

**Working instructions**  
**Swiss Module 1 Implementation Guidance**

**Identification number:** OS000\_00\_006

**Version:** 1.6

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## List of contents

1	<b>Introduction</b> .....	2
2	<b>Timelines for Implementation</b> .....	2

## 1 Introduction

This document provides guidance to applicants and tool vendors regarding the timelines for implementation of the Swiss Module 1 Specification for eCTD v1.5.

## 2 Timelines for Implementation

The Specification and DTD of the Swiss Module 1 Specification for eCTD v1.5 include several amendments due to change requests and text updates. The new Swiss validation criteria v1.5 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 April 2020, the new Swiss Module 1 Specification for eCTD v1.5 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 April 2020 to 30 September 2020.
2. As from 01 October 2020, the Swiss Module 1 Specification for eCTD v1.5 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 v1.5 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 1.5 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, additionally all newly added sections are shown within the comparison below.

```
<!--  
DTD M1 Swissmedic v1.5  
Published Date: 01. April 2020  
Authors: Swissmedic  
<!-- ..... -->  
<!ELEMENT m1-5-bioavailability (  
  m1-5-1-info-accord-app-iv-guideline-bioequivalence?,  
  m1-5-2-reference-product?,  
  m1-5-3-confirmation-identity-bioequivalence?,  
  m1-5-4-art14-tab-compare?  
)>  
<!ELEMENT m1-5-1-info-accord-app-iv-guideline-bioequivalence %leaf-node;>  
<!ELEMENT m1-5-2-reference-product %leaf-node;>  
<!ELEMENT m1-5-3-confirmation-identity-bioequivalence %leaf-node;>  
<!ELEMENT m1-5-4-art14-tab-compare %leaf-node;>  
<!-- ..... -->
```

```
<!--  
DTD M1 Swissmedic v1.4  
Published Date: 16. August 2018  
Authors: Swissmedic  
<!-- ..... -->  
<!ELEMENT m1-5-bioavailability (  
  m1-5-1-info-accord-app-IV-guideline-bioequivalence?,  
  m1-5-2-reference-product?,  
  m1-5-3-confirmation-identity-bioequivalence?  
)>  
<!ELEMENT m1-5-1-info-accord-app-IV-guideline-bioequivalence %leaf-node;>  
<!ELEMENT m1-5-2-reference-product %leaf-node;>  
<!ELEMENT m1-5-3-confirmation-identity-bioequivalence %leaf-node;>  
<!-- ..... -->
```

4. Note that during the half-year period (01 April 2020 to 30 September 2020) once an applicant has created and submitted an eCTD using Swiss Module 1 Specification for eCTD v1.5 for a particular product, all subsequent eCTD submissions for this product must be made using v1.5.

## Change history

Version	Change	sig
1.6	New layout, no content adjustments to the previous version	tsj
1.5	Final Version	OSS Division
1.4	Final Version	OSS Division