Working instructions
Swiss M1 Specification eCTD Version 1.5

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Swiss Module 1 Specification for eCTD

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Table of contents

1 List of Abbreviations 3

2 Introduction 3

3 Swiss Module 1: Regional Information 4

4 Swiss File Formats 4

5 General Conventions Using Module 1 5

5.1 Use of Electronic Signatures 5

5.2 Links 5

5.3 Handling of Empty or Missing eCTD Sections 5

6 General Architecture of Module 1 5

6.1 Envelope 6

6.2 m1-ch 7

6.3 Directory / File Structure 7

6.4 Node Extensions 7

6.5 File Naming Convention 7

6.6 Folder and Filename Path Length 8

7 Change Control 8

8 Appendices 9

1 List of Abbreviations

App.	Appendix
CD/DVD	Compact Disc/Digital Versatile Disc
CH	Switzerland
CL	Checklist
CTD	Common Technical Document
DMF	Drug Master File
DTD	Document Type Definition
eCTD	electronic Common Technical Document
EMA	European Medicines Agency
EU	European Union
FDA	Food and Drug Administration
FO	Form
GMO	Genetically Modified Organisms
GMP	Good Manufacturing Practice
ICH	International Conference on Harmonisation
INN	International Non-Proprietary Name
LoQ	List of Questions
N/A	Not applicable
OSS	Operational Support Services Division at Swissmedic
PDF	Portable Document Format
PSUR	Periodic Safety Update Report
SIMES	Solutions for the Implementation and Management of Electronic Submissions
SmPC	Summary of Product Characteristics
TPA	Federal Law on Medicinal Products and Medical Devices (Therapeutic Products Act)
TSE	Transmissible Spongiform Encephalopathy
XML	Extensible Markup Language

2 Introduction

This document specifies Module 1 for an eCTD submission in Switzerland. eCTD is a format for electronic-only submissions to the Swiss Agency for Therapeutic Products (Swissmedic).

The focus of the specification is to provide the ability to transfer the application electronically from industry to Swissmedic. Industry to industry, Swissmedic to other agencies, other agencies to Swissmedic and Swissmedic to industry transfer are not addressed in this document.

This document should be read together with the ICH eCTD Specification to prepare a valid eCTD submission in Switzerland. The latest version of the ICH eCTD Specification can be found at http://estri.ich.org/eCTD/index.htm

3 Swiss Module 1: Regional Information

The ICH Common Technical Document (CTD) specifies that Module 1 should contain region-specific administrative and product information depending on the type of application.

Appendix 1 gives a detailed overview of the structure of the Swiss Module 1. Depending on the type of application, the phase of the application and the type of product, not all elements need to be provided.
Appendix 2 includes the envelope and all application types.
Please refer to the documents *Swissmedic Guidance for Industry on Providing Regulatory Information in eCTD Format* (subsequent Swissmedic Guidance for Industry) and the directory *Overview of documents to be submitted* for further information. These documents are available on Swissmedic's website.
https://www.swissmedic.ch/swissmedic/en/home/services/submissions/ectd.html
https://www.swissmedic.ch/swissmedic/en/home/services/submissions/formale_anforderungen.html

4 Swiss File Formats

The file formats that can be included in Module 1 are given in Table 1. PDF, as defined by the ICH eCTD Specification, is the only format generally acceptable. Other formats may be accepted e.g. XML, image and archive, but are not recommended. If a submission containing these formats is planned, please liaise with Swissmedic before submission. Note that all PDF files included in an eCTD (irrespective of the module) should be v1.4, v1.5, v1.6 or PDF v1.7.

Table 1 Acceptable file formats for Module 1

Document	File Format	Remark
Cover letter	PDF	Scanned document with the original signature is mandatory. Note that this does not apply to portal submissions.
Administrative forms	PDF	Scanned documents with the original signature are mandatory. Note that this does not apply to portal submissions.
Product information text: Draft packaging material or mock-ups	PDF PDF	Include working documents as word file (.doc or .docx, please refer to the guidance document) in addition to the PDF for the product information, for ease of review.*
Other	PDF	PDF preferably generated from electronic source.

*For the correct naming of the files please refer to the Swissmedic Guidance for Industry.
In addition, the PDF files should follow the general ICH requirements of Modules 2 to 5 regarding size limitations, security settings/password protection etc. Files, folders or submissions must not be zipped.
Other file formats such as .doc or .docx may be required in addition to the PDF requirement of the eCTD.

These files should not be added as leaf elements (documents) within the eCTD structure. They should be provided in a separate folder called “<eCTD sequence>-workingdocuments” (e.g. 0000-workingdocuments) on the CD/DVD containing the eCTD or should be uploaded on the Swissmedic Portal. Please refer to the Swissmedic Guidance for Industry for guidance on the structure of this working documents folder.

5 General Conventions Using Module 1

5.1 Use of Electronic Signatures

Currently, the use of electronic signatures for electronic submissions is not supported and should therefore not be used. A document containing electronic signatures will be accepted, but the electronic signature will be ignored.
The Swissmedic Portal provides means of authentication which allow electronic submissions without electronic signature.

Please refer to the *Swissmedic Guidance for Industry* and the *MB Swissmedic eGov Portal – Standard functions* for further details.

5.2 Links

Links among objects in the eCTD submission should be relative. The intention is to make the eCTD submission self-contained.
Links among objects in Module 1 are allowed. Hyperlinks from Module 1 to other modules are allowed. Some documents require a specific way of linking and using links. For detailed requirements please refer to the *Swissmedic Guidance for Industry*, the *Verwaltungsverordnung Anleitung Anforderung an die Arzneimittelinformation von Humanarzneitmitteln* and the *WL Formal Requirements*.

5.3 Handling of Empty or Missing eCTD Sections

For new applications (including generic applications), detailed statements justifying the absence of data or specific CTD sections should be provided in the relevant Quality Overall Summary and/or Non-Clinical/Clinical Overviews (Module 2.3, 2.4, 2.5). Note that placeholder documents highlighting 'no relevant content' should not be placed in the eCTD structure, as these would create a document life cycle for non-existent documents, and lead to unnecessary complication and maintenance of the eCTD. If relevant, a justification for empty sections in Module 1 has to be provided in the cover letter.

6 General Architecture of Module 1

The Swiss Module 1 architecture is similar to that of Modules 2 to 5 of the eCTD, comprising a directory structure and a backbone with leaves. The backbone must be a valid XML document according to the Swiss Document Type Definition (DTD). The backbone (the ch-regional.xml file) contains metadata for the leaves, including pointers to the files in the directory structure. In addition, the Swiss DTD defines metadata at the submission level in the form of an envelope. The root element is *ch-backbone* and contains two elements: *ch-envelope* and *m1-ch*.

The CH DTD is modularised, i.e. the envelope and leaves are referenced from the main part of the DTD as external entities called respectively *ch-envelope.mod* and *ch-leaf.mod*. The CH *leaf* is identical to the leaf element described in the ICH eCTD DTD; reference is made to Table 6-8 of the ICH eCTD Specification. A full description of the CH DTD can be found in Appendix 5 of this specification.

Appendix 3 of this specification shows a screenshot of the eCTD structure displayed by an XML viewing tool. The leaves need to be equipped with information according to the requirements for a given type of application. The leaf titles should be short and meaningful.

Note that files can be referred to across modules i.e. content files in Modules 2 to 5 (in the index.xml) can be referred to from the ch-regional.xml (Module 1) and vice versa.

The eCTD contains more than documents and requires the applicant to deliver technical information such as the DTD, the MD5 checksum, additional metadata, and other information. The files that are required by Swissmedic in addition to the documents are as follows:

Top level folder:

- index.xml: eCTD backbone file, the table of content
- index-md5.txt the MD5 checksum file

Util folder:

- dtd folder File folder for document type definition files
- style folder File folder for style sheet

DTD folder:

- ch-envelope.mod
- ch-leaf.mod
- ch-regional.dtd Swissmedic regional DTD
- ich-ectd-3-2.dtd ICH DTD

Style folder:

- ch-regional.xsl Swiss regional style sheet file
- ectd-2-0.xsl ICH style sheet file

6.1 Envelope

The *ch-envelope* element is designed to be used for all types of applications for a given medicinal product and will mainly be used for the initial processing at the agency level. The envelope provides metadata at the submission level. A description of each envelope element is provided in Appendix 2 of this specification.

6.2 m1-ch

The *m1-ch* element of the Swiss DTD is based on the same conceptual approach as the common part of the ICH eCTD DTD. It provides an XML catalogue with metadata at the leaf level including pointers to the location of files in a directory structure. As for the ICH eCTD DTD, the *m1-ch* element maps to the directory structure.

6.3 Directory / File Structure

The Swiss Module 1 Specification provides a directory and highly recommended file structure (see Appendix 1).

6.4 Node Extensions

Node extensions are a way of providing extra organisational information to the eCTD.
The node extension should be visualised as an extra heading in the CTD structure.
The following rules apply to node extensions in Swiss eCTDs:

- Node extensions must not be used where ICH-specified sub-headings already exist (e.g. indication, manufacturer, drug substance, drug product are all-ICH specified node extensions).
- Node extensions must only be used at the lowest level of the eCTD structure (for example a node extension can be used at the level 5.3.5.1 but must not be used at the level 5.3).
- Node extensions should be used to group together documents made up of multiple leaf elements (e.g. a clinical study made up of separate files for the synopsis, main body and individual appendices) Please refer to the Swissmedic Guidance for Industry for further information.
- Node extensions must be maintained over the entire eCTD life cycle (e.g. a node extension is used in sequence 0000 to group files for a study report in module 5.3.5.1, then any files for this study report submitted in a later eCTD sequence must also be placed under this node extension. Any operations on files must be used in this specific node extension.)
- Node extensions may be nested as this is allowed by the eCTD DTD. However, as noted in bullet 2, the first node extension must be at the lowest level in the eCTD structure (e.g. in Module 5.3.7 a node extension may be added to group together files with the Study Identifier as Title attribute). Further node extensions may be added as children of the Study Identifier node, separating CRFs from individual patient listings.

6.5 File Naming Convention

Filenames have fixed and variable components. Components are separated by a hyphen. No hyphens or spaces should be used within each component.

Using fixed components is highly recommended. The variable component is optional and should be used as appropriate to further define these files. The variable component, if used, should be a meaningful concatenation of words without separation and should be kept as brief and descriptive as possible. File extensions in line with this specification should be applied as applicable.

