



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

**Draft for Public Consultation**

Version 2.0  
March 10<sup>th</sup>, 2015

## DOCUMENT CHANGE HISTORY

Version	Date	Comments
0.1	6 <sup>th</sup> Jan 2012	First draft based on ICH eCTD IG v3.1 deleting all M2 to 5 specifics and adding all EU Module 1 details, e.g. controlled vocabularies and content from the current EU Module 1 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 eCTD IG v4.0
0.3	15 <sup>th</sup> Feb 2012	Update based on ICH eCTD 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 eCTD 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 eCTD 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 eCTD 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 eCTD 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
1.01	15 <sup>th</sup> Nov 2014	Update after HL7 normative ballot and finalisation of ICH Step 2
1.02	30 <sup>th</sup> Dec 2014	Accepting all changes so far for preparing the work within the eCTD v4.0 Maintenance Group. Including some changes following the review of the draft USFDA regional IG, dated 16.12.2014
1.03	06 <sup>th</sup> Jan 2015	Revision of chapter 5, deletion of section 5.9
1.04	13 <sup>th</sup> Jan 2015	Group Review of Chap 1 to 5, mostly editorial changes
1.05	21 <sup>st</sup> Jan 2015	Consolidating comments and text improvements of

		Chap 1 to 3, change of Section 6.1 into a table
1.06	27 <sup>th</sup> Jan 2015	Consolidating comments and improvements, additional comments by AJ, AD, LS, correction of XML location stats
1.07	23 <sup>rd</sup> Feb 2015	Completing the top folder naming conventions for grouping and worksharing. Source added of CTL EU Territorial Authority and CTL EU Procedural Authority Role. Review of XML snippets. Correction of XML details of the <b>document</b> element. Addition of sample of grouped variation. Constraining the validation criteria to its minimum.
1.08	9 <sup>th</sup> March 2015	Review of XML snippets
2.0	10 <sup>th</sup> Mar 2015	Release for public consultation

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1   **NOTICE TO READER**

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

7   **INSTRUCTIONS TO READER**

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

14   This document needs to be read in conjunction with the ICH Implementation Guide  
15   on electronic Common Technical Document Version 4.0.

16   For further instructions please consult the ICH Implementation Guide on electronic  
17   Common Technical Document Version 4.0.

18  
19

20

## 21 **1. PURPOSE AND SCOPE**

22 This document serves as the Implementation Guide (IG) and a technical specification  
23 for the regional EU Module 1 of the Electronic Common Technical Document  
24 (eCTD) v4.0 using the Regulated Product Submission (RPS) Release 2 Normative.  
25 Applicable Information indicated in the ICH eCTD IG<sup>1</sup> to be regionally available is  
26 incorporated as necessary to assist in the system development requirements for  
27 publishing or displaying eCTD v4.0 compliant messages for the recipients of the  
28 information.

29



*Note to Implementers: This EU Module 1 IG will need to be used in conjunction with the ICH eCTD IG, as the eCTD v4.0 message will be incomplete without all of the contents.*

30

31 The RPS standard defines the message for exchanging regulatory information  
32 electronically between Competent Authorities and the Pharmaceutical Industry as  
33 well as between Competent Authorities in general and needs to be ruled out by  
34 implementation guides. This document only comprises the EU Module 1 part of the  
35 eCTD XML message including the Regional Administrative and EU-specific Product  
36 Information. The focus is to outline the essential components of the message which  
37 are required for EU Module 1 in addition and/or differently from common CTD  
38 Modules 2 – 5.

39 The content of eCTD v4.0 Modules 2 - 5, being shared across all ICH regions, is not  
40 included in this IG, although some principles need to be repeated to assure a better  
41 understanding. This document should be read together with the ICH eCTD IG to  
42 prepare a valid eCTD submission unit in the EU.

43 In addition, relevant rules and examples are provided to enable transition from eCTD  
44 v3.2.2 to v4.0.

45

46

## 47 **2. BACKGROUND**

48 The Pharmaceutical Industry and Competent Authorities, which serve to regulate  
49 Industry, exchange information to address a variety of regulatory processes. The  
50 scope of the ICH activities covers the human pharmaceutical product marketing  
51 authorisation processes. The eCTD format is regarded as the principal electronic  
52 submission format in the EU<sup>2</sup> and is the only electronic format that is accepted by the  
53 European Medicines Agency (hereafter referred to as EMA) and presumably all  
54 National Competent Authorities (hereafter referred to as NCAs).

---

<sup>1</sup> The ICH IG is accessible at [www.estri.org](http://www.estri.org)

<sup>2</sup> The regional implementation agreed for the EU will apply in the same way to the EEA countries Iceland, Norway and Lichtenstein according to the general agreement in regard to the legislation on medicinal products.

55 The use of an international information exchange standard is needed in the regulatory  
56 environment to ensure that mandates can be issued and standardisation enabled for  
57 increased consistency across the competent authorities with respect to the exchange of  
58 regulatory information.

