

What is the Correct Use of Submission Mode?

There are currently two validation criteria checking for the appropriate use of mode and high level tracking number. 14.BP4 checks that a high-level submission number is provided if submission mode is set to either 'grouping' or 'worksharing'. 14.BP5 checks that there is no number if the mode is not either 'grouping' or 'worksharing'. The comments on these criteria describe mode in the context of Type IA variations or PSUSA submissions for multiple marketing authorisations, but there is no check to see whether mode has been used for the appropriate submission types. As a consequence, one vendor will return errors if mode is set to either 'grouping' or 'worksharing' for a submission which is not suitable for grouping or worksharing, whereas another vendor does not.

It is therefore planned that two new validation criteria will be introduced by the time the validation criteria will be updated (see below):

14.BP7, "When submission mode = grouping, submission type must be one of: 'var-type1a', 'var-type1ain', or 'var-type1b', or 'var-type2'; or 'extension'

14.BP8, "When submission mode = 'worksharing', submission type must be one of: 'var-type1b', or 'var-type2', or 'psusa'.

As these are best practice criteria, this proposed change will be kept on hold until a more substantial change is made to either the validation criteria, or a change is made to the EU m1 Specification itself, which in turn impacts the criteria. It is expected that an update of the validation criteria will be required due to the implementation of the application data set in XML format in CESSP which is currently scheduled for March 2018.

In the meantime, in order to avoid BP errors in any of the tools, applicants are advised to ensure that the modes 'grouping' and 'worksharing' are only used with appropriate submission types as described above.

Why is Validation Errors of Criterion 11.10 Be Reported in Section 3.2.A if Using Different Tools?

The matter reported relates to automatically created attributes in section 3.2.A, using values inherited from 3.2.P or 3.2.S sections when using eCTD tool A, and no available option to modify these attributes by using another eCTD tool B and vice versa. The correct way of handling incorrect attributes would be to perform a "delete" operation using the old attributes and a "new" operation using the correct attributes. If your tool does not allow using the old (wrong) attributes for the "delete" operation, please contact your vendor. It is requested to vendors to allow manual modification of attributes in section 3.2.A and disable automatically created attributes in that section to avoid validation errors. Although it is planned to exempt section 3.2.A from criterion 11.10, the most appropriate solution is the implementation of eCTD tool functionality to modify attributes manually.

In the meantime, if your eCTD tool is generating P/F errors in section 3.2.A due to mismatches of attributes, you should avoid using operation attributes "delete" or "replace" referring to historical leaf elements where different attributes have been used and you are not able to change them. In these cases, the document should be submitted as "new" and once the vendor allows to change the attributes the previous content should then be deleted. This will leave obsolete content for a time until the deletion will be possible.