Questions & Answers Swissmedic eCTD Implementation

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Responsible:	OSS, Swissmedic
Version / Date:	Version 2.2 / 01.04.2020

Change Record

Version	Date	Comments	Author(s)
2.2	01.04.2020	Update	OSS
2.1	18.01.2019	Update	OSS
2.0	01.10.2015	Update	Submissions Division
1.9	15.11.2014	Version published on Swissmedic website	Submissions Team
1.8	01.11.2013	Version published on Swissmedic website	Submissions Team
1.7	31.07.2013	Version published on Swissmedic website	Submissions Team
1.6	01.07.2013	Version published on Swissmedic website	Submissions Team
1.5	31.03.2013	Version published on Swissmedic website	Submissions Team
1.4	08.05.2012	Version published on Swissmedic website	Submissions Team
1.3	29.11.2010	Version published on Swissmedic website	SIMES Working Group
1.2	22.10.2010	Version published on Swissmedic website	Superuser eCTD
1.1	21.05.2010	Version published on Swissmedic website	SIMES Working Group
1.0	30.10.2009	1st valid version, published on Swissmedic website	SIMES Working Group

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1 Introduction

This questions and answers document is a summary of questions that relate to the Swiss guideline documents (i.e. *Module 1 Specification for eCTD*, *Swiss eCTD Validation Criteria* and *eCTD Guidance for Industry*) and represent Swissmedic's current view. It is intended to be a dynamic document that supplements the above mentioned guideline documents. This questions and answers document will be updated as the guideline documents undergo change control or as new questions are submitted to the agency.

2 Questions about the Submission

Question 1-1: *(Q 2-1, V1.9)*	*How should a collective application be submitted which refers to both a drug product documented in paper (eDok) and a drug product documented in eCTD format?*
Answer 1-1: *(A 2-1, V1.9):*	The application must be made in eCTD and paper (eDok) formats according to their previous life cycle. However, Swissmedic recommends converting the paper-based drug product into eCTD before submitting the collective application.
Question 2-2: *(Q 2-5, V1.9)*	*How should applications referring to stock-out situations be handled?*
Answer 2-2: *(A 2-5, V1.9)*	• Applications referring to stock out situations: These refer to market surveillance, require specific documentation and are handled outside the eCTD. • Temporary marketing authorisations for new products: These can be submitted as eCTD.
Question 2-3: *(Q 2-6, V1.9)*	*Which documents should be placed in the section 'additional information' addressed in Appendix 1 of the Swiss Module 1 Specification document?*
Answer 2-3: *(A 2-6, V1.9)*	This section should not be used if a document has a defined place within module 1. The section 'additional information' is used for documents which cannot be assigned to any other section within module 1. New forms should be added to section 1.2.2.99.
Question 2-4:	*Question concerning new M1 Specification v1.4: Why is the envelope element article-13-tpa still referred to as paragraph-13-tpa in a new sequence published according to the new M1 Specification?*
Answer 2-4:	This error has been fixed in M1 Specification v1.5.
Question 2-5:	*Question concerning new M1 Specification v1.4: Why is there a fixed component of file name in table 1 under section 1.2.2? There is no document in this section.*
Answer 2-5:	This error has been fixed in M1 Specification v1.5.

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Question 2-6: *How should a life cycle in sections no longer maintained (e.g. 1.2.2.4, 1.2.2.5 etc) take place? These sections are marked as "this section is no longer applicable…" in the M1 Specification.*

Answer 2-6: Life cycle in these sections should be avoided.

Should operators 'replace' or 'delete' be applied to sections no longer maintained, the rule 15.BP3 takes effect and issues a warning. The sequence is still valid as it is a best practice warning.

Should operator 'new' be applied to sections no longer maintained, the rule 15.BP3 takes effect and issues a warning.

In general, documents that were previously allocated to such sections are either no longer up to date or have been replaced by new forms in another section.

Question 2-7: *Are the following notations in table 1 and table 4 correct?*

Answer 2-7:

- 1.2.2.16 Form PSUR/PBRER for Human Medicines = notation without space/blank is correct
- 1.2.2.23 Form Application for Recognition of Orphan Drug Status = capitalisation of the word 'Recognition' is correct
- 1.7.4 FDA Decision = use of singular is correct
- 1.4.1 Quality (Leaf) = omission of details regarding Expert is correct
- 1.4.2 Nonclinical (Leaf) = omission of details regarding Expert is correct
- 1.4.3 Clinical (Leaf) = omission of details regarding Expert is correct

Question 2-8: *How should orphan drug decisions of other authorities be filed in the eCTD? There has been a change of the country code from "CC" to "ch" in Section 1.11 (Orphan Drug Status Decision).*

Answer 2-8: Swiss documents will continue to be filed under 1.11. Decisions of foreign authorities are filed under 1.7.5. All other orphan drug documents are filed under "Additional Information".

Question 2-9: *How exactly should forms be filed in Section 1.2 ff?*

Answer 2-9: Forms should be filed under the respective nodes according to "Directory Overview of documents to be submitted HMV4". If they cannot be assigned exactly and there are no suitable predefined nodes, the documents should be filed under "Additional Information".

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