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**Electronic Common Technical Document (eCTD) v4.0**  
**EU Module 1 Implementation Guide**  
**Draft for Testing**

Version 1.0  
30. June .2012

31 **DOCUMENT CHANGE HISTORY**

32

Version	Date	Comments
0.1	6th Jan. 2012	First draft based on ICH IG v3.1 deleting all M2 to 5 specifics and adding all EU M1 details, e.g. controlled vocabularies and content from the current EU M1 specification as far as possible, except updating all XML snippets and XML elements tables.
0.2	16 <sup>th</sup> Jan 2012	Update based on ICH IG v4.0
0.3	15 <sup>th</sup> Feb 2012	Update based on ICG IG v5.0, correction of CV on EU Application Type, EU Contact Party, EU Regulatory Status, deletion of non EU specific information on life cycle management
0.4	22 <sup>nd</sup> Feb 2012	Deleting all doubled XML tables but referencing to ICH IG. Note: XML tables are frequently copied and not yet checked for consistency.
0.5	1 <sup>st</sup> Mar 2012	Update covering M8 TC 29 Feb 2012, comments from Andreas Franken
0.6	2 <sup>nd</sup> March 2012	Replace of most of the XML snippets by  <i>Note: Examples for XML snippets will be provided in one of the future versions</i>
0.7	15 <sup>th</sup> April 2012	Incorporate comments from vendors and adjusting text according ICH IG v6.0. A number of XML snippets have been added. Business scenarios in new section 9.2
0.8	30 <sup>th</sup> April 2012	Incorporate changes based on ICH IG v7.0, add more XML samples and outline missing business scenarios, add new section on message created by regulators, re-numbering of sections as appropriate.
0.81	18 <sup>th</sup> May 2012	Layout and editorial changes, deletion of duplications, consistency improvement
0.82	10 <sup>th</sup> June 2012	Editorial changes, including confirmations after TIGes Meeting 25.05.2012, incorporate changes based on Draft ICH IG for Testing v 1.0, clarification on sequence number use
1.0	30 <sup>th</sup> June 2012	Release for public consultation and testing purpose

33	<b>TABLE OF CONTENTS</b>	<b>Page</b>
34	<b><i>Notice to Reader</i></b> .....	<b>7</b>
35	<b><i>Instructions to Reader</i></b> .....	<b>7</b>
36	<b><i>Document Content</i></b> .....	<b>7</b>
37	<b><i>XML Elements Tables</i></b> .....	<b>8</b>
38	<b>1. Purpose</b> .....	<b>10</b>
39	<b>1.1 Scope</b> .....	<b>10</b>
40	<b>1.2 Business Case</b> .....	<b>10</b>
41	<b>2. Background</b> .....	<b>11</b>
42	<b>3. Change Control Rules</b> .....	<b>11</b>
43	<b>4. Essential Components of the eCTD Considering the Specific Regional EU Requirements...</b> <b>12</b>	<b>12</b>
44	<b>4.1 Files and Folder</b> .....	<b>13</b>
45	<b>4.2 Controlled Vocabularies</b> .....	<b>14</b>
46	<b>4.3 OIDS and UIIDS</b> .....	<b>14</b>
47	<b>4.4 Data Types</b> .....	<b>14</b>
48	<b>4.5 Elements for regional use covered by EU M1 Implementation Guide</b> .....	<b>14</b>
49	<b>5. Submission Contents, Folder and File Structure</b> .....	<b>16</b>
50	<b>5.1 Naming Conventions</b> .....	<b>16</b>
51	5.1.1 Allowable Characters .....	<b>16</b>
52	5.1.2 Length of Names and the Path .....	<b>16</b>
53	<b>5.2 Top Folder Naming Requirements</b> .....	<b>17</b>
54	<b>5.3 Second Level Folder Naming Requirements</b> .....	<b>17</b>
55	<b>5.4 Pathname Conventions and Best Practices</b> .....	<b>17</b>
56	<b>5.5 Folder Hierarchy</b> .....	<b>17</b>
57	<b>5.6 File Formats</b> .....	<b>19</b>
58	<b>5.7 Checksums</b> .....	<b>19</b>
59	<b>5.8 Compressed Archive</b> .....	<b>20</b>
60	5.8.1 Eudralink/e-Mail (where applicable) .....	<b>20</b>
61	5.8.2 Portals.....	<b>20</b>
62	5.8.3 CD/DVD.....	<b>20</b>
63	<b>6. Controlled Vocabularies</b> .....	<b>21</b>
64	<b>6.1 Controlled Vocabularies for EU Purpose</b> .....	<b>21</b>

65	6.1.1	EU M1 eCTD – Context of Use Codes.....	21
66	6.1.2	EU M1 eCTD – Keyword Codes .....	22
67	6.1.3	Application Codes .....	22
68	6.1.4	Application Reference Reason Codes .....	23
69	6.1.5	Category Event Codes .....	23
70	6.1.6	Contact Party Codes.....	23
71	6.1.7	DocumentType Codes.....	24
72	6.1.8	Mode Codes.....	24
73	6.1.9	Place Codes .....	25
74	6.1.10	Product Category Codes.....	26
75	6.1.11	Regulatory Status Codes .....	27
76	6.1.12	Regulatory Review Time codes .....	27
77	6.1.13	Review Procedure Codes .....	28
78	6.1.14	Submission Codes .....	28
79	6.1.15	Submission Unit Codes.....	29
80	6.1.16	Territorial Authority Codes .....	30
81	<b>6.2</b>	<b>Controlled Vocabulary specified by HL7 .....</b>	<b>31</b>
82	<b>6.3</b>	<b>Controlled Vocabulary specified by Others .....</b>	<b>31</b>
83	<b>6.4</b>	<b>Maintenance of Controlled Vocabularies .....</b>	<b>31</b>
84	<b>7.</b>	<b><i>eCTD v4.0 XML Schema .....</i></b>	<b>32</b>
85	<b>8.</b>	<b><i>eCTD 4.0 XML Message .....</i></b>	<b>32</b>
86	<b>9.</b>	<b><i>EU Regional Specific Requirements for Elements.....</i></b>	<b>38</b>
87	9.1	Applicant .....	38
88	9.2	Application .....	39
89	9.3	Application Reference .....	41
90	9.4	Category Event .....	43
91	9.5	callBackContact .....	44
92	9.6	Context of Use .....	48
93	9.7	Document.....	51
94	9.8	Document Reference .....	53
95	9.9	Keyword .....	54
96	9.10	Keyword Definition .....	55
97	9.11	Manufactured Product .....	56
98	9.12	Mode.....	60
99	9.13	Previous Keyword Definition .....	62
100	9.14	Product Category .....	63
101	9.15	Regulatory Review Time.....	64

102	9.16	Regulatory Status.....	66
103	9.17	related Context Of Use (contextOfUse Life Cycle).....	69
104	9.18	Related Document .....	69
105	9.19	Review .....	69
106	9.20	Review Procedure.....	72
107	9.21	Submission .....	73
108	9.22	Submission Group.....	77
109	9.23	Submission Reference.....	79
110	9.24	Submission Unit.....	81
111	9.25	Territorial Authority (as author of review) .....	82
112	9.26	Territorial Authority (as primary information recipient related to contextofUse) .....	83
113	9.27	Territorial Authority (as information recipient related to application) .....	84
114	<b>10.</b>	<b><i>Creating the Message.....</i></b>	<b>86</b>
115	10.1	<b>Individual Components .....</b>	<b>86</b>
116	10.1.1	Managing Country Specific Product Names in MRP and DCP .....	86
117	10.1.2	Managing Country Specific Processing Numbers.....	88
118	10.1.3	Product Information Texts in EU Module 1.3.1 .....	89
119	10.2	<b>Content Management (contextOfUse and Documents) .....</b>	<b>93</b>
120	10.3	<b>Complex Scenarios .....</b>	<b>94</b>
121	10.3.1	Referencing Multiple Applications in Case of Grouped or Workshared Regulatory Activities	
122		(Submissions) .....	94
123	10.3.2	Managing Duplicates.....	97
124	10.3.3	Referencing across submissions and application of the same pharmaceutical company .....	97
125	10.4	<b>eCTD XML message from regulators .....</b>	<b>97</b>
126	10.5	<b>Building Regulatory Activities (Submission) .....</b>	<b>101</b>
127	10.5.1	Marketing Authorisation Application (MAA) .....	101
128	10.5.2	Variation.....	101
129	<b>11.</b>	<b><i>XML Message Validation Rules.....</i></b>	<b>102</b>
130	<b>12.</b>	<b><i>Compatibility and Reference to EU M1 eCTD v1.4.1.....</i></b>	<b>102</b>
131	<b>Appendix 1</b>	<b><i>Sample Files and Folders for EU Module 1 Lite Folder Structure.....</i></b>	<b>103</b>
132	<b>Appendix 2</b>	<b><i>Sample eCTD Messages.....</i></b>	<b>104</b>
133		Marketing Authorization application .....	104
134		Variation type 2 .....	120
135	<b>Appendix 3</b>	<b><i>Abbreviations, Terms and Definitions .....</i></b>	<b>124</b>
136	<b>Appendix 4</b>	<b><i>References .....</i></b>	<b>125</b>

137

138

## LIST OF FIGURES

139	Figure 1: Folder Hierarchy of Module 1 Screenshot .....	18
140	Figure 2: Folder structure related to submission unit message.....	94
141	Figure 3: Referencing multiple applications.....	95

142

143

## LIST OF TABLES

144

145	Table 1: Legend of Symbols used in Document.....	7
146	Table 2: Legend for XML Snippets .....	8
147	Table 3: Sample XML Element Table .....	9
148	Table 4: Acceptable file formats for Module 1.....	19
149	Table 5: XML Structure- Submission Unit.....	33
150	Table 6: XML Structure - Submission.....	35
151	Table 7: XML Structure - Application.....	36
152	Table 8: Sample contextOfUse.code@code Terminology .....	50
153	Table 9: Sample contextOfUse.StatusCodes@code Terminology .....	50
154	Table 10: Sample review.StatusCodes@code Terminology.....	71
155	Table 11: XML Structure- Submission Unit from Regulators.....	98
156	Table 12: XML Structure – Submission from Regulators .....	99
157	Table 13: XML Structure - Application from Regulators .....	100

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159

160 **NOTICE TO READER**

161 Sections of this document referencing the HL7 Version 3 Standard: Regulated Product  
162 Submission Release 2 Draft Standard for Trial Use 2 are used with the publisher’s permission.  
163 These sections are copyrighted by Health Level Seven International ® ALL RIGHTS  
164 RESERVED  
165

166 **INSTRUCTIONS TO READER**

167  
168 This is a technical document that provides instructions on how to implement the eCTD v4.0  
169 specification in the European Union. The following content will be provided in a consistent  
170 manner within the document and/or the reader may be prompted by visual cues about the context  
171 or referenced information being presented in the document.  
172 This document needs to be read in conjunction with the ICH Implementation Guide on electronic  
173 Common Technical Document Version 4.0.  
174





175 **DOCUMENT CONTENT**

176 In the document there are several notations that are used to provide clarity to the subject matter  
177 and will help readers to quickly identify information they are looking for. The first is the use of  
178 XML components (e.g. elements and attributes) versus the concept that it represents. The text will  
179 take the following notation:

- 180 - XML components
  - 181 o In narrative text, it will be Bold, Italicized text in Camel case, e.g., *contextOfUse*
  - 182 o In XML, it will be as notated below for the XML Snippets.
- 183 - Concept without attribution to the model or message
  - 184 o Plain text with first letter capitalized as it is a defined concept, e.g., Context of Use

185  
186 In the text some helpful icons will point readers in the direction of useful information. The  
187 following table provides visual cues that are used in the document.  
188

189 **Table 1: Legend of Symbols used in Document**

Icon	Description
	Technical descriptions
	Items to be careful to follow
	Additional Instructions
	References to other documents

190

## 191 XML Snippets

192 The following figure indicates the colour coding used in the XML snippets and any meaning that  
193 should be inferred by the samples.

194

195 **Table 2: Legend for XML Snippets**

Text Colour	Description	Sample
Teal	Indicates the schema components	<code>&lt;?xml version "1.0" encoding="UTF-8"?&gt;</code>
Blue	Indicates the XML notations	<code>&lt; ...= " " &gt; " " &gt;</code>
Brown	Indicates the XML element	<code>id code</code>
Red	Indicates the XML attribute	<code>root extension</code>
Black	Indicates the value of the attribute	<code>2.16.840.1.113883</code>

196

197

198 The following rules were used in the development of the XML samples:

- 199 - If an element only has a value, the value attribute was not used, but instead the value was  
200 provided between the element tags (e.g., `<title>Title Label</title>`)
- 201 - The notation of `<!...notes....-->` was used to describe conditions that should be met for an  
202 element
- 203 - The notation `... [Description] ...` was used to indicate when there were additional elements  
204 not represented in the XML, but may be present in the actual XML message.

205



*Note: XML editors may display these XML components differently, please use the legend above for XML presented in this document.*

206

## 207 XML ELEMENTS TABLES

208 A table has been provided for each element in the XML message. When elements have multiple  
209 element parts or attributes, they are provided in one table. When there are no attributes or values  
210 for an element, the cell is grayed out to indicate that no value is required in the XML message.

211



212 **Table 3: Sample XML Element Table**

213 Table Name: <element>.<element 2>

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
<b>Conformance</b>				
<b>Business Rules</b>				
<b>Excluded Elements and Attributes</b>				

214  
 215 **Table Name:** Each table is named for the elements it is representing in the XML – i.e.,  
 216 <element>.<element 2>. For example, the Application element has an element for the identifier, it  
 217 would be represented as: **Application.id**

218  
 219 **Element:** Identifies the XML element

220  
 221 **Attribute:** Identifies the XML attribute

222  
 223 **Cardinality:** Provides information on how many times the element/attribute can be repeated in  
 224 the XML message.

225  
 226 **Value(s) Allowed/Examples:** Identifies the values allowed using simple data types and any  
 227 associated examples. References to controlled vocabulary will also be provided.

228  
 229 **Description/Instructions:** Provides a description of the element or attribute

230  
 231 **Conformance:** Identifies the validation requirements (e.g., XML Elements or attributes) and/or  
 232 conditions that need to be met by the element

233  
 234 **Business Rules:** Identifies any business rules specifically relevant for Regional/Module1  
 235 Implementation or references to ICG Implementation Guide in case of harmonized business rules.

236  
 237 **Excluded Elements and/or Attributes:** Identifies elements and/or attributes that are part of the  
 238 HL7 Regulated Product Submission standard that do not pertain to the eCTD v4.0  
 239 Implementation.

240

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## 1. PURPOSE

This document serves as the implementation guide and a technical specification for the Electronic Common Technical Document (eCTD) v4.0 regional EU Module 1 using the Regulated Product Submission (RPS) Release 2, Draft Standard for Trial Use (DSTU)<sup>1</sup>. In addition, information will be included to assist in the requirements for system development for publishing or displaying eCTD compliant messages for the recipients of the information.



*Note to Implementers: This implementation guide will need to be used in conjunction with the ICH Implementation Guide, as the eCTD v4.0 message will be incomplete without all of the contents.*

249

### 1.1 Scope

This document only includes eCTD v4.0 Module 1 of the eCTD XML message including the Regional Administrative and Product Information which is specifically for EU purposes. The content of eCTD v4.0 Modules 2 - 5, which is shared across regions, is not included in this implementation guide although some principles need to be repeated otherwise understanding is not guaranteed. This document should be read together with the ICH Implementation Guide to prepare a valid eCTD submission in the EU.

This standard defines the message for exchanging regulatory submission information electronically between Regulatory Authorities and the Pharmaceutical Industry. The XML message provides the ability to describe the contents of the regulatory exchange and all information needed to process the exchange between these two parties.



*The initial scope of this document is specifically for Step 2 for Testing. As testing is conducted and the standard evolves, the information in this guide will need to be updated.*

261

### 1.2 Business Case

Regulated Industry and Regulatory Authorities exchange information to address a variety of regulatory processes. The scope of the ICH activities covers the human pharmaceutical product marketing approval processes. The eCTD format is regarded as the principal electronic submission format in the EU and is the only electronic format that is accepted by the European Medicines Agency (hereafter referred to as EMA) and also widely accepted by the National Competent Authorities (hereafter referred to as NCAs). Frequently, when new information is provided, it directly relates to information previously submitted. Because information is submitted over time, usually in increments, it is difficult to efficiently process and review new information

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<sup>1</sup> For the Feasibility Step 2 Testing version of this document, HL7 Regulated Product Submission (RPS) Release 2 (R2) is being balloted as a Draft Standard for Trial Use. Once HL7 RPS R2 becomes Normative, the standard will go through the ISO process to become an ISO standard. It is expected that by the official final release of this document that an ISO standard will be referenced.

271 in light of pre-existing information. To provide improvement is one of the goals of the upgrade to  
272 eCTD v4.0. Further details are outlined in the ICH Implementation Guide and will not be repeated  
273 here.

274

## 275 **2. BACKGROUND**

276 The use of an international information exchange standard is needed in the regulatory  
277 environment to ensure that mandates can be issued and standardization enabled for increased  
278 consistency across the regulatory authorities with respect to the exchange of regulatory  
279 information.

280 As the eCTD is regarded as the principal electronic submission format in the EU, EMA and more  
281 and more national Competent Authorities developed and improved their internal workflows and  
282 review procedures on electronic submissions of marketing authorization applications. With the  
283 previous specification pharmaceutical industry and competent authorities gained a lot of  
284 experiences and many applications have been submitted in eCTD format already.

285 The goal of the upgrade to eCTD v4.0 is to facilitate the processing and review of electronic  
286 regulatory submissions as outlined in more detail in the ICH Implementation Guide.

287

288

## 289 **3. CHANGE CONTROL RULES**

290 eCTD v4.0 is based on the HL7 Regulated Product Submission Standard (RPS), which was  
291 developed in the external Standards Development Organization (SDO), Health Level Seven  
292 International (HL7) and various stakeholders, including members of ICH M8 and EU  
293 representatives amongst them. Changes to the eCTD v4.0 Implementation Guide and ICH  
294 Controlled Vocabularies will remain the responsibility of the ICH M8 Expert Working Group  
295 (EWG) and will follow the established eCTD change control process. Changes that require  
296 modifications to the standard will follow established change control processes<sup>2</sup>. More detailed  
297 information is provided in the ICH Implementation Guide. Change requests which concern the  
298 regional part only will be handled separately as outlined below.

299

300 The EU Module 1 Implementation Guide is likely to change over time. Factors that could affect  
301 the content of the document include, but are not limited to:

- 302 • Change in the content of the Module 1 for the CTD, either through the amendment of  
303 information, at the same level of detail, or by provision of more detailed definition of  
304 content and structure
- 305 • Change to the regional requirements for applications that are outside the scope of the CTD
- 306 • Update of standards that are already in use within the eCTD
- 307 • Identification of new standards that provide additional value for the creation and/or usage  
308 of the eCTD

---

<sup>2</sup> This version of the Implementation Guide references the existing standard, RPS and its change control processes.  
When an ISO standard is available, this section of the document will need to be revisited

- 309       • Identification of new functional requirements  
310       • Experience of use of the eCTD by all parties, in particular of Module 1.

311  
312 Details of the change control process are described in a separate EU document and provide an  
313 Electronic Submission Change Request/Q&A Form, use the following link:

314 <http://esubmission.ema.europa.eu/doc/index.html>.

315  
316

#### 317 **4.           ESSENTIAL COMPONENTS OF THE ECTD CONSIDERING THE SPECIFIC** 318 **REGIONAL EU REQUIREMENTS**

319 This section will provide a brief overview of the essential components of the eCTD v4.0  
320 specification. The essential components include:

- 321       • Files and Folders (see Section 4.1, Section 5 and Appendix 1)  
322       • Controlled Vocabularies (see Section 4.2 and Section 6)  
323       • ICH eCTD XML Schema (see Section 7)  
324       • eCTD v4.0 XML Message (see Section 8)  
325       • OIDS and UUIDS (see Section 4.3)  
326       • Data Types (see Section 4.4)

327

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

- 329       • ICH Implementation Guide across regions (separate document)  
330       • EU Module1 Implementation Guide (this document).

331

332 Each of these components is detailed as appropriate in the subsequent sections to include specific  
333 information about the component's role in the implementation of the specification. In order to  
334 compose a complete eCTD v4.0 compliant message, the contents of this implementation guide  
335 will need to be complemented by several other documents. The focus of this document is to  
336 outline the essential components of the eCTD v4.0 which need to be used for Module 1 in the EU  
337 in addition or differently from composing Modules 2 – 5 of the CTD.

338

339 The ICH Common Technical Document (“CTD”) specifies that Module 1 should contain  
340 region-specific administrative and product information. The content and numbering of Module 1  
341 for the EU is specified in the latest version of the *Notice to Applicants* that can be found at:

342 [http://ec.europa.eu/health/documents/eudralex/vol-2/index\\_en.htm](http://ec.europa.eu/health/documents/eudralex/vol-2/index_en.htm)

343

344 The following items listed in the Notice to Applicants should be included for an initial  
345 submission:

- 346       – a cover letter,  
347       – a comprehensive table of contents<sup>3</sup>,

---

<sup>3</sup> TOC not required for eCTD as the XML backbone acts as a table of contents

- 348 – an application form,
- 349 – product information documents,
- 350 – information on the experts,
- 351 – specific requirements for different types of applications (if required),
- 352 – an environmental risk assessment,
- 353 – information relating to orphan market exclusivity (if required),
- 354 – information relating to pharmacovigilance,
- 355 – information relating to clinical trials (if required),
- 356 – information relating to paediatrics.

357  
358 In addition, other items such as additional (nationally required) information, answers to regulatory  
359 questions, rationale for variations and renewal documentation could also be included in Module 1.

360  
361 In case regulators will use the RPS message for sending the assessment reports, list of questions or  
362 list of outstanding issues to applicants these types of submission unit will also become part of  
363 Module 1.

364  
365 It should be noted, that for subsequent submissions in the lifecycle of a medicinal product, e.g. for  
366 a variation, not all of the above mentioned types of documents need be included in Module 1.  
367 Consult the various legal documents for guidance on the exact documents to be submitted in such  
368 a case, e.g. Regulation (EC) No 1234/2008 for Type IA, Type IB and Type II variations.

369  
370 This document describes only the region-specific information that is common to all submissions  
371 in the different Member States. However, at the same time the EU Module 1 Implementation  
372 Guide allows for country-specific information to be included in Module 1, if required. Country-  
373 specific information could relate to the details of the business process applied (e.g. specifying the  
374 number and names of those parts for which a paper copy is still requested) or other local  
375 preferences.

376

#### 377 **4.1 Files and Folder**

378 The files (i.e., documents referenced in the XML message) will be sent in addition to the XML  
379 message. Each file will be organized in a folder according to the structure outlined for the CTD.  
380 Each *document.text* element within the eCTD XML message will be given a specific directory  
381 location i.e., the folders that will be used to organize the files if the document is being sent for the  
382 first time. Additional rules to handle naming conventions, length and structure are provided in  
383 Section 5.



*In the EU it is expected to be able to access the RPS message based eCTD submission also without additional review tool support. As no style sheet will be provided, a human readable and basic navigation supporting folder and file naming is required (for details see Annex1).*

384

385 **4.2 Controlled Vocabularies**

386 Controlled vocabularies are one of the essential components of the eCTD v4.0, which enable  
387 interoperability – i.e., clear, unambiguous communications between systems sending and  
388 receiving XML messages. For the XML components that have coded values, a controlled  
389 vocabulary will be referenced. Some of the codes are simple alphanumeric and others are based  
390 on a code system scheme for the specified code set. Either way, there should be a standard, unique  
391 identification of the concept that the code represents.

392 Controlled vocabularies are defined external to the message; a code is used as the identifier to  
393 convert the code value into the meaningful terms that will be used in any system that implements  
394 the viewing of the information sent in the XML message. The controlled vocabularies are outlined  
395 in Section 6 and examples are given for the XML components.

396 Controlled Vocabularies relevant to EU Module 1 will be provided at EUTCT, by the following  
397 link: <http://eutct.ema.europa.eu/eutct/>

398



*Note to implementers: As the online access to the full set is not provided right now, implementers should use the CVs provided in a separate spreadsheet for testing purpose. For review purposes the CVs are also provided within this document for the time being.*

399

400

401 **4.3 OIDS and UUIDS**

402 In the EU M1 part of the message the two types of unique identifiers, Object Identifiers (OIDs)  
403 and Universally Unique Identifiers (UUIDs), are handled in the same way as for Module 2 to 5.

404

405

406 **4.4 Data Types**

407 Data Types are another essential component of the eCTD v4.0 specification and will apply for EU  
408 M1 in the same way as for ICH M2 to 5.

409

410

411 **4.5 Elements for regional use covered by EU M1 Implementation Guide**

412 The user should be aware that principle rules for implementing eCTD v4.0 will be outlined in the  
413 ICH Implementation Guide in detail and not completely repeated in this regional Implementation  
414 Guide. The ICH Implementation Guide plays a key role in providing the complete information  
415 about the submission. Dossier information mainly provided in Modules 2 to 5, as such, is the  
416 subject of the ICH Implementation Guides. Therefore, the ICH Implementation Guide needs to be  
417 consulted as well.

418



**Note to Implementers:** *The information in this regional EU M1 eCTD v4.0 Implementation Guide is necessary, but not sufficient for creating the complete XML message for transmission. .*

419

420 The required elements and business rules that are EU-specific covered by this document are as  
421 follows:

- 422 • Application
  - 423 ○ subject.ReviewProcedure
  - 424 ○ reference.ApplicationReference
  - 425 ○ author.Applicant
  - 426 ○ informationRecipient.TerritorialAuthority
- 427 • Submission
  - 428 ○ callBackContact.ContactParty
  - 429 ○ subject.SubmissionGroup
  - 430 ○ subject.RegulatoryStatus
  - 431 ○ subject.RegulatoryReviewTime
  - 432 ○ subject.Mode
- 433 • ReviewableUnit (This element will not be used for the time being.)
- 434 • SubmissionUnit
  - 435 ○ callBackContact.ContactParty
- 436 • Review
  - 437 ○ subject.ProductCategory
  - 438 ○ subject.ManufacturedProduct
  - 439 ○ holder.Applicant
  - 440 ○ informationRecipient.TerritorialAuthority

441

442

443

444 **5. SUBMISSION CONTENTS, FOLDER AND FILE STRUCTURE**

445 The folder and file structure specified for the document contents being transmitted along with the  
446 XML message will need to follow various specifications and rules as presented below in this  
447 section.