The first component in a filename of a Swiss specific document should be the country code of Switzerland (ch). Documents which are not Swiss-specific do not need this country code to allow re-use of these files for other submissions in other countries without rework. The second component should be the document type code, as per Appendix 1, Table 3. A variable third element can be added if needed. In cases where differentiation is needed (for example between 1.5mg and 15mg), it is suggested that the word *point* is written in full i.e. *1point5mg*.

There are no recommendations for variable components in this specification. The format of the file is indicated by the file extension. Filenames should always be in lower case, in line with the ICH eCTD Specification. For more details see Appendix 1, Tables 1 and 4.

Examples:

ch-cover.pdf
ch-fofulldecl.pdf
nn-gmpcert.pdf
ch-responses-quality.pdf
ch-packaging-tablet10mg.pdf

6.6 Folder and Filename Path Length

The overall folder and filename path length starting from the sequence number should not exceed 180 characters for any file in any module. This is a CH regional requirement (similar to the EU specification), and it is acknowledged that this is less than the ICH agreed overall path length.

7 Change Control

The Swiss Module 1 Specification is likely to change with time. Factors that could affect the content of the specification include, but are not limited to:

- Change in the content of the Module 1 for the CTD, either through the amendment of information, at the same level of detail, or by provision of more detailed definition of content and structure
- Change to the regional requirements for applications that are outside the scope of the CTD
- Update of standards that are already in use within the eCTD
- Identification of new standards that provide additional value for the creation and/or usage of the eCTD
- Identification of new functional requirements
- Experience of use of the eCTD by all parties, in particular Module 1.

Please refer to the change control process outlined in the Q&A document.

8 Appendices

Appendix 1: Directory / File Structure for Module 1

The following table gives an overview on the contents of Module 1. The current practice has to be taken into account to define which documents are needed according to the application types, and the documents listed below should be provided where applicable. Please refer to the TPA, the related ordinances and the Swissmedic Guidance for Industry to identify which documents need to be included in the submission.

Filenames have fixed and variable components. Components are separated by a hyphen. No hyphens or spaces should be used within individual components.
The fixed components are defined in the table below. A filename is composed as follows: cc-fixedcomponent-variablecomponent.ext, where cc is used as a placeholder for the country code (see also Table 3). For each leaf described below node extensions are allowed.

Please note: In general, Swissmedic will now refer to the term *galenic form* as *pharmaceutical form*. For technical reasons the old term *galenic form* will still be used throughout this document and the technical files. There are no changes as to the handling of the term in the context of eCTD.

Product life cycles with more than one galenic form contain a common folder in Module 1. Table 1 provides guidance on whether specific documents can be shifted from the galenic form folder to the common folder while introducing a second galenic form. In this case the documents located in the galenic form folder should be deleted (operator is *delete*) and added in the common folder (operator is *new*). Furthermore, Table 1 provides guidance regarding the use of operators in life cycle management.

Table 1: Overview on the content of the Swiss Module 1 and their operations in follow-up submissions:

No	Title	Fixed Component of Filename	Possible shift to the folder *common* in M1 with 2nd galenic form	Life Cycle Operator on Document Level
1.0	Cover Letter	cover	-	New or Replace***
1.2	Application for Marketing Authorisation and Variation		-	
1.2.1	Form - Application	foapplvar	-	New
1.2.2	Forms - Additional		-	
1.2.2.1	Form Full Declaration	fofulldecl	-	Replace*
1.2.2.2	Form Manufacturer Information	fomanufacturer	-	Replace*
1.2.2.3	Form Status Marketing Authorisations Abroad	fostatusma	-	New or Replace**
1.2.2.4++			-	
1.2.2.5++			-	
1.2.2.6++			-	
1.2.2.7++			-	
1.2.2.8	Form Substances of Animal or Human Origin	foanimalhuman	-	Replace*
1.2.2.9++			-	
1.2.2.10++			-	
1.2.2.11++			-	
1.2.2.12++			-	
1.2.2.13	Form Change of Marketing Authorisation Holder	fochangemah	-	New
1.2.2.14++			-	
1.2.2.15++			-	
1.2.2.16	Form PSUR/PBRER for Human Medicines	fopsur	-	New
1.2.2.17	Form Declaration Radiopharmaceuticals	foradio	-	Replace*

No	Title	Fixed Component of Filename	Possible shift to the folder *common* in M1 with 2nd galenic form	Life Cycle Operator on Document Level
1.2.2.18	Form Confirmation Regarding Substances from GMO	fogmo	-	Replace *
1.2.2.19	Form DMF	fodmf	-	New
1.2.2.20	Form Information Relating to Applications under Art. 13 TPA	foart13	-	Replace*
1.2.2.21++			-	
1.2.2.22++			-	
1.2.2.23	Form Application for Recognition of Orphan Drug Status	forecogorphan	-	New
1.2.2.24++			-	
1.2.2.25	Form PIP	fopip	-	New
1.2.2.26	GCP Inspections	gcpinsp	X	Replace*
1.2.2.99	Other Forms [extensional sections allowed]	foother	-	
1.2.3	Annexes - Documents on Drug Quality		-	
1.2.3.1	DMF Letter of Access	dmfletter	X	Replace*
1.2.3.2	Ph. Eur. Certificate of Suitability for Active Substance	cosas	X	New or Replace**
1.2.3.3	Ph. Eur. Certificate of Suitability for TSE	costse	X	New or Replace**
1.2.3.4	EMA Certificate for Plasma Master File (PMF)	emacertpmf	X	New or Replace**
1.2.3.5	EMA Certificate for Vaccine Antigen Master File (VAMF)	emacertvamf	X	New or Replace**
1.2.4	Annexes – Manufacturing		-	
1.2.4.1	GMP Certificate or Other GMP Documents	gmpcert	X	New or Replace**
1.2.4.2	Documentation Concerning Manufacturing Authorisation	docmanuf	X	Replace*
1.2.4.3	Complete Manufacturing Information with Flow Chart	manufflowchart	-	Replace*
1.2.4.4	Confirmation on GMP Conformity	gmpconform	-	Replace*
1.2.5	Annexes – Others		-	

No	Title	Fixed Component of Filename	Possible shift to the folder *common* in M1 with 2nd galenic form	Life Cycle Operator on Document Level
1.2.5.1	Comparison of Approved Information for Professionals with EU SmPC (for PSURs)	smpcprofcompar	-	Replace*
1.2.5.2	Company Core Data Sheet (for PSURs)	ccds	X	Replace*
1.3	Product Information and Packaging Material		-	
1.3.1	Information for Professionals	prof	X	New or Replace*
1.3.2	Patient Information	patient	X	New or Replace**
1.3.3	Packaging Information	packaging	-	Replace*
1.3.4	Information for Professionals from Other Countries	profother	X	New or Replace**
1.4	Information About the Expert		-	
1.4.1	Quality	quality	X	New
1.4.2	Nonclinical	nonclinical	X	New
1.4.3	Clinical	clinical	X	New
1.5	Data of Bioavailability Studies (Known Active Substance without Innovation)		-	
1.5.1	Information according to Appendix IV of the Guideline on the Investigation on Bioequivalence +	bioequivalence	-	New
1.5.2	Documents on the Reference Product	bioreference	-	New
1.5.3++				
1.5.4	Art 14 Sec1 let abis TPA tabular compilation of deviations between product to be authorised in CH and foreign comparator	art14tabcompare	-	New
1.6	Environmental Risk Assessment		-	Replace*
1.6.1	Non-GMO	nongmo	X	Replace*
1.6.2	GMO	gmo	X	Replace*

No	Title	Fixed Component of Filename	Possible shift to the folder *common* in M1 with 2nd galenic form	Life Cycle Operator on Document Level
1.7	Decisions of Foreign Authorities		-	
1.7.1	Responses to LoQ	responses	-	New
1.7.2	Assessment Report	ar	-	New
1.7.3	EU Decision	eudecision	-	New
1.7.4	FDA Decision	fdadecision	-	New
1.7.5	Decisions of Other Foreign Authorities	decisionothers	-	New
1.7.6	Article 13 TPA Additional Documentation	art13adddoc	-	New or Replace**
1.8	Information Relating to Pharmacovigilance		-	
1.8.1	Pharmacovigilance System	phvigsystem	X	Replace*
1.8.2	Risk-Management System	riskmgtsystem	X	Replace*
1.9	Fast Track Status Decision	fasttrack	-	New
1.10	Information Relating to Paediatrics	paediatrics	-	Replace*
1.11	Orphan Drug Status Decision	orphandrug	X	New
1.12	Art 14 Sec 1 let abis-quater TPA Documents		-	
1.12.1	Proof of 10 Years EU/EFTA Authorisation	eueftaproof	-	New
1.12.2++			-	
1.12.3	Proof of 30 Years Overall Medical Use - 15 Years Medical Use EU/EFTA	meduseproof	-	New
1.12.4	Proof of 15 Years Cantonal Authorisation	cantauthproof	-	New
	Responses to Swissmedic LoQ	responses	-	New
	Additional Information	additionalinfo	-	New or Replace**

* The first time a document is integrated into the eCTD, the operator will always be *new*. Throughout the life cycle, the operator should be *replace*.

** If different documents are integrated in parallel into the eCTD for the first time, the operator for each of them will be *new*. Changes to one specific document throughout the life cycle require the operator *replace*.
+ CPMP/EWP/QWP/1401/98 Rev.1
++ This section is no longer applicable. The folder remains for life cycle maintenance.
*** The operator for the Cover Letter must be *new* whereas the operator for the Tracking Table should be *replace*.

The directory / file structure is defined in this appendix as a table containing the following information:

Table 2

Sequential number		Each item in the table has a unique sequentially assigned reference number. These reference numbers can change with each version of this appendix.
	Number	CTD section number
	Title	CTD title
	Element	Element name in the CH backbone
	File - Directory	File - Directory name from m1/ch – should be a relative path from ch/m1 e.g. 10-cover/ch-cover.pdf. This is consistent with ICH standards. The file extension corresponds to the file type; i.e. the *pdf* extension is only illustrative.
	Comment	Comments

Where the following conventions are used:

Table 3

Codes*	**Definition**
CC **	Country code
FIXED	Fixed component of the filename (see Table 1)
VAR *	Variable component of the filename
EXT	File extension, usually pdf
DDDD	An eCTD Sequence number made of 4 digits (e.g. 0000)
galenic-form common	Placeholder for either the dosage form-specific folder or the common folder

* The names of the actual files and directories used should be presented in lower case in accordance with the eCTD specification. The use of upper case for codes is for illustrative purposes only to show differentiation between the variable parts and the fixed part of the name.
The variable component, when used, should be a logical name and preceded by a hyphen. The variable component itself must not contain a hyphen or spaces itself, e.g. ch-foapplvar-tablets10mg.pdf.
When only one component is submitted in a directory, it is recommended that there is no variable component in the filename. E.g. when only the cover letter is submitted in the directory, the filename should be ch-cover.pdf.

