Release note for version 3.0.4 of the EU eCTD M1 Specification (minor update)

Also including some explanations on practical implementation of the changes.

Section of the document	Change
Introduction	Changed the link to ICH web
EU Module 1: Regional Information	A requirement to include a tracking table in the submission for all eCTD submissions, including national and centralised procedures (NP and CP). It is recommended that the tracking table is included in the next sequence to be submitted. Ideally, the tracking table should include the full lifecycle of the eCTD, however, if this is not feasible (for example due to large number of sequences), the tracking table can be started from that specific submission or just a small number of sequences. The recommended format for tracking tables to be used as published in the CMDh BPG on the use of eCTD in MRP/DCP, section 6. Tables. The validation criteria have not been updated to include the requirement for a tracking table within NP and CP (so it will not be a cause for rejection) but the requirement will be included in a future version.
Regional File Formats	Table 1 has been deleted. However, the validation criterion on file formats has not been updated and still refers to Table 1. Since the table included only PDF as format, this does not affect the validation as such, and validation tools should not need to be updated in any way due to this change. The format to be used in different situations has been clarified.
Use of electronic signatures --> Use of authentication measures	Changed heading to 'Use of authentication measures' and some clarifications have been made. It should be noted that documents that include digital signatures should normally be accepted. This is currently how eCTD validation are implemented (at least those tools used by authorities) and no changes in the validation tools are foreseen. Requirements on security settings in documents that include digital signatures are expected to be further specified by the ICH and would at that point also be further clarified in the validation criteria. *Please note, if digital signatures are requested in the eAF by a specific NCA, the signature needs to be included in a copy of the finalised eAF and be provided in addition to the original one.*
Handling of Empty or Missing eCTD Sections	Clarifications made.
General Architecture of Module 1 - Envelope	Clarification made whether one or more envelopes should be included.
Universal Unique Identifier (UUID)	Included the text from the earlier published Q&A on UUID and made some clarifications.
Change Control	Changed text to reflect the current Change Request process.
Appendix 1: The EU Module 1 XML Submission	References included to different lists of Referential elements (RMS list) published at the SPOR portal.
Appendix 1: Example of the use of the submission type 'referral-31'	Example on referrals are clarified.
Appendix 2.1: Destination Codes	Clarification made of how the country code 'uk' is to be used after Brexit.
Appendix 2.4: Agency Codes and Names	Clarification made on how the agency code 'UK-MHRA' should be interpretated after Brexit. Some minor updates of agency names. Please, observe that the stylesheet is not updated accordingly to reflect the changes. Also, there might still be some minor discrepancies with the RMS list.
All sections in the documents	Minor editorial updates.