448

449 **5.1 Naming Conventions**

450 The naming conventions for folders shall be consistent with the guidance provided in the ICH  
451 eCTD v3.2.2 folder naming convention and current EU eCTD specification v1.4.1. An exemption  
452 will be made in regard to the cc-folder requirement. eCTD v4.0 offers the opportunity to avoid  
453 this additional folder level by using keywords from the respective controlled vocabulary (see  
454 Section 6.3).

455 The RPS Standard allows flattening of the hierarchical folder structure. This approach will require  
456 a reviewing tool, which might be not available in some receiving agencies. Therefore, the current  
457 folder structure will be maintained temporarily. However, a light folder structure will be used for  
458 testing purpose (see Annex1).

459 Additional guidance for naming convention that is not specified in the sub-sections includes:

- 460 • Folder or file names should be written in lower case only.
- 461 • All files should have one and only one file extension.
- 462 • The file extension should be used to indicate the format of the file.

463

464

465 **5.1.1 Allowable Characters**

466 All implementations shall follow the IETF rules for Uniform Resource Locators (URLs) [for  
467 further reference Consult the IETF documentation on *Uniform Resource Identifier (URI): Generic  
468 Syntax RFC 3986* (except for period and asterisk)] for file or folder name and will apply for EU  
469 M1 in the same way as for ICH M2 to 5.

470

471 **5.1.2 Length of Names and the Path**

472 The restrictions on file or folder name lengths should follow the specifications below:

- 473 • Maximum document (i.e., file) name length: 64
- 474 • Maximum folder name length: 64
- 475 • Maximum path length including root folder: 180
  - 476 • *Note: this allows the folder structure to exist under a logical drive with high level*
  - 477 *folder that is applicable to the submitter's environment*
- 478 • File name extension = 3 or 4 characters

479



## 480 **5.2 Top Folder Naming Requirements**

481 To identify the content with a folder structure e.g. on a DVD or after extracting the content from a  
482 container should start on top with a folder named according to the main part of the application  
483 procedure number the regulatory activity relates to, e.g.

- 484 • **de2087** or **uk3456** in case of the MR/DC procedure DE/H/2087/001/MR or  
485 UK/H/3456/001-005/DC,
- 486 • **2131577** in case of a national (German) procedure,
- 487 • **ema000123** in case of the centralized procedure EMEA/H/C/000123 or  
488 EMEA/H/C/000123/II/14.

489

## 490 **5.3 Second Level Folder Naming Requirements**

491 For the second level folder name the unique identifier of the *submissionUnit* element should be  
492 used.

493

494

## 495 **5.4 Pathname Conventions and Best Practices**

496 The pathname convention for EU module 1 will follow the same rules as for ICH modules 2 to 5  
497 required.

498

## 499 **5.5 Folder Hierarchy**

500 Following the naming and pathname conventions above, the actual physical structure of the folder  
501 hierarchy should still follow the EU eCTD v1.4.1. An example is presented in Figure 1.

502

Figure 1: Folder Hierarchy of Module 1 Screenshot



503

*Note: Sub-folders within a folder should not exceed 25 folders and there should be no more than six (6) levels of folders (i.e., nesting greater than 6 levels is not acceptable) within the Second-Level Folder.*

*This allows a cushion before exceeding the limit of 8, as specified by ISO9660. This allows the additional folders that may be needed in the sender or receiver's file directory.<sup>4</sup>*

*\* In these folders the CC- or LL-folder is no longer needed and should therefore not be used. Note: instead, keywords need to be used for country at contextOfUse level. To specify the document type controlled terms will be introduced at document level. Language is included as attribute of the document element.*

504

<sup>4</sup> Note: For testing a light folder structure is expected which will minimize the issue entirely.

505 **5.6 File Formats**

506 In principle, for messages to EU agencies the file format recommendations of ICH M2 need to  
 507 considered. However, in the EU M1 part of the eCTD v4.0 message, the following file formats are  
 508 acceptable:

509 **Table 4: Acceptable file formats for Module 1**

Document	File Format	Remark
Cover letter	PDF	PDF preferably generated from electronic source.
Administrative forms: <ul style="list-style-type: none"> <li>• Application form and its annexes</li> <li>• Variation application form incl. background for the variation</li> <li>• Renewal form and its annexes</li> </ul>	XML*, PDF  XML*, PDF  XML*, PDF	Documents should be generated from electronic source documents, any signature may be embedded as a graphic file in the PDF text if desired, although this is not always necessary as the hard paper copy, if required by the receiving agency, contains the legally binding signature.
Product Information: <ul style="list-style-type: none"> <li>• Product information text**</li> <li>• Packaging mock-ups</li> <li>• Reference to specimens</li> </ul>	PDF  PDF  PDF	If a higher resolution is necessary for the mock-ups, use JPEG, GIF, PNG or SVG on a case-by-case basis.
Other	PDF	PDF preferably generated from electronic source.

510  
 511 \* = In line with the general principles of the ICH eCTD Implementation Guide, it is intended that XML will  
 512 eventually become the sole submission format for administrative forms (as they contain structured data and a  
 513 long-term goal of this development is the normalisation of data in Module 1). Note that as XML documents become  
 514 available for practical implementation (including documents other than the above), they will be introduced into  
 515 Module 1 and the current file formats may ultimately be replaced (after an appropriate transition period).

516  
 517 \*\* = SmPC, Package Leaflet and labelling  
 518

519 **5.7 Checksums**

520 The eCTD XML message will contain checksums for all *Document.text.integrityCheck* elements.  
 521 The SHA-256 integrity check algorithm should be applied to obtain a checksum for all files  
 522 referenced in a document element within a given submission unit. The purpose of the checksum is  
 523 as follows:

- 524 • The integrity of each file can be verified by comparing the checksum submitted with the  
 525 file and the computed checksum
- 526 • The checksum can be used to verify that the file has not been altered in the historical  
 527 archive of the Regulatory Authority. This is especially useful as the files are migrated from  
 528 one storage medium to another as in the case of backup to magnetic tape storage.

529

530 **5.8 Compressed Archive**

531 In order to send the eCTD message over Eudralink the entire message has to be zipped first. Some  
532 zip formats are not widely readable and therefore a submission could be rejected if the zipped  
533 format cannot be read by the agency. If in doubt, please check the intended format with the  
534 agency before sending. Please note there is a size limit of 80 MB per file. It is not possible to split  
535 an eCTD sequence. Therefore submission of an initial submission is not recommended over  
536 Eudralink as the file size will be usually over 80 MB.

537 **5.8.1 Eudralink/e-Mail (where applicable)**

538 EMA does not accept Eudralink submissions, except where specified for the provision of the  
539 annexes.

540 When using Eudralink, it is important that the expiry date is set to the maximum of 90 days to  
541 ensure that it can be opened during the process at the receiving authority. In addition, all  
542 information relating to the submission must be contained within the zipped sequence; no formal  
543 information should be included in the body of the Eudralink message.

544 Please note, in order to re-obtain the correct eCTD structure, unpack or extract the zip-file and  
545 save the content on your local path system. Otherwise the eCTD structure is not displayed in the  
546 correct way. When using Eudralink, some NCAs require an additional copy on hard media, check  
547 individual NCA web sites for details.

548 **5.8.2 Portals**

549 Generally small (<80MB) applications can be uploaded faster than huge submissions depending  
550 from the available bandwidth or other technical restrictions. Applicants should check with  
551 individual agencies for details of this process. If submissions are uploaded via a portal no data  
552 corruption should occur as a result of the process.

553 **5.8.3 CD/DVD**

554 Applicants should provide the electronic information on the smallest number of discs possible,  
555 taking into consideration the size of the submission.

556 Zipped files should not be used when sending CDs or DVDs.

557 If an individual eCTD submission is of such a size as to span several CDs, the provision of a DVD  
558 is recommended. However, if CD-R must be used, when large applications are submitted it is  
559 inevitable that the application will necessarily span multiple CDs. Where possible, individual  
560 modules should not be split over multiple CDs (e.g. if possible, a single CD should contain  
561 Module 1, Module 2, if too large to fit on the same CD should then go onto the next CD even if  
562 this requires CD 1 not to be filled to capacity and so on). If, in the case of larger modules, where a  
563 split over multiple CDs is inevitably necessary, subfolders should be distributed in sequence, and  
564 these subfolders should not be split between CDs, even if this requires a CD to be sent not full to  
565 capacity.

566 Submissions for workshare/grouping variations concerning several eCTD submissions are  
567 recommended to be supplied together on a single CD/DVD. The way how a submission unit will  
568 be assigned to relevant applications is explained in section 9.2.3 in this document.

569

570

## 571 6. CONTROLLED VOCABULARIES

572 As mentioned in Section 4.2, there is extensive use of controlled vocabularies in the execution of  
573 an eCTD v4.0 message. The information in the following sub-sections will outline the controlled  
574 vocabulary used in developing an eCTD v4.0 message. There are several different authoritative  
575 sources for the controlled vocabularies, and as such they are categorized below by the  
576 organization that controls the content. The ICH eCTD v4.0 specific terminology – i.e., the  
577 controlled vocabulary determined by ICH are stated in the ICH Implementation Guide.



*Note 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 Regulatory Authorities.*

*Note to Implementers: During Step 2 for Testing, the controlled vocabulary will be provided in a spreadsheet format (ICH and EU) but have been included in section 6.1 in this document (EU regional) for convenience.*

578

### 579 6.1 Controlled Vocabularies for EU Purpose

580 The controlled vocabularies specified for the EU M1 part of the eCTD v4.0 message are provided  
581 below with a brief description of the terminology and location for obtaining detailed information.

582

#### 583 6.1.1 EU M1 eCTD – Context of Use Codes

- 584 • This table will specify the code set for the Context of Use values that will mirror the  
585 headings found in the CTD structure for EU Module 1.

Code	eCTD Element in EU Module 1	
eu-m1-1	m1-eu	Not for document reference
eu-m1-0	<a href="#">m1-0-cover</a>	
eu-m1-2	<a href="#">m1-2-form</a>	
eu-m1-3	m1-3-pi	Not for document reference
eu-m1-3-1	<a href="#">m1-3-1-spc-label-pl</a>	
eu-m1-3-2	<a href="#">m1-3-2-mockup</a>	
eu-m1-3-3	<a href="#">m1-3-3-specimen</a>	
eu-m1-3-4	<a href="#">m1-3-4-consultation</a>	
eu-m1-3-5	<a href="#">m1-3-5-approved</a>	
eu-m1-3-6	<a href="#">m1-3-6-braille</a>	
eu-m1-4	<a href="#">m1-4-expert</a>	Not for document reference
eu-m1-4-1	<a href="#">m1-4-1-quality</a>	
eu-m1-4-2	<a href="#">m1-4-2-non-clinical</a>	
eu-m1-4-3	<a href="#">m1-4-3-clinical</a>	
eu-m1-5	<a href="#">m1-5-specific</a>	Not for document reference

eu-m1-5-1	m1-5-1-bibliographic	
eu-m1-5-2	m1-5-2-generic-hybrid-bio-similar	
eu-m1-5-3	m1-5-3-data-market-exclusivity	
eu-m1-5-4	m1-5-4-exceptional-circumstances	
eu-m1-5-5	m1-5-5-conditional-ma	
eu-m1-6	m1-6-environrisk	Not for document reference
eu-m1-6-1	m1-6-1-non-gmo	
eu-m1-6-2	m1-6-2-gmo	
eu-m1-7	m1-7-orphan	Not for document reference
eu-m1-7-1	m1-7-1-similarity	
eu-m1-7-2	m1-7-2-market-exclusivity	
eu-m1-8	m1-8-pharmacovigilance	Not for document reference
eu-m1-8-1	m1-8-1-pharmacovigilance-system	
eu-m1-8-2	m1-8-2-risk-management-system	
eu-m1-9	m1-9-clinical-trials	
eu-m1-10	m1-10-paediatrics	
eu-m1-resp	m1-responses	
eu-m1-add	m1-additional-data	
eu-m1-asmnt	m1-assessments	

586 •

587

### 588 6.1.2 EU M1 eCTD – Keyword Codes

589 • Keywords need be used to support a reader friendly presentation of content within the  
590 same context of use either by sender defined *keywordDefinition* or using a controlled  
591 vocabulary, e.g. for document type, language, country. In EU Module 1 for documents in  
592 “10-cover”, “12-form”, “13-pi”, “additional-data”, and “responses” the use of keywords for  
593 country code is required (see Section 6.3). Depending from the product, additional sender  
594 defined keywords can be used to specify the pharmaceutical form or strength a product  
595 information text is dedicated for. These user defined keywords can be used for Module 3  
596 purpose at the same time.

597 • Note: The previously required language folder in “13-pi” will be replaced by  
598 documentLanguage.code (see: Section 9.7)

599

600

### 601 6.1.3 Application Codes



Source at EUTCT domain 100000000012

Application Code	Description
100000116046	Full dossier acc. Art 8.3(i) Dir. 2001/83/EC
100000116047	New active substance (Article 8(3) of Directive No 2001/83/EC)

100000116048	Known active substance (Article 8(3) of Directive No 2001/83/EC)
100000116049	Generic, hybrid or similar biological application (Article 10 of Directive No 2001/83/EC)
100000116055	Informed consent acc. Art 10c Dir. 2001/83/EC
100000116053	Bibliographic acc. Art 10 a Dir. 2001/83/EC
100000116054	Fixed combination acc. Art 10 b Dir. 2001/83/EC
100000116050	Generic acc. Art 10.1 Dir. 2001/83/EC
100000116051	Other (hybrid) generic acc. Art 10.3 Dir. 2001/83/EC
100000116052	Generic biological acc. Art 10.4 Dir. 2001/83/EC
100000116056	Traditional use registration for herbal medicinal product acc. Art 16a Dir. 2001/83/EC

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603

#### 604 6.1.4 Application Reference Reason Codes



Source at EUTCT TBD

Code	Description
Exp	Reference medicinal product chosen for the purposes of establishing the expiry of the data protection period
BE	Reference medicinal product chosen for the demonstration of bioequivalence

605

606

#### 607 6.1.5 Category Event Codes



*This class will not be used in EU M1 eCTD v4.0 message.*

608

609

#### 610 6.1.6 Contact Party Codes



Source at EUTCT TBD.

Code	Description
2.4.1	Proposed marketing authorization holder/person legally responsible for placing the product on the market
2.4.2	Person/company authorized for communication on behalf of the applicant during the procedure

2.4.3	Person/Company authorized for communication between the marketing authorization holder and the competent authorities after authorization
2.4.4	Qualified person in the EEA for Pharmacovigilance
2.4.5	Service of the MAH in the EEA as referred to in Article 98 of Directive 2001/83/EC

611

612 **6.1.7 DocumentType Codes**



*Source at EUTCT TBD.*

Code	Description
smpc	Summary of Product Characteristics
annex2,	Annex 2 to specify all presentations
outer	Labelling of the outer package
interpack	Labelling of an intermediate part of the packaging
impack	Labelling of the immediate packaging including the blister
pl	Package Leaflet
other	Other labeling text document
combined	Any of combined labeling texts

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615 **6.1.8 Mode Codes**



*Source at EUTCT TBD.*

Code	Description
single	a single regulatory activity (e.g. a Type II variation)
grouped	grouped activity (e.g. several variations grouped into a single submission or a periodic report of type IA variations applicable to one or more marketing authorizations),
workshare	activity subject to a worksharing agreement (e.g. a Type II variation applicable to more than one marketing authorization)

616

617



**6.1.9 Place Codes**

Source at EUTCT TBD

Code	Description
AT	Austria
BE	Belgium
BG	Bulgaria
CY	Cyprus
CZ	Czech Republic-
DK	Denmark
EE	Estonia
EU	European Union
FI	Finland
FR	France
DE	Germany
EL	Greece
HU	Hungary
IS	Iceland
IE	Ireland
IT	Italy
LV	Latvia
LI	Liechtenstein
LT	Lithuania
LU	Luxembourg
MT	Malta
NL	Netherlands
NO	Norway
PL	Poland
PT	Portugal
RO	Romania
SK	Slovak Republic
SI	Slovenia
ES	Spain
SE	Sweden
UK	United Kingdom

621 **6.1.10 Product Category Codes**



Source at EUTCT TBD..

Code	Description
chemical	Medicinal product containing chemical substance, e.g. elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis
immunological	Immunological medicinal product: Any medicinal product consisting of vaccines, toxins, serums or allergen products
herbal	Herbal medicinal product: Any medicinal product, exclusively containing as active ingredients one or more herbal substances or one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations
blood	Medicinal products derived from human blood or human plasma: Medicinal products based on blood constituents which are prepared industrially by public or private establishments, such medicinal products including, in particular, albumin, coagulating factors and immunoglobulins of human origin.
Advanced	Advanced therapy medicinal product: A product as defined in Article 2 of Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products
homeopathic	Homeopathic medicinal product: Any medicinal product prepared from substances called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias currently used officially in the Member States. A homeopathic medicinal product may contain a number of principles.
Radiopharm	Radiopharmaceutical: Any medicinal product which, when ready for use, contains one or more radionuclides (radioactive isotopes) included for a medicinal purpose. For the purpose here radionuclide generators, kits, and radionuclide precursors will be included.
Traditional	Traditional herbal medicinal product: A herbal medicinal product that fulfils the conditions laid down in Article 16a(1).

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**6.1.11 Regulatory Status Codes<sup>5</sup>***Source at EUTCT domain 100000000012.*

Status Code	Description
100000072097	Application for Marketing Authorisation received.
100000072099	Application for Marketing Authorisation approved.
100000072110	Application for Marketing Authorisation not accepted before evaluation.
100000072112	Renewal application rejected by the Regulatory Authority after evaluation.
100000072123	The marketing Authorisation expired due to the end of the sunset clause time period i.e. it is no longer valid as the medicinal product was not placed on the market for 3 years.
100000072100	Renewal application not received.
100000072111	Application for Marketing Authorisation rejected by the Regulatory Authority after evaluation.
100000072098	Application withdrawn by applicant before Marketing Authorisation
100000072113	Withdrawn after Marketing Authorisation by Marketing Authorisation Holder
100000072114	Withdrawn after Marketing Authorisation – unspecified.
100000072121	Withdrawn after Marketing Authorisation by the Regulatory Authority.
100000072122	Marketing Authorization suspended means the marketing authorization is still valid but the medicinal product must not , for some reason , be placed on the market, in the meantime.

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**6.1.12 Regulatory Review Time codes***Note: During testing period experience need to be gained to evaluate the need of this element.*

Code	Description
30	30-day time scale for review, e.g. the reduced time in case of type II variations
60	60-day time scale for review, e.g. the normal time in case of type II variations
90	90-day time scale for review, e.g. the extended time in case of type II variations
210	210-day time scale for review, e.g. the normal time in case of new marketing application via DCP

<sup>5</sup> The currently defined values will not mirror any status before a final decision on an application. Therefore, it is considered to update the list to support two way communication sufficiently.

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630

631 **6.1.13 Review Procedure Codes**

Source at EUTCT TBD.

Procedure Code	Description
01	Centralised Procedure
02	Decentralised Procedure
03	Mutual Recognition Procedure
04	National Procedure e

632

633

634 **6.1.14 Submission Codes**

Source at EUTCT TBD.

Submission Code	Description
maa	Initial Marketing Authorisation Application
var-type1a	Variation Type IA
var-type1b	Variation Type IB
var-type2	Variation Type II
var-nat	National variation (e.g. national variation to apply for a pack size that is already registered within an existing MRP/DCP authorization)
extension	Extension
psur	Periodic Safety Update Report (PSUR)
renewal	Renewal (yearly or 5-yearly)
fum	Follow-Up Measure (includes post-approval commitments for national Mas)
specific-obligation	Specific Obligation
asmf	Active Substance Master File
pmf	Plasma Master File
referral	Referral under Article 29, 30, 31, 35 or 36
annual-reassessment	Annual Reassessment
usr	Urgent Safety Restriction
paed-article-29	Paediatric submission, Article 29

paed-article-46	Paediatric submission, Article 46
article-58	Article 58 (to be used for an initial application)
notification-61-3	Notification 61(3)
transfer-ma	Transfer of a marketing authorisation
lifting-suspension	Lifting of a suspension
withdrawal	Withdrawal during assessment or withdrawal of a marketing authorisation
reformat	Intended to support the reformatting of an existing submission dossier from any format to eCTD, i.e. a baseline eCTD submission containing no content change and which will not be subject to review

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636

637 **6.1.15 Submission Unit Codes**



Source at EUTCT TBD..

638 ***Applicant's submission unit types***

Code	Description
initial	Initial submission to start a regulatory activity
supplemental-info	Supplemental Information (could include, for example, response to validation issues)
RespToLoQ	Applicants response to List of Questions
RespToLoI	Applicants response to List of out-standing Issues
corrigendum	Correction to the published annexes (usually shortly after approval)

639

640 ***Regulating Authority's submission unit types***

Code	Description
LoQ	List of questions
LoI	List of out-standing issues
AuthorLetter	Authorisation letter
ConfirmReceipt	Confirmation of receipt
PrAR	Preliminary Assessment Report
DAR	Draft Assessment Report
FAR	Final Assessment Report
PrVAR	Preliminary Variation Assessment Report
FVAR	Variation Assessment Report
PrRAR	Preliminary Renewal Assessment Report
FRAR	Renewal Assessment Report

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643 **6.1.16 Territorial Authority Codes**

*Source at EUTCT TBD.*

<b>Code</b>	<b>Description</b>
AT-AGES	Austria - BASG-Federal Office for Safety in Health Care (AGES-PharmMed LCM)
BE-FAMHP	Belgium - Agence Fédérale des Médicaments et des Produits de Santé
BG-BDA	Bulgaria - Bulgarian Drug Agency
CY-VS	Cyprus - Ministry of Health Pharmaceutical Services
CZ-SUKL	Czech Rep - State Institute for Drug Control
DK-DKMA	Denmark - Danish Medicines Agency
EE-SAM	Estonia -State Agency of Medicines
EU-EMA	EMA -European Medicines Agency
FI-NAM	Finland -National Agency for Medicines
FR-AFSSAPS	France - AFSSAPS - Agence Française de Sécurité Sanitaire des Produits de Santé
DE-BFARM	Germany - BfArM -Bundesinstitut für Arzneimittel und Medizinprodukte
DE-PEI	Germany - Paul-Ehrlich Institut
EL-EOF	Greece - EOF - National Drug Organisation
HU-OGYI	Hungary - National Institute of Pharmacy
IS-IMCA	Iceland - Icelandic Medicines Control Agency
IE-IMB	Ireland - Irish Medicines Board
IT-AIFA	Italy - Agenzia Italiana del Farmaco
IT-SPV	Italy - Ministero della Salute, Direzione Generale della Sanità Pubblica Veterinaria
LV-ZVA	Latvia - State Agency of Medicines
LI-LLV	Liechtenstein -Kontrollstelle für Arzneimittel beim Amt für Lebensmittelkontrolle und Veterinärwesen
LT-SMCA	Lithuania - State Medicines Control Agency
LU-MINSANT	Luxembourg - Direction de la Santé Villa Louvigny Division de la Pharmacie et des Médicaments
MT-MEDAUTH	Malta - Medicines Authority Divizjoni Tas-Sahha Bezzjoni Ghar-Regolazzjoni Tal-Medicini
NL-MEB	Netherlands - College ter Beoordeling van Geneesmiddelen Medicines Evaluation Board
NO-NOMA	Norway - The Norwegian Medicines Agency
PL-URPL	Poland - Office for Registration of Medicinal Products, Medical Devices and Biocidal Products
PT-INFARMED	Portugal - INFARMED - Instituto Nacional da Farmácia e do Medicamento Parque da Saúde de Lisboa
RO-ANM	Romania - National Medicines Agency
SK-SIDC	Slovak Rep -State Institute for Drug Control
SI-JAZMP	Slovenia - Agencija za zdravila in medicinske pripomočke
ES-AGEMED	Spain – Agencia Española de Medicamentos y Productos Sanitarios
SE-MPA	Sweden -Medical Products Agency

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## 6.2 Controlled Vocabulary specified by HL7

The controlled vocabularies specified by Health Level 7 (HL7) will apply for EU M1 in the same way as for Module 2 to 5.

## 6.3 Controlled Vocabulary specified by Others

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

- **International Organization 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. For EU M1 purposes a constrained list will be used (see EUTCT).
- **ISO Country Code – Two-letter Country Code:** This is the country code that is specified in the ISO 3166-1 standard. For EU M1 purposes a constrained list will be used (see section 6.1.9).
- Health informatics – Identification of Medicinal Products – Structures and Controlled Vocabularies for *Ingredients (Substances)* (prEN ISO 11238)

## 6.4 Maintenance of Controlled Vocabularies

International vocabulary harmonization 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 ICH Controlled Vocabularies will be handled by the M2 Working Group.

All other controlled vocabularies will be handled by EUTCT for the purpose of EU M1 use.

676 **7. ECTD v4.0 XML SCHEMA**

677 There are no principles for using the EU part of the XML schema deviating from the ICH  
678 Implementation Guide.

679

680

681 **8. ECTD 4.0 XML MESSAGE**

682 There are no principles for creating the EU part of the XML message deviating from the ICH  
683 Implementation Guide. Nevertheless, additional regional specific requirements need to be  
684 considered as outlined below.

