

Swiss eCTD v4.0 Implementation Guide

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1 List of terms and abbreviations

The following table defines some common terms in this document and specific to eCTD v4.0. This is not a complete listing.

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 for, or to maintain, a marketing authorisation that falls within the scope of this guidance document.

eCTD Application	A collection of electronic documents compiled by a pharmaceutical company or its agent in compliance with Swiss legislation and guidelines to seek a marketing authorisation or any amendments thereof. An eCTD application may comprise several Submissions and Submission Units.
Regulatory Activity / Submission	A collection of submission units covering the start to the end of a specific business process, e.g., an initial MA application or Type II variation. It is a concept used in some review tools to group together several business-related sequences.
Submission Unit	A single set of information and/or electronic documents supplied at one time by the applicant as a part of, or the complete, eCTD Application. In the context of eCTD, this is equivalent to a sequence and is used interchangeably.
Document	The <i>document</i> element is used for the purposes of transmitting the information about each document related to an application. Documents (e.g., PDF files) are prepared by the Applicant for review by the Regulatory Authority.
Payload	The payload is the part of transmitted data that is the actual intended message. The payload excludes any headers or metadata sent solely to facilitate payload delivery.
contextOfUse (CoU)	The Context of Use defines the relationship between the table of contents heading (i.e., contextOfUse.code) and the referenced document to be associated with that heading. The Context of Use is relevant to the sequence that it was submitted, which may include one or more submissions referenced in the submissionUnit .
Object Identifier (OID)	<p>An OID is a sequence of numbers that uniquely identify an object and represent a hierarchically assigned namespace. OIDs are formally defined using the International Telecommunications Union ASN.1 standard¹. OIDs are represented as follows:</p> <ul style="list-style-type: none"> • String of digits separated by periods: 2.16.840.1.113883 • list of named branches: {joint-iso-itu-t(2) country(16) us(840) organisation(1) hl7(113883)} <p>The current OIDs for the ICH domain include:</p> <ul style="list-style-type: none"> • ich-estri – 2.16.840.1.113883.3.989 • ich-estri-msg-stds – 2.16.840.1.113883.3.989.2 • ich-estri-msg-stds-m8-ectd – 2.16.840.1.113883.3.989.2.2 • ich-estri-msg-stds-m8-ectd-code-lists – 2.16.840.1.113883.3.989.2.2.1 • ich-estri-msg-stds-m8-ectd-code-list-valueset-version – 2.16.840.1.113883.3.989.2.2.1.x.y

¹ International Telecommunication Union, x680: Information technology – Abstract Syntax Notation One (ASN.1): Specification of basic notation

Universally Unique Identifier (UUID)	<p>A UUID is hexadecimal text in the form of 8-4-4-12 characters, i.e., text value includes 32 characters and 4 hyphens.² UUIDs are formally defined by ISO/IEC 11578:1996 and ITU-T Rec X.667 ISO/IEC 9834-8:2005. UUIDs are represented as follows:</p> <ul style="list-style-type: none"> • String of digits separated by hyphens: 25635f23-a3a4-4ce0-9994-99c5f074960f <p>In ICH eCTD v4.0, UUIDs will be used for any identifier root attribute value. Each required element with an identifier (e.g., id element) will indicate when a UUID should be provided.</p>
Forward Compatibility	<p>Connecting eCTD v3.2.2 dossiers to eCTD v4.0 applications to continue life cycle.</p>

² International Telecommunication Union, x667: Information technology – Open Systems Interconnection – Procedures for the operation of OSI Registration Authorities: Generation and registration of Universally Unique Identifiers (UUIDs) and their use as ASN.1 object identifier components

2 Notice to Reader

Sections of this document referencing the Health Level Seven (HL7) Version 3 Standard: Regulated Product Submission Release 2 Normative are used with the publisher's permission. The HL7 Standard (Version 3) Regulatory Product Submission Release 2 Normative is copyrighted by Health Level Seven International ® ALL RIGHTS RESERVED

3 Instructions to Reader

This is a technical document that provides instructions on how to implement the eCTD v4.0 specification for Swiss purposes. The following content will be provided in a consistent manner within the document and/or the reader may be prompted by visual cues about the context or referenced information being presented in the document.

Please be aware that all XML samples have been created manually and may not be entirely correct or can be used by any software without careful control. For future updates to the Implementation Guide, it is expected that all XML snippets are created by software.



Note: All UUIDs and OIDs used in the XML samples and snippets are only for illustrational purposes, to demonstrate how the respective XML section will look. They cannot be used for testing.

The following table provides visual cues that are used in the document.

Table 1: Legend of Symbols used in Document

Icon	Description
	Technical descriptions
	Items to be careful to follow
	Additional Instructions
	References to other documents
	Not being used for Swissmedic Implementation Guide

4 Purpose and Scope

This document serves as the Implementation Guide (IG) and a technical specification for the regional Swiss Module 1 of the Electronic Common Technical Document (eCTD) v4.0 using the HL7 Version 3 Regulated Product Submission (RPS) Release 2 Normative for human medicinal products. Applicable information indicated in the ICH eCTD IG³ to be regionally available is incorporated as necessary to assist in the system development requirements for publishing or displaying eCTD v4.0 compliant messages for the recipients of the information.

This document has been prepared closely following the EU Implementation Guide with the purpose of a harmonised technical implementation for Switzerland. It was adapted with as few deviations as possible.



Note to Implementers: This regional Swiss eCTD v4.0 IG will need to be used in conjunction with the ICH eCTD IG, as the eCTD v4.0 message will be incomplete without understanding of its contents.

The RPS standard defines the message for exchanging regulatory information electronically between Competent Authorities and the Pharmaceutical. This document only comprises the Swiss Module 1 part of the eCTD XML message including the Regional Administrative and CH-specific Product Information. The focus is to outline the essential components of the message which are required for Swiss Module 1 in addition to or which are different from the common CTD Modules 2-5.

The content of eCTD v4.0 Modules 2-5, being shared across all regions represented in the International Council of Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), is not included in this IG, although some principles need to be repeated in the document to assure a better understanding. This document therefore should be read together with the ICH eCTD IG to prepare a valid eCTD Submission Unit.

In addition, information is provided to enable the forward compatibility between eCTD v3.2.2 and v4.0.

5 Change Control Rules

Change requests need to be addressed to the relevant organisation which is responsible for the part, the standard or the implementation, based on:

- eCTD v4.0 is based on the HL7 Version 3 Regulated Product Submission (RPS) Message Standard Release 2 Normative, which was developed in the external Standards Development Organisation (SDO), Health Level Seven International (HL7) and various stakeholders, which includes members of ICH M8.
- Changes to the ICH eCTD v4.0 IG and ICH Controlled Vocabularies remain the responsibility of the ICH M8 Expert Working Group & Implementation Working Group (ICH M8 EWG & IWG) and will follow the established [eCTD change control process](#).

³ The ICH IG is accessible at the [ICH](#) website

- In a situation where the Swiss IG needs to be changed, for example as a result of M1 content changes, changes to the regional requirements for applications that are outside the scope of the CTD, or identification of new functional requirements or experience of use of eCTD Module 1 gained by all parties, should be submitted to Swissmedic.

6 Essential Components of the eCTD in Consideration of the Specific Regional Requirements

The XML message provides the ability to describe the contents of the regulatory exchange and all information needed to process the exchange between the parties by using the following essential components:

- Object Identifier (OIDs) and Universally Unique Identifier (UUIDs) (further information provided in the ICH eCTD IG)
- Data Types (further information provided in the ICH eCTD IG)
- Files and Folders (see [Section 7](#) of this document, further information provided in the ICH eCTD IG)
- Controlled Vocabulary (see [Section 8](#) of this document, further information provided in the ICH eCTD IG)
- ICH eCTD v4.0 XML Schema and XML Message (see [Section 9](#) and [Section 10](#) further information provided in the ICH eCTD IG)
- CH regional specific requirements for elements (see [Section 11](#) of this document)
- Validation Rules (see [Section 13](#) of this document, further information provided in the ICH eCTD IG)
- Forward Compatibility (see [Section 14](#) of this document, further information provided in the ICH eCTD IG)

The principles of creation and use of these components will be defined by

- ICH eCTD IG across regions
- Swiss Module1 IG regionally (this document)

Therefore, to compose a complete eCTD v4.0 compliant message, the user additionally needs to refer to the requisite documentation published by ICH⁴.

6.1 Elements for regional use covered by Swiss Module 1 Implementation Guide

For Swiss Module 1 the following elements are **not** required in addition to those which are excluded by ICH already:

- *application*
 - *subject.reviewProcedure*
 - *holder.applicant*
 - *subject.reviewProcedure*
 - *reference.applicationReference*

⁴ A complete package for implementation is provided at [ICH electronic Common Technical Document - eCTD v4.0](#).

