Release Notes for the EU eCTD Validation Criteria version 7.0/7.1

The changes in the validation criteria relate mainly to change requests received from regulatory bodies and taking experiences with version 6.1 into account. The updated version 7.1 will come into force September 1st, 2018.

The changes in the validation criteria only affect the tab sheet "eCTD Validation Criteria"

Comparison of the new major version (7.0) and its update (7.1) with the current version (6.1)

Criterion Number in version 7.0	Criterion Number in version 6.1	Changes
Tab sheet "eCTD Validation Criteria":		
3.3 5.3 6.3	3.3 5.3 6.3	Updated md5 checksum value for EU M1 DTD in 'Comments', to reflect v.3.0.2. Note: The technical files are identical for version 3.0.2 and v.3.0.1 of the EU M1 Specification.
11.10	11.10	Leaves in Module 3.2.A will be exempt additionally as tools handling attributes differently in the past. Attributes in module 3.2.A should be allowed to be edited or not automatically copied.
11.11	-	In some cases the leaf IDs were not unique. Although unexpected, the new testing criterion will avoid these errors.
11.12	-	In some cases, multiple operations executed on the same leaf caused display issues due to inconsistent handling. The modified file must not have been subject to another replace or delete operation in any of the available sequences.
11.BP2	11.BP2	Reflecting the change of 11.10 the same exemption need to be applied to 11.BP2 as well.
11.BP3		An explicit test is added to exclude hyphens being used at the beginning or end of an attribute name even if it is an allowed character in other circumstances.
14.2	14.2	It should be omitted that an envelope 'common' will be used instead of country specific envelopes in MRP and DCP.
14.6 14.7		The previously new criteria 14.BP1 and 14.BP2 have not been sufficiently applied. Therefore, the reporting level will now be set to P/F. To allow a proper display of sequences in review tools it is essential that for submission unit types 'initial' und 'reformat' the same sequence number is inserted as related sequence and that in all other cases the correct related (different) sequence number is stated (referring to the relevant starting sequence for the regulatory activity).
--	14.BP1 14.BP2	These criteria are now deleted as BP and instead modified to become 14.6 and 14.7 with reporting level 'Pass/Fail'
14.8	-	New criterion to assure the INN data field is completed. It is strongly recommended to re-use the active ingredient name as of the application form. Separation of multiple names by colon.
14.9		It should be mandatory that an envelope 'edqm' will be used together with the procedure type 'centralised'. This is understood as an extension of 14.4
14.BP4	14.BP4	Further clarification on how to use the number element (complete it if mode is set to either 'grouping' or 'worksharing' and submission type is not 'psusa'
14.BP7 14.BP8	-	New criteria also to further clarify the use of the mode element • **'grouping':** submission type must be one of: 'var-type1a', 'vartype1ain', or 'var-type1b', or 'var-type2'; or 'extension' • **'worksharing':** submission type must be one of: 'var-type1b', or 'var-type2', or 'psusa'.
16.3	16.3	Section 1.0 will be exempt from these PDF checks for consistency as m1.0 is mentioned in criterion 16.4 specifically due to the PASS form.

Criterion Number in version 7.0	Criterion Number in version 6.1	Changes
16.4	16.4	Section 1.0 is additionally exempt from the check as it may contain unavoidable security settings based on the PAM form to be included there.
16.BP5	16.BP5	Section 1.0 is additionally exempt from the check as fast web view cannot be applied to the PAM form to be included there.
File-Folder Structure & Names	File-Folder Structure & Names	In case of Module 1.2 (Application form) the file names will be defined formally to distinguish between the form and any annexes. The identical change will be applied to the EU M1 specification. **Note:** Applicants are encouraged to use the new file name for eAF documents and their annexes with immediate effect as the newly required file names will also pass the current validation criteria.