DRAFT



Table 5: XML Structure- Submission Unit

XML Structure	
<p>The eCTD begins by identifying the <b>subject</b> element of the XML message. The payload message starts with the <b>SubmissionUnit</b> element and relates the rest of the elements to the Submission Unit being sent. The <b>SubmissionUnit</b> element contains the following elements and their attributes:</p> <ul style="list-style-type: none"> <li>• <b>callbackContact.ContactParty</b> ←</li> <li>• <b>subject.CategoryEvent</b> <ul style="list-style-type: none"> <li>○ <b>subject.CategoryEvent (sub-category)</b></li> </ul> </li> <li>• <b>component.contextOfUse</b> ←           <ul style="list-style-type: none"> <li>○ <b>links.relatedContextOfUse</b></li> <li>○ <b>sequelTo.relatedContextOfUse</b></li> <li>○ <b>derivedFrom.documentReference</b> ←</li> <li>○ <b>subjectOf.submissionReference</b></li> <li>○ <b>referencedBy.keyword</b></li> </ul> </li> <li>• <b>componentOf.Submisison</b> ←</li> </ul>	
<div style="border: 1px solid black; border-radius: 10px; padding: 5px; display: inline-block;">Mandatory elements in the message</div>	
<pre> &lt;subject typeCode="SUBJ"&gt;   &lt;submissionUnit&gt;     &lt;id&gt;&lt;/id&gt;     &lt;code&gt;&lt;/code&gt;     &lt;title&gt;&lt;/title&gt;     &lt;statusCode&gt;&lt;/statusCode&gt;     &lt;callbackContact&gt;       &lt;contactParty&gt;         &lt;id&gt;&lt;/id&gt;         &lt;statusCode&gt;&lt;/statusCode&gt;         &lt;contactPerson&gt;           &lt;name xsi:type="BAG_EN"&gt;             &lt;item&gt;&lt;part/&gt;&lt;/item&gt;           &lt;/name&gt;           &lt;telecom xsi:type="BAG_TEL"&gt;             &lt;item&gt;&lt;/item&gt;           &lt;/telecom&gt;         &lt;/contactPerson&gt;       &lt;/contactParty&gt;     &lt;/callbackContact&gt;     &lt;subject&gt;       &lt;categoryEvent&gt;         &lt;code&gt;&lt;/code&gt;         &lt;subject&gt;           &lt;categoryEvent&gt;             &lt;code&gt;&lt;/code&gt;           &lt;/categoryEvent&gt;         &lt;/subject&gt;       &lt;/categoryEvent&gt;     &lt;/subject&gt;   &lt;/submissionUnit&gt; &lt;/subject&gt;           </pre>	<div style="border: 1px solid black; border-radius: 10px; padding: 5px; margin-bottom: 20px;"> <p><b>submissionUnit ( Section 9.24)</b>  <u>Note: complementary content is provided in the ICH Implementation Guide</u></p> </div> <div style="border: 1px solid black; border-radius: 10px; padding: 5px; margin-bottom: 20px;"> <p><b>callbackContact (Section 9.5)</b></p> </div> <div style="border: 1px solid black; border-radius: 10px; padding: 5px;"> <p><b>subject.CategoryEvent</b>  <u>Note: This will not be used in the EU</u></p> </div>

## XML Structure

```

<component>
  <priorityNumber value=""/>
  <contextOfUse>
    <id></id>
    <code></code>
    <title></title>
    <statusCode></statusCode>
    <setId></setId>
    <versionNumber value=""/>
    <primaryInformationRecipient>
      <territorialAuthority>
        <governingAuthority>
          </governingAuthority>
        </territorialAuthority>
      </primaryInformationRecipient>
    <links typeCode="ELNK">
      <relatedContextOfUse>
        <id></id>
      </relatedContextOfUse>
    </links>
    <sequelTo typeCode="RPLC">
      <relatedContextOfUse>
        <id></id>
      </relatedContextOfUse>
    </sequelTo>
    <derivedFrom>
      <documentReference>
        <id></id>
      </documentReference>
    </derivedFrom>
    <subjectOf negationInd="">
      <submissionReference>
        <id xsi:type="DSET_II">
          <item></item>
        </id>
      </submissionReference>
    </subjectOf>
    <referencedBy>
      <keyword>
        <code></code>
        <statusCode></statusCode>
      </keyword>
    </referencedBy>
  </contextOfUse>
</component>

```

### *contextOfUse (Section 9.6)*

Note: Complementary content is provided in ICH Implementation Guide

### *primaryInformationRecipient.territorialAuthority (Section 9.25)*

### *links.relatedContextOfUse (Section 9.17)*

### *sequelTo.relatedContextOfUse (Section 9.7)*

Note: Complementary content is provided in ICH Implementation Guide

### *derivedFrom.documentReference (Section 9.8)*

Note: Complementary content is provided in ICH Implementation Guide

### *submissionReference (Section 9.23)*

### *Keyword (Section 9.9)*

Note: Complementary content is provided in ICH Implementation Guide

Table 6: XML Structure - Submission

XML Structure	
<p>This section of the XML relates to specifying the <b>Submission</b> element. The following elements may follow the Submission:</p> <ul style="list-style-type: none"> <li>• <b>sequenceNumber</b> (included as an element of the relationship between SubmissionUnit and Submission)</li> <li>• <b>callbackContact.ContactParty</b></li> <li>• <b>subject1.mode</b></li> <li>• <b>subject2.review</b></li> <li>• <b>subject3.regulatoryReviewTime</b></li> <li>• <b>subject4.regulatoryStatus</b></li> <li>• <b>subject5.submissionGroup</b></li> </ul>	
<div style="border: 1px solid black; border-radius: 10px; padding: 5px; display: inline-block;">Mandatory elements in the message</div>	
<pre> &lt;componentOf&gt;   &lt;sequenceNumber&gt;&lt;/sequenceNumber&gt;   &lt;submission&gt;     &lt;id&gt;&lt;/id&gt;     &lt;code&gt;&lt;/code&gt;     &lt;callbackContact&gt;       &lt;contactParty&gt;         &lt;id&gt;&lt;/id&gt;       &lt;/contactParty&gt;     &lt;/callbackContact&gt;     &lt;subject1&gt;       &lt;mode&gt;         &lt;id&gt;&lt;/id&gt;       &lt;/mode&gt;     &lt;/subject1&gt;     &lt;subject2&gt;       &lt;review&gt;         &lt;/review&gt;       &lt;/subject2&gt;     &lt;subject3&gt;       &lt;regulatoryReviewTime&gt;         &lt;code&gt;&lt;/code&gt;       &lt;/regulatoryReviewTime&gt;     &lt;/subject3&gt;     &lt;subject4&gt;       &lt;regulatoryStatus&gt;         &lt;code&gt;&lt;/code&gt;       &lt;/regulatoryStatus&gt;     &lt;/subject4&gt;     &lt;subject5&gt;       &lt;submissionGroup&gt;         &lt;id&gt;&lt;/id&gt;       &lt;/submissionGroup&gt;     &lt;/subject5&gt;   &lt;/submission&gt; &lt;/componentOf&gt; </pre>	<div style="display: flex; flex-direction: column; gap: 10px;"> <div style="border: 1px solid black; border-radius: 10px; padding: 5px; width: fit-content;">sequenceNumber.submission (Section 9 20)</div> <div style="border: 1px solid black; border-radius: 10px; padding: 5px; width: fit-content;">           submission (Section 9.5)  <u>Note: Complementary content is provided in ICH Implementation Guide</u> </div> <div style="border: 1px solid black; border-radius: 10px; padding: 5px; width: fit-content;">callbackContact (Section 9 5)</div> <div style="border: 1px solid black; border-radius: 10px; padding: 5px; width: fit-content;">mode (Section 9.12)</div> <div style="border: 1px solid black; border-radius: 10px; padding: 5px; width: fit-content;">review (Section 9 19)</div> <div style="border: 1px solid black; border-radius: 10px; padding: 5px; width: fit-content;">regulatoryReviewTime (Section 9 15)</div> <div style="border: 1px solid black; border-radius: 10px; padding: 5px; width: fit-content;">regulatoryStatus (Section 9 16)</div> <div style="border: 1px solid black; border-radius: 10px; padding: 5px; width: fit-content;">submissionGroup (Section 9.22)</div> </div>

**Table 7: XML Structure - Application**

XML Structure	
<p>This section of the XML relates to the <b>Application</b> element. The application section contains the following elements and their attributes:</p>	
<p>holder.applicant ←                  informationRecipient.territorialAuthority ←                  subject.ReviewProcedure ←                  reference.applicationReference ←                  component.document ←</p> <p>component.priorityNumberdocument                  referencedBy.keyword                  referencedBy.keywordDefinition                  replacementOf.previousKeywordDefinition</p>	<div style="border: 1px solid black; border-radius: 10px; padding: 5px; display: inline-block;"> <i>Mandatory elements in the message</i> </div>
<pre>                 &lt;componentOf&gt;                   &lt;application&gt;                     &lt;id&gt;                       &lt;item root="" extension=""/&gt;                     &lt;/id&gt;                     &lt;code&gt;&lt;/code&gt;                     &lt;holder&gt;                       &lt;applicant&gt;&lt;/applicant&gt;                     &lt;/holder&gt;                     &lt;informationRecipient&gt;                       &lt;territorialAuthority&gt;                         &lt;governingAuthority&gt;                           &lt;id&gt;&lt;/id&gt;                           &lt;name&gt;                             &lt;part value=""/&gt;                           &lt;/name&gt;                         &lt;/governingAuthority&gt;                       &lt;/territorialAuthority&gt;                     &lt;/informationRecipient&gt;                     &lt;subject&gt;                       &lt;reviewProcedure&gt;                         &lt;code&gt;&lt;/code&gt;                       &lt;/reviewProcedure&gt;                     &lt;/subject&gt;                     &lt;reference&gt;                       &lt;applicationReference&gt;                         &lt;id&gt;&lt;/id&gt;                       &lt;/applicationReference&gt;                     &lt;/reference&gt;                 </pre>	<div style="border: 1px solid black; border-radius: 10px; padding: 5px; margin-bottom: 10px;"> <i>application (Section 9.2)</i>                      Note: Complementary content is provided in ICH Implementation Guide                 </div> <div style="border: 1px solid black; border-radius: 10px; padding: 5px; margin-bottom: 10px;"> <i>holder.applicant (Section 9.1)</i> </div> <div style="border: 1px solid black; border-radius: 10px; padding: 5px; margin-bottom: 10px;"> <i>informationRecipient.territorial Authority (Section 9.27)</i> </div> <div style="border: 1px solid black; border-radius: 10px; padding: 5px; margin-bottom: 10px;"> <i>reviewProcedure(Section 9.20)</i> </div> <div style="border: 1px solid black; border-radius: 10px; padding: 5px;"> <i>applicationReference (Section 9.3)</i> </div>

## XML Structure

**document (Section 9.7)**

Note: Complementary content is provided in ICH Implementation Guide

**priorityNumber.document (Section 9.7)**

Note: Complementary content is provided in ICH Implementation Guide

**keyword (Section 9.9)**

Note: Complementary content is provided in ICH Implementation Guide

**keywordDefinition (Section 9.10)**

Note: Complementary content is provided in ICH Implementation Guide

**previousKeywordDefinition (Section 9.13)**

Note: Complementary content is provided in ICH Implementation Guide

```

<component>
  <document>
    <id></id>
    <code></code>
    <title></title>
    <text integrityCheckAlgorithm="SHA256" value=""
      language="">
      <reference value=""/>
    </text>
    <integrityCheck></integrityCheck>
    <statusCode></statusCode>
    <versionNumber value=""/>
    <component>
      <priorityNumber value=""/>
      <document>
        <id></id>
      </document>
    </component>
    <referencedBy>
      <keyword>
        <code></code>
        <statusCode></statusCode>
      </keyword>
    </referencedBy>
  </document>
</component>
<referencedBy>
  <keywordDefinition>
    <code></code>
    <statusCode></statusCode>
    <value >
      <item>
        <displayName></displayName>
      </item>
    </value>
    <replacementOf>
      <previousKeywordDefinition>
        <code></code>
        <value >
          <item>
            <displayName></displayName>
          </item>
        </value>
      </previousKeywordDefinition>
    </replacementOf>
  </keywordDefinition>
</referencedBy>

```

XML Structure
These are the closing element tags for the key elements in the eCTD v4.0 message.
<pre> &lt;/application&gt;   &lt;/componentOf&gt;     &lt;/submission&gt;       &lt;/componentOf &gt;         &lt;/submissionUnit&gt; </pre>

690

691

692 **9. EU REGIONAL SPECIFIC REQUIREMENTS FOR ELEMENTS**

693

694 **9.1 Applicant**

695 The Applicant element is presenting the role of the sponsor of the initiation of a marketing  
 696 authorization application and is mentioned in relation to *Application* and to *Review* as well. For  
 697 EU M1 participation related to *Application* is to be used only.

698 **Description**

699 The *Applicant* element provides the name of the organization of the applicant.

700 **Location in XML**

701 The *Applicant* element follows the *Holder* element, which follows directly after the *Application*  
 702 elements.

703 **XML details**

704 The following is an example of the XML for the applicant information. The applicant enters as a  
 705 *holder* element between *Submission* and *Application*.

```

706     <holder>
707         <applicant>
708             <sponsorOrganization>
709                 <name xsi:type="BAG_EN">
710                     <item>
711                         <!--Code - 123456789 is the DUNS Number for the company Name-->
712                         <part value="Good Drugs" code="123456789" codeSystemVersion="OID for
713 DUNandBradstreet"/>
714                     </item>
715                 </name>
716             </sponsorOrganization>
717         </applicant>
718     </holder>

```

719 ...

720



See [XML Color Legend](#) for color usage

## 721 **XML Elements**



*Note: The explanation will be provided in one of the future versions*



*The **classCode** is fixed to “SPNSR”. This value is not required in the XML message.*

722

723

## 724 **9.2 Application**

725 The Application element is presented also in the ICH Implementation Guide as it is the connection  
726 point for the **Document** and **keywordDefinition** elements in the XML message.



*Note: Application is primarily a Module 1 concept. Only complementary information is provided in the ICH Implementation Guide.*

727

## 728 **Description**

729 The Application element represents a request from Regulated Industry to a Regulatory Authority  
730 for the approval to market a medicinal product for human use. The application in this context  
731 typically will cover all dosage forms and strengths of a product. In the centralized procedure, this  
732 will be equivalent to all dosage forms and strengths covered by an EMA application number (e.g.  
733 EMEA/H/C/000123). In MRP/DCP, a single eCTD application should preferably be used for the  
734 procedure (e.g. DE/H/2087/001-sss/DC or MR). However if an applicant decides not to apply for  
735 all strengths and dosage forms in every member state in the procedure, the possibility of having  
736 one eCTD application per strength/dosage form should be considered. The RPS standard used for  
737 eCTD v4.0 provides the opportunity to refer across applications. However, it is not allowed to  
738 make use of this option for the initial submission unit applying for a marketing authorization.  
739 Submissions and submission units for regulatory activities after this initial one may refer to  
740 several applications at the same time.

741 An application will consist over time of multiple submissions or regulatory activities (e.g., initial  
742 marketing authorization application, variations or PSURs). For example a marketing application  
743 may consist of one or more regulatory decisions - e.g., the collection of all approvals is related to  
744 the application. Each regulatory submission (for details refer to section 6.2. controlled vocabulary  
745 of submission types) will have its own regulatory action, and most likely will be composed of one  
746 or more submission units.

747 **Location in XML**

748 The *Application* element follows the *componentOf* element, which follows directly after the  
749 *Submission* elements.

750 **XML details**

751 The following is an example of the XML for the application information. The application enters  
752 as a *componentOf* element between *Submission* and *Application*.

```
753 ...  
754 [This XML section will repeat for each Application element. A Submission element is a componentOf an  
755 Application element]  
756 ...  
757 <componentOf>  
758 <application>  
759 <id>  
760 <item root="12345678-1234-1234-1234-123456789012" extension="987654"/>  
761 ...  
762 <!--Additional item elements can be added here-->  
763 ...  
764 </id>  
765 <code code="100000116046" codeSystem="100000000012"/>  
766 ...  
767 [Additional information may appear after the addition of the Application.code, for  
768 example any of the following elements related to Application – component,  
769 referencedBy, informationRecipient, reference, subject, or holder]  
770 ...  
771 </application>  
772 </componentOf>
```

774 Remark: The id@root will never change as it serves as identifier of the application at all time.



775 See [XML Color Legend](#) for color usage

776

777 **XML Elements**

778 Tables with a complete set of XML elements and attributes required for the *Application* element  
779 are provided in the ICH IG and will not being repeated here. For EU M1 no additional  
780 requirements apply.

781 **Terminology**

782 The controlled terminology for the Application element includes codes for the type of application  
783 (e.g. Full Dossier, Bibliographic, Biosimilar, Generic) (refer to section 6.1.3).

784



785

### 786 **9.3 Application Reference**

787 The *applicationReference* element is presenting the type of reference in specific application  
788 types, e.g. generic products.

#### 789 **Description**

790 The *applicationReference* element provides information whether a reference to an already  
791 authorized medicinal product is used, e.g. in case of a generic product.

#### 792 **Location in XML**

793 The *applicationReference* element follows the *Application* element, which follows directly after  
794 the *Submission* elements.

#### 795 **XML details**

796 The following is an example of the XML for the application reference information.

```
797 ...  
798 <reference>  
799   <!--Reference to an originator product-->  
800   <applicationReference>  
801     <id root=" 5.993452.56789.12345" extension=" ema002156-001"/>  
802     <reasonCode xsi:type="DSET_CD">  
803       <item code="Code for Application Reference Codes" codeSystem="OID for EU Application  
804 Reference Codes"/>  
805     </reasonCode>  
806   </applicationReference>  
807 </reference>  
808
```

809



See [XML Color Legend](#) for color usage

#### 810 **XML Elements**

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



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

813

814 **ApplicationReference.id**

815

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
<i>id</i>		[1..1]		This is a container element of the following attributes by which it uniquely identifies the application being referenced.
	<i>root</i>	[1..1]	Valid OID or UUID	This attribute is for a global unique identifier.
<i>Conformance</i>	The <i>id</i> is a required element			
<i>Business Rules</i>	This element must be used in case of generic products or the application is submitted by informed consent.			
<i>Excluded Elements and Attributes</i>	The following attributes are not required by eCTD 4.0: <ul style="list-style-type: none"> <li>• <i>id@identifierName</i></li> <li>• <i>id@scope</i></li> <li>• <i>id@reliability</i></li> <li>• <i>id@displayable</i></li> </ul>			

816

817 **ApplicationReference.reasoncode**

818

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
<i>code</i>		[1..1]		This code is related to the reason why reference can be made..
	<i>code</i>	[1..1]		

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
	<i>codeSystem</i>	[1..1]	Valid OID or UUID	The codeSystem is a unique identifier that indicates the controlled vocabulary system  <i>This should be the OID or UUID registered for the code system.</i>
<i>Conformance</i>	The <i>id</i> is a required element			
<i>Business Rules</i>	Only if reference is made the reason code is mandatory.			
<i>Excluded Elements and Attributes</i>	The following attributes are not required by eCTD 4.0: <ul style="list-style-type: none"> <li>• <i>code@codeSystemName</i></li> <li>• <i>code@codeSystemVersion</i></li> <li>• <i>code@valueSet</i></li> <li>• <i>code@valueSetVersion</i></li> <li>• <i>code@displayName</i></li> <li>• <i>code@originalText</i></li> <li>• <i>code@codingRationale</i></li> <li>• <i>code@translation</i></li> <li>• <i>code@source</i></li> </ul>			

819

## 820 **Terminology**

821 The *applicationReference.reasonCode* element requires codes for the code element, e.g. expiry of  
822 data protection period (see Section 6.1.5).

823



*Note: HL7 terms are named differently but are semantically the same as regulatory terms*

824

825

## 826 **9.4 Category Event**

827 The *category.Event* element will not be used in the EU.

828

829

## 830 **9.5      callBackContact**

831 The *callBackContact* element is to be used for a person or department (*contactParty*) to call if  
832 there are any questions. At least one Contact Party needs to be named per each submission unit.

### 833 **Description**

834 The element indicates the information about an individual person who can be contacted in regard  
835 to the respective submission unit. Therefore, it will always be the person authorized for  
836 communication on behalf of the applicant during the regulatory activity (running procedure) (code  
837 2.4.2)

### 838 **Location in XML**

839 The *callBackContact* element follows the *submission* element, which follows the  
840 *sequenceNumber* element.

841 Alternatively, the *callBackContact* element follows the *submissionUnit* element, which follows  
842 the *subject* element. For EU purposes the *callBackContact.contactParty* element should be used in  
843 this position. Any other location will be ignored.

### 844 **XML details**

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

```
846 callBackContact
847     <callBackContact>
848         <contactParty>
849             <id root="UUID for contactParty"/>
850             <!--contactParty code of "c51862" = Regulatory contact-->
851             <code code="2.4.2" codeSystem="NCI OID"/>
852             <statusCode code="active"/>
853             <contactPerson>
854                 <name xsi:type="BAG_EN">
855                     <item>
856                         <part value="Michael" type="GIV"/>
857                         <part value="Smith" type="FAM"/>
858                     </item>
859                 </name>
860                 <!--WP= workplace phone number and MC= mobile contact number-->
861                 <telecom xsi:type="BAG_TEL">
862                     <item value="tel:+1-212-555-9876" use="WP"/>
863                     <item value="tel:+1-212-555-6789" use="MC"/>
864                     <item value="mailto:michael.smith@goodmedicine.com">
865                         </item>
866                 </telecom>
867             </contactPerson>
868         </contactParty>
869     </callBackContact>
870
```



See [XML Color Legend](#) for color usage

871 **XML Elements**

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



The *classCode* is fixed to “CON”. This value is not required in the XML message.

874

875 **ContactParty.role.id**

876

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
<i>id</i>		[1..1]		This is a container element that provides a unique identifier for the contact party that is being named
	<i>root</i>	[1..1]	Valid OID or UUID	This is the root attribute that uniquely identifies the contact party
	<i>extension</i>	[1..*]		Details will be provide, e.g. name, telephone numbers etc.
<b>Conformance</b>	The <i>id</i> is a required element			

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
<i>Business Rules</i>				<ul style="list-style-type: none"> <li>• A least one contact party needs to be named in each submission unit, the person authorized for communication on behalf of the applicant during the regulatory activity</li> <li>• An <i>id@root</i> should be provided to uniquely identify the point of contact(s) for a submission. Note: The <i>id</i> element will be used when a contact needs to be removed as a submission contact.</li> <li>• The <i>name</i> element is provided to indicate the name of the point of contact. The name should be provided with two parts, one for the given (type=GIV), or first name and one for the family (type=FAM), or last name.</li> <li>• The <i>telecom</i> element is provided to indicate all relevant phone (tel:) and email (mailto:) contact information and include the <i>item@use</i> attribute to indicate the type of phone number (e.g., WP=Work Phone, MC=Mobile contact; Note: these values are maintained by HL7). Multiple <i>telecom.item</i> elements shall be used to provide each value.</li> </ul>
<i>Excluded Elements and Attributes</i>				<p>The following attributes are not required by eCTD 4.0:</p> <ul style="list-style-type: none"> <li>• <i>id@identifierName</i></li> <li>• <i>id@scope</i></li> <li>• <i>id@reliability</i></li> <li>• <i>id@displayable</i></li> </ul>

877

878 **ContactParty.role.code**

879

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
<i>code</i>		[1..1]		This code is related to the contact party that is being named.
	<i>code</i>	[1..1]	Alpha Numeric	This is the <i>code</i> attribute for the coded value of the contact party role

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
	<i>codeSystem</i>	[1..1]	Valid OID or UUID	The codeSystem is a unique identifier that indicates the controlled vocabulary system  <i>This should be the OID or UUID registered for the code system.</i>
<i>Conformance</i>	The <i>id</i> is a required element			
<i>Business Rules</i>				
<i>Excluded Elements and Attributes</i>	The following attributes are not required by eCTD 4.0: <ul style="list-style-type: none"> <li>• <i>code@codeSystemName</i></li> <li>• <i>code@codeSystemVersion</i></li> <li>• <i>code@valueSet</i></li> <li>• <i>code@valueSetVersion</i></li> <li>• <i>code@displayName</i></li> <li>• <i>code@originalText</i></li> <li>• <i>code@codingRationale</i></li> <li>• <i>code@translation</i></li> <li>• <i>code@source</i></li> </ul>			

880

881 **ContactParty.statusCode**

882

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>statusCode</i>		[1..1]		This is a container element that has a controlled terminology code that indicates the status of the Contact Party
	<i>code</i>	[1..1]	“active” or “inactive”	The code is a specified value that indicates whether the Contact Party is the active one.

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
<i>Conformance</i>				The <i>code</i> attribute is required for all <i>statusCode</i> elements
<i>Business Rules</i>				The <i>statusCode@code</i> must always be sent in the message. The <i>statusCode@code</i> should have the value active when sending a contact for the first time, or if there has been a change. All contact information should be sent for updated – i.e., not just the information that has changed. The system will overwrite the existing information with the new content.
<i>Excluded Elements and Attributes</i>				The following attributes are not required by eCTD 4.0: <ul style="list-style-type: none"> <li>• <i>statusCode.part</i></li> <li>• <i>statusCode@validTimeLow</i></li> <li>• <i>statusCode@validTimeHigh</i></li> <li>• <i>statusCode@controlInformationRoot</i></li> <li>• <i>statusCode@controlInformationExtension</i></li> <li>• <i>statusCode@nullFlavor</i></li> <li>• <i>statusCode@flavorId</i></li> <li>• <i>statusCode@updateMode</i></li> </ul>

883

## 884 **Terminology**

885 The *ContactParty* element requires codes for the code element (see section 6.1.7) and the  
886 *statusCode* element.

