List of contents *(optional)*

Change history

Version	Valid and binding as of:	Description, comments (by author)	Author's initials
1.3	01.10.2015	Final version	Submissions 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 v1.3.

2 Timelines for Implementation

The Specification and DTD of the Swiss Module 1 Specification for eCTD v1.3 include several amendments, based on change requests and on the implementation of the new Swiss validation criteria v1.3. The validation criteria were aligned to the EU validation criteria v5.0 and CA validation criteria v3.0. Changes to the previous version have also been published in the track-change document.

The timeline for implementation is as follows:

1. On 01 October, 2015 the new Swiss Module 1 Specification for eCTD v1.3 will be implemented. Both versions of the Swiss Module 1 Specification for eCTD – the new and the former one - will be valid for a half-year period from 01 October, 2015 to 31 March, 2016.

2. As from 01 April, 2016 the Swiss Module 1 Specification for eCTD v1.3 must be used for all eCTD submissions. Any eCTD submission provided from this date using a former 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 v1.3 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 mid-lifecycle.

3. Change of attributes and elements in the new CH 1.3 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 in a different CTD section or is 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:

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```
<!--
DTD M1 Swissmedic v1.3
Published Date: 01.October 2015
Authors: Swissmedic

Meaning of the suffixes:
   ?            : element is optional; must appear 0 or 1 time
   *            : element is optional; must appear 0 or more time
   +            : element is mandatory; must appear 1 or more times
   <none>       : element is mandatory; must appear once and only once
        m1-ch
)>
<!ATTLIST ch:ch-backbone
        xmlns:ch       CDATA #FIXED   "http://www.swissmedic.ch"
        xmlns:xlink CDATA #FIXED "http://www.w3c.org/1999/xlink"
        xml:lang CDATA #IMPLIED
        dtd-version CDATA #FIXED "1.3"
>

<!ENTITY % envelope-module SYSTEM "ch-envelope.mod">
%envelope-module;
<!ENTITY % leaf-module SYSTEM "ch-leaf.mod">
%leaf-module;
<!-- ................................................................... -->
<!ELEMENT m1-0-cover (%leaf-node;)>
<!-- ................................................................... -->
<!ELEMENT m1-2-applvar (
        m1-2-1-foapplvar?,
        m1-2-2-ann-form?,
        m1-2-3-quality?,
        m1-2-4-manufacturing?,
        m1-2-5-others?
)>

<!ELEMENT m1-2-1-foapplvar (%leaf-node;)>
```

```
<!--
DTD M1 SwissMedic v1.2
Published Date: 01.July 2013
Authors: SwissMedic

Meaning of the suffixes:
   ?            : element is optional; must appear 0 or 1 time
   *            : element is optional; must appear 0 or more time
   +            : element is mandatory; must appear 1 or more times
   <none>       : element is mandatory; must appear once and only once
        m1-ch
)>
<!ATTLIST ch:ch-backbone
        xmlns:ch       CDATA #FIXED   "http://www.swissmedic.ch"
        xmlns:xlink CDATA #FIXED "http://www.w3c.org/1999/xlink"
        xml:lang CDATA #IMPLIED
        dtd-version CDATA #FIXED "1.2"
>

<!ENTITY % envelope-module SYSTEM "ch-envelope.mod">
%envelope-module;
<!ENTITY % leaf-module SYSTEM "ch-leaf.mod">
%leaf-module;
<!-- ................................................................... -->
<!ELEMENT m1-0-cover (%leaf-node;)>
<!-- ................................................................... -->
<!ELEMENT m1-2-applvar (
        m1-2-1-foapplvar?,
        m1-2-2-ann-form?,
        m1-2-3-product-quality?,
        m1-2-4-manufacturing?,
        m1-2-5-others?
)>

