Questions & Answers on Swissmedic eCTD Implementation

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Glossary

A brief glossary of terms (for the purpose of this document only) is indicated below:

Term	Definition
Applicant	A pharmaceutical company or its agent ~~that is~~ submitting information in support of an application.
Applicant's information	Regulatory information submitted by an applicant to ~~seek~~receive or to maintain a marketing authorisation that falls within the scope of this guidance document
Application	A collection of documents compiled by a pharmaceutical company or its agent in compliance with Swiss legislation and guidelines in order to seek a marketing authorisation or any amendments thereof. An application may comprise a number of submissions~~.~~ or sequences.
Application ~~number~~Number	The ~~application number~~Application Number is assigned to the application by Swissmedic. It tracks the ~~application~~Application at the agency level. ~~A submission can consist of several application numbers.~~
Regulatory Activity	It is used by some review tools to group together several related sequences of an application.
Dossier	Several dosage forms and strengths may be comprised under one product name. Some review tools describe this as a Dossier.
eCTD identifier	An eCTD identifier is a name, code or number used as the directory name in the top-level directory. This can be a proposed trade name, a company internal project code, or the Marketing Authorisation ~~number~~Number.
eCTD Submission or sequence	A single set of information and/or documents supplied by the applicant as a partial or complete, application. In the context of eCTD, this is equivalent to a **sequence**. An eCTD Submission **is an electronic-only submission** in ~~the~~ eCTD format ~~that is not~~ supported by paper ~~documents (except some documents in module 1).~~.
Marketing Authorisation Number	The Marketing Authorisation Number is the unique identifier for the medicinal product and the ~~galenic~~dosage form for the Swiss market. (Swissmedic Number)
~~Submission~~	~~A single set of information and/or documents supplied by the applicant as a part of, or as the complete application. In the context of eCTD, this is equivalent to 'eCTD Sequence'.~~
~~Teste CTD~~ Test eCTD-Submission	A **Test eCTD Submission** is an electronic-only submission by the applicant prior to the official submission. ~~The objective is to test the technical attributes and suitability of the eCTD. A Test eCTD Submission may differ from the official submission and can be incomplete.~~

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List of Abbreviations

~~CMC~~	~~Chemistry, Manufacturing, and Control Information~~
ATC	Anatomical Therapeutical Chemical
CCDS	Company Core Data Sheet
CL	Checklist
CTD	Common Technical Document
DMF	Drug Master File
DTD	Document Type Definition
eCTD	electronic Common Technical Document
EMA	European Medicines Agency
EU	European Union
FO	Form
GMO	Genetically Modified Organisms
ICH	International Conference on Harmonisation
IfP	Information for Professionals
INN	International Non-proprietary Name
LCM	Life cycle management
LoQ	List of Questions
MAH	Marketing Authorisation Holder
MAN	Marketing Authorisation Number
NeeS	Non-eCTD electronic ~~Submission~~submission
PDF	Portable Document Format
PI	Product Information
PMF	Plasma Master File
PSUR	Periodic Safety Update Report
RMP	Risk Management Plan (E2E)
Q&A	Questions and Answers document
SIMES	Project “Solution for the Implementation and Management of Electronic Submissions”
SmPC	Summary of Product Characteristics
STF	Study Tagging Files
Swissmedic	Swiss Agency for Therapeutic Products
ToC	Table of Contents
TPA	Therapeutic Product Act (Federal Law on Medicinal Products and Medical Devices) of December 15, 2000 in the past known as LTP (Law on Therapeutic Products) / SR 812.21 Bundesgesetz vom 15. Dezember 2000 über Arzneimittel und Medizinprodukte (Heilmittelgesetz HMG) / SR 812.21 Loi fédérale sur les médicaments et les dispositifs médicaux du 15 décembre 2000 (Loi sur les produits thérapeutiques LPTh)
util	Utility folder in the eCTD Sequence. Contains technical files.
VAM	Ordinance on Medicinal Products of October 17, 2001 / SR 812.212.21(Verordnung über die Arzneimittel) / SR 812.212.21 (Ordonnance sur les médicaments)
XML	Extensible Markup Language

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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 Guidance for Industry) and ~~a representation of~~represent Swissmedic's current view. It is intended to be a dynamic document that supplements and actualizes 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.