887

888

## 889 **9.6 Context of Use**

890 The Context of Use provides a linkage between the table of contents heading of the CTD and the  
891 document reference that is contained under that heading. In the sections below, the examples will  
892 be provided for Module 1.

### 893 **Description**

894 The Context of Use is used by Regulated Industry to indicate how the documents in a submission  
895 should be categorized or characterized – i.e., the Context of Use defines the use of a document in  
896 context of the submission unit. For example, the Context of Use may pertain to Module 1, EU  
897 Administrative Information, specifically Environmental Risk Assessment (i.e., eCTD 1.6) and  
898 each of its sub-sections being its own Context of Use (e.g., eCTD 1.6.1, eCTD 1.6.2)

899 The Context of Use code and reference to a document (i.e., *documentReference*) will be used to  
900 connect the content of the submission unit to one or more uses in a table of contents.



*The **contextOfUse** element will be repeated as necessary for a submission unit – i.e., there may be many **contextOfUse** elements in an XML message.*





If multiple **contextOfUse** elements using the same **contextOfUse** code are sent in the same submission unit, a **priorityNumber** will indicate the order in which they should be displayed.

## 901 **Location in XML**

902 The **contextOfUse** follows the **component** element of the **submissionUnit**, unless there is a  
903 **priorityNumber** element of the component (Details are provided in the ICH Implementation  
904 Guide).

## 905 **XML details**

906 The following is an example of the XML for the Context of Use. The **contextOfUse** enters as a  
907 **component** of the **submissionUnit**.

908 **Active contextOfUse** – a contextOfUse with an active statusCode requires an **id**, **code**,  
909 **statusCode**, **setId**, **versionNumber** and **documentReference** elements as depicted below:

```
910 <component>
911   <contextOfUse>
912     <id root="12345678-1234-1234-1234-123456789012"/>
913     <code code="1.6.1" codeSystem="100000000012" />
914     <statusCode code="active"/>
915     <setId root="12345678-1234-1234-1234-12987654321"/>
916     <versionNumber"1"/>
917     ...
918     [Additional information may appear after the addition of the contextOfUse
919     VersionNumber (if one exists, otherwise this will follow the setId (which is
920     required), for example any of the following elements related to contextOfUse –
921     primaryInformationRecipient, links, sequelTo]
922     ...
923
924     <derivedFrom>
925       <documentReference>
926         <id root="12345671-2313-5364-2786-123875636748"/>
927       </documentReference>
928       ...
929       [Additional information may appear after the addition of the contextOfUse
930       VersionNumber (if one exists, otherwise this will follow the setId (which is
931       required), for example any of the following elements: subjectOf, referencedBy,]
932       ...
933     </contextOfUse>
934   </component>
935
```

936 **Change in contextOfUse status** – to make a **contextOfUse** inactive or active only the **id**, **setId**  
937 and **statusCode** need to be provided as depicted below:

938

```

939 <component>
940   <contextOfUse>
941     <id root="12345678-1234-1234-1234-123456789012"/>
942     <statusCode code="inactive"/>
943     <setId root="12345678-1234-1234-1234-12987654321"/>
944   </contextOfUse>
945 </component>
946

```

947 For additional information on Life Cycle issues, see Section 10.

### 948 **XML Elements**

949 Tables with a complete set of XML elements and attributes required for the *contextOfUse* element  
950 are provided in the ICH IG and will not be repeated here. For EU M1 no additional  
951 requirements apply.

952

### 953 **Terminology**

954 The Context of Use codes will be defined through a different implementation guide (see Table 8:  
955 Sample contextOfUse.code@code Terminology for samples) and the HL7 status codes are  
956 provided below.

957 The Context of Use codes will be provided by the ICH and Regional or Country-specific  
958 controlled vocabularies. Below is a small sample of Context of Use codes for Module 1, Quality.

959 **Table 8: Sample contextOfUse.code@code Terminology**

Code	eCTD v4.0 Display Name
m161	M1.6.1 Non-Genetically Modified Organisms
m162	M1.6.2 Genetically Modified Organisms

960



Note: These values will be changed when they are managed by EU, but may also be published at EUTCT with the new codes/values.

961

962 The desired status codes proposed to HL7 are listed in the following table.

963

**Table 9: Sample contextOfUse.StatusCodes@code Terminology**

code	Use in eCTD v4.0
“active”	Context of Use is current
“inactive”	Context of Use is no longer relevant – i.e., it may have been replaced or reverses*

964



\* The relationship between the *contextOfUse* and *relatedContextOfUse* includes information about the *sequelTo.typeCode* value, which may either be a replacement or reverses of a *contextOfUse*. This value is not currently part of the allowable HL7 Status Codes values, but the request will be made to HL7 to include it in this vocabulary. See Related *contextOfUse* for information on *sequelTo.typeCode*.

965

## 966 **Related Elements**

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

### 968 **component.priorityNumber**

969 The *priorityNumber* provides the order of *contextOfUse* elements when the *contextOfUse.code*  
970 value is provided by multiple *contextOfUse* elements. The same principles as outlined in the ICH  
971 IG apply to EU M1.



An additional element to order multiple *contextOfUse* will be offered by the use of keywords (see Section 9.1.9)

972

973

## 974 **9.7 Document**

975 The document element is used for the purposes of transmitting the information about each  
976 document related to an application. Based on the association with a specified CoU the valid use  
977 for a specific application and the purpose of a specific regulatory activity is organized. As  
978 documents will not be retired (no status change is foreseen) a new CoU can be associated at any  
979 time regardless whether the application itself is still active or the regulatory activity is rejected or  
980 approved.

### 981 **Description**

982 Documents (e.g., PDF files) are prepared by the Applicant for review by the Regulatory  
983 Authority. In case of a Regulatory Authority that will send a submission unit to Applicants, the  
984 documents are prepared by the Regulatory Authority. A Document can be submitted as one or  
985 more files and may change over time. One document can be associated with multiple  
986 *contextOfUse* elements, and may be used in multiple submission units.

987 A document can be simple (i.e., a single file) or compound (i.e., more than one file).<sup>14</sup>



*Note to Implementers: For simple documents, the text element should be provided. For compound documents, the component element should be used*

---

<sup>14</sup> 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.

instead to indicate the documents that make up the compound document.

988

## 989 **Location in XML**

990 The *document* results from the *component* element, which follows the *application* element. The  
991 *component* directly follows the *holder* element, if it exists. If not, then the *component* directly  
992 follows the *subject* element, if it exists. If not, then the *component* directly follows the *reference*  
993 element, if it exists. If not, then the *component* directly follows the *referencedBy* element, if it  
994 exists. If not, than the *component* directly follows the *code* element.

## 995 **XML details**

996 The following is an example of the XML for Document. The Document is a component of an  
997 Application. The sample provided below establishes the identity of the file as a simple document..

```
998 <component>
999   <document>
1000     <id root="12345678-1234-1234-1234-98987654321"/>
1001     <!--Code is only used for further identifying simple documents that are part of a compound
1002 document and for which the controlled vocabulary has been defined-->
1003     <code code="b12345" codeSystem="123456789-4321-4321-4321-123456789123"/>
1004     <title value="General Information"/>
1005     <text integrityCheckAlgorithm="SHA256" language="en">
1006       <reference xsi:type="TEL" value="../../../ m1/eu/16-environrisk/161-nongmo/nongmo-var.
1007 pdf"/>
1008       <integrityCheck>618102bf07065bcc1250594201fe448515f0fa61</integrityCheck>
1009     </text>
1010     <statusCode code="active"/>
1011     <setId root="12345678-4321-4321-4321-123456789987"/>
1012     <versionNumber value="1" />
1013     ...
1014     [Additional information may appear after the addition of the text (if one exists, otherwise this will
1015 follow the component. For example, depending on the type of document the following elements
1016 may be available to select from the Document – component, sequelTo, referencedBy]
1017     ...
1018   </document>
1019 </component>
1020
```



See [XML Color Legend](#) for color usage



*Note to Implementers: For simple documents (i.e., representing a single file), the text element will be provided along with the other required elements. For compound documents, the component element should be used instead in order to indicate the simple documents that make up the compound*

*document. Each component (simple document) may require additional information (see XML Element section below for additional details).*

1021 **XML Elements**

1022 Tables with a complete set of XML elements and attributes required for the *document* element are  
1023 provided in the ICH IG and will not be repeated here. The following additional requirements  
1024 apply for EU M1.

1025 **Document.code**

1026 In Module 1.3.1 only, documents will have a *code* to further specify the file tags for the document,  
1027 e.g., smpc, according to the respective controlled vocabulary (see Section 6.1.7)  
1028

1029 **Document.text**

1030 The *text@language* attribute is mandatory in Module 1.3.1.  
1031

1032 **Terminology**

1033 The *document* element has one coded terminology for language (the ISO language codes) (see  
1034 Section 6.3) and another one for document type code (see Section 6.1.7). In Module 1.3.1 only,  
1035 *document* elements must provide this type of information

1036

1037 **Related Elements**

1038 The following elements are related to *document* and require additional information.

1039 The *priorityNumber* provides the order of *document* elements within a compound document –  
1040 i.e., when the *document* element is a component of another *document* element. The same  
1041 principles as outlined in the ICH IG apply to EU M1.

1042

1043

1044 **9.8 Document Reference**

1045 A *documentReference* allows a document to be specified for the *contextOfUse*.

1046 **Description**

1047 A document can be used many times. Each time the document is used, that document has a  
1048 different *contextOfUse*. Accordingly, each Context of Use must reference a simple or compound  
1049 document.

1050 **Location in XML**

1051 The *documentReference* follows the *derivedFrom* element, which follows the *contextOfUse*  
1052 element. The *derivedFrom* element follows the *versionNumber*, if one exists, if not, follows the  
1053 *setId* element.

1054 **XML details**

1055 The following is an example of the XML for a document reference.

```
1056 <derivedFrom>
1057   <documentReference>
1058     <id root="12345678-1234-1234-1234-98765432198"/>
1059   </documentReference>
1060 </derivedFrom>
1061
```



See [XML Color Legend](#) for color usage

1062 **XML Elements**

1063 Tables with a complete set of XML elements and attributes required for the *documentReference*  
1064 element are provided in the ICH IG and will not being repeated here. No additional requirements  
1065 apply for EU M1.

1066

1067 **Terminology**

1068



*There is no controlled terminology for this information.*

1069

1070

1071 **9.9 Keyword**

1072 The *keyword* element is used for the purposes of transmitting additional information about a  
1073 *contextOfUse* or *document* element. In the EU M1, the Country Code will be used to specify  
1074 commonly used or nationally used documents including the referenced files. The keywords on  
1075 documents will be used to identify types of product information texts in Module 1.3.1.

1076 **Description**

1077 The *keyword* is either defined by an external controlled vocabulary, e.g. document type code or  
1078 country code, or it may be defined within the message as *keywordDefinition*. For EU M1, the  
1079 latter principle will apply to product information texts in order to sort them according to  
1080 pharmaceutical form or strength.

1081 **Location in XML**

1082 As it pertains to the *Document* element, the *keyword* is linked through the *referencedBy* element,  
1083 which follows the *Document* element.

1084 As it pertains to the *contextOfUse* element, the *keyword* is linked through the *referencedBy*  
1085 element, which follows the *contextOfUse* element.

1086

## 1087 **XML Details**

1088 The following is an example of the XML for a Keyword. **Document** elements in EU Module 1.3.1  
1089 will have references to Keywords. In this context, Keywords are a coded value from a controlled  
1090 vocabulary.

1091

## 1092 **Keywords from a Controlled Vocabulary**

```
1093 <component>
1094   <document>
1095     <referencedBy>
1096       <keyword>
1097         <code code="uk" codeSystem="ISO country code"/>
1098       </keyword>
1099     </referencedBy>
1100   </document>
1101 </component>
1102
1103 <component>
1104   <contextOfUse>
1105     <referencedBy>
1106       <keyword>
1107         <code code="en" codeSystem="ISO language code"/>
1108       </keyword>
1109     </referencedBy>
1110   </contextOfUse>
1111 </component>
1112
```



See [XML Color Legend](#) for color usage

## 1113 **XML Elements**

1114 Tables with a complete set of XML elements and attributes required for the **Keyword** element are  
1115 provided in the ICH IG and will not be repeated here. For the purpose of EU Module 1, no  
1116 additional requirements apply for EU M1.

1117

## 1118 **Terminology**

1119 For EU Module 1 no controlled vocabulary is needed.

1120

1121

## 1122 **9.10 Keyword Definition**

1123 The **keywordDefinition** element is used to define a keyword by the sender that is referenced by  
1124 identifier in other parts of the message. For details see ICH Implementation guide. The usage of



1125 this element is expected to be helpful in EU Module 1 for product information text to separate  
1126 different pharmaceutical forms or strengths.

1127

## 1128 **9.11 Manufactured Product**

1129 This element must be selected in case of an eCTD v4.0 message concerning the initial application  
1130 for a human medicinal product. This determines the role of a product in the national context  
1131 within a DCP or MRP. For applications submitted nationally only this element and related  
1132 elements can be ignored. Subsequent submission units related to authorized products do not need  
1133 to provide this type of information repeatedly.

### 1134 **Description**

1135 The *ManufacturedProduct* element collects the name of the product by country and the active  
1136 ingredients. This element may support internal workflow mechanisms but will not replace the  
1137 annex 5.15 to the application form of the current Module 1.2 in the EU.

### 1138 **Location in XML**

1139 The *ManufacturedProduct* element follows the *subject* element, which follows the *Review*  
1140 element.

1141

### 1142 **XML details**

1143 The following is an example of the XML for the *ManufacturedProduct* element.

```
1144 = <subject1>
1145   = <manufacturedProduct>
1146     <id />
1147     = <manufacturedProduct>
1148       = <asNamedEntity>
1149         = <assigningTerritory>
1150           <code code="NL" />
1151           = <name>
1152             - <!-- Product name type and value -->
1153               <part value="Wonder Drug" language="nl" />
1154             </name>
1155           </assigningTerritory>
1156         </asNamedEntity>
1157       = <ingredient>
1158         = <activeIngredientSubstance>
1159           = <name>
1160             - <!-- Substance name type and value -->
1161               <part code="IND01" codeSystem="Active ingredient code system OID"
1162 value="Pioglitazone hydrochloride" />
1163               <part code="IND02" codeSystem="Active ingredient code system OID"
1164 value=" Metformin hydrochloride" />
1165             </name>
```



1166                   </activeIngredientSubstance>  
 1167                   </ingredient>  
 1168                   </manufacturedProduct>  
 1169                   </manufacturedProduct>  
 1170                   </subject1>  
 1171

1172

1173 **XML Elements**

1174 The following tables provide a complete set of XML elements and attributes required for the  
 1175 **ManufacturedProduct** element, and any special instructions.



The **classCode** is fixed to “MANU”. This value is not required in the XML message.

1176

1177 **ManufacturedProduct.id**

1178

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
<b>id</b>		[1..1]		This is a container element for a reference to the manufactured product
	<b>root</b>	[1..1]	Valid OID or UUID	This attribute is for a global unique identifier of the <b>manufactured product</b> being referenced
<b>Conformance</b>	The <b>id</b> element and <b>root</b> attribute are required.			
<b>Business Rules</b>	This element provides the referencing point for the invented name of the medicinal product per involved member state.			
<b>Excluded Elements and Attributes</b>	The following attributes are not required by eCTD 4.0: <ul style="list-style-type: none"> <li>• <b>id@extension</b></li> <li>• <b>id@identifierName</b></li> <li>• <b>id@scope</b></li> <li>• <b>id@reliability</b></li> <li>• <b>id@displayable</b></li> </ul>			

1179

1180

1181 **Related Elements**

1182 The following element is related to *manufacturedProduct* and requires additional information:

1183 **Product**

1184 The *product* element provides the information about the name of the product as used per territory  
1185 and its ingredient(s) depending on how many pharmaceutical active ingredients contained. The  
1186 following is an example for one relevant product name (case 1) and two different product names  
1187 per each country in use for the same manufactured product (case 2):

1188 **Case 1**

```
1189 <subject1>
1190   <manufacturedProduct>
1191     <manufacturedProduct>
1192       <name xsi:type="DSET_EN">
1193         <item>
1194           <part code="Product Name Type code" codeSystem="Product Name Type code system
1195 OID" value="Product Name" language="en"/>
1196         </item>
1197       </name>
1198       <asNamedEntity>
1199         <name xsi:type="DEST_EN">
1200           <item>
1201             <part value="authority name"/>
1202           </item>
1203         </name>
1204         <assigningTerritory>
1205           <code code="country code"/>
1206         </assigningTerritory>
1207       </asNamedEntity>
1208       <ingredient>
1209         <activeIngredientSubstance>
1210           <name>
1211             <part code="Substance Name Type(INN, USAN, etc)" codeSystem="Substance Name
1212 Type code system OID" value="Substance Name"/>
1213           </name>
1214         </activeIngredientSubstance>
1215       </ingredient>
1216     </manufacturedProduct>
1217   </manufacturedProduct>
1218 </subject1>
```

1220 **Case 2**

1221 To have multiple product names (e.g., Refludan and Refludin), the product.name.item.part can be  
1222 repeated, and alternatively, <subject1> can be repeated as well.

1223  
1224 (1) if you repeat the product.name.item.part;

```
1225 <subject1>
1226   <manufacturedProduct>
1227     <manufacturedProduct>
1228       <name xsi:type="DSET_EN">
1229         <item>
```

```

1230         <part code="Product Name Type code" codeSystem="Product Name Type code system
1231 OID" value="Refludan" language="en"/>
1232         <part code="Product Name Type code" codeSystem="Product Name Type code system
1233 OID" value="Refludin" language="es"/>
1234     </item>
1235 </name>.....
1236
1237 (2) if you repeat the <subject1>;
1238 <subject1>
1239     <manufacturedProduct>
1240     <manufacturedProduct>
1241         <name xsi:type="DSET_EN">
1242         <item>
1243             <part code="Product Name Type code" codeSystem="Product Name Type code system
1244 OID" value="Refludan" language="en"/>
1245             </item>
1246         </name>
1247     <asNamedEntity>
1248         <name xsi:type="DEST_EN">
1249         <item>
1250             <part value="authority name1"/>
1251             </item>
1252         </name>
1253         <assigningTerritory>
1254             <code code="country code"/>
1255         </assigningTerritory>
1256     </asNamedEntity>
1257 <ingredient>
1258     <activeIngredientSubstance>
1259     <name>
1260         <part code="Substance Name Type(INN, USAN, etc)" codeSystem="Substance Name
1261 Type code system OID" value="Substance Name1"/>
1262         </name>
1263     </activeIngredientSubstance>
1264 </ingredient>
1265 </manufacturedProduct>
1266 </manufacturedProduct>
1267 </subject1>
1268 <subject1>
1269     <manufacturedProduct>
1270     <manufacturedProduct>
1271         <name xsi:type="DSET_EN">
1272         <item>
1273             <part code="Product Name Type code" codeSystem="Product Name Type code system
1274 OID" value="Refludin" language="es"/>
1275             </item>
1276         </name>
1277     <asNamedEntity>
1278         <name xsi:type="DEST_EN">
1279         <item>
1280             <part value="authority name2"/>
1281             </item>
1282         </name>
1283         <assigningTerritory>
1284             <code code="country code"/>
1285         </assigningTerritory>

```

```

1286     </asNamedEntity>
1287     <ingredient>
1288         <activeIngredientSubstance>
1289             <name>
1290                 <part code="Substance Name Type(INN, USAN, etc)" codeSystem="Substance Name
1291 Type code system OID" value="Substance Name1"/>
1292             </name>
1293         </activeIngredientSubstance>
1294     </ingredient>
1295 </manufacturedProduct>
1296 </manufacturedProduct>
1297 </subject1>
1298
1299

```

## 1300 9.12 Mode

1301 The high-level handling of the information submitted as part of variation(s) and extension  
1302 applications will be indicated by this element. The *mode* element should only be used in variation  
1303 or line extension regulatory activities and must be included in every sequence of that activity. The  
1304 following are the valid modes: a single regulatory activity (e.g. a Type II variation), a grouped  
1305 activity (e.g. several variations grouped into a single submission or a periodic report of type IA  
1306 variations applicable to one or more marketing authorizations), and an activity subject to a  
1307 worksharing agreement (e.g. a Type II variation applicable to more than one marketing  
1308 authorization).

### 1309 **Description**

1310 The *mode* element indicates whether the regulatory activity will be handled as a group or in a  
1311 single or work shared manner.

### 1312 **Location in XML**

1313 The *mode* element follows the *submission* element, which is referenced by *contextOfUse*  
1314 element.

### 1315 **XML details**

1316 The following is an example of the XML for the *mode* element.

### 1317 **Mode**



*Note: Examples for XML snippets will be provided in one of the future versions*

1318  
1319



See [XML Color Legend](#) for color usage

### 1320 **XML Elements**

1321 The following tables provide a complete set of XML elements and attributes required for the  
1322 *Mode* element, and any special instructions.



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

1323

1324 **Mode.id**

1325

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<b>id</b>		[1..1]		This is a container element that provides a unique identifier for the mode of submission
	<b>root</b>	[1..1]	Valid OID or UUID	This is the root attribute that uniquely identifies the mode of a submission
<b>Conformance</b>	The <b>id</b> is a required element			
<b>Business Rules</b>	The mode element must be used in case of variations.			
<b>Excluded Elements and Attributes</b>	The following attributes are not required by eCTD 4.0: <ul style="list-style-type: none"> <li>• <b>id@extension</b></li> <li>• <b>id@identifierName</b></li> <li>• <b>id@scope</b></li> <li>• <b>id@reliability</b></li> <li>• <b>id@displayable</b></li> </ul>			

1326

1327 **ModeAct.code**

1328

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<b>code</b>		[1..1]		This is the <b>code</b> attribute for the coded value of the mode of a submission.

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
	<i>code</i>	[1..1]	Alpha Numeric  e.g., “single”	This is the <i>code</i> attribute for the coded value of the mode of the submission type variation.
	<i>codeSystem</i>	[1..1]	Valid OID or UUID	This is the <i>codeSystem</i> attribute that is a unique identifier for the controlled vocabulary system  <i>This should be the OID or UUID registered for the code system.</i>
<i>Conformance</i>	The <i>code</i> and <i>codeSystem</i> is a required element			
<i>Business Rules</i>	If the mode element is been used the code is required as well.			
<i>Excluded Elements and Attributes</i>	<p>The following attributes are not required by eCTD 4.0:</p> <ul style="list-style-type: none"> <li>• <i>code@codeSystemName</i></li> <li>• <i>code@codeSystemVersion</i></li> <li>• <i>code@valueSet</i></li> <li>• <i>code@valueSetVersion</i></li> <li>• <i>code@originalText</i></li> <li>• <i>code@codingRationale</i></li> <li>• <i>code@translation</i></li> <li>• <i>code@source</i></li> </ul>			

1329

### 1330 **Terminology**

1331 The *mode* element requires codes for the code element (see section 6.1.8).

1332

1333

### 1334 **9.13 Previous Keyword Definition**

1335 The *previousKeywordDefinition* element is used to replace the keyword definition that was  
 1336 defined by the sender when it changes over time. Details are provided in the ICH Implementation  
 1337 Guide.

1338

1339

1340 **9.14 Product Category**

1341 The *productCategory* is used to indicate the overall category of human medicinal product based  
1342 on the active ingredients, e.g. chemical, herbal or biotech product.

1343 **Description**

1344 The *ProductCategory* element is used to provide information about a class of medicinal products  
1345 related to the top level group its active ingredient is belonging to..

1346 **Location in XML**

1347 The *ProductCategory* element follows the *sequelTo* element, which follows the *Review* element.

1348 **XML details**

1349 The following is an example of the XML for *ProductCategory*.

1350



*Note: Examples for XML snippets will be provided in one of the future versions*

1351

1352



See [XML Color Legend](#) for color usage

1353 **XML Elements**

1354 The following tables provide a complete set of XML elements and attributes required for the  
1355 *ProductCategory* element, and any special instructions.



*The classCode is fixed to "CATEGORY" and moodCode is fixed to "EVN". These values are not required in the XML message.*

1356

1357 **ProductCategory.code**

1358

Element	Attribute	Cardinalit y	Value(s) Allowed Examples	Description Instructions
<i>code</i>		[1..1]		This is a container element for the <i>ProductCategory</i>

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
	<i>code</i>	[1..1]	Valid OID or UUID	This is the <i>code</i> attribute for the coded value of the <i>ProductCategory</i>
	<i>codeSystem</i>	[1..1]	Valid OID or UUID	This is the <i>codeSystem</i> attribute that is a unique identifier for the controlled vocabulary system  <i>This should be the OID or UUID registered for the code system.</i>
<i>Conformance</i>	The <i>code</i> and <i>codeSystem</i> is a required element			
<i>Business Rules</i>				
<i>Excluded Elements and Attributes</i>	<p>The following attributes are not required by eCTD 4.0:</p> <ul style="list-style-type: none"> <li>• <i>code@codeSystemName</i></li> <li>• <i>code@codeSystemVersion</i></li> <li>• <i>code@valueSet</i></li> <li>• <i>code@valueSetVersion</i></li> <li>• <i>code@originalText</i></li> <li>• <i>code@codingRationale</i></li> <li>• <i>code@translation</i></li> <li>• <i>code@source</i></li> </ul>			

1359

## 1360 **Terminology**

1361 The *productCategory* element requires codes for the code element (see section 6.1.11).

1362

1363

## 1364 **9.15 Regulatory Review Time**

1365 The Regulatory Review Time element need to be used in case of variations where the same type  
1366 of variation can be assessed within different time periods, e.g. variation type II in 60 or 90 days.

### 1367 **Description**

1368 The *regulatoryReviewTime* element indicates the time period in which the action by authority can  
1369 be expected or is defined by law or business rules.



1370 **Location in XML**

1371 The *regulatoryReviewTime* element follows the *submission* element, which is referenced by  
1372 *contextOfUse* element.

