April 5, 2017

Release Notes

Detailing the updates of the EU eCTD Module 1 Specification

The published version 3.0.1 has been subsequently updated when clarifications were required and an updated version 3.0.2 is now available.

Note: The version change does not result in a change of the DTD. No further action is needed.

The following aspects are addressed:

1. Due to an update of the EMA procedural guidance regarding documents displaying tracked changes in PDF format inside an eCTD sequence the following sentence was deleted:

> "An exception to this rule is in the provision of either product labelling or risk management plan documentation in the Centralised Procedure, where the tracked changes version of the document in PDF format should be placed inside the eCTD, alongside the clean, non-tracked version."

2. For **submission type** 'var-type1ain' a clarification is added, that this submission type should also be used in case of a grouped type IA variation where at least one variation type IA_{IN} is included.

3. For **submission type** 'pass107n' a clarification is added, that this submission type should also be used for submission of post authorisation safety study protocol according to Article 107o Dir 2001/83/EC as a workaround until a major update of the specification is made.

4. For **submission type** 'referral-294' a clarification is added, that this submission type should also be used for Referral under Article 29(1) Dir 2001/83/EC and Referral under Article 13 Commission Reg (EC) 1234/2008 as a workaround until a major update of the specification is made.

5. For **submission mode** 'worksharing' a clarification is added, that this should also be used for all PSUSA submissions even if only one product is covered.

6. For **number** a clarification is added, that in case of a grouping concerning only one single marketing authorisation or for any PSUSA submissions, this number field should be left empty.
In addition, the examples have been corrected into: EMEA/H/C/xxxxxx/WSxxxx (for worksharing) and EMEA/H/C/xxxxxx/IGxxxx (for grouped IAs)

7. For **procedure tracking number** a clarification is added, that if the full procedure number including the suffix for the variation is known, it must be added in this field to allow an appropriate display in the Central Repository, e. g. EMEA/H/C/000123/II/0014.
In addition, reference is now provided to the numbering conventions for CP as well as for DCP/MRP. Moreover, the example for PSUSA is specified and clarification is given that the PSUSA procedure number should always be included here for all PSUSA submissions and that no individual procedure numbers are required.

8. In the table of **Example of the use of the Related Sequence and the Submission Unit type elements** the first comment displayed a copy and paste error. The correct sentence should read: "The related sequence will be identical with the sequence number (0000)."