59 As the eCTD is regarded as the principal electronic submission format in the EU, the  
60 goal of the upgrade to 4.0 is to enhance significantly the capability of eCTD to  
61 facilitate the processing and review of electronic regulatory submissions. Examples of  
62 enhancement features and the re-use of data are in the ‘contents of use’ which will  
63 allow one piece of data to be used across many applications, avoiding the need for  
64 duplication of data elements. More details can be found in [Section 4.3](#) of this  
65 document as well as in the ICH eCTD IG.

66

67

68 **3. CHANGE CONTROL RULES**

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

71 eCTD v4.0 is based on the HL7 Regulated Product Submission (RPS) Message  
72 Standard Version 2 Normative, which was developed in the external Standards  
73 Development Organisation (SDO), Health Level Seven International (HL7) and  
74 various stakeholders, which includes members of ICH M8 and EU representatives.

75 Changes of the RPS Standard need to be addressed according rules [outlined at HL7](#).

76 Changes to the ICH eCTD v4.0 IG and ICH Controlled Vocabularies remain the  
77 responsibility of the ICH M8 Expert Working Group (EWG) and will follow the  
78 established [eCTD change control process](#).

79 In a situation where EU M1 IG need to be changed for example as a result of EU M1  
80 content changes, changes to the regional requirements for applications that are outside  
81 the scope of the CTD or identification of new functional requirements or experience  
82 of use of eCTD Module 1 gained by all parties, an Electronic Submission Change  
83 Request/Q&A Form -should be provided and this can be found at  
84 <http://esubmission.ema.europa.eu/doc/index.html>.

85

86

87 **4. ESSENTIAL COMPONENTS OF THE ECTD IN CONSIDERATION  
88 OF THE SPECIFIC REGIONAL EU REQUIREMENTS**

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

- 92 • Object Identifier (OIDs) and Universal Unique Identifier (UUIDs) (further  
93 information provided in the ICH eCTD IG, Section 4.5)
- 94 • Data Types (further information provided in the ICH eCTD IG, Section 4.6)
- 95 • Files and Folders (see [Section 5](#) of this document, further information provided  
96 in the ICH eCTD IG, Section 5 and Section 11)
- 97 • Controlled Vocabulary (see [Section 6](#) of this document, further information  
98 provided in the ICH eCTD IG, Section 6)

- 99           • ICH eCTD v4.0 XML Schema (further information provided in the ICH eCTD  
100          IG, Section 7)  
101          • eCTD v4.0 XML Message (see [Section 8](#) of this document, further information  
102          provided in the ICH eCTD IG, Section 8)  
103          • Validation Rules (see [Section 11](#) of this document, further information provided  
104          in the ICH eCTD IG, Section 12)  
105          • Forward Compatibility (see [Section 12](#) of this document, further information  
106          provided in the ICH eCTD IG, Section 10)

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

- 109           • ICH eCTD IG across regions (separate document<sup>3</sup>)
- 110           • EU Module1 IG regionally (this document).

111         Therefore, in order to compose a complete eCTD v4.0 compliant message, the user needs to refer to the requisite documentation published by ICH<sup>4</sup>.

#### 114         **4.1 Elements for regional use covered by EU Module 1** 115         **Implementation Guide**

116         For EU Module 1 the following elements are required and EU-specific business rules  
117         apply:

- 118           • *application*
  - 119              ○ *subject8.reviewProcedure*
  - 120              ○ *reference.applicationReference*
  - 121              ○ *holder.applicant*
  - 122              ○ *informationRecipient.territorialAuthority*

- 123           • *submission*
  - 124              ○ *subject3.regulatoryReviewTime*
  - 125              ○ *subject4.submissionGroup*
  - 126              ○ *subject5.mode*

- 127           • *review*
  - 128              ○ *subject1.manufacturedProduct*
  - 129              ○ *subject2.productCategory*
  - 130              ○ *subject3.regulatoryStatus*
  - 131              ○ *holder.applicant*
  - 132              ○ *author.territorialAuthority*

133         For EU Module 1 the following elements are excluded

---

<sup>3</sup> The document will be accessible at [www.estri.org](http://www.estri.org)

<sup>4</sup> A complete package for implementation will be provided at [www.estri.org](http://www.estri.org) once the Step 4 of the acknowledgement process has been reached.

- 135 •*categoryEvent*  
136       ○ *categoryEvent*  
137 •*submission*  
138       ○ *subject6.regulatoryReviewTime*

139

140 **4.2 Regional Business Processes Covered by EU Module 1**  
141 **Implementation Guide**

142 This document will address the following regional business processes:

- 143     • **Dossier Management/Submission Life Cycle** – includes rules for  
144       Submission Unit, Submission and Applications (see [Section 10.2](#) of this  
145       document).  
146     • **Submission Units with Multiple Submission components** (e.g. EU PSUR  
147       single assessment, grouped variations, work share procedures) – includes rules  
148       for sending submission units that will reference more than one submission  
149       component (see [Section 10.3](#) of this document).  
150     • **Two-way Communication** – includes information on Regulatory Authority  
151       communication with the Applicant (see [Section 10.4](#) of this document).

