Specification v2.0 will be required by EMA and National Competent Authorities in EU from **1 September 2013**.

EU Validation Criteria

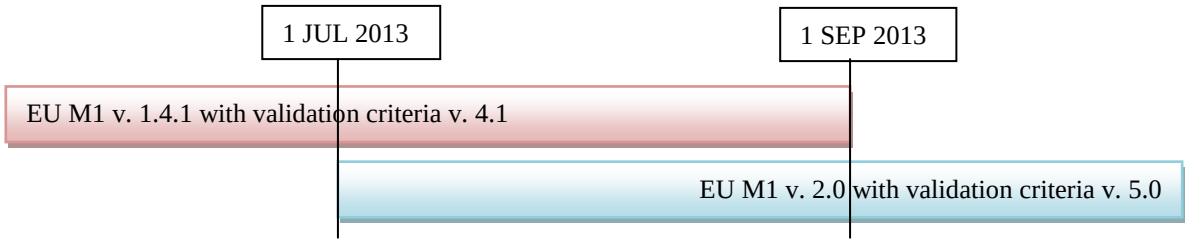
New versions of the validation criteria have been published at the EMA eSubmission website. They are mainly related to the EU Module 1 Specification version 2.0 and will come into force on **1 September 2013**. They will be used for the technical validation for all electronic submissions received from that day to the NCAs and EMA.

The earlier version of the criteria, version 4.1, will be withdrawn by close of business on 31 August 2013. Therefore, it is important that applicants plan their submissions very carefully around this date to prevent problems in the validation.

Transition period

During a transition period from **1 July 2013 to 31 August 2013**, applicants can *either* submit eCTDs compliant with EU M1 v.1.4.1 and validation criteria version 4.1 *or* eCTDs compliant with EU M1 v.2.0 and validation criteria version 5.0.

From 1 September 2013 *only* eCTDs compliant with EU M1 v.2.0 and validation criteria v.5.0 are accepted.



Provision of copies of sequences previously submitted for a Marketing Authorisation Application in the centralised procedure

For CAPs, previously submitted, technically valid eCTD sequences should be provided to Croatian Agency only on Croatian Agency's request.

eCTD submissions in EU procedures after the accession of Croatia

Croatia will be a member of EU as from 1 July 2013. If there is a need to submit information relevant to Croatia in any EU procedure (MRP, DCP or CP) before 1 September, it is acceptable to use EU Module 1 v1.4.1. The information relevant for Croatia (i.e. product information in Croatian language and any specific Croatian documents) can be submitted in a "working documents" folder outside the eCTD structure and should be provided together with the submission in a subfolder named "HR". It is strongly recommended to mention the inclusion of the Croatian documentation in the application cover letter.

In the Centralised Procedure, if the submission of the Croatian Product Information is required prior to the accession on 1 July 2013, the relevant documents should be included in the "working documents" folder outside the eCTD structure and should be provided together with the submission in a subfolder named "HR" with a note on the cover letter.

If the submission of the Croatian Annex A is required it may be included in the "working documents" folder or within the eCTD structure of EU Module 1, section 1.2 Application form, in the EMEA sub folder.

For MRP/DCP the relevant documents in Croatian can only be included after 1.7.2013.

After 1 September, only EU Module 1 v2.0 should be used in all EU procedures and the eCTD should include all relevant documents.

NeeS submissions

The timelines and transition arrangement stated above for technical validation of eCTD submissions are applicable also for NeeS submissions within the EU. NeeS submissions have to fulfil the EU NeeS Validation criteria version 4.0 from 1 September. *(Please note that NeeS submissions are not accepted within the centralised procedure.)*