- *informationRecipient.territorialAuthority*
- *submission*
 - *subject2.review*
 - *subject1.manufacturedProduct*
 - *holder.applicant*
 - *author.territorialAuthority*
 - *subject2.productCategory*
 - *subject3.regulatoryStatus*
 - *subject3.mode*
 - *subject4.regulatoryReviewTime*
 - *subject5.submissionGroup*
- *componentOf2.categoryEvent*
 - *component.categoryEvent*



Note to Implementers: If the above listed elements and associated elements and attributes, which are not required, are included in the XML message, they will be ignored by the receiver.

6.2 Regional Business Processes Covered by Swiss eCTD v4.0 Implementation Guide

This document will address the following regional business processes:

- **Dossier Management/Submission Life Cycle** – includes rules for Submission Unit, Submission and Applications (see [Section 11.1](#) of this document).

7 Submission Contents, Folder and File Structure

Although the eCTD v4.0 specification does not require a specific folder and file structuring or naming convention, the following rules may provide a best practice recommendation on practical aspects on storing the files locally.

7.1 Submission Unit Content in eCTD v4.0 Messages

The Submission Unit consists of

- a First Level Folder (see [section 7.3](#)),
- The Second Level Folder (see [section 7.4](#))
- the eCTD v4.0 XML Message for that individual Submission Unit, named “*submissionunit.xml*”,
- the text file providing the checksum (sha256) of the submissionunit.xml file, named “*sha256.txt*”,
- the folder m1 (see [section 7.6](#)) and, as appropriate,
- folders m2 to m5.

Notes:



- The sender should not send the schema files – i.e., the util folder of previous versions of the eCTD is no longer required. The XML should reference the interaction schema being used.
- All files included in these folders should be accounted for in the XML message.
- Files previously sent do not need to be sent again.
- It is possible to reference documents across applications (equivalent to the previously used term dossier).

It is not the intent of the eCTDv4.0 Implementation Guide to introduce content related business rules which may be used for business validation after structured authoring of content has been introduced and may offer additional validation rules.

7.2 Naming Conventions

The naming conventions for files and folders for Swiss Module 1 will be replaced by keywords using controlled vocabularies (see [Section 8.1](#)) at the level of **submissionUnit.component.contextOfUse**, which is also required for selective display of information. Additional guidance is outlined in the ICH IG section 5.2.

7.2.1 Allowable Characters

There are no additional requirements other than those outlined in the ICH eCTD IG.

7.2.2 Length of Names and the Path

There are no additional requirements other than those outlined in the ICH eCTD IG.

7.3 First Level Folder Naming Convention

The first level folder structure is required to identify the content within it, e.g., when on portable electronic media or after extracting compressed content from a container. Swissmedic recommends using the proposed trade name or a company internal project code as an identifier. Once defined, it should remain unchanged during the whole life cycle.

Only the following characters may be used:

- A to Z (upper case)
- a to z (lower case)
- 0 to 9 (numbers zero to nine)
- - (hyphen)
- _ (underscore)

No other characters, blank spaces, etc. are permitted.

The length is limited to a maximum of 20 characters. Actual preparation names that are longer than 20 characters must be abbreviated. This is only due to technical reasons and does not affect the intended naming of the product.

Regardless of the naming convention of the root folder, the eCTD tool should independently manage the storing of the sequences at the correct location.

7.4 Second Level Folder Naming Requirements

The second level folder name is the sequence or submission unit number. It is a positive whole number between “1” and “999999”.

7.5 Pathname Conventions and Best Practices

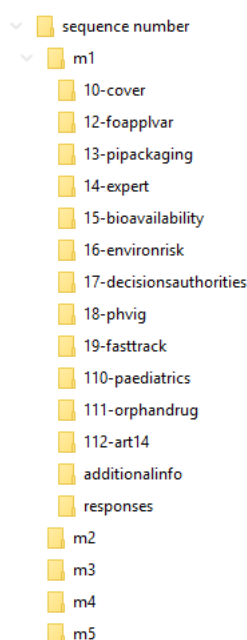
There are no additional requirements other than those outlined in the ICH eCTD IG.

7.6 Folder Hierarchy

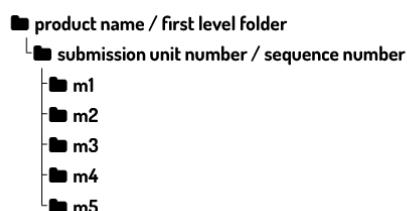
Module 1 will be a single folder with no additional folder structure. Some information will be defined using keywords for Controlled Vocabulary and ContextofUse rather than folder structure. (Figure 1):

Figure 1: Folder Hierarchy of Module 1 Screenshot

Message in eCTD v3.2.2 format



Message in eCTD v4.0 format



7.7 File Formats

In general, for messages to Swissmedic, the ICH M2 recommendations on file format⁵ and the specification for submission formats of ICH M8 need to be considered. In addition, in the Swiss Module 1, files and formats are acceptable as described in Table 2.



Please note that these additional file formats are currently not required and should not be used in eCTD submissions until otherwise described in future versions of this document.

⁵ <https://www.ich.org/page/m2-recommendations-technical-references>

Table 2: Currently required and possible future file formats in Swiss eCTD

File Type	File Format	Format Name	To be used with the following context of use values	Permissible Uses / Comments
Documents				
	.pdf*	Portable Document Format	any	PDF/A-1, PDF/A-2, 1.4, 1.5, 1.6, 1.7
Images				
	.bmp	Bitmap Graphics		Currently not required
	.gif	Graphics Interchange Format		
	.jpg, .jpeg	Joint Photographic Experts Group		
	.png	Portable Network Graphics		
Audio/Video				
	.mp4	MPEG-4 Part 14		Currently not required
Coding Language				
	.xml	Extensible Markup Language		Currently not required
	.xsd	XML Schema Definition		
	.xsl	Extensible Stylesheet Language		
Data				
	.csv	Comma Separated Values file		Currently not required
	.svg	Scalable Vector Graphics		Currently not required

	.xpt	SAS Transport file		Use for SEND data, see specification and Portal guidance documents for details
	.txt	Text file		Currently not required
	.xlsx	Microsoft Excel Open XML document		Currently not required

* Additional details on PDF and PDF/A formats can also be found in [ICH M2 recommendations](#).

In addition, the PDF files should follow the general ICH requirements of Modules 2 to 5 regarding size limitations, security settings/password protection etc.
Other file formats such as .doc or .docx may be required in addition to the eCTD as Working Documents, depending on the Swissmedic formal requirements. These files should not be added within the eCTD structure. They should be provided in a separate folder called “<eCTD submissionunit>-workingdocuments” (e.g., 1-workingdocuments) on the CD/DVD containing the eCTD or should be uploaded separately on the Swissmedic eGov Portal. Please refer also to the available guidance documents for the use of the Swissmedic eGov Portal on the handling of these documents.

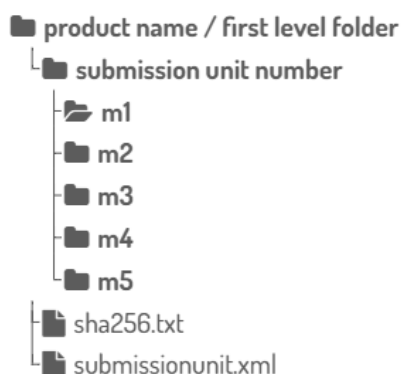
7.8 Checksums

The purpose of the checksum is as follows:

- The integrity of each file can be verified by comparing the checksum submitted in the XML message and a computed checksum by the receiving system.
- The checksum can be used to verify that the file has not been altered in the historical archive of the Regulatory Authority.

The checksum of the submissionunit.xml needs to be provided as a separate text file, named sha256.txt and will be located in the sequence number folder:

Figure 2: Submission Unit Folder Structure



There is no need to repeat the value of the checksum in the cover letter. The value will be checked against the submissionunit.xml file submitted. In case the value is not matching, the message will be rejected.

8 Controlled Vocabularies

As mentioned in the ICH implementation guide, controlled vocabularies are one of the essential components of the eCTD v4.0, which enable interoperability, i.e., clear, unambiguous communications between systems sending and receiving XML messages.

For the XML elements that have coded values, a controlled vocabulary will be required to indicate the value of the concept. Each code has a code system. The code system may be managed by ICH, Region, or the Applicant. The specific assignment of code system values can be found in the detailed description of OIDs and controlled vocabularies.

Controlled vocabularies are defined external to the message; a code is used as the identifier to convert the code value into the meaningful terms that will be used in any system that implements the viewing of the information sent in the XML message.

For Controlled Vocabularies that will be maintained by ICH, the Expert Working Groups M8 and M2 will work on establishing governance of the eCTD v4.0 controlled vocabulary. All other controlled vocabularies will be maintained by each Regulatory Authority or designated External organisation.

The information in the following sub-sections will outline the controlled vocabulary used in composing an eCTD v4.0 message. There are several different authoritative sources for the controlled vocabularies, and as such they are categorised below by the organisation that controls the content. The ICH eCTD v4.0 specific terminologies, i.e., the controlled vocabulary determined by ICH, are stated in the ICH Implementation Guide.