** CC is used as a placeholder when a document is not Swiss-specific but is assigned to a specific country (for example ema-certpmf.pdf). For Swiss-specific documents CC is replaced by *ch* (for example ch-foapplvar-VAR.pdf). For documents not assigned to a specific country, CC is replaced by *common* (for example common-gmpcert.pdf, see Table 4). For other countries the destination code is an ISO-3166-1-alpha-2 code usually called *country code* or *CC* in this specification. Exceptions: If the *country* is EU, *ema* or *emea* as country code can be used. For United Kingdom, *uk* and for Greece, *el* can be used.

Table 4: Directory / File Structure for Swiss Module 1

Please note: In general, Swissmedic will now refer to the term *galenic form* as *pharmaceutical form*. For technical reasons the old term *galenic form* will still be used throughout this document and the technical files. There are no changes as to the handling of the term in the context of eCTD.

A separate folder structure should be created for each galenic form. The term *galenic-form* is used as a placeholder for the actual galenic form. It is highly recommended that the English terms as defined in the EU standard terms are used. Documents applicable for all galenic forms should be placed in a common folder instead of the galenic form folder. Please refer also to Table 1 in Appendix 1 and Appendix 2. For further information regarding Granularity and Life Cycle Management see Swissmedic Guidance for Industry, chapters 3 and 5.

1	Number	
	Title	
	Element	
	File	m1/ch/ch-regional.xml
	Comment	The Swiss Regional XML instance including the envelope information. Note that the operation attribute for the ch.regional.xml should always be set to ‘new’.

2	Number	
	Title	Module 1 CH
	Element	m1-ch
	Directory	m1/ch/
	Comment	Top level directory for the Swiss Module 1 as per ICH eCTD Specification
3	Number	
	Title	Galenic Form
	Element	m1-galenic-form
	Directory	m1/ch/*galenic-form*
	Comment	In general, Swissmedic will now refer to the term *galenic form* as ***pharmaceutical form***. For technical reasons the old term *galenic form* will still be used throughout this document and the technical files. There are no changes as to the handling of the term in the context of eCTD. The galenic form should be included in the file path e.g. tablet, capsule etc. The M1 directory structure should be provided with each galenic form. For example, tablets, with all relevant m1 sub-directories, followed by capsules, with all relevant sub-directories. Where files are shared between all galenic forms a 'common' directory should be created with all relevant sub-directories. The name of the galenic form should be provided according to EU standard terms (e.g. tablets, capsules). It is highly recommended that the denomination of the galenic form is identical in the envelope and for the files. A self-explanatory abbreviation can be used. Attributes and folder name need not to be similar.
4	Number	1.0
	Title	Cover Letter
	Element	m1-0-cover
	Directory	m1/ch/*galenic-form*/10-cover
	File	m1/ch/*galenic-form*/10-cover/ch-cover-*VAR.EXT*
	Comment	Filename for the Cover Letter composed of a fixed component *ch*, a fixed component *cover* and an optional variable component if required (e.g. ch-cover-variationrationale.pdf).
5	Number	1.2
	Title	Application for Marketing Authorisation and Variation
	Element	m1-2-applvar
	Directory	m1/ch/*galenic-form*/12-foapplvar
	Comment	
6	Number	1.2.1
	Title	Form - Application

	Element	m1-2-1-foapplvar
	Directory	m1/ch/*galenic-form*/12-foapplvar/121-foapplvar
	File	m1/ch/*galenic-form*/12-foapplvar/121-foapplvar/ch-foapplvar-*VAR.EXT*
	Comment	Filename for the Form Application for Authorisation / Variation Human Medicines composed of a fixed component *ch*, a fixed component *foapplvar* and an optional variable component if required (e.g. ch-foapplvar-newdosagestrength.pdf).
7	Number	1.2.2
	Title	Forms - Additional
	Element	m1-2-2-form-add
	Directory	m1/ch/*galenic-form*/12-foapplvar/122-form-add
	Comment	
8	Number	1.2.2.1
	Title	Form Full Declaration
	Element	m1-2-2-1-form-full-declaration
	Directory	m1/ch/*galenic-form*/12-foapplvar/122-form-add/1221-formfulldecl
	File	m1/ch/*galenic-form*/12-foapplvar/122-form-add/1221-formfulldecl/ch-fofulldecl-*VAR.EXT*
	Comment	Filename for the Form Full Declaration is composed of a fixed component *ch*, a fixed component *fofulldecl* and an optional variable component to be used if required (e.g. ch-fofulldecl.pdf).
9	Number	1.2.2.2
	Title	Form Manufacturer Information
	Element	m1-2-2-2-form-manufacturer-information
	Directory	m1/ch/*galenic-form*/12-foapplvar/122-form-add/1222-formmanufacturerinfo
	File	m1/ch/*galenic-form*/12-foapplvar/122-form-add/1222-formmanufacturerinfo/ch-fomanufacturer-*VAR.EXT*
	Comment	Filename for the Form Manufacturer Information is composed of a fixed component *ch*, a fixed component *fomanufacturer* and an optional variable component to be used if required.
10	Number	1.2.2.3
	Title	Form Status Marketing Authorisations Abroad
	Element	m1-2-2-3-form-status-marketing-authorisations-abroad
	Directory	m1/ch/*galenic-form*/12-foapplvar/122-form-add/1223-formstatusmaabroad/
	File	m1/ch/*galenic-form*/12-foapplvar/122-form-add/1223-formstatusmaabroad/ch-fostatusma-*VAR.EXT*

	Comment	Filename is composed of a fixed component *ch*, a fixed component *fostatusma* and an optional variable component to be used if required.
11	Number	1.2.2.4
	Title	Form Variation Requiring Notification
	Element	
	Directory	
	File	
	Comment	This section is no longer applicable. The folder remains for life cycle maintenance.
12	Number	1.2.2.5
	Title	Form Quality Variation Requiring Approval
	Element	
	Directory	
	File	
	Comment	This section is no longer applicable. The folder remains for life cycle maintenance.
13	Number	1.2.2.6
	Title	Form Application for Extension of Authorisation
	Element	
	Directory	
	File	
	Comment	This section is no longer applicable. The folder remains for life cycle maintenance.
14	Number	1.2.2.7
	Title	Form Human Blood Components
	Element	
	Directory	
	File	
	Comment	This section is no longer applicable. The folder remains for life cycle maintenance.
15	Number	1.2.2.8
	Title	Form Substances of Animal or Human Origin
	Element	m1-2-2-8-form-substances-of-animal-or-human-origin

	Directory	m1/ch/*galenic-form*/12-foapplvar/122-form-add/1228-formsubstancesanimalorhuman
	File	m1/ch/*galenic-form*/12-foapplvar/122-form-add/1228-formsubstancesanimalorhuman/ch-foanimalhuman-*VAR.EXT*
	Comment	Filename is composed of a fixed component *ch*, a fixed component *foanimalhuman* and an optional variable component to be used if required.
16	Number	1.2.2.9
	Title	Form Pharmaceutical Information for Parenteral Preparations
	Element	
	Directory	
	File	
	Comment	This section is no longer applicable. The folder remains for life cycle maintenance.
17	Number	1.2.2.10
	Title	Form Co-Marketing Confirmation
	Element	
	Directory	
	File	
	Comment	This section is no longer applicable. The folder remains for life cycle maintenance.
18	Number	1.2.2.11
	Title	Form Import According to Paragraph 14 Section 2 TPA
	Element	
	Directory	
	File	
	Comment	This section is no longer applicable. The folder remains for life cycle maintenance.
19	Number	1.2.2.12
	Title	Form Safety Changes to Product Information
	Element	
	Directory	
	File	
	Comment	This section is no longer applicable. The folder remains for life cycle maintenance.
20	Number	1.2.2.13

	Title	Form Change of Marketing Authorisation Holder
	Element	m1-2-2-13-form-change-of-marketing-authorisation-holder
	Directory	m1/ch/*galenic-form*/12-foapplvar/122-form-add/12213-formchangeofmaholder
	File	m1/ch/*galenic-form*/12-foapplvar/122-form-add/12213-formchangeofmaholder/ch-fochangemah-*VAR.EXT*
	Comment	Filename is composed of a fixed component *ch*, a fixed component *fochangemah* and an optional variable component to be used if required.
21	Number	1.2.2.14
	Title	Checklist Formal Control Application Authorisation Human Medicines
	Element	
	Directory	
	File	
	Comment	This section is no longer applicable. The folder remains for life cycle maintenance.
22	Number	1.2.2.15
	Title	Checklist Formal Control Application Authorisation Human Medicines Art.13, TPA
	Element	
	Directory	
	File	
	Comment	This section is no longer applicable. The folder remains for life cycle maintenance.
23	Number	1.2.2.16
	Title	Form PSUR/PBRER for Human Medicines
	Element	m1-2-2-16-form-psur-for-human-medicines
	Directory	m1/ch/*galenic-form*/12-foapplvar/122-form-add/12216-formpsurhumanmedicines
	File	m1/ch/*galenic-form*/12-foapplvar/122-form-add/12216-formpsurhumanmedicines/ch-fopsur-*VAR.EXT*
	Comment	Filename is composed of a fixed component *ch*, a fixed component *fopsur* and an optional variable component to be used if required.
24	Number	1.2.2.17
	Title	Form Declaration Radiopharmaceuticals
	Element	m1-2-2-17-form-declaration-radiopharmaceuticals
	Directory	m1/ch/*galenic-form*/12-foapplvar/122-form-add/12217-formdeclarationradio
	File	m1/ch/*galenic-form*/12-foapplvar/122-form-add/12217-formdeclarationradio/ch-foradio-*VAR.EXT*