1373 **XML details**

1374 The following is an example of the XML for the *regulatoryReviewTime* element.

1375 **RegulatoryReviewTime**



*Note: Examples for XML snippets will be provided in one of the future versions*

1376

1377



See [XML Color Legend](#) for color usage

1378 **XML Elements**

1379 The following tables provide a complete set of XML elements and attributes required for the  
1380 *regulatoryReviewTime* 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.*

1381

1382 **RegulatoryReviewTime.code**

1383

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
<i>code</i>		[1..1]		This is a container element that identifies the type of review time class-
	<i>code</i>	[1..1]	Alpha Numeric  e.g., “30”, “60” or “210”  This is a controlled vocabulary	This is the <i>code</i> attribute for the coded value of the <i>ReviewTime</i> -type that indicates the regulatory review requirements for the respective submission.

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
	<i>codeSystem</i>	[1..1]	Valid OID or UUID	This is the <i>codeSystem</i> attribute that is a unique identifier for the controlled vocabulary system  <i>This should be the OID or UUID registered for the code system.</i>
<i>Conformance</i>	The <i>code</i> and <i>codeSystem</i> is a required element			
<i>Business Rules</i>				
<i>Excluded Elements and Attributes</i>	The following attributes are not required by eCTD 4.0: <ul style="list-style-type: none"> <li>• <i>code@codeSystemName</i></li> <li>• <i>code@codeSystemVersion</i></li> <li>• <i>code@valueSet</i></li> <li>• <i>code@valueSetVersion</i></li> <li>• <i>code@originalText</i></li> <li>• <i>code@codingRationale</i></li> <li>• <i>code@translation</i></li> <li>• <i>code@source</i></li> </ul>			

1384

### 1385 **Terminology**

1386 The *regulatoryReviewTime* element requires codes for the code element (see section 6.1.11).

1387

1388

## 1389 **9.16 Regulatory Status**

1390 The Regulatory Status element defines the outcome of regulatory action on a submission.

### 1391 **Description**

1392 The *RegulatoryStatus* element is to assign the status of a regulatory activity applied for once the  
1393 authority has decided to respond to the applicant. This element will be used by Regulatory  
1394 Authorities only and supports therefore two-way communication.

### 1395 **Location in XML**

1396 The *regulatoryStatus* element follows the *submission* element, which is referenced by  
1397 *contextOfUse* element.

1398 **XML details**

1399 The following is an example of the XML for the *regulatoryStatus* element.

1400 **RegulatoryStatus**



*Note: Examples for XML snippets will be provided in one of the future versions*

1401

1402



See [XML Color Legend](#) for color usage

1403 **XML Elements**

1404 The following tables provide a complete set of XML elements and attributes required for the  
1405 *regulatoryStatus* 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.*

1406

1407 **RegulatoryStatus.code**

1408

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
<i>code</i>		[1..1]		This is a container element that identifies the regulatory status of the submission
	<i>code</i>	[1..1]	Alpha Numeric  e.g., “Approved”, “Withdrawn”,	This is the <i>code</i> attribute for the coded value of the regulatory status assigned by the responsible CA

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
	<b><i>codeSystem</i></b>	[1..1]	Valid OID or UUID	This is the <b><i>codeSystem</i></b> attribute that is a unique identifier for the controlled vocabulary system  <i>This should be the OID or UUID registered for the code system.</i>
<b><i>Conformance</i></b>	The <b><i>code</i></b> and <b><i>codeSystem</i></b> is a required element			
<b><i>Business Rules</i></b>	This element should be used by the responsible competent authority only, e.g. EMA in case of centralized procedures or the RMS in case of DCP or MRP.			
<b><i>Excluded Elements and Attributes</i></b>	The following attributes are not required by eCTD 4.0: <ul style="list-style-type: none"> <li>• <b><i>code@codeSystemName</i></b></li> <li>• <b><i>code@codeSystemVersion</i></b></li> <li>• <b><i>code@valueSet</i></b></li> <li>• <b><i>code@valueSetVersion</i></b></li> <li>• <b><i>code@originalText</i></b></li> <li>• <b><i>code@codingRationale</i></b></li> <li>• <b><i>code@translation</i></b></li> <li>• <b><i>code@source</i></b></li> </ul>			

1409

1410 ***RegulatoryStatus.effectiveTime***

1411

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<b><i>effective time</i></b>		[1..1]		This is a container element that provides the time stamp when a new regulatory status is assigned.

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
	<i>timestamp</i>	[1..1]	timestamp (GREG)  "2000040103 1520.34+00" means April 1, 2000, 3:15 and 20.34 seconds expressed for UTC	This value describes the precise time of assigning a regulatory status.
<i>Conformance</i>	The <i>effective time</i> is a required element			
<i>Business Rules</i>				
<i>Excluded Elements and Attributes</i>				

1412

### 1413 **Terminology**

1414 The *regulatoryStatus* element requires codes for the code element (see section 6.1.12).

1415

1416

### 1417 **9.17 related Context Of Use (contextOfUse Life Cycle)**

1418 The *relatedContextOfUse* is used to connect one context of use with another. The *sequelTo*  
1419 relationship is used for tracking the life cycle of context of uses. Details are provided in the ICH  
1420 Implementation Guide.

1421

### 1422 **9.18 Related Document**

1423 The Related Document element will not be used in the EU M1.

1424


### 1425 **9.19 Review**

1426 The *review* element is related to the regulatory activity (as defined by the submission), is  
1427 associated with the holder and an author in the meaning of the Reference Member State or  
1428 responsible authority, e.g. EMA in centralized procedures, and refers to the product and the  
1429 product category.

1430 **Description**  
 1431 The *review* element connects product, product category and the regulatory activity (submission  
 1432 element). Optionally, additional information about the reference member state and the applicant  
 1433 can be provided, but will not required for the EU.


1434 **Location in XML**  
 1435 The *review* element follows the *subject* element, which follows the *submission* element.

1436 **XML details**  
 1437 The following is an example of the XML for the *review* element.

1438 **Review**  
 *Note: Examples for XML snippets will be provided in one of the future versions*

1439  
 1440  See [XML Color Legend](#) for color usage

1441 **XML Elements**  
 1442 The following tables provide a complete set of XML elements and attributes required for the  
 1443 *review* element, and any special instructions.

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

1444  
 1445 **Review.id**  
 1446

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
<i>id</i>		[1..1]		This is a container element that provides a unique identifier for the review activity
	<i>root</i>	[1..1]	Valid OID or UUID	This is the root attribute that uniquely identifies the review activity
<b>Conformance</b>	The <i>id</i> is a required element			

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
<i>Business Rules</i>				
<i>Excluded Elements and Attributes</i>				The following attributes are not required by eCTD 4.0: <ul style="list-style-type: none"> <li>• <i>id@extension</i></li> <li>• <i>id@identifierName</i></li> <li>• <i>id@scope</i></li> <li>• <i>id@reliability</i></li> <li>• <i>id@displayable</i></li> </ul>

1447

1448 **Review.statusCode**

1449

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
<i>status</i>		[1..1]		This is a container element that provides .....
	<i>root</i>	[1..1]	Valid OID or UUID	This is the root attribute that .....
<i>Conformance</i>	The <i>status</i> is a required element			
<i>Business Rules</i>				
<i>Excluded Elements and Attributes</i>				The following attributes are not required by eCTD 4.0: <ul style="list-style-type: none"> <li>• <i>id@extension</i></li> <li>• <i>id@displayable</i></li> </ul>

1450

1451 **Terminology**

1452 The *review* element requires codes for the status code element.

1453 The desired status codes proposed to HL7 are listed in the following table.

1454

**Table 10: Sample review.StatusCodes@code Terminology**

code	Use in eCTD v4.0
“active”	Review is current
“inactive”	Review is no longer relevant – i.e., the submission may be withdrawn

1455

1456 **9.20 Review Procedure**

1457 The *reviewProcedure* defines the type of procedure to assess the marketing authorisation  
1458 application whether it is a centralized, decentralized, mutual recognition or purely national  
1459 procedure

1460 **Description**

1461 The *reviewProcedure* element provides the procedure type explicitly.

1462 **Location in XML**

1463 The *reviewProcedure* element follows the *application* element.

1464 **XML details**

1465 The following is an example of the XML for the *reviewProcedure* element.

1466 **ReviewProcedure**

1467



*Note: Examples for XML snippets will be provided in one of the future versions*

1468



See [XML Color Legend](#) for color usage

1469 **XML Elements**

1470 The following tables provide a complete set of XML elements and attributes required for the  
1471 *reviewProcedure* element, and any special instructions.



*The classCode is fixed to "POLICY" and moodCode is fixed to "EVN".  
These values are not required in the XML message.*

1472

1473 **ReviewProcedure.code**

1474

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
<i>code</i>		[1..1]		This is a container element that provides a unique identifier for the review procedure type code



Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
	<i>root</i>	[1..1]	Valid OID or UUID	This is the root attribute that uniquely identifies the review procedure type
<i>Conformance</i>	The <i>id</i> is a required element			
<i>Business Rules</i>	The review procedure type needs to be provided in each case.			
<i>Excluded Elements and Attributes</i>	The following attributes are not required by eCTD 4.0: <ul style="list-style-type: none"> <li>• <i>id@extension</i></li> <li>• <i>id@identifierName</i></li> <li>• <i>id@scope</i></li> <li>• <i>id@reliability</i></li> <li>• <i>id@displayable</i></li> </ul>			

1475

## 1476 **Terminology**

1477 The *reviewProcedure* element requires codes for the *code* element (see section 6.1.14).

1478

1479

## 1480 **9.21 Submission**

1481 The *submission* is the representation of a regulatory activity constituted by several submission  
1482 units and referring to at least one application.

### 1483 **Description**

1484 The *submission* element defines the relationship between a submission unit, the Contexts of Use  
1485 mentioned and the application. Depending from the regulatory activity multiple applications can  
1486 be mentioned.

### 1487 **Location in XML**

1488 The *submission* element follows the *component* element, which follows the *sequenceNumber*  
1489 element, if it exists. If not, it follows the *component* element of a Context Of Use.

### 1490 **XML details**

1491 The following is an example of the XML for the *submission* element.

### 1492 **Submission**



*Note: Examples for XML snippets will be provided in one of the future versions*



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

1493  
1494

1495 **Submission componentOf Application**



Note: Examples for XML snippets will be provided in one of the future versions

1496



See [XML Color Legend](#) for color usage

1497 **XML Elements**

1498 The following tables provide a complete set of XML elements and attributes required for the  
1499 **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.

1500 **Submission.id**  
1501

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
<i>id</i>		[1..1]		This is a container element that provides a unique identifier for the submission
	<i>root</i>	[1..1]	Valid OID or UUID	This is the root attribute that uniquely identifies the submission
<b>Conformance</b>	The <i>id</i> is a required element			
<b>Business Rules</b>	Only one <i>item</i> element should be provided for a Submission.			

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
<i>Excluded Elements and Attributes</i>	The following attributes are not required by eCTD 4.0: <ul style="list-style-type: none"> <li>• <i>id@extension</i></li> <li>• <i>id@identifierName</i></li> <li>• <i>id@scope</i></li> <li>• <i>id@reliability</i></li> <li>• <i>id@displayable</i></li> </ul>			

1502

1503 **Submission.code**

1504

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
<i>code</i>		[0..1]		This is a container element for the submission
	<i>code</i>	[1..1]	Alpha Numeric  e.g., maa, var-nat, var-type1b	This is the code attribute, which is a unique value that indicates the type of content in the <b>Submission</b>
	<i>codeSystem</i>	[1..1]	Valid OID or GUID	This is the codeSystem attribute
<i>Conformance</i>				
<i>Business Rules</i>	<b>Submission</b> codes may vary for different product types. In case of eCTD for human medicinal product the relevant code list is in section 6.1.15.			
<i>Excluded Elements and Attributes</i>	The following attributes are not required by eCTD 4.0: <ul style="list-style-type: none"> <li>• <i>code@codeSystemName</i></li> <li>• <i>code@codeSystemVersion</i></li> <li>• <i>code@valueSet</i></li> <li>• <i>code@valueSetVersion</i></li> <li>• <i>code@originalText</i></li> <li>• <i>code@codingRationale</i></li> <li>• <i>code@translation</i></li> <li>• <i>code@source</i></li> </ul>			

1505

1506 **Submission.statusCode**

1507

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
<i>statusCode</i>		[0..1]		This is a container element for the <i>statusCode</i> of the Submission
	<i>code</i>	[1..1]	Alpha Numeric e.g., active, nullified	This is the <i>statusCode</i> attribute that indicates the status of the submission
<i>Conformance</i>	If the <i>statusCode</i> element is provided, the <i>code</i> attribute is required			
<i>Business Rules</i>				
<i>Excluded Elements and Attributes</i>	The following attributes are not required by eCTD 4.0: <ul style="list-style-type: none"> <li>• <i>code@codeSystemName</i></li> <li>• <i>code@codeSystemVersion</i></li> </ul>			

1508

1509 **Terminology**

1510 Type of submission will be defined by the sender (see section 6.1.15).

1511 **Related Elements**

1512 The following elements are related to *submission* and require additional information:

1513 **component.sequenceNumber**

1514 The *sequenceNumber* provides the sequence in a *submission* for the *submissionUnit* being  
1515 submitted and should follow the rules stated below:

- 1516 • The *sequenceNumber* element is always required
- 1517 • The *sequenceNumber.value* is a non-negative integer (i.e., non-negative whole number)
- 1518 • The *sequenceNumber.value* should always start with 000001 in the application life cycle
- 1519 • The *sequenceNumber.value* is always unique within an application, and may skip  
1520 numbers within regulatory activities (i.e., multiple regulatory activities may be active at  
1521 the same time).
- 1522 • The *sequenceNumber.value* should include 6-digits – i.e., the sender should pad the value  
1523 with zeros so that there is no question about the number sequence.

1524 The following is an example:

1525 <componentOf>

```

1526     <sequenceNumber value="000001"/>
1527     <submission>
1528         ...
1529         [Additional information appears for the Submission element.]
1530         ...
1531     </submission>
1532 </componentOf>
1533 <componentOf>
1534     <sequenceNumber value="000002"/>
1535     <submission>
1536         ...
1537         [Additional information appears for the Submission element]
1538         ...
1539     </submission>
1540 </componentOf>

```

1541  
1542

## 1543 9.22 Submission Group

1544 The Submission Group represents an option to process regulatory activities together in case the  
1545 assessment will cover same content but the regulatory activity cannot be handled as one  
1546 procedure, e.g several generic applications with different product names but identical  
1547 pharmaceutical composition and properties cannot be assessed like grouped variations or other  
1548 formal workshare procedures but in one go. A submission group needs to be defined per  
1549 regulatory activity and is required to be stated within each submission unit submitted during that  
1550 course of assessment.

### 1551 **Description**

1552 The *submissionGroup* element can be used in case same regulatory activity will be processed the  
1553 same way but formally not running under the same procedure number or can be grouped or shared  
1554 according legal rules. The UUID will connect the different applications for this submission  
1555 (regulatory activity) in the submission group (id:0987.997).

### 1556 **Location in XML**

1557 The *submissionGroup* element follows the *submission* element, which follows the *subjectOf*  
1558 element.

### 1559 **XML details**

1560 The following is an example of the XML for the *submissionGroup* element.

### 1561 **SubmissionGroup derived from Submission**

```

1562 <subject5>
1563     <submissionGroup>
1564         <id root="UUID for the submissionGroup" extension="0987.997" />
1565     </submissionGroup>
1566 </subject5>

```

```

1567 <componentOf>
1568   <application>
1569     <id>
1570       - <!-- Application ID -->
1571       - <!-- ===== -->
1572       - <!-- Should EU use this item to store the number used by an agency to track the
1573 submission, in any procedure, in relation to a particular product. -->
1574       - <!-- This could be a MRP Number, the EMEA application number, or any other number
1575 used by an agency to track a submission. -->
1576       - <!-- ===== -->
1577         <item root="fr-2083-001-dc" extension="de-2189072"/>
1578         <item root="fr-2083-001-dc" extension="nl-456789"/>
1579         <item root="fr-2083-001-dc" extension="uk-341974"/>
1580         <item root="fr-2083-001-dc" extension="fr-234-345"/>
1581       </id>
1582       ...
1583       [Additional information may appear after the addition of the Application.code, for
1584 example any of the following elements related to Application – component,
1585 referencedBy, informationRecipient, reference, subject, or holder]
1586       ...
1587     </application>
1588   </componentOf>
1589
1590
1591 <subject5>
1592   <submissionGroup>
1593     <id root="UUID of the SubmissionGroup" extension="0987.997"/>
1594   /submissionGroup>
1595 </subject5>
1596 <componentOf>
1597   <application>
1598     <id>
1599       <item root="fr-2084-001-dc" extension="de-2189073"/>
1600       <item root="fr-2084-001-dc" extension="nl-456790"/>
1601       <item root="fr-2084-001-dc" extension="uk-341975"/>
1602       <item root="fr-2084-001-dc" extension="fr-234-432"/>
1603     </id>
1604   </application>
1605 </componentOf>
1606
1607

```

1608



See [XML Color Legend](#) for color usage

1609 **XML Elements**

1610 The following tables provide a complete set of XML elements and attributes required for the  
 1611 *submissionGroup* element, and any special instructions.



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

1612

1613 **SubmissionGroup.id**

1614

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
<i>id</i>		[1..1]		This is a container element that provides a unique identifier for the submission unit
	<i>root</i>	[1..1]	Valid OID or UUID	This is the root attribute that uniquely identifies the submission group of which the submission is part of
<i>Conformance</i>	The <i>id</i> is a required element			
<i>Business Rules</i>				
<i>Excluded Elements and Attributes</i>	The following attributes are not required by eCTD 4.0: <ul style="list-style-type: none"> <li>• <i>id@extension</i></li> <li>• <i>id@identifierName</i></li> <li>• <i>id@scope</i></li> <li>• <i>id@reliability</i></li> <li>• <i>id@displayable</i></li> </ul>			

1615

1616 **Terminology**

1617 There is no further terminology foreseen.

1618

1619

1620 **9.23 Submission Reference**

1621 The Submission Reference provides the option to refer to a submission sent by applicant in case  
 1622 the authority will use two-way communication and will be used by regulators only.

1623 **Description**

1624 The *submissionReference* element indicates the previously started regulatory activity to which the  
1625 authority response relates.

1626 **Location in XML**

1627 The *submissionReference* element follows the *subject* element next to *contextOfUse* element.

1628 **XML details**

1629 The following is an example of the XML for the *SubmissionReference* element.

1630 **Submission Reference**



*Note: Examples for XML snippets will be provided in one of the future versions*

1631



See [XML Color Legend](#) for color usage

1632 **XML Elements**

1633 The following tables provide a complete set of XML elements and attributes required for the  
1634 *SubmissionReference* element, and any special instructions.



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

1635

1636 **SubmissionReference.id**

1637

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>Id.item</i>		[1..1]		This is a container element for the <i>SubmissionReference</i>
	<i>root</i>	[1..1]	Valid OID or UUID	This is the root attribute that provides the global unique identifier for the <i>SubmissionReference</i> element
<b>Conformance</b>		The <i>id.item@root</i> is a required element		



Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
<i>Business Rules</i>				More than one <i>item</i> element may be provided.
<i>Excluded Elements and Attributes</i>				The following attributes are not required by eCTD 4.0: <ul style="list-style-type: none"> <li>• <i>id@extension</i></li> <li>• <i>id@identifierName</i></li> <li>• <i>id@scope</i></li> <li>• <i>id@reliability</i></li> <li>• <i>id@displayable</i></li> </ul>

1638

### 1639 **Terminology**

1640 There is no further terminology foreseen

1641

1642

## 1643 **9.24 Submission Unit**

1644 The Submission Unit is a collection of documents provided to the Regulatory Authority at one  
1645 time or to the Applicant incase the Regulatory Authority will send their list of question or  
1646 assessment report using the same messaging standard. A submission unit always relates to a  
1647 regulatory activity specified by the submission that is related to a specified application.

1648 In case a submission unit needs to be withdrawn by the applicant a new message needs to be sent  
1649 just providing the new status code “nullified” of that previously submitted unit. Content  
1650 references are not required as the status code of document elements will not change and also CoU  
1651 elements are not affected.

1652

### 1653 **Description**

1654 The *submissionUnit* element indicates the information about an individual eCTD v4.0 XML  
1655 message – i.e., only one submission unit can be sent at a time.

### 1656 **Location in XML**

1657 The *submissionUnit* element follows the *subject* element, which follows the *controlActProcess*  
1658 element.

### 1659 **XML details**

1660 The following is an example of the XML for the *submissionUnit* element.

### 1661 **Submission Unit**

1662 `<subject_typeCode="SUBJ">`

1663 `<submissionUnit>`

1664 `<id root="78965412-3214-5698-7856-985412563254"/>`

```

1665     <code code="ICH-Amendment" codeSystem="12365478-9874-5632-11235-
1666 951268473654"/>
1667     <statusCode code="active"/>
1668     .....
1669     [Additional information may appear after the addition of the statusCode (if one exists,
1670 otherwise this will follow the title or code elements. For example, depending on the type of
1671 submission unit the additional elements may be available to select from the submission unit-
1672 component, callBackContact, componentOf or subject elements]
1673     ...
1674     <componentOf>
1675     <sequenceNumber value="00001"/>
1676     <submission>
1677     ...
1678     [Additional information will follow for the submission and application elements.]
1679     ...
1680     </submission>
1681     </componentOf>
1682 </submissionUnit>
1683 </subject>

```

1686 **XML Elements**

1687 Tables with a complete set of XML elements and attributes required for the **SubmissionUnit**  
1688 element are provided in the ICH IG and will not be repeated here. No additional requirements  
1689 apply for EU M1.

1691 **Terminology**

1692 Type of submission unit will be defined by a controlled vocabulary (see section 6.1.15) either for  
1693 Applicants or for Regulatory Authorities. Note: There are different submission unit types  
1694 codes applicable whether the sender is a Applicant or a Regulatory Authority. The regulatory status  
1695 codes are used for status. (see Section 6.1.11)

1696 **Related Elements**

1697 The following elements are related to **submissionUnit** and require additional information:

- 1698 • **callBack.Contact** (see Section 9.1.5)
- 1699 • **primaryInformationRecipient** (see Section 9.1.25)
- 1700 • **submissionReference** (see Section 9.1.23)

1703 **9.25 Territorial Authority (as author of review)**

1704 This element refers to the author of the review in the meaning of the Reference Member State or  
1705 responsible authority, e.g. EMA in centralized procedures, and refers to the product and the  
1706 product category and states the respective authority and the territory of responsibility. This

1707 element will be used if the message is created by Regulatory Authority sending back e.g. the  
1708 Assessment Report or List of Questions.

#### 1709 **XML details**

```
1710 <author>
1711   <territorialAuthority>
1712     - <!-- Recipient review authority's country if applied to review level -->
1713     <territory>
1714       <code code="FR" codeSystem="Country Code system OID" />
1715     </territory>
1716     <governingAuthority>
1717       <name>
1718         <!-- Recipient review authority -->
1719         <part code="ansm" value=" L'Agence nationale de sécurité du médica-
1720         ment et des produits de santé " codeSystem="Authority Code syst OID" />
1721       </name>
1722     </governingAuthority>
1723   </territorialAuthority>
1724 </author>
1725
1726
```

#### 1727 **9.26 Territorial Authority (as primary information recipient related to** 1728 **contextofUse)**

1729 The elements *primaryInformationRecipient* and *informationRecipient* (see section below) will  
1730 provide names of *territorialAuthority*. For centralized procedure this does mean the EMA will be  
1731 stated in both cases. In case of DCP the Reference Member State, i.e. France, will be named by  
1732 using the *primaryInformationRecipient* element and the *informationRecipient* element, all  
1733 Member States involved, i.e. The Netherlands, France, Germany (BfArM), will be named by  
1734 using only the *informationRecipient* element. This element will be provided once as always only  
1735 one agency will serve as a primary recipient..

#### 1736 **XML details**

```
1737 <primaryInformationRecipient>
1738 <!-- Specific Health Authority and/or country to which this CoU is for (if needed
1739 to be specified) -->
1740   <territorialAuthority>
1741     <territory>
1742       <code code="FR" codeSystem="country code system OID"
1743       codeSystemName="country code system name" />
1744     </territory>
1745     <governingAuthority>
1746       <id root="52345678-1234-1234-1234-12345678901" />
1747       <name>
1748         <part value="ansm" code="FR-ansm" />
1749       </name>
```

```
1750         </governingAuthority>
1751     </territorialAuthority>
1752 </primaryInformationRecipient>
1753
```

1754

## 1755 **9.27 Territorial Authority (as information recipient related to application)**

1756 This element refers to the recipients receiving the submission unit / submission and being  
1757 involved into the procedure. In consequence those recipients need to be named in whose country  
1758 the medicinal product is applied for being marketed.

### 1759 **Description**

1760 The *territorialAuthority* element indicates the country for which the authority decision will be  
1761 relevant and which NCA is the recipient in case more than one is responsible to authorize  
1762 medicinal products in one country, e.g. PEI for vaccines and BfArM for herbal medicinal products  
1763 in Germany.

### 1764 **Location in XML**

1765 The *territorialAuthority* element follows the *informationRecipient* element, which related to the  
1766 *Application* element.