Swissmedic has its own organisation root OID registered on the HL7 registry:

{joint-iso-itu-t(2) country(16) us(840) organisation(1) hl7(113883) externalUseRoots(3) ich-estri(989) regional-specialised(5) sub-reg(1) smc(5)} or being read as:

2.16.840.1.113883.3.989.5.1.5 (optional child OIDs can added),

which is extended to assign a specified OID for Dossier Management ("1"), where the Swiss M1 IG ("1") is being part of and which relates to its current version for implementation use:

2.16.840.1.113883.3.989.5.1.5.1.1.3 (Swiss M1 IG v2.0)

A different OID assigned to Swissmedic is valid for controlled vocabularies⁶.

The relevant controlled vocabularies are provided in the Implementation Package as Excel sheets:

2.16.840.1.113883.3.989.5.1.5.1.2.3 (CH M1 Controlled Vocabularies v2.0)

2.16.840.1.113883.3.989.5.1.5.1.3.3 (table Application Submission Type v2.0)

2.16.840.1.113883.3.989.5.1.5.1.4.3 (table Context of Use v2.0)

2.16.840.1.113883.3.989.5.1.5.1.5.3 (table Submission Unit Type v2.0)

6

Controlled vocabularies are lists of terms that refer to attributes of the medicinal and the pharmaceutical product, e.g., dosage form, route of administration, unit of measurement.

Notes to Implementers:



- The controlled vocabulary required enables system to system communications and is not always the ideal way to display concepts in a system graphical user interface (GUI). Be cautious not to apply the technical codes in the GUI, instead use the business-friendly terms that are specified by Competent Authorities.
- For implementation, the controlled vocabulary will be provided using an OID assigned specifically. All regionally required controlled terms are available as Excel and genericode files in the package.

8.1 Keywords and Controlled Vocabularies for Swiss Purpose

Keywords need to be used to support a reader friendly presentation of content within the same Context of use, either by sender defined **keywordDefinition** or using a controlled vocabulary, i.e., for document type, language, country. Depending on the product, additional sender defined keywords can be used to specify the pharmaceutical form or strength for which a product information text is dedicated. These sender-defined keywords should be used for Module 3 purpose at the same time. However, dedicated rules cannot be stated here as they will depend on individual products or sender specific rules to be applied across their product portfolio. It is not foreseen to re-submit **keywordDefinition** values in each sequence. However, sender defined keywords can be modified but will be executed then for all applications making use of them (see [Section 10.27](#)).

The controlled vocabularies specified for the Swiss Module 1 part of the eCTD v4.0 message are exemplified below including terminology and location for obtaining detailed information. The controlled vocabularies will follow the ICH model and versioning is available. The lists are provided in a separate package, in both spreadsheet (.xlsx) and genericode formats (.xml), where applicable.



Note to Implementers: For convenience, the `displayName` values of several codes are provided in the XML snippets. However, the `displayName` is not required for processing of a `submissionunit.xml` file. Instead, any `displayName` value will be ignored as it should be retrieved from the respective `codeSystem` as described in the section above.

Table 2: Controlled Vocabularies for CH purpose

Referenced Controlled Term List	List Name	Purpose	Source

Context of Use Codes	CH eCTD Context of Use	Specifies the code set to represent the headings found in the CTD structure that are specified by regional authorities (specifically Module 1). Examples of enhancement features and the reuse of data are in the Context of use which will allow one piece of data to be used across many applications, avoiding the need for duplication of data elements.	2.16.840.1.113883.3.989.5.1.5.1.4.3
Submission Codes	Application Submission Type	Type of regulatory activity constituted by one or several Submission Units and referring to exactly one application.	2.16.840.1.113883.3.989.5.1.5.1.3.3
Submission Unit Codes	Submission Unit Type	Specifies the type of Submission Unit	2.16.840.1.113883.3.989.5.1.5.1.5.3

8.2 Controlled Vocabulary specified by HL7

The controlled vocabularies specified by Health Level 7 (HL7) will apply for Swiss Module 1 in the same way as for Modules 2-5, see ICH eCTD IG for details.

8.3 Controlled Vocabulary specified by ISO

The controlled vocabulary specified by other organisations (i.e., not managed by ICH, Region or HL7) are provided below, denoting the responsible organisation, a brief description of the terminology and location for obtaining detailed information.

Not all of the controlled vocabularies listed below, and the corresponding XML elements are currently used at Swissmedic. If they are used in the XML message, they will be ignored. Chapter is retained in Swiss Implementation Guide for reasons of traceability.

- **International Organisation for Standardization (ISO) - Two-Letter Language Code:** This is a two-letter code that is specified for the language as specified in the ISO 639.1 standard. This vocabulary is used to define the **text@language** attribute.
- **ISO Country Code – Two-letter Country Code:** This is the country code that is specified in the ISO 3166-1 standard. For Swiss Module 1 purposes a constrained list will be used (see current eCTD Guidance for Industry).

8.4 Maintenance of Controlled Vocabularies

International vocabulary harmonisation for eCTD v4.0 is out of scope for the initial release of eCTD v4.0 and implementers may use existing vocabularies that are unique to their message exchange requirements between parties.

Maintenance of Controlled Vocabularies from outside Swissmedic will be handled by the M2 Working Group.

9 eCTD v4.0 XML Schema

There are no principles deviating from the ICH Implementation Guide for creating the Swiss part of the XML schema.

10 eCTD v4.0 XML Message

There are no principles deviating from the ICH Implementation Guide for creating the Swiss part of the XML message. Especially regarding the header of the message, the same elements/attributes apply as outlined in the ICH eCTD IG. In addition, the conceptual model is identical to what is described in the ICH IG.

Additional regional specific requirements need to be considered for other elements/attributes as outlined below.



Note to Implementers: The **value** elements could be provided in the XML alongside the **codeSystem** and **code** elements. However, the display name provided by the **value** element will not be validated and should not be displayed by tools. The **codeSystem** and **code** values will be validated and the associated name value from the Code System itself should be displayed in tools instead.

All information in this section is organised to enable the eCTD v4.0 XML components to appear within the schema. Elements/attributes that are not required in Switzerland are indicated as such in table 4, below.



Note to Implementers: Elements, associated elements and attributes that are not required in Switzerland but are included in the XML message will be ignored by the receiver. Required and Swissmedic specific elements are highlighted in this document. Also note that examples below might show XML elements which are not needed by Swissmedic. The examples were taken from EMA's Implementation Guide with the intention as to have as little deviations as possible and were adapted to Swissmedic's needs. Refer to [Section 10](#) for relevant XML elements.

10.1 Example for the header as to be used in Switzerland

```
<PORP_IN000001UV ITSVersion="XML_1.0" xmlns="urn:hl7-org:v3"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xsi:schemaLocation="urn:hl7-org:v3
PORP_IN000001UV.xsd">
  <id/><creationTime/>
  <interactionId/>
  <processingCode/>
  <processingModeCode/>
  <acceptAckCode/>
  <receiver>
    <device classCode="DEV" determinerCode="INSTANCE">
      <id>
        <item root="" identifierName=""/>
      </id>
    </device>
  </receiver>
</PORP_IN000001UV>
```

```

</device>
</receiver>
<sender>
<device classCode="DEV" determinerCode="INSTANCE">
<id>
</device>
</sender>

```

- **ITSVersion** must provide the value of "XML_1.0"
- **xmlns** must have the value "urn:hl7-org:v3"
- **xmlns:xsi** must have the value "<http://www.w3.org/2001/XMLSchema-instance>"
- **xsi:schemaLocation** must reference the current interaction schema file i.e., **xsi:schemaLocation=**
- **receiver@typeCode** has a fixed value of "RCV" and it does not need to be included in the message.
- **receiver.device@classCode** must have a value of "DEV"
- **receiver.device@determinerCode** must have a value of "INSTANCE"
- Include two **id.item** elements with the following information:
 - **receiver.device.id.item@root** should indicate the OID of the ICH eCTD v4.0 Implementation Guide or the Regional/Module 1 Implementation Guide used to create the message.
 - **receiver.device.id.item@identifierName** should indicate the version name of the ICH eCTD v4.0 Implementation Guide or the Regional/Module 1 Implementation Guide used to create the message. This value can be used to indicate the version number of the IG, but will not be used by the Regulatory Authority.
- **sender@typeCode** has a fixed value of "SND" and it does not need to be included in the message
- **sender.device@classCode** must have a value of "DEV"
- **sender.device@determinerCode** must have a value of "INSTANCE"

10.1.1 XML Sample

```

<id>
<creationTime/>
<interactionId/>control
<processingCode/>
<processingModeCode/>
<acceptAckCode/>
<receiver>
<device classCode="DEV" determinerCode="INSTANCE">
<id>
  <item root="2.16.840.1.113883.3.989.2.2.1.11.6" identifierName="ICH eCTD v4.0 IG v1.7"/>
  <item root="2.16.840.1.113883.3.989.5.1.5.1.1.3" identifierName="CH M1 IG v2.0"/>
</id>
</device>
</receiver>
<sender>
<device classCode="DEV" determinerCode="INSTANCE">
<id>
</device>
</sender>

