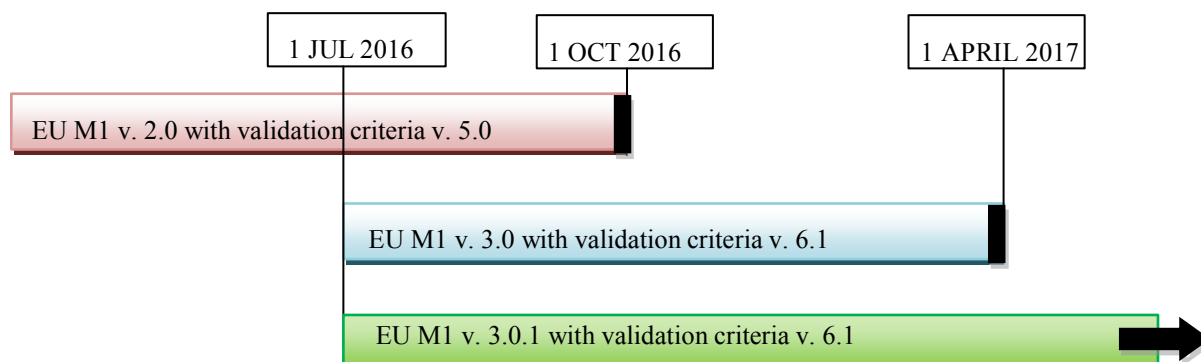# Release Notes for the EU eCTD Validation Criteria version 6.1

The currently valid version of the eCTD validation criteria is version 6.1 and it needs to be applied as of 1 July 2016 in combination with EU M1 specification versions 3.0 and 3.0.1.

The changes to version 6.0 of the validation criteria relate mainly to the updated eCTD EU Module 1 Specification v3.0. In March 2016, minor changes were made to the published eCTD EU M1 specification version 3.0 when errors were detected in the checksums. A further update to the specification to correct pick list values was published in May 2016, this updated version was published as EU M1 v3.0.1. Both versions 3.0 and 3.0.1 entered into force on 1st July 2016. The versions 3.0 and v3.0.1 will replace v2.0 on 1 October 2016 after which submissions in v2.0 will no longer be accepted. Submissions following versions 3.0 and 3.0.1 will both be accepted from 1st October 2016 for a parallel period of 6 months until 1 April 2017. The use of version 3.0.1 will be mandatory from 1 April 2017.

The eCTD validation criteria 6.0 were updated into version 6.1 to reflect the changes in EU Module 1. The changes in the validation criteria only affect the tab sheet "eCTD Validation Criteria" with the exemption of only additional recommendation for file naming rules in Module 1.2 for application forms and appendices and due to addressing ICH eCTD Q&A #81 for control strategy summary documents. The validation criteria were not updated as a result of the change from 3.0 to 3.0.1 of the specification as the criteria checking versions of technical files, such as the DTD, stylesheet and envelope.mod, refer to the currently acceptable version, as published on the eSubmission website. The actual MD5 checksums quoted in the validation criteria v6.1 are examples only, and are still the values from EU M1 v3.0. When submitting an eCTD with EU M1 v3.0 or v3.0.1, validation tools should automatically check for the relevant checksum.

Comparison of the new major version (6.1) with the version (5.0)

Criterion Number in version 6.1	Criterion Number in version 5.0	Changes
Tab sheet "eCTD Validation Criteria":		
3.3 4.3 5.3 6.3	3.3 4.3 5.3 6.3	Updated md5 checksum value for EU M1 DTD in 'Comments', to reflect v.3.0
9.3	9.3	No changes in the text as such, however, please notice that the additional elements in the envelope (UUID, submission-unit) and related sequences being changed to mandatory in the new specification will be covered by the requirement of a well formed XML being submitted

Criterion Number in version 6.1	Criterion Number in version 5.0	Changes
9.7	-	The conformity with the recommended ISO Standard on UUID to be checked
9.8	-	The consistency of UUID across sequences to be checked (requires access to previous submitted sequences)
9.9		The identity of the UUIDs in all envelopes of a sequence is required.
11.9	11.9	Modified criterion to exclude some files with specific country attribute in Module 1 from this check. The attributes 'common', 'ema', or 'edqm' are not considered to be country specific attributes. At the same time exactly these files will be checked as well but only indicating mismatches as a warning (Criterion 11.BP1).
11.10	11.10	Modifying the existing criterion, leaves within node extension within the same CTD section will now be exempted For those leaves the existence of the file to be modified still need be checked but compliance is considered to be best practice, see 11.BP2.
11.BP1	-	See above, 11.9
11.BP2		Newly added criterion to address issues occurring with 11.10 cheks.
-	11.BP2 11.BP3	Deleted as the checks are not necessary on leaf attributes
14.1		The submission type 'cep' has been added as an excluded submission type from this case where a single envelope is expected.
14.5		This criterion has been added to define the additional case of a single envelope for submission type 'cep'. The term 'centralised' is recommended to be used in this case as well. This criterion has been added as a consequential change to the more precise definition of criterion 14.1
14.BP1 14.BP2	-	New criterion where the envelope is checked whether related sequence is either completed with the current sequence number (in case of submission unit type 'initial' or 'reformat') or with the sequence number the regulatory activity has been started with. If the element is always #REQUIRED, then a missing related sequence is P/F; applicants can no longer fail to supply a related sequence for a lifecycle submission and get only a BP error. It makes it easier for review tools to come up with a regulatory activity view. The logic now is 'everything with the same related sequence', rather than sequence = xxxx and find other submissions where related sequence also = xxxx
14.BP4 14.BP5 14.BP6	-	New criteria to assure consistency between the stated submission mode and the eCTD envelope of the Number element/ procedure tracking and the high-level numbers for grouped applications and worksharing applications. However, the criteria are set to be BP as not in all cases such numbers will be available in advance.
15.BP1	15.BP1	Changes so that only files larger than 200 MB will be indicated
15.BP4 15.BP5	-	New criterion to check whether the country code has been used consistently in the leaf, the folder and the file specifically in m1-0-cover, m1-2-form, m1-3-1-spc, m1-3-2-mockup, m1-3-3-specimen, m1-3-4-consultation, m1-3-5-approved, m1-responses and m1-additional-data, completing the criteria 11.9 and 11.BP1.
16.BP5	16.BP5	The comment is extended to more clearly state that for eAF PDF files the 'Fast Web View' cannot be set.

Criterion Number in version 6.1	Criterion Number in version 5.0	Changes
Line 33	12-form	Recommended usage of the variable part of the file name in this section has been added: 'cc-form-eaf-var.pdf' and 'cc-form-annex-var.pdf'
Line 160	32s4-contr-drug-sub	Refer to ICH eCTD Q&A 81, additional files are now allowed for control strategy summary document.
Line 205	32p5-contr-drug-prod	Refer to ICH eCTD Q&A 81, additional files are now allowed for control strategy summary document.