	Comment	Filename is composed of a fixed component *ch*, a fixed component *foradio* and an optional variable component to be used if required.
25	Number	1.2.2.18
	Title	Form Confirmation Regarding Substances from GMO
	Element	m1-2-2-18-form-confirmation-substances-from-gmo
	Directory	m1/ch/*galenic-form*/12-foapplvar/122-form-add/12218-formconfirmationsubstancesgmo
	File	m1/ch/*galenic-form*/12-foapplvar/122-form-add/12218-formconfirmationsubstancesgmo/ch-fogmo-*VAR.EXT*
	Comment	Filename is composed of a fixed component *ch*, a fixed component *fogmo* and an optional variable component to be used if required.
26	Number	1.2.2.19
	Title	Form DMF
	Element	m1-2-2-19-form-dmf
	Directory	m1/ch/*galenic-form*/12-foapplvar/122-form-add/12219-formdmf
	File	m1/ch/*galenic-form*/12-foapplvar/122-form-add/12219-formdmf/ch-fodmf-*VAR.EXT*
	Comment	Filename is composed of a fixed component *ch*, a fixed component *fodmf* and an optional variable component to be used if required.
27	Number	1.2.2.20
	Title	Form Information Relating to Applications under Art. 13 TPA
	Element	m1-2-2-20-form-information-applications-art-13-tpa
	Directory	m1/ch/*galenic-form*/12-foapplvar/122-form-add/12220-forminfoapplicationsart13tpa
	File	m1/ch/*galenic-form*/12-foapplvar/122-form-add/12220-forminfoapplicationsart13tpa/ch-foart13-VAR.EXT
	Comment	Filename is composed of a fixed component *ch*, a fixed component *foart13* and an optional variable component to be used if required.
28	Number	1.2.2.21
	Title	Form Notification Sample Packages
	Element	
	Directory	
	File	
	Comment	This section is no longer applicable. The folder remains for life cycle maintenance.
29	Number	1.2.2.22
	Title	Form Notification of No Marketing or Interruption to Distribution
	Element	

	Directory	
	File	
	Comment	This section is no longer applicable. The folder remains for life cycle maintenance.
30	Number	1.2.2.23
	Title	Form Application for Recognition of Orphan Drug Status
	Element	m1-2-2-23-form-application-for-recognition-of-orphan-drug-status
	Directory	m1/ch/*galenic-form*/12-foapplvar/122-form-add/12223-formapplicationrecogorphan
	File	m1/ch/*galenic-form*/12-foapplvar/122-form-add/12223-formapplicationrecogorphan/ch-forecogorphan-*VAR.EXT*
	Comment	Filename is composed of a fixed component *ch*, a fixed component *forecogorphan* and an optional variable component to be used if required.
31	Number	1.2.2.24
	Title	Application for Recognition of Fast Track Status
	Element	
	Directory	
	File	
	Comment	This section is no longer applicable. The folder remains for life cycle maintenance.
32	Number	1.2.2.25
	Title	Form PIP
	Element	m1-2-2-25-form-pip
	Directory	m1/ch/*galenic-form*/12-foapplvar/122-form-add/12225-formpip
	File	m1/ch/*galenic-form*/12-foapplvar/122-form-add/12225-formpip/ch-fopip-*VAR.EXT*
	Comment	Filename is composed of a fixed component *ch*, a fixed component *fopip* and an optional variable component to be used if required.
33	Number	1.2.2.26
	Title	GCP Inspections
	Element	m1-2-2-26-gcpinspections
	Directory	m1/ch/*galenic-form*/12-foapplvar/122-form-add/12226-gcpinspections
	File	m1/ch/*galenic-form*/12-foapplvar/122-form-add/12226-gcpinspections/ch-gcpinsp-*VAR.EXT*
	Comment	Filename is composed of a fixed component *ch*, a fixed component *gcpinsp* and an optional variable component to be used if required.
34	Number	1.2.2.99

	Title	Other Forms
	Element	m1-2-2-99-other-forms
	Directory	m1/ch/*galenic-form*/12-foapplvar/122-form-add/12299-otherforms
	File	m1/ch/*galenic-form*/12-foapplvar/122-form-add/12299-otherforms/ch-foother-*VAR.EXT*
	Comment	Filename is composed of a fixed component *ch*, a fixed component *foother* and an optional variable component to be used if required.
35	Number	1.2.3
	Title	Annexes - Documents on Drug Quality
	Element	m1-2-3-quality
	Directory	m1/ch/*galenic-form*/12-foapplvar/123-quality
	Comment	
36	Number	1.2.3.1
	Title	DMF Letter of Access
	Element	m1-2-3-1-dmf-letter-of-access
	Directory	m1/ch/*galenic-form*/12-foapplvar/123-quality/1231-dmfletterofaccess
	File	m1/ch/*galenic-form*/12-foapplvar/123-quality/1231-dmfletterofaccess/ch-dmfletter-*VAR.EXT*
	Comment	Filename is composed of a fixed component *ch*, a fixed component *dmfletter* and an optional variable component to be used if required.
37	Number	1.2.3.2
	Title	Ph. Eur. Certificate of Suitability for Active Substance
	Element	m1-2-3-2-certificate-of-suitability-for-active-substance
	Directory	m1/ch/*galenic-form*/12-foapplvar/123-quality/1232-certificatesuitabilityactivesubstance
	File	m1/ch/*galenic-form*/12-foapplvar/123-quality/1232-certificatesuitabilityactivesubstance/cosas-*VAR.EXT*
	Comment	No country code needed
38	Number	1.2.3.3
	Title	Ph. Eur. Certificate of Suitability for TSE
	Element	m1-2-3-3-certificate-of-suitability-for-tse
	Directory	m1/ch/*galenic-form*/12-foapplvar/123-quality/1233-certificateofsuitabilityfortse
	File	m1/ch/*galenic-form*/12-foapplvar/123-quality/1233-certificateofsuitabilityfortse/costse-*VAR.EXT*
	Comment	No country code needed

39	Number	1.2.3.4
	Title	EMA Certificate for Plasma Master File (PMF)
	Element	m1-2-3-4-ema-certificate-for-plasma-master-file-pmf
	Directory	m1/ch/*galenic-form*/12-foapplvar/123-quality/1234-emacertificatepmf
	File	m1/ch/*galenic-form*/12-foapplvar/123-quality/1234-emacertificatepmf/emacertpmf-*VAR.EXT*
	Comment	Filename is composed of a fixed component *emacertpmf* and an optional variable component to be used if required.
40	Number	1.2.3.5
	Title	EMA Certificate for Vaccine Antigen Master File (VAMF)
	Element	m1-2-3-5-ema-certificate-for-vaccine-antigen-master-file-vamf
	Directory	m1/ch/*galenic-form*/12-foapplvar/123-quality/1235-emacertificatevamf
	File	m1/ch/*galenic-form*/12-foapplvar/123-quality/1235-emacertificatevamf/emacertvamf-*VAR.EXT*
	Comment	Filename is composed of a fixed component *emacertvamf* and an optional variable component to be used if required.
41	Number	1.2.4
	Title	Annexes - Manufacturing
	Element	m1-2-4-manufacturing
	Directory	m1/ch/*galenic-form*/12-foapplvar/124-manufacturing
	Comment	
42	Number	1.2.4.1
	Title	GMP Certificate or Other GMP Documents
	Element	m1-2-4-1-gmp-certificate-or-other-gmp-documents
	Directory	m1/ch/*galenic-form*/12-foapplvar/124-manufacturing/1241-gmpcertificateorothergmpdoc
	File	m1/ch/*galenic-form*/12-foapplvar/124-manufacturing/1241-gmpcertificateorothergmpdoc/*CC*-gmpcert-*VAR.EXT*
	Comment	Country code according to Appendix 1 Table 3
43	Number	1.2.4.2
	Title	Documentation Concerning Manufacturing Authorisation
	Element	m1-2-4-2-manufacturing-authorisation
	Directory	m1/ch/*galenic-form*/12-foapplvar/124-manufacturing/1242-manufacturingauthorisation
	File	m1/ch/*galenic-form*/12-foapplvar/124-manufacturing/1242-manufacturingauthorisation/*CC*-docmanuf-*VAR.EXT*

	Comment	Country code according to Appendix 1 Table 3
44	Number	1.2.4.3
	Title	Complete Manufacturing Information with Flow Chart
	Element	m1-2-4-3-complete-manufacturing-information-with-flow-chart
	Directory	m1/ch/*galenic-form*/12-foapplvar/124-manufacturing/1243-completemanufacturinginfoflowchart
	File	m1/ch/*galenic-form*/12-foapplvar/124-manufacturing/1243-completemanufacturinginfoflowchart/manufflowchart-*VAR.EXT*
	Comment	No country code needed
45	Number	1.2.4.4
	Title	Confirmation on GMP Conformity
	Element	m1-2-4-4-confirmation-on-gmp-conformity
	Directory	m1/ch/*galenic-form*/12-foapplvar/124-manufacturing/1244-confirmationongmpconform
	File	m1/ch/*galenic-form*/12-foapplvar/124-manufacturing/1244-confirmationongmpconform/gmpconform-*VAR.EXT*
	Comment	No country code needed
46	Number	1.2.5
	Title	Annexes - Others
	Element	m1-2-5-others
	Directory	m1/ch/*galenic-form*/12-foapplvar/125-others
	Comment	
47	Number	1.2.5.1
	Title	Comparison of Approved Information for Professionals with EU SmPC (for PSURs)
	Element	m1-2-5-1-comparison-of-approved-product-information
	Directory	m1/ch/*galenic-form*/12-foapplvar/125-others/1251-comparisonapprovedproductinfo
	File	m1/ch/*galenic-form*/12-foapplvar/125-others/1251-comparisonapprovedproductinfo/ch-smpcprofcompar-*VAR.EXT*
	Comment	Filename is composed of a fixed component *ch*, a fixed component *smpcprofcompar* and an optional variable component to be used if required.
48	Number	1.2.5.2
	Title	Company Core Data Sheet (for PSURs)
	Element	m1-2-5-2-company-core-data-sheet
	Directory	m1/ch/*galenic-form*/12-foapplvar/125-others/1252-companycoredatasheet