```

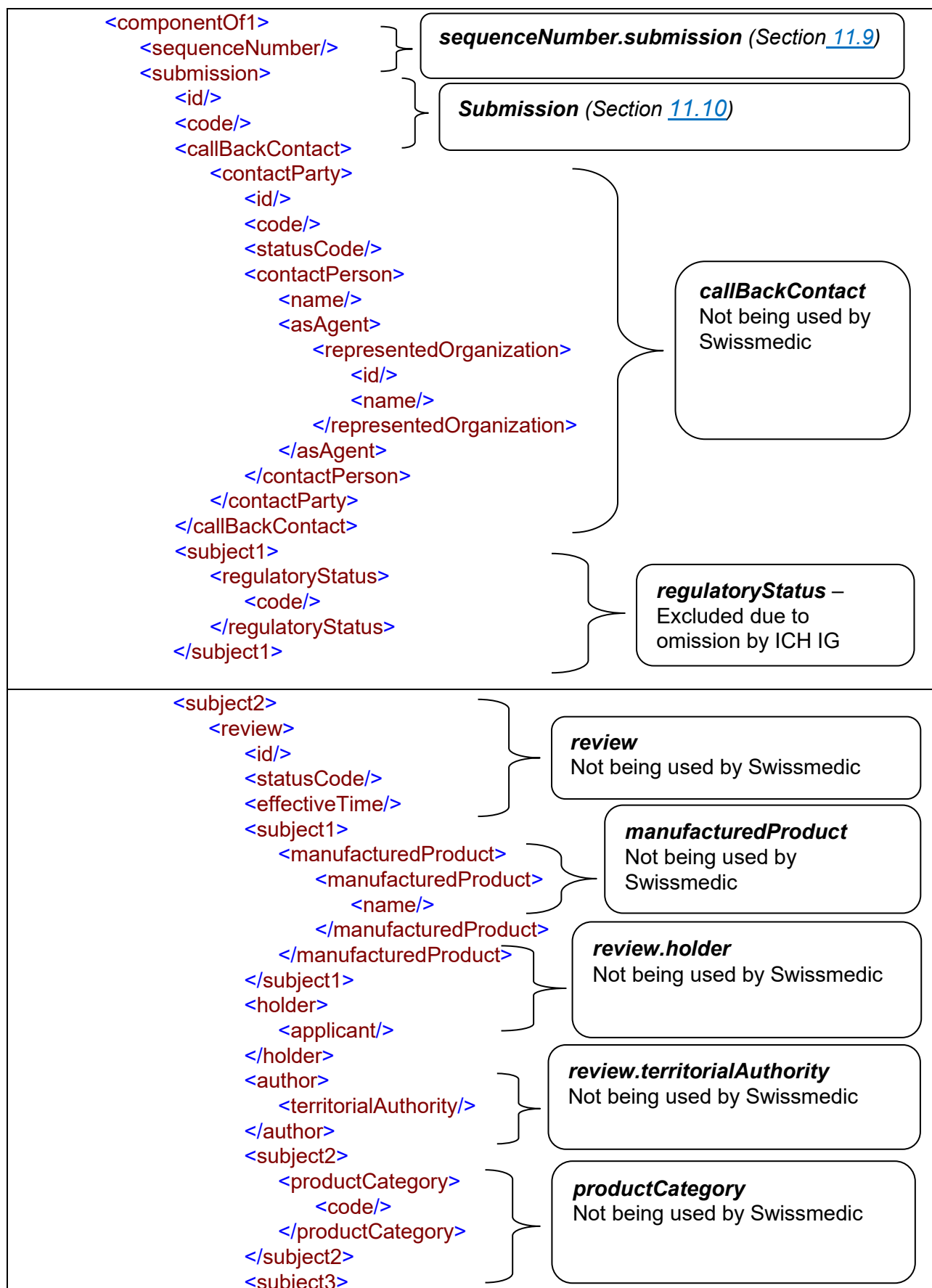
10.2 Structure of the eCTD v4.0 payload message adapted to Swiss purposes

The following tables provide the structure of the payload message and indicate the relevant section for detailed explanations.

Table 3: XML Structure

XML Structure	
The eCTD v4.0 begins at the controlActProcess of the payload XML message related to Module 1 content.	
<pre><controlActProcess classCode="ACTN" moodCode="EVN"> <subject typeCode="SUBJ"></pre>	
<p>The submissionUnit element contains the following Context of Use elements and their attributes:</p> <ul style="list-style-type: none"> • component.contextOfUse <ul style="list-style-type: none"> ○ primaryInformationRecipient.TerritorialAuthority (not being used by Swissmedic) ○ replacementOf.relatedContextOfUse ○ derivedFrom.documentReference ○ subjectOf.submissionReference ○ referencedBy.keyword 	
<pre><submissionUnit> <id/> <code/> <title/> <statusCode/> <component> <priorityNumber value=""/> <contextOfUse> <id/> <code/> <statusCode/> <primaryInformationRecipient> <territorialAuthority> <governingAuthority> <id/> <name/> </governingAuthority> </territorialAuthority> </primaryInformationRecipient> <replacementOf typeCode="RPLC"> <relatedContextOfUse> <id/> </relatedContextOfUse> </replacementOf> <derivedFrom> <documentReference> <id/> </documentReference> </derivedFrom></pre>	<div style="border: 1px solid black; padding: 5px; margin-bottom: 10px;"> submissionUnit (Section Fehler! Verweisquelle konnte nicht gefunden werden.) </div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 10px;"> priorityNumber (Section 11.2) as a supplement to the ICH eCTD IG </div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 10px;"> contextOfUse (Section 11.3) as a supplement to the ICH eCTD IG </div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 10px;"> primaryInformationRecipient.territorialAuthority (Section 11.4) Not being used by Swissmedic </div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 10px;"> replacementOf.relatedContextOfUse (Section 11.5) </div> <div style="border: 1px solid black; padding: 5px;"> derivedFrom.documentReference (Section 11.6) </div>

<pre> <subjectOf> <submissionReference> <id><item/></id> </submissionReference> </subjectOf> <referencedBy typeCode="REFR"> <keyword> <code/> </keyword> </referencedBy> </contextOfUse> </component> </pre>	<div data-bbox="957 280 1452 392"> submissionReference (Section 11.7) </div> <div data-bbox="957 448 1452 627"> keyword (Section 11.8) as a supplement to the ICH eCTD IG and specific for Swiss Module 1 IG </div>
<p>This section of the XML relates to specifying the submission element. The following elements may follow the Submission:</p> <ul style="list-style-type: none"> • sequenceNumber (included as an element of the relationship between submissionUnit and submission elements) • callbackContact.contactParty (not being used by Swissmedic) • subject1.regulatoryStatus (excluded) (not being used by Swissmedic) • subject2.review <ul style="list-style-type: none"> ○ subject1.manufacturedProduct (not being used by Swissmedic) ○ holder.applicant (not being used by Swissmedic) ○ author.territorialAuthority (not being used by Swissmedic) ○ subject2.productCategory (not being used by Swissmedic) • subject3.mode (not being used by Swissmedic) • subject4.regulatoryReviewTime (excluded) (not being used by Swissmedic) • subject5.submissionGroup (not being used by Swissmedic) 	



<pre> <regulatoryStatus> <code/> </regulatoryStatus> </subject3> </review> </subject2> <subject3> <mode> <code/> </mode> </subject3> <subject4> <regulatoryReviewTime> <code/> </regulatoryReviewTime> </subject4> <subject5> <submissionGroup> <id/> </submissionGroup> </subject5> </pre>	<p>regulatoryStatus – Not being used by Swissmedic</p> <p>mode Not being used by Swissmedic</p> <p>regulatoryReviewTime – excluded due to omission by ICH</p> <p>submissionGroup Not being used by Swissmedic</p>
---	---

XML Structure

This section of the XML relates to the **application** element. The application section contains the following elements and their attributes:

holder.applicant (not being used by Swissmedic)

informationRecipient.territorialAuthority (not being used by Swissmedic)

