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Change history

Version	Valid and binding as of:	Description, comments (by author)	Author's initials
1.4	01.11.2018	Final Version	OSS Division

1 Introduction

This document provides guidance to applicants and tool vendors regarding the timelines for implementation of the Swiss Module 1 Specification for eCTD v1.4.

2 Timelines for Implementation

The Specification and DTD of the Swiss Module 1 Specification for eCTD v1.4 include several amendments due to revision 4 of Therapeutic Product Ordinances and text updates. The new Swiss validation criteria v1.4 have been amended accordingly. Changes to the previous version have also been published in the track-change document.

The timeline for implementation is as follows:

1. On 01 January 2019 the new Swiss Module 1 Specification for eCTD v1.4 will be implemented. Both versions of the Swiss Module 1 Specification for eCTD – the new and the previous one - will be valid for a half-year period from 01 January 2019 to 30 June 2019.

2. As from 01 July 2019 the Swiss Module 1 Specification for eCTD v1.4 must be used for all eCTD submissions. Any eCTD submission provided from this date using a previous version of the Swiss Module 1 Specification for eCTD will be rejected.

   This deadline applies to all relevant lifecycle sequences/submissions for applications ongoing at the time. Please note that, for existing applications, it is not expected to update all previous existing submissions to v1.4 of the Swiss Module 1 Specification for eCTD and to resubmit them; it is, however, expected that authoring and review tools will allow for a change in DTD by mid-lifecycle.

3. Change of attributes and elements in the new CH 1.4 M1 Specification and its consequences on the lifecycle: In general, validation criteria report a 'fail' for any lifecycle operation where the leaf targeted by the modified file is located either in a different CTD section or in the same CTD section with different metadata applied. However, this rule is not suitable if regulatory changes in the M1 specification become necessary. The eCTD sections in the screenshot below shall be considered equivalent and lifecycle must be allowed between them, additionally all newly added sections are shown within the comparison below.

4. Note that during the half-year period (01 January 2019 to 01 July 2019) once an applicant has created and submitted an eCTD using Swiss Module 1 Specification for eCTD v1.4 for a particular product, all subsequent eCTD submissions for this product must be made using v1.4.

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<!--	=	<!--
DTD M1 Swissmedic v1.4 Published Date: 27. September 2018	<>	DTD M1 Swissmedic v1.3 Published Date: 01.October 2015
Authors: Swissmedic	=	Authors: Swissmedic
m1-6-environrisk?, m1-7-decisions-authorities?, m1-8-pharmacovigilance?, m1-9-fast-track-decision?, m1-10-paediatrics?, m1-11-orphandrug?,	=	m1-6-environrisk?, m1-7-decisions-authorities?, m1-8-pharmacovigilance?, m1-9-fast-track-decision?, m1-10-paediatrics?, m1-11-orphandrug?,
m1-12-art14sec1letabisquater?,	+-	
m1-swiss-responses?, m1-additional-info?	=	m1-swiss-responses?, m1-additional-info?
<!ELEMENT m1-2-applvar (m1-2-1-foapplvar?,		<!ELEMENT m1-2-applvar (m1-2-1-foapplvar?,
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m1-2-3-quality?, m1-2-4-manufacturing?, m1-2-5-others?)> <!ELEMENT m1-2-1-foapplvar (%leaf-node;)>	=	m1-2-3-quality?, m1-2-4-manufacturing?, m1-2-5-others?)> <!ELEMENT m1-2-1-foapplvar (%leaf-node;)>
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m1-2-2-19-form-dmf?, m1-2-2-20-form-information-applications-art-13-tpa?,	<>	m1-2-2-19-form-dmf-for-first-authorisation-variations?, m1-2-2-20-form-information-quality?,
m1-2-2-21-form-notification-sample-packages?, m1-2-2-22-form-notification-of-no-marketing-or-interruption-to-distribution?, m1-2-2-23-form-application-for-recognition-of-orphan-drug-status?, m1-2-2-24-application-for-recognition-of-fast-track-status?,	=	m1-2-2-21-form-notification-sample-packages?, m1-2-2-22-form-notification-of-no-marketing-or-interruption-to-distribution?, m1-2-2-23-form-application-for-recognition-of-orphan-drug-status?, m1-2-2-24-application-for-recognition-of-fast-track-status?,
m1-2-2-25-form-pip?, m1-2-2-26-gcpinspections?,	+-	
m1-2-2-99-other-forms?)> <!ELEMENT m1-2-2-1-form-full-declaration (%leaf-node;)> <!ELEMENT m1-2-2-2-form-manufacturer-information (%leaf-node;)> <!ELEMENT m1-2-2-3-form-status-marketing-authorisations-abroad (%leaf-node;)>	=	m1-2-2-99-other-forms?)> <!ELEMENT m1-2-2-1-form-full-declaration (%leaf-node;)> <!ELEMENT m1-2-2-2-form-manufacturer-information (%leaf-node;)> <!ELEMENT m1-2-2-3-form-status-marketing-authorisations-abroad (%leaf-node;)>
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<!ELEMENT m1-5-bioavailability (		<!ELEMENT m1-5-bioavailability (
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m1-5-2-reference-product?, m1-5-3-confirmation-identity-bioequivalence?)>	=	m1-5-2-reference-product?, m1-5-3-confirmation-identity-bioequivalence?)>
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