	File	m1/ch/*galenic-form*/12-foapplvar/125-others/1252-companycoredatasheet/ccds-*VAR.EXT*
	Comment	No country code needed
49	Number	1.3
	Title	Product Information and Packaging Material
	Element	m1-3-pi
	Directory	m1/ch/*galenic-form*/13-pipackaging
	Comment	General placeholder for Product Information and Packaging Material
50	Number	1.3.1
	Title	Information for Professionals
	Element	m1-3-1-professionals
	Directory	m1/ch/*galenic-form*/13-pipackaging/131-prof
	File	m1/ch/*galenic-form*/13-pipackaging/131-prof/ch-prof-*VAR.EXT*
	Comment	Filename for the Information for Professionals document composed of a fixed component *ch*, a fixed component *prof* and an optional variable component to be used if required (e.g. ch-prof-tablet10mg.pdf).
51	Number	1.3.2
	Title	Patient Information
	Element	m1-3-2-patient
	Directory	m1/ch/*galenic-form*/13-pipackaging/132-patient
	File	m1/ch/*galenic-form*/13-pipackaging/132-patient/ch-patient-*VAR.EXT*
	Comment	Filename for the patient information document composed of a fixed component *ch*, a fixed component *patient* and an optional variable component to be used if required (e.g. ch-patient-tablets.pdf).
52	Number	1.3.3
	Title	Packaging Information
	Element	m1-3-3-packaging
	Directory	m1/ch/*galenic-form*/13-pipackaging/133-packaging
	File	m1/ch/*galenic-form*/13-pipackaging/133-packaging/ch-packaging-*VAR.EXT*
	Comment	Filename for the list of folding boxes (mock-ups or draft) provided with the submission composed of a fixed component *ch*, a fixed component *packaging* and an optional variable component to be used if required (e.g. ch-packaging-tabletsdraft.pdf or ch-packaging-tabletsmockup.pdf).
53	Number	1.3.4

	Title	Information for Professionals from Other Countries
	Element	m1-3-4-professionals-other-countries
	Directory	m1/ch/*galenic-form*/13-pipackaging/134-profother
	File	m1/ch/*galenic-form*/13-pipackaging/134-profother/*CC*-profother-*VAR.EXT*
	Comment	Filename for the blisters and other information, composed of a fixed component *CC* (see Appendix 1 Table 3), a fixed component *profother* and an optional variable component to be used if required (e.g. ema-profother-producttablets10mg.pdf).
54	Number	1.4
	Title	Information about the Expert
	Element	m1-4-expert
	Directory	m1/ch/*galenic-form*/14-expert
	Comment	General placeholder for Expert Information.
55	Number	1.4.1
	Title	Quality
	Element	m1-4-1-quality
	Directory	m1/ch/*galenic-form*/14-expert/141-quality
	File	m1/ch/*galenic-form*/14-expert/141-quality/quality-*VAR.EXT*
	Comment	No country code needed.
56	Number	1.4.2
	Title	Nonclinical
	Element	m1-4-2-non-clinical
	Directory	m1/ch/*galenic-form*/14-expert/142-nonclinical
	File	m1/ch/*galenic-form*/14-expert/142-nonclinical/nonclinical-*VAR.EXT*
	Comment	No country code needed.
57	Number	1.4.3
	Title	Clinical
	Element	m1-4-3-clinical
	Directory	m1/ch/*galenic-form*/14-expert/143-clinical
	File	m1/ch/*galenic-form*/14-expert/143-clinical/clinical-*VAR.EXT*

	Comment	No country code needed.
58	Number	1.5
	Title	Data of Bioavailability Studies (Known Active Substance without Innovation)
	Element	m1-5-bioavailability
	Directory	m1/ch/*galenic-form*/15-bioavailability
	Comment	
59	Number	1.5.1
	Title	Information according to Appendix IV of the Guideline on the Investigation on Bioequivalence
	Element	m1-5-1-info-accord-app-iv-guideline-bioequivalence
	Directory	m1/ch/*galenic-form*/15-bioavailability/151-infoaccordappivguidelinebioequivalence
	File	m1/ch/*galenic-form*/15-bioavailability/151-infoaccordappivguidelinebioequivalence/ch-bioequivalence-*VAR.EXT*
	Comment	Filename is composed of a fixed component *ch*, a fixed component *bioequivalence* and an optional variable component to be used if required.
60	Number	1.5.2
	Title	Documents on the Reference Product
	Element	m1-5-2-reference-product
	Directory	m1/ch/*galenic-form*/15-bioavailability/152-bioreference
	File	m1/ch/*galenic-form*/15-bioavailability/152-bioreference/ch-bioreference-*VAR.EXT*
	Comment	Filename is composed of a fixed component *ch*, a fixed component *bioreference* and an optional variable component to be used if required.
61	Number	1.5.3
	Title	Confirmation of Identity of Submitted Product and Reference Product Used in the Bioequivalence Studies
	Element	
	Directory	
	File	
	Comment	This section is no longer applicable. The folder remains for life cycle maintenance.
62	Number	1.5.4
	Title	Art 14 Sec1 let abis TPA tabular compilation of deviations between product to be authorised in CH and foreign comparator
	Element	m1-5-4-art14-tab-compare
	Directory	m1/ch/*galenic-form*/15-bioavailability/154-art14tabcomp/

	File	m1/ch/*galenic-form*/15-bioavailability/154-art14tabcomp/art14tabcompare-*VAR.EXT*
	Comment	
63	Number	1.6
	Title	Environmental Risk Assessment
	Element	m1-6-environrisk
	Directory	m1/ch/*galenic-form*/16-environrisk
	Comment	General placeholder for Environmental Risk Assessment.
64	Number	1.6.1
	Title	Non-GMO
	Element	m1-6-1-nongmo
	Directory	m1/ch/*galenic-form*/16-environrisk/161-nongmo
	File	m1/ch/*galenic-form*/16-environrisk/161-nongmo/nongmo-*VAR.EXT*
	Comment	No country code needed.
65	Number	1.6.2
	Title	GMO
	Element	m1-6-2-gmo
	Directory	m1/ch/*galenic-form*/16-environrisk/162-gmo
	File	m1/ch/*galenic-form*/16-environrisk/162-gmo/gmo-*VAR.EXT*
	Comment	No country code needed.
66	Number	1.7
	Title	Decisions of Foreign Authorities
	Element	m1-7-decisions-authorities
	Directory	m1/ch/*galenic-form*/17-decisionsauthorities
	Comment	General placeholder for information on decisions from other Health Authorities.
67	Number	1.7.1
	Title	Responses to LoQ
	Element	m1-7-1-responses
	Directory	m1/ch/*galenic-form*/17-decisionsauthorities/171-responses

	File	m1/ch/*galenic-form*/17-decisionsauthorities/171-responses/*CC*-responses-*VAR*.pdf
	Comment	Filename for the Responses composed of a fixed component *CC* (according to Appendix 1 Table 3), a fixed component *responses* and an optional variable component to be used if required (e.g. ema-responses-quality.pdf).
68	Number	1.7.2
	Title	Assessment Report
	Element	m1-7-2-assessment
	Directory	m1/ch/*galenic-form*/17-decisionsauthorities/172-ar
	File	m1/ch/*galenic-form*/17-decisionsauthorities/172-ar/*CC*-ar-*VAR*.pdf
	Comment	Country code according to Appendix 1 Table 3
69	Number	1.7.3
	Title	EU Decision
	Element	m1-7-3-eu-decisions
	Directory	m1/ch/*galenic-form*/17-decisionsauthorities/173-eudecision
	File	m1/ch/*galenic-form*/17-decisionsauthorities/173-eudecision/*CC*-eudecision-*VAR*.pdf
	Comment	Country code according to Appendix 1 Table 3
70	Number	1.7.4
	Title	FDA Decision
	Element	m1-7-4-fda-decision
	Directory	m1/ch/*galenic-form*/17-decisionsauthorities/174-fdadecision
	File	m1/ch/*galenic-form*/17-decisionsauthorities/174-fdadecision/fdadecision-*VAR*.pdf
	Comment	No country code needed.
71	Number	1.7.5
	Title	Decisions of Other Foreign Authorities
	Element	m1-7-5-foreign-decisions
	Directory	m1/ch/*galenic-form*/17-decisionsauthorities/175-decisionothers
	File	m1/ch/*galenic-form*/17-decisionsauthorities/175-decisionothers/*CC*-decisionothers-*VAR*.pdf
	Comment	Country code according to Appendix 1 Table 3
72	Number	1.7.6

	Title	Article 13 TPA Additional Documentation
	Element	m1-7-6-article13adddoc
	Directory	m1/ch/*galenic-form*/17-decisionsauthorities/176-article13adddoc
	File	m1/ch/*galenic-form*/17-decisionsauthorities/176-article13adddoc/*CC*-art13adddoc-*VAR*.pdf
	Comment	Country code according to Appendix 1 Table 3
73	Number	1.8
	Title	Information Relating to Pharmacovigilance
	Element	m1-8-pharmacovigilance
	Directory	m1/ch/*galenic-form*/18-phvig
	Comment	General placeholder for information on pharmacovigilance.
74	Number	1.8.1
	Title	Pharmacovigilance System
	Element	m1-8-1-pharmacovigilance-system
	Directory	m1/ch/*galenic-form*/18-phvig/181-phvigsystem
	File	m1/ch/*galenic-form*/18-phvig/181-phvigsystem/phvigsystem-*VAR.EXT*
	Comment	No country code needed.
75	Number	1.8.2
	Title	Risk-Management System
	Element	m1-8-2-risk-management-system
	Directory	m1/ch/*galenic-form*/18-phvig/182-riskmgtsystem
	File	m1/ch/*galenic-form*/18-phvig/182-riskmgtsystem/riskmgtsystem-*VAR.EXT*
	Comment	No country code needed.
76	Number	1.9
	Title	Fast Track Status Decision
	Element	m1-9-fast-track-decision
	Directory	m1/ch/*galenic-form*/19-fasttrack
	Comment	General placeholder for information on Fast Track Status Decision.
77	Number	1.9