### 1767 **XML details**

```
1768     <informationRecipient>
1769         <territorialAuthority>
1770             <territory>
1771                 <code code="FR" />
1772             </territory>
1773             <governingAuthority>
1774                 id root="52345678-1234-1234-1234-12345678901" />
1775                 <name>
1776                     <part value="ansm" code="FR-ansm" />
1777                 </name>
1778             </governingAuthority>
1779         </territorialAuthority>
1780     </informationRecipient>
1781     <informationRecipient>
1782         <territorialAuthority>
1783             <territory>
1784                 <code code="NL" />
1785             </territory>
1786             <governingAuthority>
1787                 id root="62345678-1234-1234-1234-12345678901" />
1788                 <name>
1789                     <part value=" MEB " code=" NL-MEB " />
1790                 </name>
1791             </governingAuthority>
```

```

1792         </territorialAuthority>
1793     </informationRecipient>
1794 <informationRecipient>
1795     <territorialAuthority>
1796         <territory>
1797             <code code="DE" />
1798         </territory>
1799         <governingAuthority>
1800             id root="72345678-1234-1234-1234-12345678901" />
1801         <name>
1802             <part value=" BFARM " code=" DE-BFARM " />
1803         </name>
1804         </governingAuthority>
1805     </territorialAuthority>
1806 </informationRecipient>
1807

```

## 1808 **XML Elements**

1809 The following tables provide a complete set of XML elements and attributes required for the  
1810 *territorialAuthority* element, and any special instructions.



*The **classCode** is fixed to "TERR". This value is not required in the XML message.*

1811

## 1812 **Related Elements**

1813 The following elements are related to *territorialAuthority* and require additional information:

### 1814 **Territory**

1815 The *Territory* provides the information about the area of responsibility to authorize medicinal  
1816 products for marketing.

### 1817 **Terminology**

1818 The name of the territory is provided in the respective controlled vocabulary (see section 7.1.10).

1819

### 1820 **GoverningAuthority**

1821 The *governingAuthority* provides the information about the authority responsible to authorize  
1822 medicinal products for marketing. As not only one authority may take the responsibility per  
1823 country both elements are required.

### 1824 **Terminology**

1825 The name of the authority is provided in the respective controlled vocabulary (see section 7.1.17).

1826

1827

## 1828 **10. CREATING THE MESSAGE**

1829 With the individual components of the XML message described above, each of those components  
1830 will now be used to demonstrate how to compose multiple components to address a specific  
1831 scenario and to explain how to address the creation and modifications to the content transmitted  
1832 during the lifecycle of a submission focusing on EU M1 as recommendations need to differ from  
1833 ICH recommendations or cover EU specific scenarios.

1834

1835

### 1836 **10.1 Individual Components**

#### 1837 **10.1.1 Managing Country Specific Product Names in MRP and DCP**

1838 Different from the centralized and purely national procedures, in MRP and DCP different product  
1839 names per Member State may occur. Not copying content from the annexes of the application  
1840 form, but supporting agency specific processing the product names related to the territory of the  
1841 assigning authority can be stated in *ManufacturedProduct* and related elements.

1842

#### 1843 **XML example for different product names in MRP/DCP:**

```
1844 = <subject1>  
1845   - <!-- to have multiple product name (e.g. WonderMat in Germany, Wonder Drug in NL,  
1846     WonderPil in UK and PileWonder in France -->  
1847   = <manufacturedProduct>  
1848     <id />  
1849   = <manufacturedProduct>  
1850     = <asNamedEntity>  
1851       = <assigningTerritory>  
1852         <code code="DE" />  
1853         = <name>  
1854           - <!-- Product name type and value -->  
1855             <part value="WonderMat" language="de" />  
1856           </name>  
1857         </assigningTerritory>  
1858       </asNamedEntity>  
1859     = <ingredient>  
1860       = <activeIngredientSubstance>  
1861         = <name>  
1862           - <!-- Substance name type and value -->  
1863             <part code="INDO1" codeSystem="Active ingredient code system OID"  
1864 value="Pioglitazone hydrochloride" />  
1865             <part code="INDO2" codeSystem="Active ingredient code system OID"  
1866 value="Metformin hydrochloride " />  
1867           </name>  
1868         </activeIngredientSubstance>
```

```

1869         </ingredient>
1870     </manufacturedProduct>
1871 </manufacturedProduct>
1872 </subject1>
1873 = <subject1>
1874     = <manufacturedProduct>
1875         <id />
1876     = <manufacturedProduct>
1877     = <asNamedEntity>
1878         = <assigningTerritory>
1879             <code code="NL" />
1880             = <name>
1881                 - <!-- Product name type and value -->
1882                 <part value="Wonder Drug" language="nl" />
1883                 </name>
1884             </assigningTerritory>
1885         </asNamedEntity>
1886     = <ingredient>
1887         = <activeIngredientSubstance>
1888             = <name>
1889                 - <!-- Substance name type and value -->
1890                 <part code="INDO1" codeSystem="Active ingredient code system OID"
1891 value="Pioglitazone hydrochloride" />
1892                 <part code="INDO2" codeSystem="Active ingredient code system OID"
1893 value=" Metformin hydrochloride" />
1894                 </name>
1895             </activeIngredientSubstance>
1896         </ingredient>
1897     </manufacturedProduct>
1898 </manufacturedProduct>
1899 </subject1>
1900 = <subject1>
1901     = <manufacturedProduct>
1902         <id />
1903     = <manufacturedProduct>
1904     = <asNamedEntity>
1905         = <assigningTerritory>
1906             <code code="UK" />
1907             = <name>
1908                 - <!-- Product name type and value -->
1909                 <part value="WonderPil" language="en" />
1910                 </name>
1911             </assigningTerritory>
1912         </asNamedEntity>
1913     = <ingredient>
1914         = <activeIngredientSubstance>

```

```

1915     = <name>
1916     - <!-- Substance name type and value -->
1917         <part code="IND01" codeSystem="Active ingredient code system OID"
1918 value="Pioglitazone hydrochloride" />
1919         <part code="IND02" codeSystem="Active ingredient code system OID"
1920 value=" Metformin hydrochloride" />
1921     </name>
1922 </activeIngredientSubstance>
1923 </ingredient>
1924 </manufacturedProduct>
1925 </manufacturedProduct>
1926 </subject1>
1927 = <subject1>
1928     = <manufacturedProduct>
1929         <id />
1930     = <manufacturedProduct>
1931     = <asNamedEntity>
1932     = <assigningTerritory>
1933         <code code="FR" />
1934     = <name>
1935     - <!-- Product name type and value -->
1936         <part value="Pile Wonder" language="fr" />
1937     </name>
1938 </assigningTerritory>
1939 </asNamedEntity>
1940 = <ingredient>
1941     = <activeIngredientSubstance>
1942     = <name>
1943     - <!-- Substance name type and value -->
1944         <part code="IND01" codeSystem="Active ingredient code system OID"
1945 value="Pioglitazone hydrochloride" />
1946         <part code="IND02" codeSystem="Active ingredient code system OID"
1947 value=" Metformin hydrochloride" />
1948     </name>
1949 </activeIngredientSubstance>
1950 </ingredient>
1951 </manufacturedProduct>
1952 </manufacturedProduct>
1953 </subject1>
1954 = <subject1>
1955

```

### 1956 10.1.2 Managing Country Specific Processing Numbers

1957 Only in case of MRP and DCP multiple national procedure numbers need to be stated in addition  
1958 to the procedure number. The latter is inserted as UUID of the application. The application.id.item



1959 element will be repeated as many as needed. The extension provides the container for a national  
1960 procedure number.

1961 **XML example:**

```
1962 <componentOf>  
1963   <application>  
1964     <id xsi:type="DSET_II">  
1965       <item root="fr-2083-001-dc" extension="de-2189072"/>  
1966       <item root="fr-2083-001-dc" extension="nl-456789"/>  
1967       <item root="fr-2083-001-dc" extension="uk-341974"/>  
1968       <item root="fr-2083-001-dc" extension="fr-234-345"/>  
1969     </id>  
1970     ...  
1971     [Additional information may appear after the addition of the Application.code, for  
1972     example any of the following elements related to Application – component, referencedBy,  
1973     informationRecipient, reference, subject, or holder]  
1974     ...  
1975   </application>  
1976 </componentOf>  
1977
```

1978 **10.1.3 Product Information Texts in EU Module 1.3.1**

1979 Product information texts need to have a set of metadata to specify the country of applicability,  
1980 the language, the type of text and – depending from the product structure – information regarding  
1981 pharmaceutical form or strength this text is dedicated to be used. These metadata will be assigned  
1982 using different elements of the eCTD XML message:

1983 The *document.text* element holds a *language* element

1984 The *document* element holds a *code* element specifying document types like smpc or pl

1985 A keyword from the controlled vocabulary of ISO country codes specifies the country of  
1986 applicability.

1987 A keyword value from the sponsor defined *keywordDefinition* of pharmaceutical form or strength  
1988 will allow a presentation of the set of product information texts provided in the QRD template per  
1989 pharmaceutical form or strength.

1990 Note: The keyword value for pharmaceutical form must not use a standard term according  
1991 EDQM. The purpose of this value is just to differentiate the product presentations and could be  
1992 simple as possible.

1993 **XML example:**

```
1994 -<component>  
1995   -<contextOfUse> <id root="12345678-1234-5678-3456-127536489712"/>  
1996     <!-- CTD Heading -->  
1997     -<code codeSystem="Code system OID " code="m131-smplabelpl">  
1998       <displayName value="1.3.1 SmPC, Label ,PL">  
1999     </code>  
2000     <title value="SmPC-PL-Label"/>  
2001     <!-- CTD Heading status -->  
2002     <statusCode code="active"/>
```

```

2003     <setId root="set ID"/>
2004     <versionNumber value="1.0"/>
2005     -<primaryInformationRecipient>
2006     <!-- Specific Health Authority and/or country to which this CoU is for (if needed to be specified) -->
2007         -<territorialAuthority>
2008             -<territory>
2009                 <code codeSystem="FR" codeSystemName="country code system name"/>
2010             </territory>
2011         </territorialAuthority>
2012     </primaryInformationRecipient>
2013     -<derivedFrom>
2014         -<documentReference>
2015             <id root="12345678-1234-1234-1234-198765432198" extension="12345"/>
2016         </documentReference>
2017     </derivedFrom>
2018     -<subjectOf>
2019         <!-- The SubmissionReference element is used to indicate when a ContextOfUse is not
2020              relevant to a specific Submission within a submissionUnit.-->
2021         -<submissionReference>
2022             <id xsi:type="DSET_II">
2023                 <item root="12345678-1234-5678-3456-127536489712"/>
2024             </id>
2025         </submissionReference>
2026     </subjectOf>
2027 </contextOfUse>
2028 </component>
2029

```

2030 Product information text may be presented as simple documents or compound document consisting of  
2031 SmPC, PL, and Labelling

```

2032
2033     <component>
2034     <!--Compound Document (SmPC, Label, PL)-->
2035         <document>
2036             <id root="12345678-1234-1234-1234-198765432198"/>
2037             <title value="SmPC-PL-Label"/>
2038             <statusCode code="active"/>
2039             <setId root="12345678-3333-2222-1111-123456789012"/>
2040             <versionNumber value="1"/>
2041             <!--Id reference to Simple Document A1 (SmPC)-->
2042             <component>
2043                 <priorityNumber value="1"/>
2044                 <document>
2045                     <id root="12345678-5555-9999-9999-123456789013"/>
2046                 </document>
2047             </component>
2048             <!--Id reference to Simple Document A2 (Package Leaflet)-->
2049             <component>
2050                 <priorityNumber value="3"/>
2051                 <document>
2052                 ^ <id root="12345678-4444-9999-9999-123456789014"/>
2053                 </document>
2054             </component>
2055             <!--Id reference to Simple Document A3 (Labelling)-->

```

```

2056     <component>
2057         <priorityNumber value="2"/>
2058         <document>
2059             <id root="12345678-6666 -9999-9999-123456789016"/>
2060         </document>
2061     </component>
2062     <referencedBy>
2063         <keyword>
2064             <code code="common" codeSystem= "CC-Code"/>
2065         </keyword>
2066     </referencedBy>
2067     -<referencedBy>
2068         <keyword>
2069             <code code="200mg" codeSystem= "Sponsor-Strength-Id"/>
2070         </keyword>
2071     </referencedBy>
2072 </document>
2073 </component>

```

It will also be possible to use simple documents without a compound document element to cover the set. In this example the simple documents serving as the reference of the compound document

```

2078 <component>
2079 <!--Simple Document #A1 - SmPC-->
2080     <document>
2081         <id root="12345678-9999-9999-9999-123456789013"/>
2082         <code code="smpc" codeSystem="OID for EU Document Code"/>
2083         <title value="SmPC"/>
2084         <text integrityCheckAlgorithm="SHA256" language="en">
2085             <reference value="../../../m1/13-pi/131-smpclabelpi/131-smpc.pdf"/>
2086             <integrityCheck> e3b0c44298fc1c149afb4c8996fb92427ae41e4649b934ca495991b7852b855</integrity Check>
2087         </text>
2088         <statusCode code="active"/>
2089         <setId root="12345678-1111-1111-1111-123456789013"/>
2090         <versionNumber value="1"/>
2091         <referencedBy>
2092             <keyword>
2093                 <code code="common" codeSystem= "CC-Code"/>
2094             </keyword>
2095         </referencedBy>
2096         -<referencedBy>
2097             <keyword>
2098                 <code code="200mg" codeSystem= "Sponsor-Strength-Id"/>
2099             </keyword>
2100         </referencedBy>
2101     </document>
2102 </component>
2103 <component>
2104 <!--Simple Document #A2 – Package Leaflet-->
2105     <document>
2106         <id root="12345678-9999-9999-9999-123456789014"/>

```

```

2107     <code code="pl" codeSystem="OID for EU Document Code"/>
2108     <title value="Package Leaflet"/>
2109     <text integrityCheckAlgorithm="SHA256" language="en">
2110         <reference value="../../m1/13-pi/131-smpclabelpl/131-pl.pdf"/>
2111         <integrityCheck> 3b0c44298fc1c149afb4c8996fb92427ae41e4649b934ca45991b7852b855</integrityCheck>
2112     </text>
2113     <statusCode code="active"/>
2114     <setId root="12345678-1111-1111-1111-123456789014"/>
2115     <versionNumber value="1"/>
2116 <referencedBy>
2117     <keyword>
2118         <code code="common" codeSystem="CC-Code"/>
2119     </keyword>
2120 </referencedBy>
2121 -<referencedBy>
2122 <keyword>
2123     <code code="200mg" codeSystem="Sponsor-Strength-Id"/>
2124 </keyword>
2125 </referencedBy>
2126 </document>
2127 </component>
2128 <component>
2129 <!--Simple Document #A3 – Labelling-->
2130 <document>
2131     <id root="12345678-9999-9999-9999-123456789016"/>
2132     <code code="label" codeSystem="OID for EU Document Code"/>
2133     <title value="Labelling"/>
2134     <text integrityCheckAlgorithm="SHA256" language="en">
2135         <reference value="../../m1/13-pi/131-smpclabelpl/131-label.pdf"/>
2136         <integrityCheck> e3b0c44298fc1c149afb4c8996fb92427ae41e4649b934ca495991855</integrityCheck>
2137     </text>
2138     <statusCode code="active"/>
2139     <setId root="12345678-1111-1111-1111-123456789015"/>
2140     <versionNumber value="1"/>
2141 <referencedBy>
2142     <keyword>
2143         <code code="common" codeSystem="CC-Code"/>
2144     </keyword>
2145 </referencedBy>
2146 -<referencedBy>
2147 <keyword>
2148     <code code="200mg" codeSystem="Sponsor-Strength-Id"/>
2149 </keyword>
2150 </referencedBy>
2151 </document>
2152 </component>
2153
2154

```

2155 **10.2 Content Management (contextOfUse and Documents)**

2156 There are no deviating principles to apply in case of an EU eCTD XML message. The example  
2157 below shows a short sample of *contextOfUse* and *Document* elements referencing a few EU M1  
2158 files.

2159 XML example:

2160 <componentOf>  
2161 <application>

2163 *[Additional information may appear after the addition of the Application.code, for  
2164 example any of the following elements related to holder, informationRecipient,  
2165 ReviewProcedure, Application.Reference]*

```
2166 <component>  
2167 <document>  
2168 <id root="12345678-5555-5555-5555-555555550001"/>  
2169 <title value="Cover Letter"/>  
2170 <text integrityCheckAlgorithm="SHA256">  
2171 <reference value="../../../m1/eu/10-cover/common-cover-20120420.pdf"/>  
2172 <integrityCheck>3285a776897425b9a3b87abbaaf163fb261242397997b003efe3201e</integrityCheck>  
2173 </text>  
2174 <statusCode code="active"/>  
2175 <setId root="57694301"/>  
2176 <versionNumber value="1"/>  
2177 </document>  
2178 </component>  
2179 <component>  
2180 <document>  
2181 <id root="12345678-5555-5555-5555-555555550001"/>  
2182 <title value="Tracking Table"/>  
2183 <text integrityCheckAlgorithm="SHA256">  
2184 <reference value="../../../m1/eu/10-cover/common-cover-tracking-20120420.pdf"/>  
2185 <integrityCheck>3285a776xv745a25b9a3b87abbaaf163f726ec91242397997b003efe3201e</integrityCheck>  
2186 </text>  
2187 <statusCode code="active"/>  
2188 <setId root="573421301"/>  
2189 <versionNumber value="1"/>  
2190 </document>  
2191 </component>  
2192 <component>  
2193 <document>  
2194 <id root="12345678-5555-5555-5555-555555550002"/>  
2195 <title value="Expert Quality"/>  
2196 <text integrityCheckAlgorithm="SHA256">  
2197 <reference value="../../../m1/eu/14-expert/141-quality/quality-meier.pdf"/>  
2198 <integrityCheck>3285a776897425b9a3b877z45abbaaf1726ec91242397997b003efe3202e</integrityCheck>  
2199 </text>  
2200 <statusCode code="active"/>  
2201 <setId root="29872638"/>  
2202 <versionNumber value="1"/>  
2203 </document>  
2204 </component>  
2205 </component>  
2206 </component>
```

```

2207 <document>
2208   <id root="12345678-5555-5555-5555-555555550003"/>
2209   <title value="Expert Non-Clinical"/>
2210   <text integrityCheckAlgorithm="SHA256">
2211     <reference value="../../../m1/eu/14-expert/142-nonclinical/nonclinical-schulz.pdf"/>
2212     <integrityCheck>3285a776897425b9a3b87abbaaf16
2213       3fb2646726ec91242397997b003efe3203e</integrityCheck>
2214   </text>
2215   <statusCode code="active"/>
2216   <setId root="6910897729"/>
2217   <versionNumber value="1"/>
2218 </document>
2219 </component>
2220 </application>
2221 </componentOf>
2222

```

The respective folder structure is provided below:

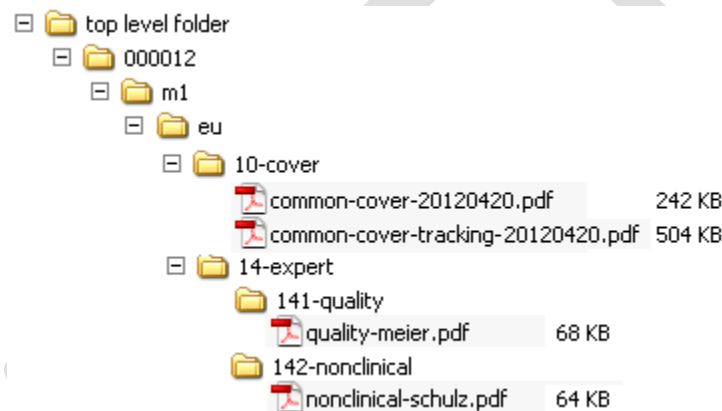


Figure 2: Folder structure related to submission unit message

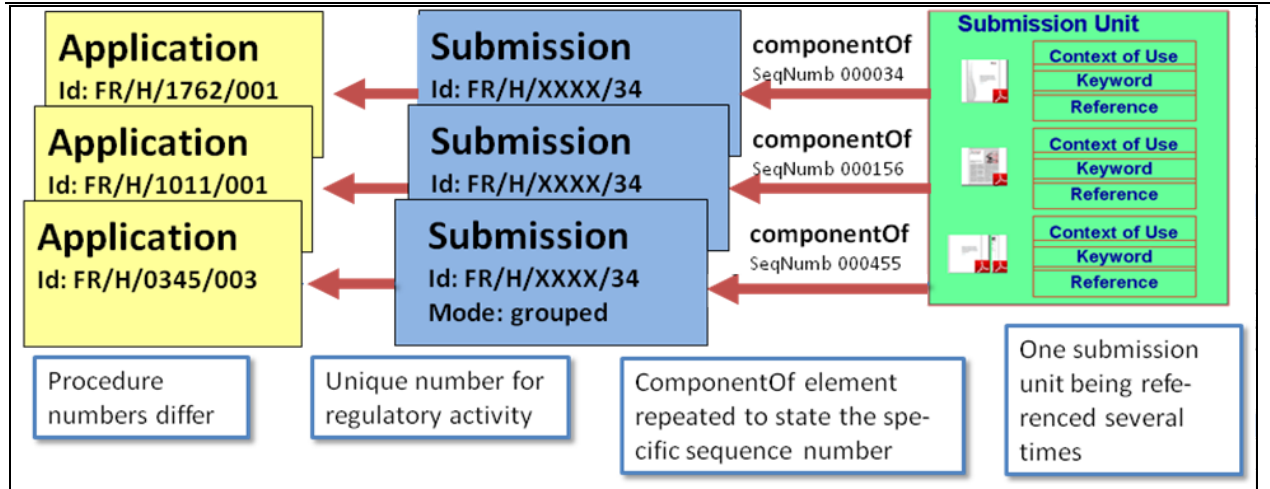
## 10.3 Complex Scenarios

### 10.3.1 Referencing Multiple Applications in Case of Grouped or Workshared Regulatory Activities (Submissions)

Grouped and workshared variations are the only business case for sending a Submission Unit with more than one *componentOf.Submission* element (e.g., manufacturing changes that affect more than one application) to associated this *submissionUnit* via multiple *submission* elements to all *applications* concerned by the grouped variation.

2236  
2237

Figure 3: Referencing multiple applications



2238  
2239

2240 **XML example:**

```

2241 <subject typeCode="SUBJ">
2242   <submissionUnit>
2243     <id></id>
2244     <code></code>
2245     <title></title>
2246     <statusCode></statusCode>
2247     <callBackContact>
2248       <contactParty>
2249         ...
2250       </contactParty>
2251     </callBackContact>
2252     <component>
2253       <priorityNumber value="1"/>
2254       <contextOfUse>
2255         ...
2256       </contextOfUse>
2257     </component>
2258     <componentOf>
2259       <sequenceNumber>
2260         <sequenceNumber value="000001"/>
2261       </sequenceNumber>
2262       <submission>
2263         <id>
2264           <item root="Globally unique submission ID" extension="FR/H/XXXX/34" />
2265           <code code="var-type2" codeSystem="Submission Type Code system OID" codeSystemName="Submission
2266             Type Codes" />
2267             <subject1>
2268               <mode>
2269                 <id>
2270                   <code="grouped" />
2271                 </id>
2272               </mode>
2273             </subject1>
2274             <subject2>
2275               <review>
2276                 <author>
2277                   ...
2278                 </author>
2279               </review>
2280             </subject2>
2281           </submission>
        </componentOf>
      </sequenceNumber>
    </componentOf>
  </submissionUnit>
</subject>

```



```

2282     -<componentOf>
2283         -<application>
2284             <id xsi:type="DSET_II">
2285                 <item root="fr-2083-001-dc" extension="de-2189072"/>
2286                 <item root="fr-2083-001-dc" extension="nl-456789"/>
2287                 <item root="fr-2083-001-dc" extension="uk-341974"/>
2288                 <item root="fr-2083-001-dc" extension="fr-234-345"/>
2289             </id>
2290             ...
2291             [Additional information may appear after the addition of the Application.code, for example any of the following
2292             elements related to Application – component, referencedBy, informationRecipient, reference, subject, or
2293             holder]
2294             ...
2295             </application>
2296         </component>
2297     -<component>
2298         <sequenceNumber>
2299             <sequenceNumber value="000021"/>
2300         </sequenceNumber>
2301         <submission>
2302             <id/>
2303             <item root="Globally unique submission ID" extension="FR/H/XXX/34" />
2304             <code code="var-type2" codeSystem="Submission Type Code system OID" codeSystemName="Submission
Type Codes " />
2305             <subject1>
2306                 <mode>
2307                     <id/>
2308                     <code="grouped" />
2309                 </mode>
2310             </subject1>
2311             <subject2>
2312                 <review>
2313                     <author>
2314                         ...
2315                     </author>
2316                 </review>
2317             </subject2>
2318         </submission>
2319     </component>
2320 </componentOf>
2321 -<componentOf>
2322     -<application>
2323         <id xsi:type="DSET_II">
2324             <item root="de-0353-001-dc" extension="de-2172912"/>
2325             <item root=" de-0353-001-dc" extension="nl-34810"/>
2326             <item root=" de-0353-001-dc" extension="uk-287645"/>
2327             <item root=" de-0353-001-dc" extension="fr-293867"/>
2328         </id>
2329         ...
2330         [Additional information may appear after the addition of the Application.code, for example any of the following
2331         elements related to Application – component, referencedBy, informationRecipient, reference, subject, or
2332         holder]
2333         ...
2334         </application>
2335     </component>
2336     -<component>
2337         <sequenceNumber>
2338             <sequenceNumber value="000045"/>
2339         </sequenceNumber>
2340         <submission>
2341             ...
2342             </submission>
2343         </component>
2344     </componentOf>
2345     -<application>
2346         ...
2347         </application>
2348     </componentOf>
2349 </submission>
2350 </componentOf>
2351 </submissionUnit>

```

*The complete section needs to be repeated as needed by number of applications involved.*



2352 </subject>

2353

2354

### 2355 **10.3.2 Managing Duplicates**

2356 In case of submitting duplicates of a new marketing authorization application (different product  
2357 names but one sponsor using the identical dossier) the assessment and processing of these  
2358 duplicates can be simplified by building a group. This will be managed by the *submissionGroup*  
2359 element. This serves as an indicator in the review system to manage all related MAA as a group  
2360 (see Section 6.22)

2361

### 2362 **10.3.3 Referencing across submissions and application of the same** 2363 **pharmaceutical company**

2364 The principles of referencing is entirely the same regardless whether a reference should be  
2365 presented within a submission unit, where a document is to be displayed with two different  
2366 context of use, or across submissions, or across applications. Always a *document* element will be  
2367 referenced by the new *contextOfUse* element by its ID. The *document* element provides the link  
2368 to the PDF-file. The *document* element ID needs to be known which might not work, if the  
2369 compiling systems of different companies are not interoperable once the medicinal product was  
2370 transferred to another MAH. As a general rule, no *document* elements can be referenced if they  
2371 are not submitted to all member states involved. From technical point of view the rules outlined in  
2372 the ICH Implementation Guide apply entirely to EU Module 1 as well.