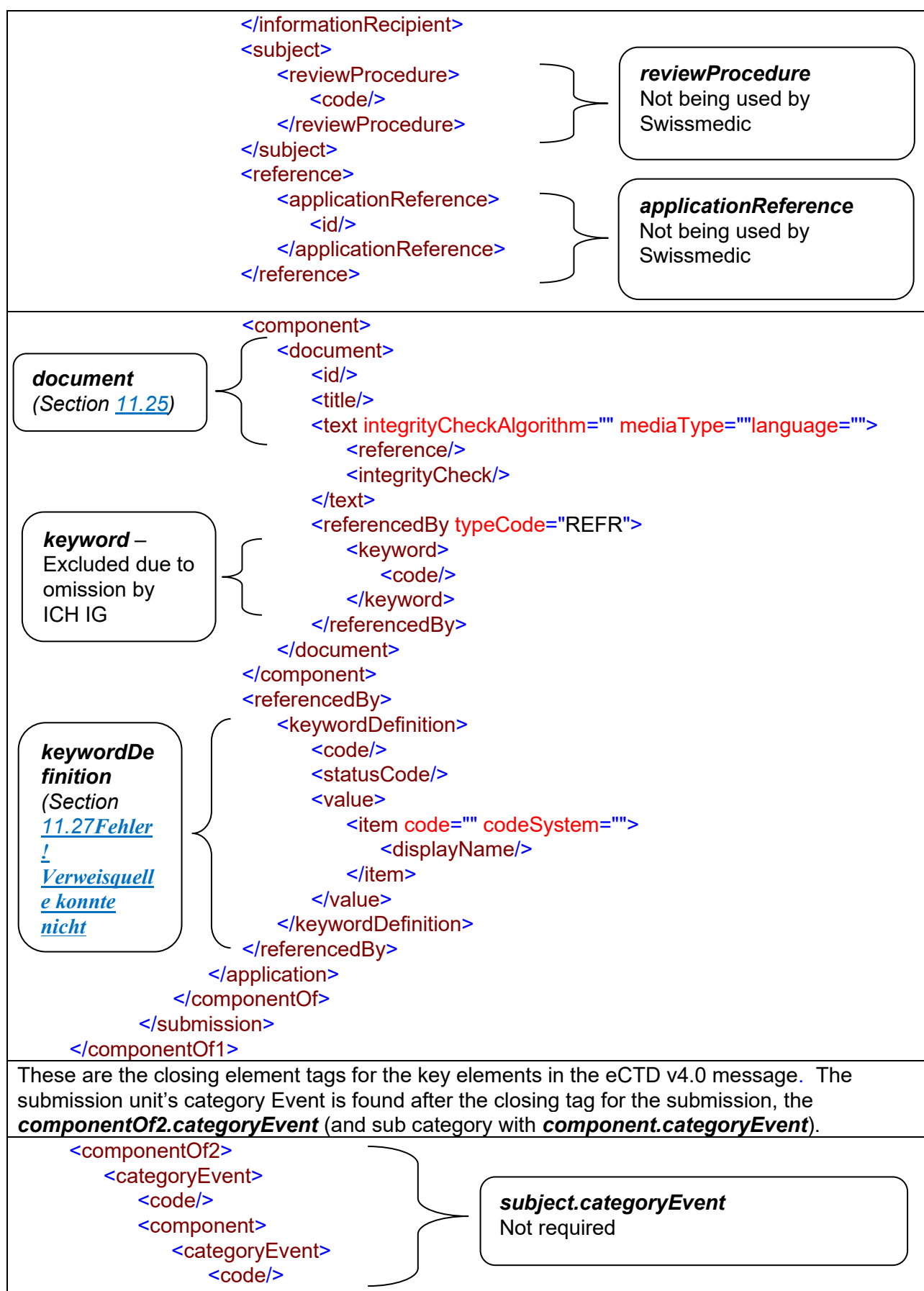
subject.reviewProcedure (not being used by Swissmedic)

reference.applicationReference (not being used by Swissmedic)

component.document

referencedBy.keywordDefinition (excluded)

<pre> <componentOf> <application> <id> <item/> </id> <code/> <holder> <applicant> <sponsorOrganization> <id><item></item></id> <name></name> </sponsorOrganization> </applicant> </holder> <informationRecipient> <territorialAuthority> <governingAuthority> <id/> <name/> </governingAuthority> </territorialAuthority> </informationRecipient> </application> </componentOf> </pre>	<p>application (Section 11.20) as a Supplement to the ICH eCTD IG and Specific for Swiss Module 1 IG</p> <p>holder.applicant Not being used by Swissmedic</p> <p>informationRecipient.ter ritorialAuthority Not being used by Swissmedic</p>
--	---



```

        </categoryEvent>
      </component>
    </categoryEvent>
  </componentOf2>
</submissionUnit>
</subject>
</controlActProcess>
</PORP_IN000001UV>

```

11 CH Regional Specific Requirements for Elements

11.1 Submission Unit

The Submission Unit is a collection of documents provided to the Regulatory Authority. A Submission Unit always relates to a regulatory activity specified by the Submission that is related to a specified Application.

Only one Submission Unit can be sent at a time related to one regulatory activity and application. The Submission Unit may be in response to one or more lists of questions from a Regulatory Authority, with respect to the specified Application and Submission Unit.

If a regulatory activity is withdrawn, fully or partially or rejected fully or partially, then the documentation must be updated accordingly with a consolidation submission unit. Context of Use elements and documents that are no longer relevant should be suspended, and context of use elements and documents where the content needs to be adjusted to reflect the withdrawal or rejection be replaced. The application form and cover letter should always be retained to keep the history. A consolidation submission unit should be submitted to restore the current view of the application to what it was before the rejected activity was submitted. This would also apply where documentation needs to be adjusted as a result of a commitment or a partially rejected variation. The submission type should be 'consolidating'.

Note, in Switzerland it is not possible to delete/suspend a submission unit from the life cycle to accommodate the withdrawal or rejection.

11.1.1 Location in XML

The **submissionUnit** element in the XML message is in the following location:

- **controlActProcess >> subject >> submissionUnit**

Refer to [Table 4](#): XML Structure.

11.1.2 XML details

There are no additional requirements other than those outlined in the ICH eCTD IG.

11.1.2.1 XML Elements

Tables with a complete set of XML elements and attributes required for the **submissionUnit** element are provided in the ICH eCTD IG and will not be repeated in this document. No additional requirements apply for Swiss Module 1.

11.1.2.2 XML Sample: Submission Unit

The following is an example of the XML for the **submissionUnit** element.

```
<subject typeCode="SUBJ">
  <submissionUnit>
    <id root="c503dce7-d628-42c1-861a-ab738afe739d"/>
    <code code="120001" codeSystem="2.16.840.1.113883.3.989.5.1.5.1.5.3"/>
    <!-- Initial submission to start a regulatory activity -->
    <title value="Initial"/>
    <statusCode code="active"/>
    <!--[Additional information may appear after the addition of the statusCode (if one exists), otherwise this
    will come after the title or code elements. For example, depending on the type of Submission Unit the
    additional elements may be available to select from the Submission Unit component or componentOf1
    elements.-->
    <componentOf1>
      <sequenceNumber value="1"/>
      <submission>
        <!--Additional information will follow for the submission elements. -->
      </submission>
    </componentOf1>
    <componentOf>
      <application>
        <!-- Additional information appears for the application element. -->
      </application>
    </componentOf>
  </submissionUnit>
</subject>
```



Note: If a status code is provided, Code must be provided as well. The only accepted status code value is 'active'.

11.2 Priority Number

There are no additional requirements other than those outlined in the ICH eCTD IG.



Note: The life cycle will be executed by inserting a new contextOfUse element including the respective combination of keywords and by assigning the appropriate priority number. All life cycle considerations outlined in the ICH eCTD IG will apply to Swiss Module 1 in the same manner.

11.3 Context of Use

The Context of Use (CoU) provides a link between the table of contents heading of the CTD and the referenced document that is associated to that heading including a label for a short instructive information on the document referenced (document label). There are no additional technical requirements other than those outlined in the ICH eCTD IG. In the sections below, the examples will be provided for Swiss Module 1.



*Note: The life cycle will be executed by inserting a new **contextOfUse** element including the respective combination of keywords and codes and by assigning the appropriate priority number. All life cycle considerations outlined in the ICH eCTD IG will apply to Swiss Module 1 in the same manner.*

11.3.1 Location in XML

The **contextOfUse** element in the XML message is in the following location:

- **controlActProcess>> subject>>submissionUnit>>component>>contextOfUse**

Refer to [Table 4](#): XML Structure for the XML representation.

11.3.2 XML Details

There are no additional requirements other than those outlined in the ICH eCTD IG.

11.3.3 Terminology

The contextOfUse codes will be provided by CH-specific controlled vocabularies (see [Section 8.1](#)). The desired status codes will be used in line with ICH eCTD IG definitions.

11.4 Territorial Authority (as primary information recipient related to Context of Use)



This element will not be used in Switzerland. Any occurrence in the XML message will be ignored.

11.5 Related Context of Use (Context of Use Life Cycle)

There are no additional requirements other than those outlined in the ICH eCTD IG.

11.6 Document Reference

There are no additional requirements other than those outlined in the ICH eCTD IG.

11.7 Submission Reference



This element will not be used in Switzerland. Any occurrence in the XML message will be ignored.

11.8 Keyword

The **keyword** element is used for the purpose of transmitting additional information about a **contextOfUse** element.

The **keyword** is either defined by an external controlled vocabulary, e.g., Document Type Code, Language Code or Country Code, or it may be defined within the message as **keywordDefinition**.