	Title	Fast Track Status Decision
	Element	m1-9-fast-track-decision
	File	m1/ch/*galenic-form*/19-fasttrack/ch-fasttrack-*VAR.EXT*
	Comment	Filename for the Fast Track Status Decision composed of a fixed component *ch*, a fixed component *fasttrack* and an optional variable component if required (e.g. ch-fasttrack-renalcancer.pdf).
78	Number	1.10
	Title	Information Relating to Paediatrics
	Element	m1-10-paediatrics
	Directory	m1/ch/*galenic-form*/110-paediatrics
	Comment	General placeholder for information on paediatrics.
79	Number	1.10
	Title	Information Relating to Paediatrics
	Element	m1-10-paediatrics
	File	m1/ch/*galenic-form*/110-paediatrics/paediatrics-*VAR.EXT*
	Comment	No country code needed.
80	Number	1.11
	Title	Orphan Drug Status Decision
	Element	m1-11-orphandrug
	Directory	m1/ch/*galenic-form*/111-orphandrug
	Comment	General placeholder for information on Orphan Drug Status Decision.
81	Number	1.11
	Title	Orphan Drug Status Decision
	Element	m1-11-orphandrug
	File	m1/ch/*galenic-form*/111-orphandrug/*ch*-orphandrug-*VAR.EXT*
	Comment	Filename for the Orphan Drug Status Decision composed of a fixed component *ch*, a fixed component *orphandrug* and an optional variable component if required (e.g. ch-orphandrug-indication.pdf).
82	Number	1.12
	Title	Art 14 Sec 1 let abis-quater TPA Documents

	Element	m1-12-art14sec1letabisquater
	Directory	m1/ch/*galenic-form*/112-art14
	Comment	General placeholder for information on Art 14 Sec 1 let abis-quater TPA Documents
83	Number	1.12.1
	Title	Proof of 10 Years EU/EFTA Authorisation
	Element	m1-12-1-eueftaauthorisation
	Directory	m1/ch/*galenic-form*/112-art14/1121-eueftaauthorisation
	File	m1/ch/*galenic-form*/112-art14/1121-eueftaauthorisation/*ch*-eueftaproof-*VAR.EXT*
	Comment	Filename for the 10 years EU EFTA authorisation composed of a fixed component *ch*, a fixed component *eueftaproof* and an optional variable component if required (e.g. ch-eueftaproof-productname.pdf).
84	Number	1.12.2
	Title	10 Years EU/EFTA Authorisation – Documents on the Reference Product
	Element	
	Directory	
	File	
	Comment	This section is no longer applicable. The folder remains for life cycle maintenance.
85	Number	1.12.3
	Title	Proof of 30 Years Overall Medical Use – 15 Years Medical Use EU/EFTA
	Element	m1-12-3-overallmedicaluse
	Directory	m1/ch/*galenic-form*/112-art14/1123-overallmedicaluse
	File	m1/ch/*galenic-form*/112-art14/1123-overallmedicaluse/*ch*-meduseproof-*VAR.EXT*
	Comment	Filename for 30 years overall medical use - 15 years medical use EU/EFTA composed of a fixed component *ch*, a fixed component *meduseproof* and an optional variable component if required (e.g. ch-meduseproof-productname.pdf).
86	Number	1.12.4
	Title	Proof of 15 Years Cantonal Authorisation
	Element	m1-12-4-cantonalauthorisation
	Directory	m1/ch/*galenic-form*/112-art14/1124-cantonalauthorisation
	File	m1/ch/*galenic-form*/112-art14/1124-cantonalauthorisation/*ch*-cantauthproof-*VAR.EXT*

	Comment	Filename for 15 years cantonal authorisation composed of a fixed component *ch*, a fixed component *cantauthproof* and an optional variable component if required (e.g. ch-cantauthproof-productname.pdf).
87	Number	
	Title	Responses to Swissmedic LoQ
	Element	m1-swiss-responses
	Directory	m1/ch/*galenic-form*/responses
	Comment	No number is assigned to this element.
88	Number	
	Title	Responses to Swissmedic LoQ
	Element	m1-swiss-responses
	File	m1/ch/*galenic-form*/responses/ch-responses-*VAR.EXT*
	Comment	Filename for additional information requested composed by a fixed component *ch*, a fixed component *responses* and an optional variable component to be used if needed (e.g. ch-responses-quality.pdf).
89	Number	
	Title	Additional Information
	Element	m1-additional-info
	Directory	m1/ch/*galenic-form*/additionalinfo
	Comment	No number is assigned to this element.
90	Number	
	Title	Additional Information
	Element	m1-additional-info
	Directory	
	File	m1/ch/*galenic-form*/additionalinfo/*CC*-additionalinfo-*VAR.EXT*
	Comment	Country code according to Appendix 1 Table 3

Appendix 2: Envelope Element Description

The *ch-envelope* element is the root element that defines metadata of the submission. All envelope elements are mandatory.

element	attribute	Description/instruction	example	occurence
ch envelope		Root element that provides metadata of the submission		unique
envelope	country	Parent element for the submission metadata. This element must be *ch* (case sensitive).	ch	unique
application number (*Gesuchs-ID*)		Number assigned to the application by Swissmedic, not known before initial submission, Must be included for all subsequent submissions. It is 9 digits w/o leading zeros. Element can be repeated for multiple application numbers that apply. Use *pending* (case sensitive) if not known	102501123	repeatable
submission description		This element is used to link the application to the application number (in case of more than one application per eCTD Sequence).	The manufacturing of the finished product has been transferred from A to B. As a consequence, some minor changes in the manufacturing process occur.	unique
invented name		The name of the medicinal product. Put in even if not yet definitive, use *pending* (case sensitive) only as a last choice.	wonderpill	repeatable
galenic form	name	Dosage form in English (EU standard terms strongly recommended) – lower case letters preferred	capsules	one per galenic form
galenic form	swissmedic number (Marketing Authorisation number)	The number assigned to the product identifying the product and its galenic form. Use *pending* (case sensitive) if not known.	41962	one per galenic form
galenic form	galenic name	German, French or Italian term of the dosage form (EU standard terms strongly recommended) Please refer to App. 1, Table 4, element No. 3.	Kapseln or capsules or capsule	one per galenic form
galenic name	language	Language of galenic name. Possible values are *de*, *fr*, *it*.	de	one per galenic name

element	attribute	Description/instruction	example	occurence
dmf number		The number assigned to the DMF (alphanumeric). Use *pending* (case sensitive) if the assigned DMF number is not known. Use *n/a* (case sensitive) if the submission is not a DMF.	D3459	unique
pmf number		The number assigned to the PMF. Use *pending* (case sensitive) if the assigned PMF number is not known. Use *n/a* (case sensitive) if the submission is not a PMF.	n/a	unique
inn		International Non-proprietary Name, used to identify pharmaceutical substances or active pharmaceutical ingredients. Each INN is a unique name that is globally recognized and is public property. Use *pending* (case sensitive) if not yet approved.	wonderdrug	repeatable
applicant		The name of the company submitting the eCTD. Use *n/a* (case sensitive) if the submission is a DMF or PMF.	Pharma SA	unique
dmf holder		The name of the company submitting the DMF. Use *n/a* (case sensitive) if the submission is not a DMF.	Farma SA	unique
pmf holder		The name of the company submitting the PMF. Use *n/a* (case sensitive) if the submission is not a PMF.	Farmos SA	unique
agency		Identification of the receiving agency: *Swissmedic* (case sensitive)	Swissmedic	unique
application	type	The type of procedure for the submission. The following are the valid values (bold text indicates the allowed values, case sensitive without blanks): **na** = New application, including: **na-nas**: New Active Substance **na-bws**: Known Active Substance **na-co-marketing**: Co-Marketing Medicinal Product **na-pi**: Parallel Import **var-type1a** = Type Ia variation	na-nas	repeatable

element	attribute	Description/instruction	example	occurence
		var-type1ain = Type Ia variation for immediate notification **var-type1b** = Type Ib variation **var-type2** = Type II variation **extension** = Extension **renewal** = Prolongation, renouncement of prolongation of Marketing Authorisation, notification of no marketing or interruption to distribution **fum** = Follow-up Measure **psur** = Submission of PSUR **withdrawal** = Withdrawal of authorised medicinal products **transfer** = Transfer of a Marketing Authorisation, Change of name of applicant, change of address of applicant **dmf** = Drug Master File **pmf** = Plasma Master File **orphan-fasttrack** = Application for recognition of orphan drug status or fast track status **reformat** = A baseline eCTD submission containing no content change and which will not be subject to review **supplemental-info** = Supplemental information (could include, for example, response to content validation issues, a consolidation sequence, withdrawal of an application, or answers to question) **corrigendum** = Correction of errors detected in a sequence **advice** = Used for meetings		
article-13-tpa		Use *yes* (case sensitive) if the submission is according to article 13 TPA and *no* (case sensitive) if the submission is not according to article 13 TPA (no other value than *yes* or *no* is allowed)	no	unique

element	attribute	Description/instruction	example	occurence
eCTD Sequence		The Sequence number of the submission – this must start at 0000 for the initial submission, and then increase incrementally with each subsequent submission, for example 0000, 0001, 0002 etc. The increase must occur in chronological order. The Sequence number must have 4 digits.	0005	unique
related eCTD Sequence		The Sequence number of a previous submission to which this submission is related, e.g., the responses to questions to a new application. Use the numeric value (must have 4 digits) or – in case there is no related sequence – use *none* (case sensitive)	0003	repeatable

Example of the use of the Related eCTD Sequence

A regulatory activity is a logical entity of submission activity (for example a new indication) with a defined start and end point (for example: initial submission to final approval). In the eCTD world, a regulatory activity consists of all the eCTD Sequences that together make up the life cycle of that particular regulatory activity.