2373 Remark: Document title corrections will be displayed wherever the document element is  
2374 referenced. This effect is acceptable as no regulatory content will be changed.

2375

## 2376 **10.4 eCTD XML message from regulators**

2377 As it was the purpose of eCTD improvement version 4.0 supports two way communication. To  
2378 this regard XML messages have to be built by regulators as well. These messages should include  
2379 any type of assessment reports and list of questions, but in case of messages at the end of a  
2380 procedure is should provide the updated regulatory status as well, the authorization letter and the  
2381 finally agreed product information texts. Several elements relevant for a messages sent by  
2382 applicants will not be needed by regulators. The following tables will illustrate the constrained  
2383 part.

**Table 11: XML Structure- Submission Unit from Regulators**

XML Structure	
<p>The eCTD begins by identifying the <b>subject</b> element of the XML message. The payload message starts with the <b>SubmissionUnit</b> element and relates the rest of the elements to the Submission Unit being sent. The <b>SubmissionUnit</b> element in case of a message from regulators contains the following elements and their attributes:</p> <ul style="list-style-type: none"> <li>• <b>callbackContact.ContactParty</b></li> <li>• <b>component.contextOfUse</b> <ul style="list-style-type: none"> <li>○ <b>derivedFrom.documentReference</b></li> </ul> </li> <li>• <b>componentOf.Submission</b></li> </ul>	
<div style="border: 1px solid black; padding: 5px; display: inline-block;">Mandatory elements in the message</div>	
<pre> &lt;subject typeCode="SUBJ"&gt;   &lt;submissionUnit&gt;     &lt;id&gt;&lt;/id&gt;     &lt;code&gt;&lt;/code&gt;     &lt;title&gt;&lt;/title&gt;     &lt;statusCode&gt;&lt;/statusCode&gt;     &lt;callbackContact&gt;       &lt;contactParty&gt;         &lt;id&gt;&lt;/id&gt;         &lt;statusCode&gt;&lt;/statusCode&gt;         &lt;contactPerson&gt;           &lt;name xsi:type="BAG_EN"&gt;             &lt;item&gt;&lt;part&gt;&lt;/item&gt;           &lt;/name&gt;           &lt;telecom xsi:type="BAG_TEL"&gt;             &lt;item&gt;&lt;/item&gt;           &lt;/telecom&gt;         &lt;/contactPerson&gt;       &lt;/contactParty&gt;     &lt;/callbackContact&gt;     &lt;component&gt;       &lt;priorityNumber value=""/&gt;       &lt;contextOfUse&gt;         &lt;id&gt;&lt;/id&gt;         &lt;code&gt;&lt;/code&gt;         &lt;title&gt;&lt;/title&gt;         &lt;statusCode&gt;&lt;/statusCode&gt;         &lt;setId&gt;&lt;/setId&gt;         &lt;versionNumber value=""/&gt;         &lt;primaryInformationRecipient&gt;           &lt;territorialAuthority&gt;             &lt;governingAuthority&gt;               &lt;/governingAuthority&gt;             &lt;/territorialAuthority&gt;           &lt;/primaryInformationRecipient&gt;         &lt;/component&gt;       &lt;/subject&gt;           </pre>	<div style="border: 1px solid black; padding: 5px; margin-bottom: 10px;"> <p><b>submissionUnit</b> (see Section 6.1.15).</p> </div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 10px;"> <p><b>callbackContact</b> Details of process management contact</p> </div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 10px;"> <p><b>contextOfUse</b> <u>This is for EU Module 1 e.g. "assessments"</u></p> </div> <div style="border: 1px solid black; padding: 5px;"> <p><b>primaryInformationRecipient.territorialAuthority</b> In case of comments from CMS, this element can be used for recipient role of the RMS . If the message is created by the RMS, this element should not be used.</p> </div>

XML Structure	
<pre> &lt;/sequelTo&gt; &lt;derivedFrom&gt;   &lt;documentReference&gt;     &lt;id&gt;&lt;/id&gt;   &lt;/documentReference&gt; &lt;/derivedFrom&gt; </pre>	<p><b>derivedFrom.documentReference</b>  <u>Any assessment report, list of question or letter to the applicant will be referenced here..</u></p>

2385

**Table 12: XML Structure – Submission from Regulators**

XML Structure	
<p>This section of the XML relates to specifying the <b>Submission</b> element. The following elements may follow the Submission:</p> <ul style="list-style-type: none"> <li>• <b>sequenceNumber</b> (included as an element of the relationship between SubmissionUnit and Submission)</li> <li>• <b>subject2.review</b></li> <li>• <b>subject4.regulatoryStatus</b></li> <li>• <b>subject5.submissionGroup</b></li> </ul>	
<p><b>Mandatory elements in the message</b></p>	
<pre> &lt;componentOf&gt;   &lt;sequenceNumber&gt;&lt;/sequenceNumber&gt;   &lt;submission&gt;     &lt;id&gt;&lt;/id&gt;     &lt;code&gt;&lt;/code&gt;     &lt;subject2&gt;       &lt;review&gt;         &lt;/review&gt;     &lt;/subject2&gt;     &lt;subject4&gt;       &lt;regulatoryStatus&gt;         &lt;code&gt;&lt;/code&gt;       &lt;/regulatoryStatus&gt;     &lt;/subject4&gt;     &lt;subject5&gt;       &lt;submissionGroup&gt;         &lt;id&gt;&lt;/id&gt;       &lt;/submissionGroup&gt;     &lt;/subject5&gt;   &lt;/submission&gt; &lt;/componentOf&gt; </pre>	<p><b>sequenceNumber.submission )</b>  The same number as used by the applicant can be used. The reviewing system need to use the time stamp of the header for display purpose.</p> <p><b>submission )</b></p> <p><b>review</b>  This will include information about the author (RMS) of e.g the assessment report.</p> <p><b>regulatoryStatus</b></p> <p><b>submissionGroup</b>  This element is mandatory only if the assessment reports apply to more than one application.</p>

2386

2387

**Table 13: XML Structure - Application from Regulators**

XML Structure	
<p>This section of the XML relates to the <b>Application</b> element. The application section is constrained to the following elements and their attributes in case of a message from regulators:</p>	
<p><b>informationRecipient.territorialAuthority</b> ←</p> <p><b>component.document</b> ←</p> <p><b>component.priorityNumberdocument</b></p>	<p><i>Mandatory elements in the message</i></p>
<pre> &lt;componentOf&gt;   &lt;application&gt;     &lt;id&gt;       &lt;item root="" extension=""/&gt;     &lt;/id&gt;     &lt;code&gt;&lt;/code&gt;     &lt;informationRecipient&gt;       &lt;territorialAuthority&gt;         &lt;governingAuthority&gt;           &lt;id&gt;&lt;/id&gt;           &lt;name&gt;             &lt;part value=""/&gt;           &lt;/name&gt;         &lt;/governingAuthority&gt;       &lt;/territorialAuthority&gt;     &lt;/informationRecipient&gt;           </pre>	<div style="border: 1px solid black; border-radius: 10px; padding: 5px; margin-bottom: 10px;"> <p><i>application</i></p> </div> <div style="border: 1px solid black; border-radius: 10px; padding: 5px;"> <p><i>informationRecipient.territorial Authority</i> Details of the receiving member states)</p> </div>
<div style="border: 1px solid black; border-radius: 10px; padding: 5px; margin-bottom: 10px;"> <p><i>document</i> This will reference e.g. the assessment report</p> </div> <div style="border: 1px solid black; border-radius: 10px; padding: 5px;"> <p><i>priorityNumber.document</i> Note: in most cases this is not needed.</p> </div>	<pre> &lt;component&gt;   &lt;document&gt;     &lt;id&gt;&lt;/id&gt;     &lt;code&gt;&lt;/code&gt;     &lt;title&gt;&lt;/title&gt;     &lt;text integrityCheckAlgorithm="SHA256" value="" language=""&gt;       &lt;reference value=""/&gt;     &lt;/text&gt;     &lt;integrityCheck&gt;&lt;/integrityCheck&gt;     &lt;statusCode&gt;&lt;/statusCode&gt;     &lt;versionNumber value=""/&gt;     &lt;component&gt;       &lt;priorityNumber value=""/&gt;       &lt;document&gt;         &lt;id&gt;&lt;/id&gt;       &lt;/document&gt;     &lt;/component&gt;   &lt;/document&gt;           </pre>
<p>The the closing element tags for the key elements in the eCTD v4.0 message are not displayed..</p>	

2390 The most consistent way to make use of a sequence number will be to re-use the same of the  
2391 sponsor's submission unit to which the regulator's message responds. For display purpose and to  
2392 support an appropriate ordering the time stamp of the header might be used: the incoming  
2393 message can be presented first (receiving date at agency) and the outgoing message second  
2394 (sending date by agency).

2395

## 2396 **10.5 Building Regulatory Activities (Submission)**

2397 The following section provides a set of message snippets that highlight the Module 1 content.  
2398 These XML samples do not include the information that is relevant to Modules 2-5. All samples  
2399 in this section provide a regulatory activity life cycle within an application.

2400

### 2401 **10.5.1 Marketing Authorisation Application (MAA)**

2402 Examples are provided in Appendix 2

2403

### 2404 **10.5.2 Variation**

2405 Examples are provided in Appendix 2

2406

2407

2408

2409

2410 **11. XML MESSAGE VALIDATION RULES**

2411 [This section should describe how validate an eCTD v4.0 message.]

2412

2413

2414 **12. COMPATIBILITY AND REFERENCE TO EU M1 eCTD v1.4.1**

2415 [This section should describe how to continue an eCTD life cycle started with v3.x using the v4.0  
2416 specification. This should include topics like how to reference eCTD v3.x leafs and sequences  
2417 from within eCTD v4.0 messages, mapping of controlled vocabulary terms used in v3.x into v4.0,  
2418 and any expectations on the display of information from v3.x sequences from tools for displaying  
2419 v4.0 messages.

2420 This section will include commented examples to show the transition/migration of eCTD v3.2.2  
2421 messages into the eCTD v4.0 format.

2422 NOTE: Subsections will be added as ICH defines the various compatibility areas.]

2423

2424













DRAFT

2425

2426 **APPENDIX 1 SAMPLE FILES AND FOLDERS FOR EU MODULE 1 LITE FOLDER**  
2427 **STRUCTURE**

2428 **Module 1**

2429 Current M1 Folder Structure

- [-]  m1
  - [+]  10-cover
  - [+]  12-form
  - [+]  13-pi
  - [+]  14-expert
  - [+]  15-specific
  - [+]  16-environrisk
  - [+]  18-pharmacovigilance
  - [+]  19-clinical-trials
  - [+]  110-paediatrics
  - [+]  additional-data
  - [+]  responses

2430

2431

2432 Proposed Lite M1 Folder Structure

- [-]  m1

2433

2434 Note: Filenames provide sufficient specificity

2435

2436 **APPENDIX 2 SAMPLE ECTD MESSAGES**

2437 This section includes general examples on marketing authorization application and variation type  
2438 2 for illustration.

2439

2440 **Marketing Authorization application**

2441

2442 `<?xml version="1.0" encoding="UTF-8"?>`

2443 `<!-- =====>`

2444 `<!-- ===== Reference Instance for EU =====>`

2445 `<!-- =====>`

2446 `<PORP_IN000001UV ITSVersion="XML_1.0" xsi:schemaLocation="urn:hl7-org:v3`

2447 `RPS_FlatSchema_Jan2012Ballot.xsd" xmlns="urn:hl7-org:v3"`

2448 `xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">`

2449 `<id root="MessageID"/>`

2450 `<creationTime/>`

2451 `<interactionId/>`

2452 `<processingCode/>`

2453 `<processingModeCode/>`

2454 `<acceptAckCode/> =`

2455 `<receiver typeCode="RCV">`

2456

2457 `</receiver>`

2458 `=<sender typeCode="SND">`

2459 `</sender>`

2460 `=<controlActProcess classCode="ACTN" moodCode="EVN">`

2461 `<!-- =====>`

2462 `<!-- classCode is required and has options of CACT, INFO, ACTN, STC Which is appropriate for eCTD purpose ?`

2463 `==>`

2464 `<!-- =====>`

2465 `=<subject typeCode="SUBJ">`

2466 `<!-- Submission Unit =The classCode is fixed to "ACT" and moodCode is fixed to "EVN". .==>`

2467 `<!-- These values are not required in the XML message.==>`

2468 `<!-- The SubmissionUnit element indicates the information about an .==>`

2469 `<!-- individual eCTD v4.0 XML message – i.e., only one submission unit can be sent at a time.==>`

2470 `=<submissionUnit>`

2471 `<!-- This is the root attribute that uniquely identifies the submission ==>`

2472 `<id root="87454521=9874=6541=1236=159842345687"/>`

2473 `<!--The Submission Unit code is provided to indicate the type of submission unit being submitted.==>`

2474 `<!-- Note: that all submissions referenced in the message will have the same submission unit code`

2475 `value.==>`

2476 `<code code="SubmissionUnit code" codeSystem="Submission Code System OID"/>`

2477 `<title value="Submission Unit Description in EU"/>`

2478 `<statusCode code="active"/> =`

2479 `<callbackContact typeCode="CALLBCK">`



```

2480     =<contactParty>
2481 <!-- =====>
2482 <!-- ContactParty can be provided for each contact in a Submission and the following elements . -->
2483 <!-- and attributes are required when the ContactParty element is provided: -->
2484 <!-- An id@root should be provided to uniquely identify the point of contact(s) for a submission. -->
2485 <!-- Note: The id element will be used when a contact needs to be removed as a submission contact. -->
2486 <!-- UUID is a hexadecimal digit in the form of 8=4=4=4=12, . -->
2487 <!-- including 32 digits abd 4 hyphens <id root="UUID for ContacParty" -->
2488 <!-- =====>
2489     <id root="32568794-1234-5467-9874-123654789874" identifierName="Mycontact"/>
2490 <!-- =====>
2491 <!-- The code is provided for the type of contact for the company for the ContactParty.code@code -->
2492 <!-- The ContactParty.code@codeSystem should be provided for the code associated with ContactParty-->
2493 <!-- OID is a sequence of numbers that are uniquely identifying an object and -->
2494 <!-- represent a hierarchically=assigned namesapce. string of digits separated by commas -->
2495 <!-- The HL7 France affiliate organization (which has OID root 2.16.840.1.113883.2.8) allocates -->
2496 <!-- OIDs to its member organizations upon request. -->
2497 <!-- There is no known country=specific OID registry -->
2498 <!-- =====>
2499     <code code="c2125" codeSystem="contactParty Event Code System OID"/>
2500 <!-- The statusCode@code should have the value active when sending a contact for the first time, -->
2501 <!-- or if there has been a change. All contact information should be sent for updated – i.e., -->
2502 <!-- not just the information that has changed. The system will overwrite the existing -->
2503 <!-- information with the new content. ==>
2504 <!-- =====>
2505     <statusCode code="active"/>
2506     =<contactPerson>
2507     =<id>
2508         <item root="Globally unique contact ID"/>
2509     </id>
2510     =<name xsi:type="BAG_EN">
2511         =<item>
2512             <part value="Richard" type="GIV"/>
2513             <part value="Dumont" type="FAM"/>
2514         </item>
2515     </name>
2516 <!-- =====>
2517 <!-- the name element is provided to indicate the name of the point of contact. The name should be provided
2518 with two parts, one for the given (type=GIV), or first name and one for the family (type=FAM), or last name. The
2519 telecom element is provided to indicate all relevant phone (tel:) and email (mailto:) contact information and include
2520 the item@use attribute to indicate the type of phone number (e.g., WP=Work Phone, MC=Mobile contact; Note:
2521 these values are maintained by HL7). Multiple telecom.item elements shall be used to provide each value. ==>
2522 <!-- =====>
2523     =<telecom xsi:type="BAG_TEL">
2524         <item value="tel: +33 1 55 87 31 80" use="WP"/>
2525         <item value="tel: +33 6 25 30 31 80" use="MC"/>

```

```

2526     <item value="mailto:richard.dumont@pharmacompany.com"/>
2527 </telecom>
2528     = <asAgent classCode="AGNT">
2529         = <representedOrganization>
2530             = <name xsi:type="BAG_EN">
2531                 = <item>
2532                     <part value="Organization name"/>
2533                 </item>
2534             </name>
2535         </representedOrganization>
2536     </asAgent>
2537 </contactPerson>
2538 </contactParty>
2539 </callbackContact>
2540 = <subject>
2541     <!-- Category Event ==>
2542     = <categoryEvent>
2543         <code code="Category Event Code" codeSystem="Category Event Code System OID"
2544 codeSystemName="Category Event Code System Name"/>
2545     </categoryEvent>
2546 </subject>
2547 = <component>
2548     <priorityNumber value="1"/>
2549     <!-- =====>
2550     <!-- A UUID is a 16-byte (128-bit) number.. In its canonical form, a UUID is represented by 32 -->
2551     <!-- hexadecimal digits, displayed in five groups separated by hyphens, in the form 8-4-4-4-12-->
2552     <!-- for a total of 36 characters (32 digits and four hyphens) -->
2553     <!-- =====>
2554     = <contextOfUse> <id root="12345678=1234=5678=3456=127536489712"/>
2555         = <code codeSystem="Code system OID for Cover Letter" code="m10cover"> <displayName
2556 value="1.0 Cover Letter"/>
2557     </code>
2558         <title value="1.0 Cover Letter"/>
2559     <!-- =====>
2560     <!-- CTD Heading status ==>
2561     <!-- =====>
2562     <statusCode code="active"/>
2563     <setId root="set ID"/>
2564     <versionNumber value="1.0"/>
2565     = <primaryInformationRecipient>
2566     <!-- Specific Health Authority and/or country to which this CoU is for (if needed to be specified) ==>
2567     = <territorialAuthority>
2568         = <territory>
2569             <code codeSystem="country code system OID" code="DE" codeSystemName="country code
2570 system name"/>
2571         </territory>

```

```

2572     =<governingAuthority>
2573         <id root="DE=BFARM" extension="cover=letter"/>
2574         =<name>
2575             <part code="DE=BFARM" value="BFARM"/>
2576             <part code="FR=AFSSAPS" value="AFSSAPS"/>
2577             <part code="NL=MEB" value="MEB"/>
2578         </name>
2579     </governingAuthority>
2580 </territorialAuthority>
2581 </primaryInformationRecipient>
2582 <!-- =====>
2583 <!-- Lifecycle Operation (replace) the sequelTo is used for tracking the lifecycle of context of uses ==>
2584 <!-- The RelatedContextOfUse is used to connect one context of use with another. .==>
2585 <!-- =====>
2586     =<sequelTo typeCode="RPLC">
2587 <!-- =====>
2588 <!-- the relatedContextOfUse is linked by the sequelTo element, which follows the ContextOfUse element.==>
2589 <!-- The RelatedContextOfUse element provides the sender the ability to relate two contexts of use elements
2590 ==>
2591 <!-- =====>
2592     =<relatedContextOfUse>
2593 <!-- This is the root element that provides the global unique identifier for the RelatedContextOf Use element
2594 ==>
2595         <id root="87454521=9874=6541=1236=159842345687"/>
2596 <!-- The version number indicates which version of the ContextOfUse is being related. ==>
2597         <versionNumber value="1"/>
2598     </relatedContextOfUse>
2599 </sequelTo>
2600 =<derivedFrom>
2601     =<documentReference>
2602         <id root="12345678=1234=1234=1234=198765432198" extension="12345"/>
2603     </documentReference>
2604 </derivedFrom>
2605 =<subjectOf>
2606 <!-- The SubmissionReference element is used to indicate when a ContextOfUse is not relevant to a specific
2607 Submission within a submissionUnit. ==>
2608     =<submissionReference>
2609         =<id xsi:type="DSET_II">
2610             <item root="12345678=1234=5678=3456=127536489712"/>
2611         </id>
2612     </submissionReference>
2613 </subjectOf>
2614 </contextOfUse>
2615 </component>
2616 =<component>
2617     <priorityNumber value="1"/>

```

```

2618     =<contextOfUse>
2619         <id root="Context of Use ID"/>
2620         =<code codeSystem="Code system OID for Application Form" code="m12form">
2621             <displayName value="1.2 application form"/>
2622         </code>
2623             <title value="1.2 application form"/>
2624             <statusCode code="active"/>
2625             <setId root="set ID"/>
2626     <versionNumber value="1.0"/>
2627     =<primaryInformationRecipient>
2628     <!-- Specific Health Authority and/or country to which this CoU is for (if needed to be specified) ==>
2629     =<territorialAuthority>
2630         =<territory>
2631             <code codeSystem="country code system OID" code="DE" codeSystemName="country code system
2632 name"/>
2633         </territory>
2634         =<governingAuthority> <id root="82586972=1254=2356=213698547123"/>
2635             =<name>
2636                 <part code="DE=BFARM" value="BFARM"/>
2637                 <part code="FR=AFSSAPS" value="AFSSAPS"/>
2638                 <part code="NL=MEB" value="MEB"/>
2639             </name>
2640         </governingAuthority>
2641     </territorialAuthority>
2642 </primaryInformationRecipient>
2643 =<derivedFrom>
2644     =<documentReference> <id root="12121212=1234=1234=1234=98765432198" extension="23456"/>
2645     </documentReference>
2646 </derivedFrom>
2647 </contextOfUse>
2648 </component>
2649 =<component>
2650     <priorityNumber value="1"/>
2651     =<contextOfUse> <id root="Context of Use ID"/>
2652     <!-- CTD Heading ==>
2653         =<code codeSystem="Code system OID for Quality Overall Summary" code="m23qos">
2654             <displayName value="2.3 Quality Overall Summary"/>
2655         </code>
2656             <title value="2.3 Quality Overall Summary"/>
2657             <statusCode code="active"/>
2658             <setId root="set ID"/>
2659             <versionNumber value="1.0"/>
2660         =<primaryInformationRecipient>
2661         <!-- Specific Health Authority and/or country to which this CoU is for (if needed to be specified) ==>
2662             =<territorialAuthority>
2663                 =<territory>

```

```

2664         <code codeSystem="country code system OID" code="DE" codeSystemName="country code
2665 system name"/>
2666     </territory>
2667     =<governingAuthority>
2668         <id root="82586972=1254=2356=213698547123"/>
2669         =<name>
2670             <part code="DE=BFARM" value="BFARM"/>
2671             <part code="FR=AFSSAPS" value="AFSSAPS"/>
2672             <part code="NL=MEB" value="MEB"/>
2673         </name>
2674     </governingAuthority>
2675 </territorialAuthority>
2676 </primaryInformationRecipient>
2677 =<derivedFrom>
2678     =<documentReference>
2679         <id root="23232323=1234=1234=1234=98765432198" extension="34567"/>
2680     </documentReference>
2681 </derivedFrom>
2682 </contextOfUse>
2683 </component>
2684 =<component>
2685     <priorityNumber value="1"/>
2686     =<contextOfUse> <id root="Context of Use ID"/>
2687     <!-- CTD Heading -->
2688     =<code codeSystem="Code system OID for Manufacturer" code="m32s2manuf">
2689     <displayName value="3.2.S.2 Manufacturer"/>
2690 </code>
2691     <title value="3.2.S.2 Manufacture"/>
2692     <!-- =====>
2693     <!-- CTD Heading status -->
2694     <!-- =====>
2695     <statusCode code="active"/>
2696     <setId root="set ID"/>
2697     <versionNumber value="1.0"/>
2698     =<primaryInformationRecipient>
2699     <!-- Specific Health Authority and/or country to which this CoU is for (if needed to be specified) -->
2700     =<territorialAuthority>
2701         =<territory>
2702             <code codeSystem="country code system OID" code="DE" codeSystemName="country code
2703 system name"/>
2704         </territory>
2705         =<governingAuthority>
2706             <id root="82586972=1254=2356=213698547123"/>
2707             =<name>
2708                 <part code="DE=BFARM" value="BFARM"/>
2709                 <part code="FR=AFSSAPS" value="AFSSAPS"/>

```

```

2710         <part code="NL=MEB" value="MEB"/> </name>
2711     </governingAuthority>
2712 </territorialAuthority>
2713 </primaryInformationRecipient>
2714 = <derivedFrom>
2715     = <documentReference>
2716         <id root="32323232=1234=1234=1234=98765432198" extension="45678"/>
2717     </documentReference>
2718 </derivedFrom>
2719 = <referencedBy>
2720     = <keyword>
2721         <!-- Context of Use Keyword type (e.g. manufacturer) ==>
2722         = <code codeSystem="Company=OID for manufacturer" code="MANU001">
2723         <!-- Context of Use Keyword value ==>
2724         <displayName value="Hillside Manufacturer"/>
2725         </code>
2726         <statusCode code="active"/>
2727     </keyword>
2728 </referencedBy>
2729 </contextOfUse>
2730 </component> =
2731 <component>
2732 <priorityNumber value="1"/>
2733 <!-- =====>
2734 = <contextOfUse> <id root="Context of Use ID"/>
2735 <!-- CTD Heading ==>
2736 = <code codeSystem="Code system OID for Manufacturer" code="m32s2manuf">
2737     <displayName value="3.2.S.2 Manufacturer"/>
2738 </code> <title value="3.2.S.2 Manufacture"/>
2739 <!-- =====>
2740 <!-- CTD Heading status ==>
2741 <!-- =====>
2742 <statusCode code="active"/>
2743 <setId root="set ID"/>
2744 <versionNumber value="1.0"/>
2745 = <primaryInformationRecipient>
2746 <!-- Specific Health Authority and/or country to which this CoU is for (if needed to be specified) ==>
2747     = <territorialAuthority>
2748         = <territory>
2749             <code codeSystem="country code system OID" code="DE" codeSystemName="country code
2750 system name"/>
2751         </territory>
2752     = <governingAuthority>
2753         <id root="82586972=1254=2356=213698547123"/>
2754     = <name>
2755         <part code="DE=BFARM" value="BFARM"/>