Please consult the controlled vocabulary package for further details on how the definition of the keyword is recommended to be built.



Note: The life cycle will be executed by inserting a new contextOfUse element including the respective combination of keywords and codes and by assigning the appropriate priority number. All life cycle considerations outlined in the ICH eCTD IG will apply to Swiss Module 1 in the same manner.

11.8.1 Location in XML

The **keyword** element in the XML message is in the following location:

- **controlActProcess>>subject>>submissionUnit>>component>>contextOfUse>>referencedBy>>keyword**

Refer to [Table 4](#): XML Structure.

11.8.2 XML Details

There are no additional requirements other than those outlined in the ICH eCTD IG.

11.8.3 Terminology

Swiss Module 1 controlled vocabularies are provided in the Implementation Guide package and later on Swissmedic's website, see also [Section 8.1](#).

11.9 Sequence Number

There are no additional requirements other than those outlined in the ICH eCTD IG.

11.10 Submission

The **submission** is the representation of a regulatory activity constituted by one or several Submission Units and referring to exactly one application. The respective controlled vocabulary is CH specific.

A Submission Unit may contain more than one submission, each referring to one application (see [Section 11.1](#)).



Remark: The id.item@root will change for a new regulatory activity only. As long as Submission Units refer to the same regulatory activity the same id.item@root will be used.

11.10.1 Location in XML

The **submission** element in the XML message is in the following location:

- **controlActProcess>> subject>> submissionUnit>>componentOf1>> submission**

Refer to [Table 4](#): XML Structure.

11.10.2 XML Details

The following attributes are used with the **submission** element:

XML Elements

The following tables provide a complete set of XML elements and attributes required for the **Submission** element, and any special instructions.



*The **classCode** is fixed to “ACT” and **moodCode** is fixed to “EVN”. These values are not required in the XML message.*

Submission.id

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
id		[1..1]		This is a container element that provides a unique identifier for the submission.
id.item		[1..1]		This is the container element of the following attributes by which it uniquely identifies the application. <i>Note: This is a regional constraint.</i>
	root	[1..1]	Valid OID or UUID	This is the root attribute that uniquely identifies the submission.
	extension	[1..n]	alpha-numeric e.g., 123456789	The extension attribute of the id element provides a location to specify the Swissmedic application number (9 digit Swissmedic application number, not the marketing authorisation number) including specific extensions related to the regulatory activity. Use “ pending ” as value if actual Swissmedic application number is not known yet. “Pending” must be replaced in follow-up Submission units with the assigned application number.
Conformance The id.item@root attribute is required for the submission element.				

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
Business Rules	Only one item element should be provided for a submission. The id@extension is the extended procedure number for the regulatory activity. This value will stay the same for all Submission Units within the regulatory activity.			
Excluded Elements and Attributes	The following attributes are not required by eCTD v4.0: <ul style="list-style-type: none"> • id.item@identifierName • id.item@scope • id.item@reliability • id.item@displayable • id@validTimeLow • id@validTimeHigh • id@controlInformationRoot • id@controlInformationExtension • id@nullFlavor • id@flavorId • id@updateMode 			

Submission.code

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
code		[0..1]		This is a container element for the submission .
	code	[1..1]	Alpha Numeric	This is the code attribute, which is a unique value that indicates the type of content in the submission .
	codeSystem	[1..1]	Valid OID or UUID	This is the codeSystem attribute and it is the OID of the list representing the application submission types.
Conformance	There must be one, and only one, code@code attribute specified for a submission.			
Business Rules	Submission codes may vary for different product types. In case of eCTD for human medicinal product the relevant code list is referenced in section 8.1 .			

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
Excluded Elements and Attributes	The following attributes are not required by eCTD v4.0: <ul style="list-style-type: none"> • code.displayName • code.originalText • code.translation • code.source • code@codeSystemName • code@codeSystemVersion • code@valueSet • code@valueSetVersion • code@codingRationale • code@validTimeLow • code@validTimeHigh • code@controllInformationRoot • code@controllInformationExtension • code@nullFlavor • code@flavorId • code@updateMode 			

Submission.statusCode

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
statusCode		[0..1]		This is a container element for the statusCode of the submission.
	code	[1..1]	Alpha Numeric e.g., active	This is the statusCode attribute that indicates the status of the submission.
Conformance	If the statusCode element is provided, the code attribute is required.			
Business Rules	Only “active” is allowed as a code for the Submission.statusCode in Switzerland.			
Excluded Elements and Attributes	The following attributes are not required by eCTD v4.0: <ul style="list-style-type: none"> • code@codeSystemName • code@codeSystemVersion 			

XML sample: Submission

The following is an example of the XML for the **submission** element.

```
<componentOf1>
  <sequenceNumber value="1"/>
  <submission>
    <id>
      <item root="0d84467e-f20b-42ad-a69a-63e61a4f7ea7" extension="123456789"/>
    </id>
  </submission>
</componentOf1>
```

```
<code code="100001" codeSystem="2.16.840.1.113883.3.989.5.1.5.1.3.3/>
  <!-- displayName value="na-nas" as retrieved from the code system...!
</code>
<statusCode code="active"/>
<!-- Additional information will follow in the submission element.-->
<componentOf>
  <!-- Additional information appears for the application element. -->
</componentOf>
</submission>
</componentOf1>
```

11.10.3 Terminology

The **submission** element code values will be provided by CH-specific controlled vocabularies (see [Section 8.1](#)).

The desired status codes will be used in line with ICH eCTD IG definitions.

11.10.4 Related Elements

The **following** elements are related to **submission** and require additional information:

- **subject2.review** (not being used by Swissmedic, see [Section 11.12](#))
- **subject3.mode** (not being used by Swissmedic, see [Section 11.18](#))
- **subject5.submissionGroup** (not being used by Swissmedic, see [Section 11.19](#))

11.11 Contact Party



This element will not be used in Switzerland. Any occurrence in the XML message will be ignored.

11.12 Review



This element will not be used in Switzerland. Any occurrence in the XML message will be ignored.

11.13 Manufactured Product



This element will not be used in Switzerland. Any occurrence in the XML message will be ignored.

11.14 Holder



This element will not be used in Switzerland. Any occurrence in the XML message will be ignored.

11.15 Territorial Authority (as author of review) [used by regulators only]



This element will not be used in Switzerland. Any occurrence in the XML message will be ignored.

11.16 Product Category



This element will not be used in Switzerland. Any occurrence in the XML message will be ignored.

11.17 Regulatory Status [used by regulators only]



This element will not be used in Switzerland. Any occurrence in the XML message will be ignored.

11.18 Mode



This element will not be used in Switzerland. Any occurrence in the XML message will be ignored.

11.19 Submission Group



This element will not be used in Switzerland. Any occurrence in the XML message will be ignored.

11.20 Application

The **application** element represents a request from Regulated Industry to a Regulatory Authority, for the approval to market a medicinal product for human use. The application, in this context, will typically cover all dosage forms and strengths of a product.

Referencing across applications is possible when all content is identifiable by using an eCTD v4.0 compliant identifier. Content previously submitted according to the eCTD v3.2.2 specification can be referenced using the appropriate mechanism as detailed in ICH eCTD IG Section 8.1.1 and Section 9.2.17.1

An application will consist over time of multiple submissions or regulatory activities (e.g., initial marketing authorisation application, variations or PSURs). For example, a marketing application may consist of one or more regulatory decisions e.g., the collection of all approvals is related to the application. Each regulatory submission (for details refer to [section 8.1](#) for controlled vocabulary of Application Submission Types) will have its own regulatory action, and most likely will be composed of one or more Submission Units.

The **application** element is also presented in the ICH eCTD IG, as it is the connection point for the **document** and **keywordDefinition** elements in the XML message, but only complementary information is provided.



An application cannot be “suspended”, please refer to chapter 11.1.