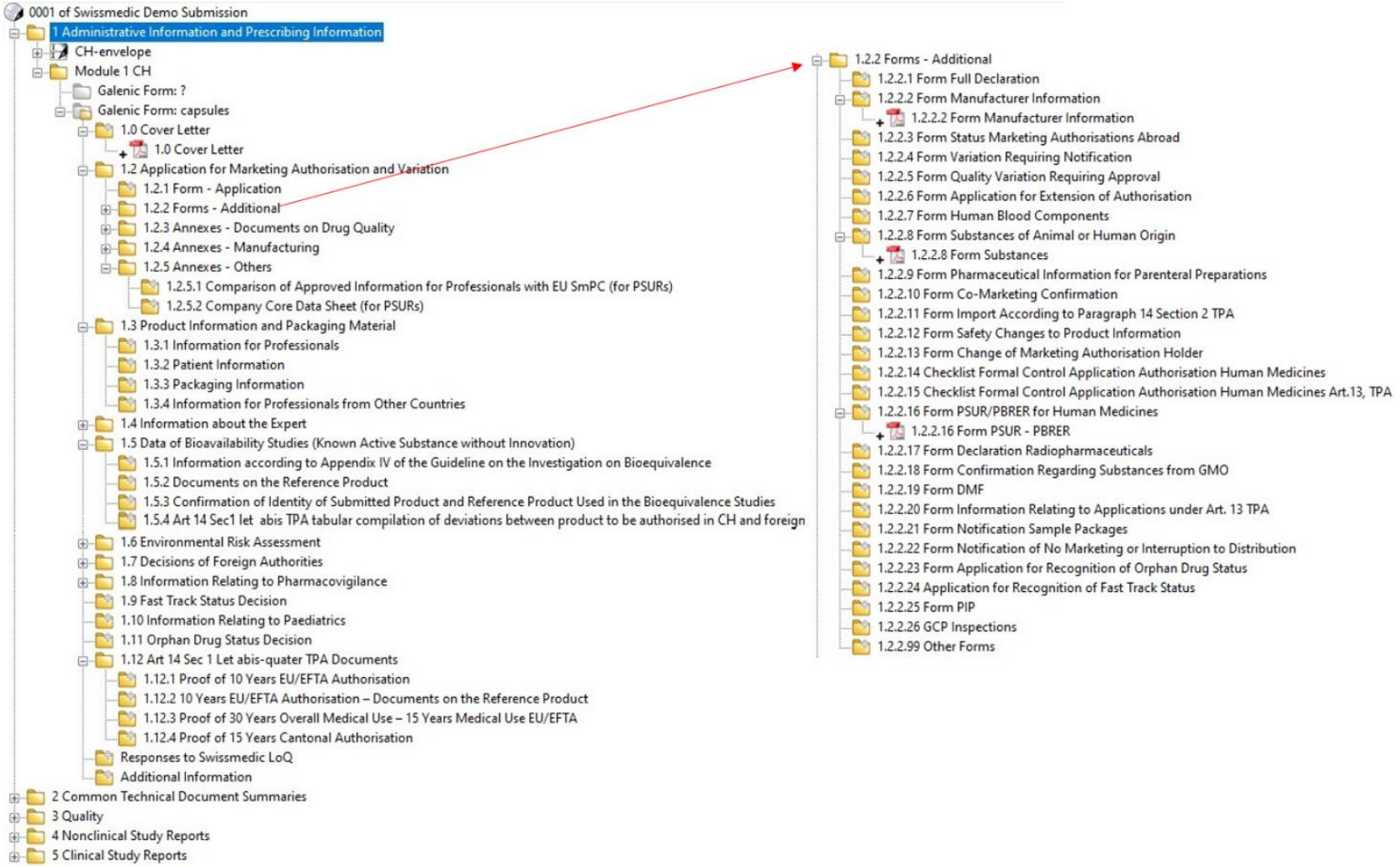
The related eCTD Sequence attribute should always be *none* for new applications or new regulatory activities (for example variations, PSURs). When submitting life cycle eCTD Sequences within an existing activity, the related eCTD Sequence attribute should be populated with the eCTD Sequence number of the first eCTD Sequence in the activity, regardless of how many eCTD Sequences make up the activity. The related eCTD Sequence attribute should be considered independent of any modified file attributes in a submission. For example, if an eCTD Sequence 0010 modifies files (leaves) in eCTD Sequence 0008 and 0009, the entry for related eCTD Sequence in eCTD Sequence 0010 should be the eCTD Sequence number that started the regulatory activity that 0010 falls within, which will not necessarily be eCTD Sequence 0008 or 0009. See below for some illustrative examples.

eCTD Sequence	Submission description	Related eCTD Sequence	Type	Comment
0000	Original application	none	na-nas	
0001	Response after negative content validation outcome	0000	supplemental-info	This is a continuation of the regulatory activity initiated in 0000 and so the related eCTD Sequence points to the beginning of that activity

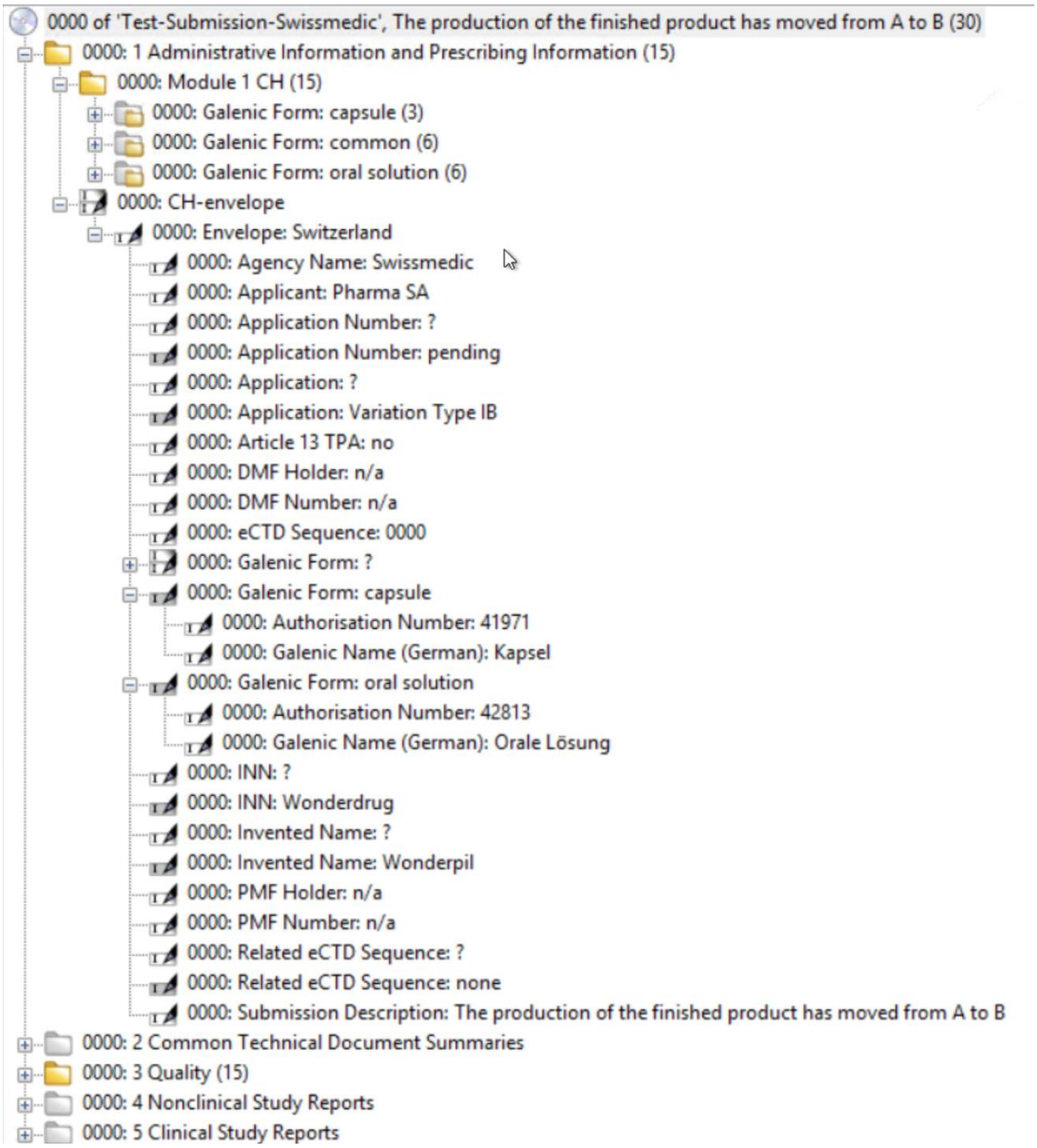
0002	Answers to Questions	0000	supplemental-info	This is a continuation of the regulatory activity initiated in 0000 and so the related eCTD Sequence points to the beginning of that activity
0003	Application for a new indication (treatment of pain)	none	var-type2	This is the beginning of a new regulatory activity and so no related eCTD Sequence is included
0004	Application for a change in manufacturing site	none	var-type1b	This is the beginning of a new regulatory activity and so no related eCTD Sequence is included
0005	Answers to Questions on application of a new indication for 'Treatment of Pain' indication	0003	supplemental-info	This is a continuation of the regulatory activity initiated in 0003 and so the related eCTD Sequence points to the beginning of that activity
0006	Answers to List of Questions for change in manufacturing site	0004	supplemental-info	This is a continuation of the regulatory activity initiated in 0004 and so the related eCTD Sequence points to the beginning of that activity
0007	Line extension to introduce a new dosage form (iv solution) that amends information provided in the original application and the manufacturing change variation	none	extension	This is the beginning of a new regulatory activity and so no related eCTD Sequence is included

Appendix 3: Example Screenshots

This appendix is included to demonstrate how the backbone is displayed using an XML viewing tool.