In addition further eCTD Q&A issued by ICH and relating to all regions can be found at http://estri.ich.org/eCTD/index.htm.

2 Questions about the Submission

Question 1-1: *(Q 2-1~~:~~ ~~(Q 3-1-5~~, V1.~~8~~9)*	*How should a collective application be submitted which refers to a paper documented drug product and a drug product in eCTD format?*
Answer 1-1: *(A 2-1~~:~~ ~~(A 3-1-5~~, V1.~~8~~9):*	The application must be made in eCTD and paper formats according to their previous life cycle. However, Swissmedic recommends the conversion of the paper-based drug product into eCTD before the collective application is submitted.
Question 2-2: *(Q 2-5, V1.9)*	*How should* applications due to stock out situations *be handled?*
Answer 2-2: *(A 2-5, V1.9)*	• Applications due 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 2-2:* *(Q 3-3-7, V1.8)*~~	~~*What has to be done in case of withdrawal or rejection of an application?*~~
~~Answer 2-2: *(A 3-3-7, V1.8)*~~	~~If an application is withdrawn or rejected, a consolidation sequence has to be submitted.~~ ~~With regard to module 1, only documents with a life cycle should be consolidated. As a rule, rejected / withdrawn information concerning modules 2.3 and 3 should also be consolidated to preserve previously approved content in the current view.~~ ~~However, if the rejected / withdrawn application contains information considered as important and therefore should be preserved in the eCTD, please liaise with the responsible Case Manager.~~
Question 2-3: *(Q ~~6~~2-6, V1.~~8~~9)*	~~*What has to be done if a variation requiring notification is formally objected or technically rejected?*~~*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 ~~6~~2-6, V1.~~8~~ 9)*	~~If a variation requiring notification is formally objected or technically rejected, the form "variations requiring notification" with the preliminary decision~~

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mustThis section should not be included (underused if a document has a defined place within module 1. The section "additional information")" can be used for re-submission.documents which cannot be assigned to the other sections within module 1. New forms should be added to section 1.2.2.99.
In case of a reject notifications, a copy of the form Variations Requiring Notification containing the preliminary decision of Swissmedic should be placed here (please refer to question 2-2 for information about the required consolidation sequence.3).

Question 2-4: *(Q 3-5-15, V1.8)*

How should follow-up measures imposed by Quality Review, Preclinical Review and Clinical Review be submitted?

Answer 2-4: *(A 3-5-15, V1.8)*

A separate application must be made for each follow-up measure according to the WL Formal requirements. Each bullet / number in the decision letter reflects one follow-up measure. The related eCTD-sequence-number in the envelope and in the cover letter should therefore be left empty. Until further notice the application type should be „variations requiring authorisation incl. scientific review" together with the „submission description" „follow-up measure".

Question 2-5: *(Q 3-3-4, V1.8)*

How should applications due to stock out situations *be handled?*

Answer 2-5: *(A 3-3-4, V1.8)*

- Applications due 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 2-6: *(Q 3-5-6, V1.8)*

Which documents should be placed in the section "additional information" addressed in Appendix 1 of the Swiss Module 1 Specification document?

Answer 2-6: *(A 3-5-6, V1.8)*

This section should not be used if a document has a defined place within module 1. The section "additional information" can be used for documents which cannot be assigned to the other sections within module 1. New forms should be added to section 1.2.2.99.
In case of notifications, a copy of the form Variations Requiring Notification containing the preliminary decision of Swissmedic should be placed here (please refer to question 2-3).

Question 2-7: *(Q 4-3, V1.8)*

How should applicants handle the inconsistency regarding module 1.2.2.19 "Form DMF for first authorisation and variations" in the DTD and the style sheet of version 1.2 of the Swiss Module 1 Specification?

Answer 2-7: *(A 4-3, V1.8)*

The section name in the style sheet "m1-2-2-19-form-dmf-for-first-**application**-and-variations" is different from the section name in the DTD "m1-2-2-19-form-dmf-for-first-**authorisation**-and-variations". Due to this element name mismatch the section will not be displayed if the ch-regional.xml is opened in Internet Explorer. However, if the regional.xml is opened in XML pad/word pad the section is displayed correctly.
Swissmedic will correct the current style sheet with the next regular update of the Module 1 Specification.

