

Questions & Answers Swissmedic eCTD Implementation

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1 Document Control

Change Record

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1.9	15.11.2014	Version published on Swissmedic website	Submissions Team
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1.6	01.07.2013	Version published on Swissmedic website	Submissions Team
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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

Table of contents

1	Document Control	1
2	Glossary and List of Abbreviations.....	3
3	Introduction	3
4	Questions about the Submission	3

2 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.

3 Questions about the Submission

Question 1-1: *How should a collective application be submitted which refers to both a drug product documented in paper and a drug product documented in eCTD format?*
 (Q 2-1, V1.9)

Answer 1-1: The application must be made in eCTD and paper formats according to their previous life cycle. However, Swissmedic recommends converting the paper-based drug product into eCTD before submitting the collective application.
 (A 2-1, V1.9)

Question 2-2: *How should applications referring to stock out situations be handled?*
 (Q 2-5, V1.9)

Answer 2-2:

- Applications referring to stock out situations: These refer to market surveillance, require specific documentation and are handled outside of the eCTD.
- Temporary marketing authorisations for new products: These can be submitted as eCTD

Question 2-3: *Which documents should be placed in the section 'additional information' addressed in Appendix 1 of the Swiss Module 1 Specification document?*
 (Q 2-6, V1.9)

Answer 2-3: 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.
 (A 2-6, V1.9)

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 is an error in the M1 Specification v1.4 and will be subsequently corrected in a later version 1.5. The element value should be *article-13-tpa*.

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 is an error in the M1 Specification v1.4 and will be subsequently corrected in a later version 1.5. There is no fixed component of file name necessary.

Question 2-6: Question concerning new M1 Specification v1.4: 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: Should operators ‘replace’ or ‘delete’ be necessary to 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 necessary to be applied to sections no longer maintained, the rule 15.BP3 takes effect and issues a warning. There should be no life cycle in this section.

Life cycle in a document in the section 1.5.3 (that is no longer maintained) is not anticipated.

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: Question concerning new M1 Specification v1.4: 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