EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 September 2022
Version 1

Submitted Change Requests for a planned update of the EU M1 eCTD Specification during 2023

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1	Appendix 1.1: Envelope Element Description, Table element Identifier	11	25635f23-a3a4-c4e0b994-99c5f074960f 596	25635f23-a3a4-c4e0b994-99c5f074960f ~~596~~	There is, by mistake, a blank, and extra digits included in the UUID number example given in the table.	Medium	No	EFPIA	xx
2	Appendix 1 – Example of the use of the Related Sequence	21	For new regulatory activities, the related-sequence attribute should always be equal to the sequence number. When submitting lifecycle sequences within an existing activity, the related-sequence attribute should be populated with the sequence number the regulatory activity has been started with. The submission unit type should be populated with the respective term describing the content of the sequence to be filed at that point in time. See below for some illustrative examples.	For new regulatory activities, the related-sequence attribute should always be equal to the sequence number. When submitting lifecycle sequences within an existing activity, the related-sequence attribute should be populated with the sequence number the regulatory activity has been started with. This is also applicable if any kind of resubmission (same or new sequence) is provided. The submission unit type should be populated with the respective term describing the content of the sequence to be filed at that point in time. See below for some illustrative examples.	To prevent mistakes as have been seen in the past.	Low	No	SE MPA	xx
3	General Architecture of Module 1	6	If a particular sequence is being sent to a CMS for information only (for example, if the concerned strength is	If a particular sequence is being sent to a CMS for information only (for example, if the concerned strength is not registered in that	To clarify for NCAs if sequences are only provided for information.	Medium	No	SE MPA	xx

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000
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			not registered in that country), no "envelope" element is needed for this CMS. However, it should be clear from the cover letter which CMSs are concerned.	country), no "envelope" element ~~is needed~~ should be created for this CMS. However, it should be clear from the cover letter which CMSs are concerned.	To facilitate further, including specific element in the envelope with the attribute "For information only" could be considered.		Yes		
4	Appendix 1.1: Envelope Element Description; submission-unit	20	N/A (add a new entry to the existing list)	• *Rolling review* = any submission that is part of a rolling review of an MAA or a variation (except for the initial submission)	Include an additional submission unit to be used for rolling reviews (MAA and variations)	Medium	Yes	EMA	xx
5	Appendix 2.4: Agency Codes and Names	50-51		*Harmonise so that all NCA names are in English, or all are in local language*	Currently, there is a mix of languages. All the NCA names should preferably be in English and only where really needed in the national language.	Low	Yes	EMA	xx
7	Use of authentication measures	8	**Use of authentication measures** If a digital signature is required by any authority it will be accepted as a part of the eCTD submission. However, some agencies continue to request wet signed documents while others will accept the log-in credentials for portals as a sufficient authentication. For details on requirements on signatures, please refer to European and/or national legislation on the use of digital signatures and also refer to EMA and CMDh websites.	~~**Use of authentication measures**~~ **Use of electronic signatures** Electronic signatures are regulated in EU by Regulation (EU) No 910/2014 of the European Parliament and of the council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC. For applications of Marketing Authorisations including post-authorisation submissions, most NCAs and EMA do not require wet or digitally signed cover letters or application forms if submitted through a portal (e.g. CESP and EMA Gateway) with logon credentials. However, some NCAs still require additional signatures and might accept wet signatures, scanned signatures and/or electronic signatures as specified in the CMDh documents 'Requirements on submissions for New Applications within MRP, DCP or National procedures' and 'Requirements on submissions for Variations and Renewals within MRP and National procedures'.	Align guidance in eCTD specification with text from EU harmonised technical guidance v5.0 Should also be reflected in the validation criteria (rule 16.2 PDF security settings)	Medium	No	EFPIA	xx

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				For EMA submissions, in general, qualified and advanced electronic signatures as per the European Commission eIDAS regulation (Regulation (EU) No 910/2014) are accepted.					
8	Appendix 2.1: Destination Codes	48	uk ¦ United Kingdom	xi ¦ United Kingdom (Northern Ireland)	Correct the country name/code to reflect the situation after Brexit	Medium	Yes	EMA	xx
9	Appendix 2.2: Language Codes	49	N/A	ga ¦ Irish	Needs to be added as an official EU language	Medium	Yes	EMA	xx
10	Enable alternative formats for submission	7-8	The currently accepted file format for documents in Module 1 is PDF. All PDF files included in an eCTD (irrespective of the module) should be v1.4, v1.5, v1.6 or v1.7 (see ICH Q&A for eCTD v3.2.2 question 71 for further detail re PDF version acceptability), except where there is an agency-specific requirement for a later version (e.g. for an application form). Although the use of PDF is currently mandatory, other formats for Module 1 content provided outside of the eCTD in the working-documents folder should be used as required by the receiving authority. For example, MS Word is requested for Product Information documents and also, provision of other authority required content which is not provided as a part of the Module 1. For details, please refer to the Harmonised Technical Guidance for eCTD Submissions in the EU and/or other local guidance documents. In case information related to the application needs to be provided in other formats (for example videos) these should not be included in the eCTD nor in the working-documents, but should be available in a secure cloud location with a link from a document provided within the eCTD sequence. For data requested by authorities which needs to be provided in any other	*TBD*	New formats: XML, video formats (MP4, AVI, etc.), Dataset & raw data formats, image / graphics formats, Word, Excel, etc. Consider showing only file types that are NOT allowed? And the validation criteria contains the specific list.	Medium	No		xx

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			format than specified above, please follow the instructions given by requestor.						
11	Appendix 2: Directory / File Structure for Module 1 Include tracking table as mandatory for NP and CP	32	Note that the tracking table required with MPR/DCP submissions should be located within a 'common' directory, with the filename 'common-tracking-var.pdf' When used for submissions within centralised or national procedures, the respective country code should be used, e.g. ema-tracking-var.pdf in case of a centralised procedure or de-tracking-var.pdf in case of a national procedure with BfArM or PEI.	~~Note that the tracking table required with MPR/DCP submissions should be located within a 'common' directory, with the filename 'common-tracking-var.pdf'~~ ~~When used for submissions within centralised or national procedures, the respective country code should be used, e.g. ema-tracking-var.pdf in case of a centralised procedure or de-tracking-var.pdf in case of a national procedure with BfArM or PEI.~~ A tracking table should always be included as an annex to the cover letter for submissions within all procedures. The file should be named cc-tracking-var.pdf and be placed in /XXXX/m1/eu/10-cover/cc (e.g. ema-tracking-var.pdf for a CP, common-tracking-var.pdf in an MRP/DCP, or be-tracking-var.pdf in a NP.)	Already implemented as mandatory in the EU harmonised guidance but need alignment in the specification. (Validation criteria need to be updated.)	Medium	No	EMA	xx
12	Regional File Formats - Module 1	7	Although the use of PDF is currently mandatory, other formats for Module 1 content provided outside of the eCTD in the working-documents folder should be used as required by the receiving authority. For example, MS Word is requested for Product Information documents and also, provision of other authority required content which is not provided as a part of the Module 1. For details, please refer to the Harmonised Technical Guidance for eCTD Submissions in the EU and/or other local guidance documents. In case information related to the application needs to be provided in other formats (for example videos) these should not be included in the eCTD nor in the working-documents, but should be available in a secure cloud location with a link from a document provided within the eCTD sequence.	*TBD*	Reduce actual submission content submitted in workingdocuments folder – include in the eCTD itself Translations (word), proposed labelling (word), eCTD validation checklist (excel), instructional product videos, etc. Consider validation of contents of workingdocuments folder?	Medium	Yes	HHG	xx

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