11.20.1 application.id

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description <i>Instructions</i>
id		[1..1]		This is a container element that provides a unique identifier for the submission.
id.item		[1..1]		This is the container element of the following attributes by which it uniquely identifies the application, because an application can be given multiple identifiers across territories, one id.item element should be used for each unique application identifier.
	root	[1..1]	Valid OID or UUID	The root attribute of the id.item element provides a global unique identifier for the application element.
	extension	[1..1]	alpha-numeric e.g., 12345	The extension attribute of the id element provides a location to specify the Swissmedic 5 digit marketing authorisation number (Zulassungsnummer). Use "pending" as value if actual Swissmedic marketing authorisation number is not known yet. "Pending" must be replaced in follow-up Submission units with the assigned marketing authorisation number.
Conformance	The id.item@root attribute is required for the application element.			
Business Rules	Only one item element should be provided for an application. The id@extension is the marketing authorisation number of the application. This value will stay the same for all Submission Units within the application.			
Excluded Elements and Attributes	The following attributes are not required by eCTD v4.0: <ul style="list-style-type: none"> • id.item@identifierName • id.item@scope • id.item@reliability • id.item@displayable • id@controlInformationExtension • id@controlInformationRoot • id@flavorId • id@nullFlavor • id@updateMode • id@validTimeLow • id@validTimeHigh 			

11.20.2 application.code

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
code		[1..1]		This is a container element that organizes the coded value for the application.
	nullFlavor	[1..1]	NA	The container element is required for technical reasons. The value NA indicates that the attribute is not applicable. See the following example.
Conformance	The code@nullFlavor attribute is required for the application.code element.			
Business Rules	NA			
Excluded Elements and Attributes	The following attributes are not required by eCTD v4.0: <ul style="list-style-type: none"> • code.displayName • code.originalText • code.translation • code.source • code@codeSystemName • code@codeSystemVersion • code@codingRationale • code@controllInformationExtension • code@controllInformationRoot • code@flavorId • code@id • code@updateMode • code@validTimeLow • code@validTimeHigh • code@valueSet • code@valueSetVersion • code@xsi:type 			

11.20.3 Location in XML

The **application** element in the XML message is in the following location:

- **controlActProcess>> subject>> submissionUnit>>componentOf1>> submission>>componentOf>>application**

Refer to [Table 4](#): XML Structure.

11.20.4 XML details

There are no additional requirements other than those outlined in the ICH eCTD IG.

```
<componentOf>
<application>
```

```
<id>
  <!-- =====-->
  <!-- Root reflects the UUID provided by the publishing software-->
  <!-- Extension reflects the Swissmedic authorisation number in this example -->
  <!-- Code reflects that the value is not applicable (NA)-->
  <!-- =====-->
<<application">
  <id>
    <item root="4309305e-48c6-4216-a0ca-def7c9d05c7b" extension="12345"/>
  </id>
  <code nullFlavor="NA"/>
  ...
</application>
```

11.20.5 Terminology

The controlled terminology for the **application** element includes codes for application types (refer to 8.1).

11.20.6 Related Elements

The **following** elements are related to **application** and require additional information:

- **holder.applicant** (not being used by Swissmedic)
- **informationRecipient.territorialAuthority** (not being used by Swissmedic)
- **subject.reviewProcedure** (not being used by Swissmedic)
- **reference.applicationReference** (not being used by Swissmedic)
- **component.document**. (see 11.25)
- **referencedBy.keywordDefinition** (see 11.27)

11.21 Applicant

 This element will not be used in Switzerland. Any occurrence in the XML message will be ignored.

11.22 Territorial Authority (as information recipient related to application)

 This element will not be used in Switzerland. Any occurrence in the XML message will be ignored.

11.23 Review Procedure

 This element will not be used in Switzerland. Any occurrence in the XML message will be ignored.

11.24 Application Reference

 This element will not be used in Switzerland. Any occurrence in the XML message will be ignored.

11.25 Document

The **document** element is used for the purposes of transmitting the information about each document related to an application. The valid use for a specific application and the purpose of a specific regulatory activity is based on the association with a specified CoU. As documents will not be deleted or set to inactive (no status change is foreseen), a new CoU can be associated at any time regardless of whether the application itself is still active or the regulatory activity is rejected or approved.

Document elements (referencing e.g., PDF files) will be prepared by the sender, i.e., the Applicant, for review by the Regulatory Authority. A document element is applicable to one file and is referenced by one or multiple contextOfUse elements. The same CoU element combinations may be used in multiple Submission Units (reuse of documents)¹⁷. Re-use using Forward Compatibility is detailed in ICH eCTD IG Section 9.2.17.1. To the **contextOfUse** element an additional label can be assigned if the document title is not instructive enough or too general or too detailed.

11.25.1 Location in XML

The **document** element in the XML message is in the following location:

- **controlActProcess>> subject>> submissionUnit>>componentOf1>> submission>>componentOf>>application>>component>>document**

Refer to [Table 4](#): XML Structure for the XML representation.

11.25.2 XML details

XML Elements

Tables with a complete set of XML elements and attributes required for the **document** element are provided in the ICH eCTD IG and will not be repeated here. The following additional requirements apply for CH M1.

¹⁴ The CTD granularity document specifies where one or more documents may be submitted for each CTD section. Because the eCTD v3.2.2 does not distinguish files and documents, those terms have been previously used interchangeably. The granularity document has been updated to specify the opportunities when using eCTD v4.0.
(http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/CTD/M4_R4_Organisation/M4_R4_Granularity_Document.pdf)

document.text

Business Rules	<p>In CH: The text element should be used when sending a document.</p> <p>The text@language is not to be used in the context of Swiss M1.</p> <p>The text@mediaType is not to be used in the context of Swiss M1.</p> <p>The text.thumbnail element is not to be used in the context of Swiss M1.</p> <p>The text.description@value attribute is not to be used in the context of Swiss M1.</p> <p>For file reuse, the documentReference element provides the UUID of the document element to be reused. It is prerequisite that the metadata as well as the content cannot be changed for any reuse.</p>
Excluded Elements and Attributes	No other elements than indicated in the ICH eCTD v4.0 IG will be excluded.

XML Samples

The following is an example of the XML for **document** elements. The Document is a component of an Application.

```
<component>
<document>
  <id root="50cf78aa-7c32-4994-859b-49500369fe1d"/>
  <title value="General Information"/>
  <text integrityCheckAlgorithm="SHA256" charset=" utf8">
    <reference value="m1/nongmo-var.pdf"/>
    <!-- =====>
    <integrityCheck>56df6492f724ee2e76e12cb4b001bd2fdc43603
fb15d70afc89813398739fb9c</integrityCheck>
  </text>
</document>
</component>
```



Note to Implementers: For documents (i.e., each representing each a single file), the text element will be provided along with the other required elements.

11.25.3 Terminology

The **document** element has one coded terminology for language (the ISO language codes) (see [Section 8.3](#)).

11.26 Document reuse

Documents reuse is the ability to submit a document once to a Regulatory Authority and refer to the document by its unique identifier in future submissions if the document was successfully sent to the regulatory authority.

Document reuse will only be possible if the files have been previously submitted (just submitted and not approved) and are validly retained.

Documents can be referenced/reused without resubmitting the physical file, by referencing each document's unique identifier (UUID). This can occur:

- Across a submission unit
- Across regulatory activities within an application
- Across different applications

All the contents of the reused document, including references and hypertext links to other documents, should be relevant to the submission that reuses the document.

The **documentReference** element provides the UUID of the document to be reused.

11.27 Keyword Definition

The **keywordDefinition** element is used by the sender to define a keyword that is referenced by an identifier in other parts of the message. For details see the ICH Implementation guide. The usage of this element is expected to be helpful in Swiss Module 1 for product information text to separate different pharmaceutical forms or strengths. It should be noted that the sender defined keywords will not be understood as regulatory content. The purpose is simply to support presentation of content that shall be displayed together and will provide a meaningful orientation for reviewers.

11.27.1 Location in XML

The document element in the XML message is in the following location:

- **controlActProcess>> subject>> submissionUnit>>componentOf1>> submission>>componentOf>>application>>referencedBy>>keywordDefinition**

Refer to [Table 4: XML Structure](#) for the XML representation.

11.27.2 XML details

Tables with a complete set of XML elements and attributes required for the **keywordDefinition** element are provided in the ICH eCTD IG and will be specified for Swiss M1 purpose here. The following requirements apply for Swiss M1.

11.27.2.1.1 keywordDefinition.code



This element will not be used in Switzerland. Any occurrence in the XML message will be ignored.

11.27.2.1.2 keywordDefinition.statusCode



This element will not be used in Switzerland. Any occurrence in the XML message will be ignored.

11.27.2.1.3 *keywordDefinition.value*

 This element will not be used in Switzerland. Any occurrence in the XML message will be ignored.

11.27.3 Guidance regarding Keyword Definition values

 This element will not be used in Switzerland. Any occurrence in the XML message will be ignored.

12 Creating the Message

With the individual components of the XML message described above, each of those components will now be used to demonstrate how to compose multiple components to address a specific scenario. This will also explain how to address the creation and modifications to the content transmitted during the lifecycle of a submission focusing on Swiss Module 1, as recommendations need to differ from ICH recommendations to cover CH-specific scenarios.

12.1 Content Life Cycle Management (contextOfUse and Documents)

There are no deviating principles to apply in comparison to the general rules set out by ICH. The example below shows a short sample of **contextOfUse** and **Document** elements referencing some Swiss Module 1 files. See above chapters for elements required for Swiss submissions. Not required elements in the XML payload are ignored by Swissmedic.