```

```

2756         <part code="FR=AFSSAPS" value="AFSSAPS"/>
2757         <part code="NL=MEB" value="MEB"/> </name>
2758     </governingAuthority>
2759 </territorialAuthority>
2760 </primaryInformationRecipient>
2761 =<derivedFrom>
2762     =<documentReference>
2763         <id root="12345678=1234=1234=1234=98765432198" extension="56789"/>
2764     </documentReference>
2765 </derivedFrom>
2766 =<referencedBy>
2767     =<keyword>
2768         <!-- Context of Use Keyword type (e.g. manufacturer) ==>
2769         =<code codeSystem="Company=OID for manufacturer" code="MANU001">
2770         <!-- Context of Use Keyword value ==>
2771             <displayName value="Context of use Keyword value"/>
2772         </code>
2773         <statusCode code="active"/>
2774     </keyword>
2775 </referencedBy>
2776 </contextOfUse>
2777 </component>
2778 =<componentOf>
2779 <!-- =====>
2780 <!-- The sequenceNumber provides the sequence in a Submission for the SubmissionUnit being submitted. ==>
2781 <!-- It is always required. It is always unique within an application. The sequenceNumber.value ==>
2782 <!-- should include 6=digits – i.e., the sender should pad the value with zeros so that there is ==>
2783 <!-- no question about the number sequence. The sequenceNumber.value is a non=negative integer →
2784 <!-- (i.e., non=negative whole number) ==>
2785 <!-- =====>
2786     <sequenceNumber value="000067"/>
2787     =<reviewableUnit> =<id> <item root="12345678=1234=1234=1234=123456789012"
2788 extension="de=xxx=021"/> </id>
2789     <code code="Code for the reviewable unit"/>
2790     <statusCode code="active"/>
2791 =<componentOf>
2792     =<submission>
2793         <!-- Submission ID ==>
2794         =<id> <item root="Globally unique submission ID" extension="Regionally defined submission ID"/>
2795 </id>
2796         <!-- =====>
2797         <!-- Submission Type ==>
2798         <!-- The Submission code is provided to indicate the regulatory activity/ ==>
2799         <!-- submission type being submitted, e.g. Marketing authorisation application==>
2800         <!-- =====>

```

```

2801         <code codeSystem="Submission Type Code system OID" code="maa" codeSystemName="Submission
2802 Type Code system Name"/>
2803     =<callbackContact>
2804         =<contactParty> <id root="Contact Party ID"/>
2805         <statusCode code="active"/>
2806         =<contactPerson>
2807             =<id>
2808                 <item root="Contact Person ID"/>
2809             </id>
2810             <name xsi:type="BAG_EN">
2811                 =<item>
2812                     <part value="Jean Petit"/>
2813                     <part value="Pharmacist"/>
2814                 </item>
2815             </name>
2816             =<telecom xsi:type="BAG_TEL">
2817                 <!-- value : data, voice, fax, tty, sms, no email address ==>
2818                 <item value="+33155873180" capabilities="voice"/>
2819                 <item value="+33155873172" capabilities="fax"/>
2820             </telecom>
2821             =<addr xsi:type="BAG_AD">
2822                 =<item xsi:type="AD">
2823                     <part value="93285" type="ZIP"/>
2824                     <part value="143-147 Bld Anatole France" type="STR"/>
2825                     <part value="Saint-Denis" type="CTY"/>
2826                 </item>
2827             </addr>
2828             =<asAgent classCode="AGNT">
2829             =<representedOrganization determinerCode="INSTANCE" classCode="ORG">
2830                 =<id>
2831                     <item root=""/>
2832                 </id>
2833                 <name xsi:type="LIST_EN"/>
2834                 <telecom xsi:type="LIST_TEL"/>
2835                 <addr xsi:type="LIST_AD"/>
2836             </representedOrganization>
2837         </asAgent>
2838     </contactPerson>
2839 </contactParty>
2840 </callbackContact>
2841 =<subject1>
2842     =<mode>
2843         <id root="Globally unique review ID" extension="regionally defined review ID"/>
2844         <code code="single"/>
2845     </mode>
2846 </subject1>

```



```

2847 =<subject2>
2848   =<review>
2849     <id/> <statusCode code="active"/>
2850   =<subject1>
2851     <!-- to have multiple product name (e.g. Reactolin Germany, Vital in NL and Vitol in France ==>
2852   =<manufacturedProduct>
2853     <id/>
2854   =<manufacturedProduct>
2855     =<asNamedEntity>
2856       =<assigningTerritory>
2857         <code code="DE"/>
2858         =<name>
2859           <!-- Product name type and value==>
2860           <part language="de" value="Reactol Tabl"/>
2861         </name>
2862       </assigningTerritory>
2863     </asNamedEntity>
2864   =<ingredient>
2865     =<activeIngredientSubstance>
2866       =<name>
2867         <!-- Substance name type and value==>
2868         <part codeSystem="Active ingredient code system OID" code="IND01" value="Pioglitazone"/>
2869         <part codeSystem="Active ingredient code system OID" code="IND02" value="hydrochloride"/>
2870       </name>
2871     </activeIngredientSubstance>
2872   </ingredient>
2873 </manufacturedProduct>
2874 </manufacturedProduct>
2875 </subject1>
2876 =<subject1>
2877   =<manufacturedProduct>
2878     <id/>
2879   =<manufacturedProduct>
2880     =<asNamedEntity>
2881       =<assigningTerritory>
2882         <code code="NL"/>
2883         =<name>
2884           <part language="nl" value="Vital Tabl"/>
2885         </name>
2886       </assigningTerritory>
2887     </asNamedEntity>
2888   =<ingredient>
2889     =<activeIngredientSubstance>
2890       =<name>
2891         <part codeSystem="Active ingredient code system OID" code="IND01" value="Pioglitazone"/>
2892         <part codeSystem="Active ingredient code system OID" code="IND02" value="hydrochloride"/>

```

```

2893         </name>
2894     </activeIngredientSubstance>
2895 </ingredient>
2896 </manufacturedProduct>
2897 </manufacturedProduct>
2898 </subject1>
2899 =<subject1>
2900     =<manufacturedProduct>
2901         <id/>
2902     =<manufacturedProduct>
2903         =<asNamedEntity>
2904             =<assigningTerritory>
2905                 <code code="FR"/>
2906                 =<name>
2907                     <part language="fr" value="Vitol Tabl"/>
2908                 </name>
2909             </assigningTerritory>
2910         </asNamedEntity>
2911     =<ingredient>
2912         =<activeIngredientSubstance>
2913             =<name>
2914                 <part codeSystem="Active ingredient code system OID" code="IND01" value="Pioglitazone"/>
2915                 <part codeSystem="Active ingredient code system OID" code="IND02" value="hydrochloride"/>
2916             </name>
2917         </activeIngredientSubstance>
2918     </ingredient>
2919 </manufacturedProduct>
2920 </manufacturedProduct>
2921 </subject1>
2922 =<holder>
2923     =<applicant>
2924         =<sponsorOrganization>
2925             =<name xsi:type="BAG_EN">
2926                 =<item>
2927 <!-- =====>
2928 <!-- Applicant if applied to review level==>
2929 <!-- DUNS number as suggested by EudraDMP" the code ="888528" is the DUNS number foo the company ==>
2930 <!-- =====>
2931                 <part code="888528" value="PharmaCompany" codeSystemVersion="OID for Duns"/>
2932             </item>
2933         </name>
2934         =<telecom xsi:type="BAG_TEL">
2935             <item value="tel: +33 1 55 87 31 80" use="WP"/>
2936             <item value="tel: +33 6 25 30 31 80" use="MC"/>
2937             <item value="mailto:richard.dumont@pharmacompany.com"/>
2938         </telecom>

```

```

2939     =<addr xsi:type="BAG_AD">
2940         =<item xsi:type="AD">
2941             <part value="93285" type="ZIP"/>
2942             <part value="143=147 Bld Anatole France" type="STR"/>
2943             <part value="Saint=Denis" type="CTY"/>
2944         </item>
2945     </addr>
2946 </sponsorOrganization>
2947 </applicant>
2948 </holder>
2949 =<author>
2950     =<territorialAuthority>
2951     <!-- Recipient review authority's country if applied to review level -->
2952     =<territory>
2953         <code codeSystem="Country Code system OID" code="FR"/>
2954     </territory>
2955     =<governingAuthority>
2956         =<name>
2957             <!-- Recipient review authority -->
2958             <part codeSystem="Authority Code system OID" code="AFSSAPS" value="Agence Francaise de
2959 Securite Sanitaire des Produits de Sante"/>
2960         </name>
2961     </governingAuthority>
2962 </territorialAuthority>
2963 </author>
2964 =<subject2>
2965     =<productCategory>
2966     <!-- Product Category -->
2967     <code codeSystem="ProductCategory Code system OID" code="chemical"/>
2968 </productCategory> </subject2> </review> </subject2>
2969 =<subject3>
2970     <!-- The RegulatoryReviewTime codes provide the specific review timelines for certain submission types -->
2971     =<regulatoryReviewTime>
2972     <code codeSystem="OID Extended Time in case of Type II variations" code="90"/>
2973 </regulatoryReviewTime>
2974 </subject3>
2975 =<subject4>
2976     =<regulatoryStatus>
2977     =<code code="100000072097">
2978     <displayName value="Application for Marketing Authorisation received."/>
2979 </code>
2980 </regulatoryStatus>
2981 </subject4>
2982 =<subject5>
2983     =<submissionGroup>
2984     <id root="UUID of the SubmissionGroup" extension="0987.997"/>

```

```

2985     </submissionGroup>
2986 </subject5>
2987 = <componentOf>
2988     = <application>
2989     = <id>
2990     <!-- Application ID =====>
2991     <!-- Should EU use this item to store the number used by an agency to track the submission, in any procedure,
2992 in relation to a particular product. ==>
2993     <!-- This could be a MRP Number, the EMEA application number, or any other number used by an agency to
2994 track a submission.===== >
2995     <!-- =====>
2996         <item root="12345678=1234=1234=1234=123456789012"/>
2997         <item extension="2134599=de"/>
2998         <item extension="348309=fr"/>
2999         <item extension="39992912=nl"/>
3000     </id>
3001     <code codeSystem="OID for the Application Type" code="de=0124=001"/>
3002 = <holder>
3003     = <applicant>
3004         = <sponsorOrganization>
3005             = <name xsi:type="BAG_EN">
3006                 = <item>
3007                 <!-- =====>
3008                 <!-- Applicant if applied to review level==>
3009                 <!-- DUNS number as suggested by EudraGMP. the code ="888528" is the DUNS number for the
3010 sponsor PharmaCompany ==>
3011                 <!-- =====>
3012                 <part code="888528" value="PharmaCompany" codeSystemVersion="OID for DUNS"/>
3013                 </item>
3014             </name>
3015             = <telecom xsi:type="BAG_TEL">
3016                 <item value="tel: +33 1 55 87 31 80" use="WP"/>
3017                 <item value="tel: +33 6 25 30 31 80" use="MC"/>
3018                 <item value="mailto:richard.dumont@pharmacompany.com"/>
3019             </telecom>
3020             = <addr xsi:type="BAG_AD">
3021                 = <item xsi:type="AD">
3022                     <part value="93285" type="ZIP"/>
3023                     <part value="143=147 Bld Anatole France" type="STR"/>
3024                     <part value="Saint=Denis" type="CTY"/>
3025                 </item>
3026             </addr>
3027         </sponsorOrganization>
3028     </applicant>
3029 </holder>
3030 = <informationRecipient>

```

```

3031     =<territorialAuthority>
3032         =<territory>
3033             <code code="FR"/>
3034         </territory>
3035     =<governingAuthority>
3036         <id root="52345678=1234=1234=1234=12345678901"/>
3037     =<name>
3038         <part code="FR=AFSSAPS" value="AFSSAPS"/>
3039     </name>
3040 </governingAuthority>
3041 </territorialAuthority>
3042 </informationRecipient>
3043 =<informationRecipient>
3044     =<territorialAuthority>
3045         =<territory>
3046             <code code="NL"/>
3047         </territory>
3048     =<governingAuthority>
3049         <id root="62345678=1234=1234=1234=12345678901"/> =
3050     <name>
3051         <part code="NL=MEB" value="MEB"/>
3052     </name>
3053 </governingAuthority>
3054 </territorialAuthority>
3055 </informationRecipient>
3056 =<informationRecipient>
3057     =<territorialAuthority>
3058         =<territory>
3059             <code code="DE"/>
3060         </territory>
3061     =<governingAuthority>
3062         <id root="72345678=1234=1234=1234=12345678901"/>
3063     =<name>
3064         <part code="DE=BFARM" value="BFARM"/>
3065     </name>
3066 </governingAuthority>
3067 </territorialAuthority>
3068 </informationRecipient>
3069 =<subject>
3070     =<reviewProcedure>
3071         <code codeSystem="code system MRP" code="DE/H/0126/001/MR"/>
3072     </reviewProcedure>
3073 </subject>
3074 =<reference>
3075     =<applicationReference>
3076         <id root="UUID identifying the submission unit"/>

```

```

3077     =<reasonCode>
3078     <!-- Reference medicinal product chosen for the demonstration of bioequivalence -->
3079         <item code="BE"/>
3080     </reasonCode>
3081 </applicationReference>
3082 </reference>
3083 =<component>
3084     =<document>
3085         <id root="Globally unique document ID" extension="34567"/>
3086         <code code="code for the type of application"/>
3087         <title value="Cover Letter"/>
3088         =<text language="en" integrityCheckAlgorithm="SHA256">
3089             <reference value="../../../m1/eu/10=cover/de=cover.pdf" xsi:type="TEL"/>
3090
3091         <integrityCheck>39bd11dc87c42f2f15dab6f1eedaf83b2b91703c145c349cd944866c177581</integrityCheck>
3092         </text>
3093         <statusCode code="active"/>
3094         <setId root="Globally unique document set ID"/>
3095         <versionNumber value="1"/>
3096     </document>
3097 </component>
3098 =<component>
3099     =<document>
3100         <id root="Globally unique document ID" extension="89012"/>
3101         <code code="code for the type of application"/>
3102         <title value="Form"/>
3103         =<text language="en" integrityCheckAlgorithm="SHA256">
3104             <reference value="../../../m1/eu/10=form/de=form.pdf" xsi:type="TEL"/>
3105
3106         <integrityCheck>c8d6e7c9df15815a50623ceb638cdf7c1b468c923078db351121b973d8351</integrityCheck>
3107         </text>
3108         <statusCode code="active"/>
3109         <setId root="Globally unique document set ID"/> <versionNumber value="1"/>
3110     </document>
3111 </component>
3112 =<component>
3113     =<document>
3114         <id root="Globally unique document ID" extension="34567"/>
3115         <code code="code for the type of application"/> <title value="QOS=Add"/>
3116         =<text language="en" integrityCheckAlgorithm="SHA256">
3117             <reference value="../../../m2/23=qos/qos.pdf" xsi:type="TEL"/>
3118
3119         <integrityCheck>ec28b2b8b6db40b8d6590b1d2c395f35214e681959adba2b93cd5b9558a8</integrityCheck>
3120         </text>
3121         <statusCode code="active"/>
3122         <setId root="Globally unique document set ID"/>

```

```

3123     <versionNumber value="1"/>
3124 </document>
3125 </component>
3126 =<component>
3127   =<document>
3128     <id root="Globally unique document ID" extension="89123"/>
3129     <code code="code for the type of application"/>
3130     <title value="Manuf New"/>
3131     <text language="en" integrityCheckAlgorithm="SHA256">
3132       <reference value="../../../m3/32=body=data/32s=drug=sub/32s2=manuf/manufacture.pdf"
3133 xsi:type="TEL"/>
3134
3135     <integrityCheck>39f2fda4742070a454ff91b9191f2d34dfca973ef6b0e6c65a0663a91f5c28</integrityCheck>
3136     </text>
3137     <statusCode code="active"/>
3138     <setId root="Globally unique document set ID"/>
3139     <versionNumber value="1"/>
3140   </document>
3141 </component>
3142 =<component>
3143   =<document>
3144     <id root="Globally unique document ID" extension="45612"/>
3145     <code code="code for the type of application"/>
3146     <title value="Validation New"/>
3147     =<text language="en" integrityCheckAlgorithm="SHA256">
3148       <reference value="../../../m3/32=body=data/32s=drug=sub/32s2=manuf/process=validation.pdf"
3149 xsi:type="TEL"/>
3150
3151     <integrityCheck>e409e62ab35e31da185a9971cc876d0cca59ce78b9f1d3fd7a3d3dae0a890</integrityCheck>
3152     </text>
3153     <statusCode code="active"/>
3154     <setId root="Globally unique document set ID"/>
3155     <versionNumber value="1"/>
3156   </document>
3157 </component>
3158 =<referencedBy>
3159   <!-- =====>
3160   <!-- Keyword Definition =====>
3161   <!-- Keyword Definition elements will be coded values and require the following attributes ==>
3162   <!-- code@code, code@codeSystem, @statusCode@code, value.item.displayName@value ==>
3163   <!-- =====0=====>
3164   =<keywordDefinition>
3165     <code codeSystem="ICH=OID=KeywordType" code="ICH=manufacturer=001"/>
3166     <statusCode code="active"/>
3167     =<value>
3168       =<item code="MANU001">

```

```

3169         <displayName value="Hillside Manufacturer"/>
3170     </item>
3171 </value>
3172 = <replacementOf typeCode="RPLC">
3173     = <previousKeywordDefinition>
3174         <code codeSystem="ICH=OID=KeywordType" code="ICH=manufacturer=002"/>
3175         = <value>
3176             = <item code="MANU002">
3177                 <displayName value="Mountainside Manufacturer"/>
3178             </item>
3179         </value>
3180     </previousKeywordDefinition>
3181 </replacementOf>
3182 </keywordDefinition>
3183 </referencedBy>
3184 </application>
3185 </componentOf>
3186 </submission>
3187 </componentOf>
3188 </reviewableUnit>
3189 </componentOf>
3190 </submissionUnit>
3191 </subject>
3192 </controlActProcess>
3193 </PORP_IN000001UV>
3194

```

## 3195 Variation type 2

```

3196     <id root="87454521-9874-6541-1236-159842345687" />
3197     <code code="var-type2" codeSystem="Submission Code System OID" />
3198     <title value="Variation Type II" />
3199     <statusCode code="active" />
3200
3201     = <review>
3202         <id />
3203         <statusCode code="active" />
3204         = <holder>
3205             = <applicant>
3206                 = <sponsorOrganization>
3207                     = <name xsi:type="BAG_EN">
3208                         = <item>
3209                             <part value="PharmaCompany" code="888528" codeSystemVersion="OID for
3210 Duns" />
3211                         </item>
3212                     </name>
3213                 = <telecom xsi:type="BAG_TEL">

```



```

3214         <item value="tel: +33 1 55 87 31 80" use="WP" />
3215         <item value="tel: +33 6 25 30 31 80" use="MC" />
3216         <item value="mailto:richard.dumont@pharmacompany.com" />
3217     </telecom>
3218     <= <addr xsi:type="BAG_AD">
3219         <= <item xsi:type="AD">
3220             <part type="ZIP" value="93285" />
3221             <part type="STR" value="143-147 Bld Anatole France" />
3222             <part type="CTY" value="Saint-Denis" />
3223         </item>
3224     </addr>
3225 </sponsorOrganization>
3226 </applicant>
3227 </holder>
3228 <= <author>
3229     <= <territorialAuthority>
3230         <= <territory>
3231             <code code="FR" codeSystem="Country Code system OID" />
3232         </territory>
3233         <= <governingAuthority>
3234             <= <name>
3235                 <part code="AFSSAPS" value="Agence Francaise de Securite Sanitaire des Produits de
3236 Sante" codeSystem="Authority Code system OID" />
3237             </name>
3238         </governingAuthority>
3239     </territorialAuthority>
3240 </author>
3241 <= <subject2>
3242     <= <productCategory>
3243         <code code="chemical" codeSystem="ProductCategory Code system OID" />
3244     </productCategory>
3245 </subject2>
3246 </review>
3247
3248
3249 <= <callBackContact typeCode="CALLBCK">
3250     <= <contactParty>
3251         <id root="32568794-789874" identifierName="Mycontact" />
3252 <code code="c2125" codeSystem="contactParty Event Code System OID" />
3253         <statusCode code="active" />
3254     <= <contactPerson>
3255         <= <id>
3256             <item root="Globally unique contact ID" />
3257         </id>
3258     <= <name xsi:type="BAG_EN">
3259         <= <item>

```

```

3260         <part value="Richard" type="GIV" />
3261         <part value="Dumont" type="FAM" />
3262     </item>
3263 </name>
3264     = <telecom xsi:type="BAG_TEL">
3265         <item value="tel: +33 1 55 87 31 80" use="WP" />
3266         <item value="tel: +33 6 25 30 31 80" use="MC" />
3267         <item value="mailto:richard.dumont@pharmacompany.com" />
3268     </telecom>
3269     = <asAgent classCode="AGNT">
3270         = <representedOrganization>
3271             = <name xsi:type="BAG_EN">
3272                 = <item>
3273                     <part value="Organization name" />
3274                 </item>
3275             </name>
3276         </representedOrganization>
3277     </asAgent>
3278 </contactPerson>
3279 </contactParty>
3280 </callbackContact>
3281 = <component>
3282     <priorityNumber value="1" />
3283 = <contextOfUse>
3284     <id root="12345678-1234-5678-3456-127536489712" />
3285     = <code code="m10cover" codeSystem="Code system OID for Cover Letter">
3286         <displayName value="1.0 Cover Letter" />
3287     </code>
3288     <title value="1.0 Cover Letter" />
3289     <statusCode code="active" />
3290     <setId root="set ID" />
3291     <versionNumber value="1.0" />
3292 = <primaryInformationRecipient>
3293     = <territorialAuthority>
3294         = <territory>
3295             <code code="DE" codeSystem="country code system OID" codeSystemName="country code
3296 system name" />
3297         </territory>
3298         = <governingAuthority>
3299             <id root="DE-BFARM" value="BFARM" />
3300         </governingAuthority>
3301     </territorialAuthority>
3302 </primaryInformationRecipient>
3303 = <sequelTo typeCode="RPLC">
3304     = <relatedContextOfUse>
3305         <id root="87454521-9874-6541-1236-159842345687" />

```

```

3306         <versionNumber value="1" />
3307     </relatedContextOfUse>
3308 </sequelTo>
3309     = <derivedFrom>
3310         = <documentReference>
3311             <id root="12345678-1234-1234-1234-198765432198" extension="12345" />
3312         </documentReference>
3313     </derivedFrom>
3314     = <subjectOf>
3315         = <submissionReference>
3316             = <id xsi:type="DSET_II">
3317                 <item root="12345678-1234-5678-3456-127536489712" />
3318             </id>
3319         </submissionReference>
3320     </subjectOf>
3321 </contextOfUse>
3322 </component>
3323     = <component>
3324         <priorityNumber value="1" />
3325     = <contextOfUse>
3326         <id root="Context of Use ID" />
3327         = <code code="m12form" codeSystem="Code system OID for Application Form">
3328             <displayName value="1.2 application form" />
3329         </code>
3330         <title value="1.2 application form" />
3331         <statusCode code="active" />
3332         <setId root="set ID" />
3333         <versionNumber value="1.0" />
3334     = <primaryInformationRecipient>
3335     ....
3336 </primaryInformationRecipient>
3337         = <derivedFrom>
3338             = <documentReference>
3339                 <id root="12121212-1234-1234-1234-98765432198" extension="23456" />
3340             </documentReference>
3341         </derivedFrom>
3342     </contextOfUse>
3343 </component>
3344     = <componentOf>
3345
3346

```

3347

3348 **APPENDIX 3 ABBREVIATIONS, TERMS AND DEFINITIONS**

3349 The following table defines some common terms in this document and specific to eCTD v4.0.

3350 This is not a complete listing,

Term	Definition
<b>Applicant</b>	A pharmaceutical company or its agent that is submitting information in support of an application.
<b>Applicant's Information</b>	Regulatory information submitted by an applicant for, or to maintain, a marketing authorisation that falls within the scope of this guidance document.
<b>eCTD Application</b>	A collection of electronic documents compiled by a pharmaceutical company or its agent in compliance with European legislation and guidelines in order to seek a marketing authorisation or any amendments thereof. An eCTD application may comprise a number of submissions and submission units. In the EU an eCTD application may comprise several dosage forms and strengths, all under one invented product name. This is understood to be equivalent to a Global Marketing Authorisation according to Art. 6 para 2 Dir. 2001/83/EC as amended. Some review tools describe such a collection as a dossier.
<b>Procedure</b>	A Community registration procedure for the authorisation of medicinal products in the European Community. There are 4 types of procedure that operate within the EC – Centralised, Decentralised, Mutual Recognition and National.
<b>Regulatory Activity</b>	A collection of sequences 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.
<b>Submission Unit</b>	A single set of information and / or electronic documents supplied at one particular time by the applicant as a part of, or the complete, eCTD Application. In the context of eCTD, this is equivalent to a sequence.
<b>Document</b>	See ICH IG
<b>Simple Document</b>	See ICH IG
<b>Compound Document</b>	See ICH IG
<b>Payload</b>	See ICH IG

3351

3352

3353 **APPENDIX 4 REFERENCES**

3354 [This section will include references to procedures described in the IG (e.g., The SHA256  
3355 Message-Digest Algorithm).

3356

DRAFT