Structure of the Envelope using an XML viewing tool



Appendix 4: Modularised DTD for CH Module 1

ch-regional.dtd v1.5

```
<!--
DTD M1 Swissmedic v1.5
Published Date: 01. April 2020
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
-->

<!-- countries, languages and leaf-node declarations used as references -->
<!ENTITY % countries "(ch)">
<!ENTITY % languages "(de|fr|it)">
<!ENTITY % leaf-node "(( leaf | node-extension )*)">

<!-- Root element ch-backbone -->
<!ELEMENT ch:ch-backbone (
      ch-envelope,
      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 "1.4"
>

<!ENTITY % envelope-module SYSTEM "ch-envelope.mod">
%envelope-module;
<!ENTITY % leaf-module SYSTEM "ch-leaf.mod">
%leaf-module;

<!-- ..................................................................... -->
<!ELEMENT m1-ch (m1-galenic-form*)>


<!ELEMENT m1-galenic-form (
      m1-0-cover?,
      m1-2-applvar?,
      m1-3-pi?,
      m1-4-expert?,
      m1-5-bioavailability?,
      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?
)>

<!ATTLIST m1-galenic-form
      name CDATA #REQUIRED
>

<!-- ..................................................................... -->
<!ELEMENT m1-0-cover (%leaf-node;)>
<!-- ..................................................................... -->
<!ELEMENT m1-2-applvar (
      m1-2-1-foapplvar?,
      m1-2-2-form-add?,
      m1-2-3-quality?,
      m1-2-4-manufacturing?,
      m1-2-5-others?
)>

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

<!ELEMENT m1-2-2-form-add (
      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?,
      m1-2-2-20-form-information-applications-art-13-tpa?,
      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;)>
<!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 m1-2-2-19-form-dmf (%leaf-node;)>
<!ELEMENT m1-2-2-20-form-information-applications-art-13-tpa (%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 m1-2-2-25-form-pip (%leaf-node;)>
<!ELEMENT m1-2-2-26-gcpinspections (%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 m1-2-3-1-dmf-letter-of-access (%leaf-node;)>
<!ELEMENT m1-2-3-2-certificate-of-suitability-for-active-substance (%leaf-node;)>
<!ELEMENT m1-2-3-3-certificate-of-suitability-for-tse (%leaf-node;)>
<!ELEMENT m1-2-3-4-ema-certificate-for-plasma-master-file-pmf (%leaf-node;)>
<!ELEMENT m1-2-3-5-ema-certificate-for-vaccine-antigen-master-file-vamf (%leaf-
node;)>


<!ELEMENT m1-2-4-manufacturing (
      m1-2-4-1-gmp-certificate-or-other-gmp-documents?,
      m1-2-4-2-manufacturing-authorisation?,
      m1-2-4-3-complete-manufacturing-information-with-flow-chart?,
      m1-2-4-4-confirmation-on-gmp-conformity?
)>

<!ELEMENT m1-2-4-1-gmp-certificate-or-other-gmp-documents (%leaf-node;)>
<!ELEMENT m1-2-4-2-manufacturing-authorisation (%leaf-node;)>
<!ELEMENT m1-2-4-3-complete-manufacturing-information-with-flow-chart (%leaf-
node;)>
<!ELEMENT m1-2-4-4-confirmation-on-gmp-conformity (%leaf-node;)>


<!ELEMENT m1-2-5-others (
      m1-2-5-1-comparison-of-approved-product-information?,
      m1-2-5-2-company-core-data-sheet?
)>

<!ELEMENT m1-2-5-1-comparison-of-approved-product-information (%leaf-node;)>
<!ELEMENT m1-2-5-2-company-core-data-sheet (%leaf-node;)>


<!-- ..................................................................... -->
<!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 (
      m1-4-1-quality?,
      m1-4-2-non-clinical?,
```

```
      m1-4-3-clinical?
)>
<!ELEMENT m1-4-1-quality (%leaf-node;)>
<!ELEMENT m1-4-2-non-clinical (%leaf-node;)>
<!ELEMENT m1-4-3-clinical (%leaf-node;)>

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

<!-- ..................................................................... -->
<!ELEMENT m1-6-environrisk ((m1-6-1-nongmo | m1-6-2-gmo)?)>
<!ELEMENT m1-6-1-nongmo %leaf-node;>
<!ELEMENT m1-6-2-gmo %leaf-node;>

<!-- ..................................................................... -->
<!ELEMENT m1-7-decisions-authorities (
      m1-7-1-responses?,
      m1-7-2-assessment?,
      m1-7-3-eu-decisions?,
      m1-7-4-fda-decision?,
      m1-7-5-foreign-decisions?,
      m1-7-6-article13adddoc?
)>
<!ELEMENT m1-7-1-responses %leaf-node;>
<!ELEMENT m1-7-2-assessment %leaf-node;>
<!ELEMENT m1-7-3-eu-decisions %leaf-node;>
<!ELEMENT m1-7-4-fda-decision %leaf-node;>
<!ELEMENT m1-7-5-foreign-decisions %leaf-node;>
<!ELEMENT m1-7-6-article13adddoc %leaf-node;>

<!-- ..................................................................... -->
<!ELEMENT m1-8-pharmacovigilance (
      m1-8-1-pharmacovigilance-system?,
      m1-8-2-risk-management-system?
)>
<!ELEMENT m1-8-1-pharmacovigilance-system %leaf-node;>
<!ELEMENT m1-8-2-risk-management-system %leaf-node;>

<!-- ..................................................................... -->
<!ELEMENT m1-9-fast-track-decision %leaf-node;>
```

```
<!-- ..................................................................... -->
<!ELEMENT m1-10-paediatrics %leaf-node;>

<!-- ..................................................................... -->
<!ELEMENT m1-11-orphandrug %leaf-node;>

<!-- ..................................................................... -->
<!ELEMENT m1-12-art14sec1letabisquater (
      m1-12-1-eueftaauthorisation?,
      m1-12-2-eueftadocreference?,
      m1-12-3-overallmedicaluse?,
      m1-12-4-cantonalauthorisation?
)>
<!ELEMENT m1-12-1-eueftaauthorisation %leaf-node;>
<!ELEMENT m1-12-2-eueftadocreference %leaf-node;>
<!ELEMENT m1-12-3-overallmedicaluse %leaf-node;>
<!ELEMENT m1-12-4-cantonalauthorisation %leaf-node;>

<!-- ..................................................................... -->
<!ELEMENT m1-swiss-responses (%leaf-node;)>

<!-- ..................................................................... -->
<!ELEMENT m1-additional-info (%leaf-node;)>
```

ch-envelope.mod v1.5

```
<!--
DTD M1 Swissmedic v1.5
Published Date: 01. April 2020
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
-->

<!-- ..................................................................... -->
<!ELEMENT ch-envelope (envelope)>

<!ELEMENT envelope (
      application-number+,
      submission-description,
      invented-name+,
      galenic-form+,
      dmf-number,
      pmf-number,
      inn+,
      applicant,
```

```
      dmf-holder,
      pmf-holder,
      agency,
      application+,
      article-13-tpa,
      ectd-sequence,
      related-ectd-sequence+
)>

<!-- ..................................................................... -->
<!ELEMENT application-number (#PCDATA)>
<!ELEMENT submission-description (#PCDATA)>
<!ELEMENT invented-name (#PCDATA)>
<!ELEMENT galenic-form (swissmedic-number, galenic-name)>
<!ELEMENT galenic-name (#PCDATA)>
<!ELEMENT swissmedic-number (#PCDATA)>
<!ELEMENT dmf-number (#PCDATA)>
<!ELEMENT pmf-number (#PCDATA)>
<!ELEMENT inn (#PCDATA)>
<!ELEMENT applicant (#PCDATA)>
<!ELEMENT dmf-holder (#PCDATA)>
<!ELEMENT pmf-holder (#PCDATA)>
<!ELEMENT agency (#PCDATA)>
<!ELEMENT application EMPTY>
<!ELEMENT article-13-tpa (#PCDATA)>
<!ELEMENT ectd-sequence (#PCDATA)>
<!ELEMENT related-ectd-sequence (#PCDATA)>

<!-- ..................................................................... -->
<!ENTITY % countries "(ch)">
<!ENTITY % languages "(de|fr|it)">

<!-- ..................................................................... -->
<!ATTLIST envelope country %countries; #REQUIRED >
<!ATTLIST galenic-form name CDATA #REQUIRED    >
<!ATTLIST galenic-name language %languages; #REQUIRED>

<!-- ..................................................................... -->
<!ATTLIST application
      type (
            advice |
            na-nas |
            na-bws |
            na-co-marketing |
            na-pi |
            var-type1a |
            var-type1ain |
            var-type1b |
            var-type2 |
            extension |
```

```
            renewal |
            fum |
            psur |
            withdrawal |
            transfer |
            dmf |
            pmf |
            orphan-fasttrack |
            reformat |
            supplemental-info |
            corrigendum
      ) #REQUIRED
>
```

ch-leaf.mod v1.5

```
<!--
DTD M1 Swissmedic v1.5
Published Date: 01. Apri 2020
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
-->

<!-- ============================================================= -->
<!ELEMENT node-extension (title, (leaf | node-extension)+)>
<!ATTLIST node-extension
      ID ID #IMPLIED
      xml:lang CDATA #IMPLIED
>
<!-- ============================================================= -->
<!ENTITY % show-list " (new | replace | embed | other | none) ">
<!ENTITY % actuate-list " (onLoad | onRequest | other | none) ">
<!ENTITY % operation-list " (new | append | replace | delete) ">
<!ENTITY % leaf-element " (title, link-text?) ">
<!ENTITY % leaf-att '
 ID                  ID                #REQUIRED
 application-version CDATA             #IMPLIED
 version             CDATA             #IMPLIED
 font-library        CDATA             #IMPLIED
 operation           %operation-list;  #REQUIRED
 modified-file       CDATA             #IMPLIED
 checksum            CDATA             #REQUIRED
 checksum-type       CDATA             #REQUIRED
 keywords            CDATA             #IMPLIED
 xmlns:xlink         CDATA             #FIXED    "http://www.w3c.org/1999/xlink"
```

```
 xlink:type          CDATA              #FIXED    "simple"
 xlink:role          CDATA              #IMPLIED
 xlink:href          CDATA              #IMPLIED
 xlink:show          %show-list;        #IMPLIED
 xlink:actuate       %actuate-list;     #IMPLIED
 xml:lang            CDATA              #IMPLIED
 '>
<!ELEMENT leaf %leaf-element;>
<!ATTLIST leaf
      %leaf-att;
>
<!ELEMENT title (#PCDATA)>
<!ELEMENT link-text (#PCDATA | xref)*>

<!ELEMENT xref EMPTY>
<!ATTLIST xref
      ID ID #REQUIRED
      xmlns:xlink CDATA #FIXED "http://www.w3c.org/1999/xlink"
      xlink:type CDATA #FIXED "simple"
      xlink:role CDATA #IMPLIED
      xlink:title CDATA #REQUIRED
      xlink:href CDATA #REQUIRED
      xlink:show %show-list; #IMPLIED
      xlink:actuate %actuate-list; #IMPLIED
>
<!-- +++ -->
```

[End of Document]

Change history

Version	Change	sig
1.6	New layout, no content adjustments to the previous version	tsj
1.5	Corrections and updates	OSS
1.4	Minor corrections to the published version 1.4. Version number does not change.	OSS
1.4	Update due to revision 4 of the Therapeutic Product Ordinances, text updates	OSS
1.3	Update	Submissions Division
1.2	Update, published on Swissmedic website	Submissions Division
1.2	Update, published on Swissmedic website	Submissions Division
1.1	Final version, published on Swissmedic website	SIMES Working Group
1.0.9	Draft version for the introduction of Step 2	SIMES Working Group
1.0.1	Alignment to Change Requests	SIMES Working Group
1.0	1st valid version, published on Swissmedic website	SIMES Working Group
0.95	Draft version, published on Swissmedic website	SIMES Working Group
0.92	Draft version, published on Swissmedic website	SIMES Working Group