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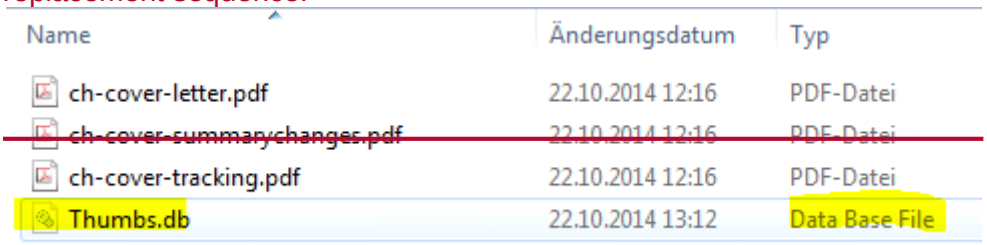
Question 2-8: *(new)*

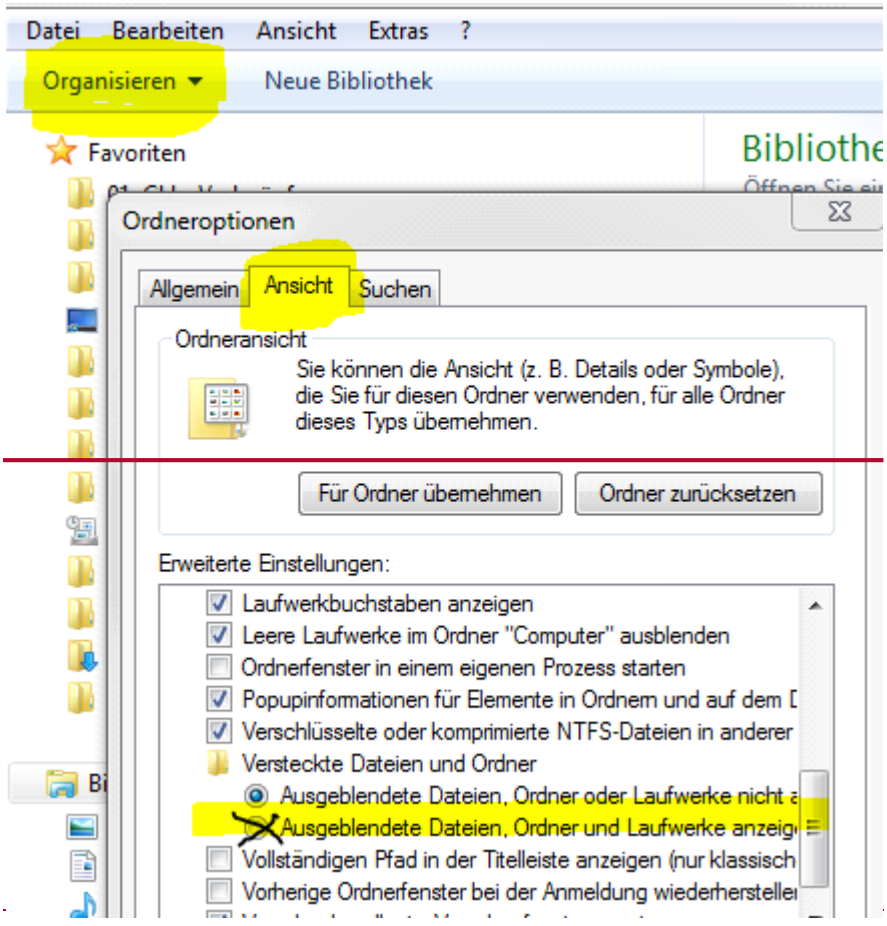
*How should **thumbs.db** be handled?*

Answer 2-8: *(new)*

Technically these files are system files created by Microsoft Windows every time a file is opened. In terms of eCTD these files are unreferenced files, as they may appear within an eCTD sequence and are not referenced in the XML backbone. The validation tools mark them as unreferenced and therefore the sequence is invalid. Swissmedic will reject these sequences and demand a replacement sequence.



Unfortunately these files are hidden unless you tell Microsoft Windows otherwise.



In order to avoid these thumbs.db files it is strongly advised to close all files or folders of a published eCTD sequence before burning them on CD.

It is possible and highly recommended to prevent Microsoft Windows from creating these files. Please refer to your IT department for further information.

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