XML example:

```
<componentOf>
  <application>
    <!-- =====-->
    <!-- Additional information may appear after the Application.code, for example any-->
    <!-- of the following elements related to holder, informationRecipient, -->
    <!-- ReviewProcedure, Application.Reference-->
    <!-- =====-->
  </application>
  <component>
    <document>
      <id root="88c5b0a4-8042-4110-a0c2-af8e51d87e26"/>
      <title value="Cover Letter"/>
      <text integrityCheckAlgorithm="SHA256" charset="utf-8">
        <reference value="m1/cover-20120420.pdf"/>
        <integrityCheck>3285a776897425b9a3b87abbaaf163fb261242397997b003efe3201e</integrityCheck>
      </text>
    </document>
  </component>
</componentOf>
```

```

<text integrityCheckAlgorithm="SHA256" charset="utf-8">
  <reference value="m1/cover-tracking-20120420.pdf"/>
  <integrityCheck>3285a776xv745a25b9a3b87abbaaf163f726ec912423979 97b003efe3201e</integrityCheck>
</text>
</document>
</component>
<component>
<document>
  <id root="3bd2276d-fa45-47c7-9360-fa833cffbb1f"/>
  <title value="Expert Quality"/>
  <text integrityCheckAlgorithm="SHA256" charset="utf-8">
    <reference value="m1/quality-meier.pdf"/>
    <integrityCheck>3285a776897425b9a3b877z45abbaaf1726ec912423979 97b003efe3202e</integrityCheck>
  </text>
</document>
</component>
<component>
<document>
  <id root="0b4229b0-6c98-4fe9-9575-556019c12fc5"/>
  <title value="Expert Non-Clinical"/>
  <text integrityCheckAlgorithm="SHA256" charset="utf-8">
    <reference value="m1/nonclinical-schulz.pdf"/>
    <integrityCheck>3285a776897425b9a3b87abbaaf163fb2646726ec912423979 97b003efe3203e</integrityCheck>
  </text>
</document>
</component>
</application>
</componentOf>

```

12.2 Complex Scenarios

12.2.1 Referencing across submissions and applications of the same pharmaceutical company

In general, there is no deviation to the known process of submitting documents to Swissmedic by post or via the Swissmedic eGov portal as it was with eCTD v3.2.2.



Note: Documents may only be reused and referred to across applications if they are available to Swissmedic, i.e., are present in the eCTD repository.

The principles of referencing are entirely the same, regardless of whether a reference should be presented within a Submission Unit, where a document is to be displayed with two different contexts of use elements, across submissions, or across applications. A **document** element will always be referenced by the new **contextOfUse** element and its ID. The **document** element provides the link to the PDF file. Compiler tool interoperability would require a continued access to any cross application referenced documents and that they are also provided in the transfer of ownership. Generally, no **document** elements can be referenced if they have not been submitted to Swissmedic. In cases of MAH transfers a separate consolidating sequence might be necessary to complete the document archive of Swissmedic. In those cases, it is not foreseen that the document title should be changed. Changes of the document title **are intended to mainly include corrections of typos. The update mode is not considered appropriate** to be used for

establishing a new meaning / usage of a file. In that case a new CoU is required. From a technical point of view, the rules outlined in the ICH eCTD IG apply entirely to Swiss Module 1 as well.



Note: Document title corrections will be displayed wherever the document element is referenced. This effect is acceptable as no regulatory content will be changed. Further guidance as to when a document title change is allowed or recommended is provided in the ICH Implementation Guide, section on Document Element Updates.

12.2.2 Example of Document Reuse

A Context of Use references a document that was already submitted in a previous Submission Unit. Therefore, the Document element is not included again in the current Submission Unit, and the document is not resubmitted.

```
<?xml version="1.0" encoding="utf-8"?>

<PORP_IN000001UV xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:xsd="http://www.w3.org/2001/XMLSchema" xsi:schemaLocation="urn:hl7-org:v3
PORP_IN000001UV.xsd ITSVersion="XML_1.0" xmlns="urn:hl7-org:v3">

  <id />
  <creationTime />
  <interactionId />
  <processingCode />
  <processingModeCode />
  <acceptAckCode />
  <receiver typeCode="RCV">
    <device classCode="DEV" determinerCode="INSTANCE">
      <id>
        <item identifierName="ICH eCTD v4.0 IG v1.7" root="2.16.840.1.113883.3.989.2.2.1.11.6" />
        <item identifierName="CH eCTD v4.0 IG v2.0" root="2.16.840.1.113883.3.989.5.1.5.1.1.3" />
      </id>
    </device>
  </receiver>

  <sender typeCode="SND">
    <device classCode="DEV" determinerCode="INSTANCE">
      <id />
    </device>
  </sender>

  <controlActProcess classCode="ACTN" moodCode="EVN">
    <subject typeCode="SUBJ">
      <submissionUnit classCode="ACT" moodCode="EVN">
        <id root="e2597812-d074-47f7-95dc-360dbf317294" />
        <code code="120002" codeSystem="2.16.840.1.113883.3.989.5.1.5.1.1.3" />
        <title value="Sample Submission Unit with Document Reuse" />
        <statusCode code="active" />
        <component typeCode="COMP">
          <priorityNumber value="1000" />
        </component>
      </submissionUnit>
    </subject>
  </controlActProcess>
</PORP_IN000001UV>
```

```

<contextOfUse classCode="DOC" moodCode="EVN">
  <id root="573f6e82-6ca1-485c-8a98-c28661400387" />
  <code code="ich_2.2" codeSystem="2.16.840.1.113883.3.989.2.2.1.1.6" />
  <statusCode code="active" />
  <derivedFrom typeCode="DRIV">
    <documentReference classCode="DOC" moodCode="EVN">
      <id root="3bd2276d-fa45-47c7-9360-fa833cffbb1f" />
    </documentReference>
  </derivedFrom>
</contextOfUse>
</component>
<componentOf1 typeCode="COMP">
  <sequenceNumber value="2" />
  <submission classCode="ACT" moodCode="EVN">
    <id>
      <item extension="9876543321" root="e41539f4-a61d-488f-a252-78a2a1e47a31" />
    </id>
    <code code="100006" codeSystem="2.16.840.1.113883.3.989.5.1.5.1.3.3" />
    <componentOf typeCode="COMP">
      <application classCode="ACT" moodCode="EVN">
        <id>
          <item extension="54321" root="0d535062-59e1-4ba9-b7fb-94a522be6420" />
        </id>
        <code nullFlavor="NA" />
      </application>
    </componentOf>
  </submission>
</componentOf1>
</submissionUnit>
</subject>
</controlActProcess>
</PORP_IN000001UV>

```

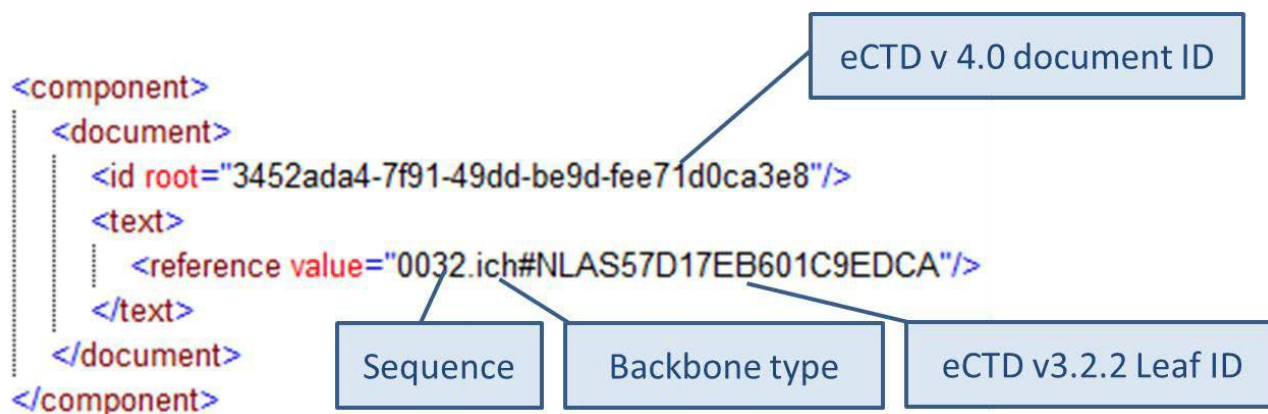
13 XML Message Validation Rules

For Validation Rules, please refer to the separate document available on Swissmedic's website. The principles of validation rules for eCTD v4.0 messages will not differ between regions. For details, please refer to the ICH Implementation Guide. Checks already mentioned in the ICH IG will not be repeated in the document. All code / codeSystem combinations are expected to be currently valid. If an error is detected, the Submission Unit needs to be resubmitted including the corrected item.

14 Compatibility With and Reference to Previous Versions of Module 1

Forward Compatibility is used for any dossier that has v3.2.2 content and the application is being converted to a v4.0 message.

The principles of forward compatibility will not differ between regions.



In case of the regional module, the backbone type will be changed into 'ch-regional' for the Swissmedic Module 1.

The ICH Implementation Guide describes a Forward Compatibility mechanism for conversion of a v3.2.2 application to a v4.0 message. This mechanism will enable both life cycle of active v3.2.2 content and the document re-use of v3.2.2 content, including applications that have not been converted to v4.0. Detail on Forward compatibility is provided in the ICH eCTD IG Section 8.