<!ELEMENT m1-2-1-foapplvar (%leaf-node;)>
```


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```
<!ELEMENT m1-2-2-ann-form (
        m1-2-2-1-form-full-declaration?,
        m1-2-2-2-form-manufacturer-information?,
        m1-2-2-3-form-status-marketing-authorisations-abroad?,
        m1-2-2-4-form-variation-requiring-notification?,
        m1-2-2-5-form-quality-variation-requiring-approval?,
        m1-2-2-6-form-application-for-extension-of-authorisation?,
        m1-2-2-7-form-human-blood-components?,
        m1-2-2-8-form-substances-of-animal-or-human-origin?,
        m1-2-2-9-form-pharmaceutical-information-for-parenteral-preparations?,
        m1-2-2-10-form-co-marketing-confirmation?,
        m1-2-2-11-form-import-according-to-paragraph-14-section-2-tpa?,
        m1-2-2-12-form-safety-changes-to-product-information?,
        m1-2-2-13-form-change-of-marketing-authorisation-holder?,
        m1-2-2-14-cl-formal-control?,
        m1-2-2-15-cl-formal-control-13?,
        m1-2-2-16-form-psur-for-human-medicines?,
        m1-2-2-17-form-declaration-radiopharmaceuticals?,
        m1-2-2-18-form-confirmation-substances-from-gmo?,
        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?,
        m1-2-2-99-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;)>
<!ELEMENT m1-2-2-4-form-variation-requiring-notification (%leaf-node;)>
<!ELEMENT m1-2-2-5-form-quality-variation-requiring-approval (%leaf-node;)>
<!ELEMENT m1-2-2-6-form-application-for-extension-of-authorisation (%leaf-node;)>
<!ELEMENT m1-2-2-7-form-human-blood-components (%leaf-node;)>
<!ELEMENT m1-2-2-8-form-substances-of-animal-or-human-origin (%leaf-node;)>
<!ELEMENT m1-2-2-9-form-pharmaceutical-information-for-parenteral-preparations (%leaf-node;)>
<!ELEMENT m1-2-2-10-form-co-marketing-confirmation (%leaf-node;)>
<!ELEMENT m1-2-2-11-form-import-according-to-paragraph-14-section-2-tpa (%leaf-node;)>
<!ELEMENT m1-2-2-12-form-safety-changes-to-product-information (%leaf-node;)>
<!ELEMENT m1-2-2-13-form-change-of-marketing-authorisation-holder (%leaf-node;)>
<!ELEMENT m1-2-2-14-cl-formal-control (%leaf-node;)>
<!ELEMENT m1-2-2-15-cl-formal-control-13 (%leaf-node;)>
<!ELEMENT m1-2-2-16-form-psur-for-human-medicines (%leaf-node;)>
<!ELEMENT m1-2-2-17-form-declaration-radiopharmaceuticals (%leaf-node;)>
<!ELEMENT m1-2-2-18-form-confirmation-substances-from-gmo (%leaf-node;)>
```

```
<!ELEMENT m1-2-2-ann-form (
        m1-2-2-1-form-full-declaration?,
        m1-2-2-2-form-manufacturer-information?,
        m1-2-2-3-form-status-marketing-authorisations-abroad?,
        m1-2-2-4-form-variations-requiring-notification?,
        m1-2-2-5-form-variations-requiring-authorisation?,
        m1-2-2-6-form-application-for-renewal-of-marketing-authorisation?,
        m1-2-2-7-form-human-blood-components?,
        m1-2-2-8-form-substances-of-animal-and-human-origin?,
        m1-2-2-9-form-pharmaceutical-information-for-parenteral-preparations?,
        m1-2-2-10-form-co-marketing-confirmation?,
        m1-2-2-11-form-import-according-to-paragraph-14-section-2-tpa?,
        m1-2-2-12-form-safety-changes-to-product-information?,
        m1-2-2-13-form-change-of-marketing-authorisation-holder?,
        m1-2-2-14-checklist-content-validation?,
        m1-2-2-15-checklist-paragraph-13?,
        m1-2-2-16-form-psur-for-human-medicinal-products?,
        m1-2-2-17-form-declaration-radiopharmaceuticals?,
        m1-2-2-18-form-confirmation-substances-from-gmo?,
        m1-2-2-19-form-dmf-for-first-authorisation-and-variations?,
        m1-2-2-20-form-information-on-product-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?,
        m1-2-2-99-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;)>
<!ELEMENT m1-2-2-4-form-variations-requiring-notification (%leaf-node;)>
<!ELEMENT m1-2-2-5-form-variations-requiring-authorisation (%leaf-node;)>
<!ELEMENT m1-2-2-6-form-application-for-renewal-of-marketing-authorisation (%leaf-node;)>
<!ELEMENT m1-2-2-7-form-human-blood-components (%leaf-node;)>
<!ELEMENT m1-2-2-8-form-substances-of-animal-and-human-origin (%leaf-node;)>
<!ELEMENT m1-2-2-9-form-pharmaceutical-information-for-parenteral-preparations (%leaf-node;)>
<!ELEMENT m1-2-2-10-form-co-marketing-confirmation (%leaf-node;)>
<!ELEMENT m1-2-2-11-form-import-according-to-paragraph-14-section-2-tpa (%leaf-node;)>
<!ELEMENT m1-2-2-12-form-safety-changes-to-product-information (%leaf-node;)>
<!ELEMENT m1-2-2-13-form-change-of-marketing-authorisation-holder (%leaf-node;)>
<!ELEMENT m1-2-2-14-checklist-content-validation (%leaf-node;)>
<!ELEMENT m1-2-2-15-checklist-paragraph-13 (%leaf-node;)>
<!ELEMENT m1-2-2-16-form-psur-for-human-medicinal-products (%leaf-node;)>
<!ELEMENT m1-2-2-17-form-declaration-radiopharmaceuticals (%leaf-node;)>
<!ELEMENT m1-2-2-18-form-confirmation-substances-from-gmo (%leaf-node;)>
```


