Release notes for version 3.1 of the EU eCTD M1 Specification (major update)
June 2024

Changes in the Implementation Guide

Section of the document	Change
File formats	Explanations added about the generally accepted file format (i.e. PDF) and the reference to the **newly introduced Annex** "EU Accepted file formats for eCTD". Reminder: The generally accepted file format is the PDF, however, in specific cases, other formats will be **exceptionally** accepted in the eCTD modules.
Use of electronic signatures	Name of the chapter updated from "Use of authentication measures" to "Use of electronic signatures" and clarifications added for the topic
Handling of Empty or Missing eCTD Sections	Paragraph added related to information about missing eCTD sections
General architecture of Module 1	Paragraph added related to the recommendation on not re-sending existing documents
Envelope	Clarification added
Appendix 1	Typo corrected for the sample UUID New submission type added (Article-18) New submission unit added (Re-examination) Clarification added for submission units "closing" and "consolidating"
Appendix 1 - Example of the use of the Related Sequence and the Submission Unit type elements	Clarification added Introduced paragraph with explanation for the sequence number Element 0010 – rewording
Appendix 1 - Example of how to use the submission type 'withdrawal' and how to indicate the withdrawal of a single regulatory activity or a strength or pharmaceutical form	Rewording and paragraph with reference to Q&A document added
Appendix 2	Element 6 (tracking table) – rewording Element 9 – clarifications added Element 24 – rewording Element 52 – Clarification added Element 70 – Clarification added
Appendix 2.1 (Country codes)	New code "xi" (UK(NI)) added Explanation for "uk" added
Appendix 2.2 (Language codes)	New code "ga" (Irish)
Appendix 2.3	Explanation added for Interpack package label
Appendix 2.4 (Agency codes and names)	Multiple names updated
Appendix 3	Updated content to reflect the changes done in eu-regional.dtd and eu-envelope.mod)

Changes in the Util files

File*	Change
dtd\eu-envelope.mod	Update of the version to 3.1 Addition of "Article-18" in the "submission" element Addition of "re-examination" in the "submission-unit" element Addition of "xi" in the "env-countries" element
dtd\eu-regional.dtd	Update of the version to 3.1 Addition of "xi" in the "countries" element Addition of ga" in the "languages" element
style\eu-regional.xsl	Update of the version to 3.1 Update of multiple Agencies names Addition of "Article-18" for Submission mode Addition of "re-examination" for Submission-unit mode

the other files in the Util package remain unchanged