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```
<!ELEMENT m1-2-2-19-form-dmf-for-first-authorisation-variations (%leaf-node;)>
<!ELEMENT m1-2-2-20-form-information-quality (%leaf-node;)>
<!ELEMENT m1-2-2-21-form-notification-sample-packages (%leaf-node;)>
<!ELEMENT m1-2-2-22-form-notification-of-no-marketing-or-interruption-to-distribution (%leaf-node;)>
<!ELEMENT m1-2-2-23-form-application-for-recognition-of-orphan-drug-status (%leaf-node;)>
<!ELEMENT m1-2-2-24-application-for-recognition-of-fast-track-status (%leaf-node;)>
<!ELEMENT m1-2-2-99-other-forms (%leaf-node;)>

<!ELEMENT m1-2-3-quality (
        m1-2-3-1-dmf-letter-of-access?,
        m1-2-3-2-certificate-of-suitability-for-active-substance?,
        m1-2-3-3-certificate-of-suitability-for-tse?,
        m1-2-3-4-ema-certificate-for-plasma-master-file-pmf?,
        m1-2-3-5-ema-certificate-for-vaccine-antigen-master-file-vamf?
)>

<!-- ..................................................................... -->
<!ELEMENT m1-3-pi (
        m1-3-1-professionals?,
        m1-3-2-patient?,
        m1-3-3-packaging?,
        m1-3-4-professionals-other-countries?
)>
<!ELEMENT m1-3-1-professionals (%leaf-node;)>
<!ELEMENT m1-3-2-patient (%leaf-node;)>
<!ELEMENT m1-3-3-packaging (%leaf-node;)>
<!ELEMENT m1-3-4-professionals-other-countries (%leaf-node;)>

<!-- ..................................................................... -->


<!-- ..................................................................... -->
<!ELEMENT m1-4-expert (
```

```
<!ELEMENT m1-2-2-19-form-dmf-for-first-authorisation-and-variations (%leaf-node;)>
<!ELEMENT m1-2-2-20-form-information-on-product-quality (%leaf-node;)>
<!ELEMENT m1-2-2-21-form-notification-sample-packages (%leaf-node;)>
<!ELEMENT m1-2-2-22-form-notification-of-no-marketing-or-interruption-to-distribution (%leaf-node;)>
<!ELEMENT m1-2-2-23-form-application-for-recognition-of-orphan-drug-status (%leaf-node;)>
<!ELEMENT m1-2-2-24-application-for-recognition-of-fast-track-status (%leaf-node;)>
<!ELEMENT m1-2-2-99-other-forms (%leaf-node;)>

<!ELEMENT m1-2-3-product-quality (
        m1-2-3-1-dmf-letter-of-access?,
        m1-2-3-2-certificate-of-suitability-for-active-substance?,
        m1-2-3-3-certificate-of-suitability-for-tse?,
        m1-2-3-4-ema-certificate-for-plasma-master-file-pmf?,
        m1-2-3-5-ema-certificate-for-vaccine-antigen-master-file-vamf?
)>

<!-- ..................................................................... -->
<!ELEMENT m1-3-pi (
        m1-3-1-professionals?,
        m1-3-2-patient?,
        m1-3-3-packaging?,
        m1-3-4-professional-other-countries?
)>
<!ELEMENT m1-3-1-professionals (%leaf-node;)>
<!ELEMENT m1-3-2-patient (%leaf-node;)>
<!ELEMENT m1-3-3-packaging (%leaf-node;)>
<!ELEMENT m1-3-4-professional-other-countries (%leaf-node;)>

<!-- ..................................................................... -->


<!-- ..................................................................... -->
<!ELEMENT m1-4-expert (
```


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4. Note that during the half-year period (01 October, 2015 to 01 April, 2016) once an applicant has created and submitted an eCTD using Swiss Module 1 Specification for eCTD v1.3 for a particular product, all subsequent eCTD submissions for this product must be made using v1.3.

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