152

153 **4.3 Major Changes and Advantages of eCTD v4.0**

154 The new version of the eCTD implementation based on the HL7 RPS Standard will  
155 offer:

- 156     • Options to accomodate regulatory changes without delay and major technical  
157       changes  
158     • Simplification of life cycle  
159     • Flexibility of dossier granularity and grouping of documents  
160     • Assigning submission units to different applications by only referencing a  
161       sequence number and application ID  
162     • Referencing documents across applications  
163     • Two way communication  
164     • Applicability to all kind of products

165

166

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

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

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

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

176

177 The following items listed in the Notice to Applicants should be included in an initial  
178 application submission unit

- 179 – cover letter,
- 180 – comprehensive table of contents<sup>5</sup>,
- 181 – application form,
- 182 – product information documents,
- 183 – information on the experts,
- 184 – specific requirements for different types of applications (if required),
- 185 – environmental risk assessment,
- 186 – information relating to orphan market exclusivity (if required),
- 187 – information relating to pharmacovigilance,
- 188 – information relating to clinical trials (if required),
- 189 – information relating to paediatrics.

190

191 In addition, other items as applicable including nationally required information,  
192 answers to regulatory questions, rationale for variations and renewal documentation  
193 should also be included in Module 1.

194

195 Whenever regulators use the eCTD v4.0 message for sending assessment reports, lists  
196 of questions or lists of outstanding issues to applicants, these types of submission  
197 units will become contained within Module 1 of the applicable application.

198

199 It should be noted, that for subsequent submissions in the lifecycle of a medicinal  
200 product, e.g. for a variation, not all of the above mentioned types of documents need  
201 be included in Module 1. Consult the various legal documents for guidance on the  
202 exact documents to be submitted in such cases, e.g. Regulation Guidance for Type IA,  
203 Type IB and Type II variations as well as respective business guidance documents.

204

## 205 **5.1 Submission Unit Content**

206 The submission unit consist of a *First Level Folder* (see section 5.3), the *Second Level*  
207 *Folder* (see section 5.4), the eCTD v4.0 XML Message for that individual Submission  
208 Unit, named “submissionunit.xml”, and the folder m1 (see section 5.6) and, as  
209 appropriate, m2 to m5.

### **Notes:**



- The sender should not send the schema files – i.e., the util folder of previous versions of the eCTD is no longer required. The XML should reference the interaction schema being used.
- All files included in these folders should be accounted for in the XML message.

---

<sup>5</sup> TOC not required for eCTD as the XML message acts as a table of contents

- Files previously sent do not need to be sent again.
- It is possible to reference documents across applications (equivalent to the term dossier)

210

211 **5.2 Naming Conventions**

212 The naming conventions for folders for EU Module 1 will remain the same as in  
213 previous versions of the eCTD. eCTD v4.0 enables the applicant to omit the  
214 additional folder level for language or country-specific documents. This will be  
215 replaced by using keywords from the respective controlled vocabulary (see [Section](#)  
216 [6.3](#)), which is also required for selective display of information. Aside from this  
217 change the EU Module 1 folder structure will remain the same.

218 Additional guidance for naming conventions on folders is provided in the ICH eCTD  
219 IG and will be applicable commonly.

220 **5.2.1 Allowable Characters**

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

222 **5.2.2 Length of Names and the Path**

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

224

225 **5.3 Top Folder Naming Requirements**

226 In **general**, to identify the content with a folder structure e.g. when on portable  
227 electronic media or after extracting compressed content from a container, the top  
228 folder must be named according to the main part of the application procedure number  
229 relating to the regulatory. Below are examples, e.g.

- **de2087** or **uk3456** in case of the MR/DC procedure (e.g. DE/H/2087/001/MR  
or UK/H/3456/001-005/DC respectively),
- **2131577** in case of a national (German) procedure,
- **ema000123** in case of the centralised procedure EMEA/H/C/000123 or  
EMEA/H/C/000123/II/14 (if known).

235

236 In case of **grouping or worksharing** regulatory activities including PSUR  
237 worksharing and single assessment procedures the top folder naming needs to reflect  
238 the procedures type more specifically, e.g.

- **de0001g** or **uk0019g** **respectively es0002ws or fi 0005ws** in case of the  
grouping where DE or UK respectively ES or FI are the RMS and the first or  
nineteenth grouping respectively the second or fifth worksharing for national  
procedures across some member states is submitted.,
- **se1234psur** in case of a PSUR worksharing where SE is RMS (The number  
will be taken from the EURD list).,

- 245       • **ema0011g or ema0009ws** in case a centrally authorized product is involved  
246        in the worksharing.
- 247       • **PSUSA00002172** in case of EU PSUR Single Assessment Procedure e.g.  
248        PSUSA/00002172/2015
- 249       •

250      In these cases a short life cycle will be established referencing the documentation to  
251      all applications involved. Thereby an URL can be established to the physical storage  
252      area where the submission units will be archived.

253

#### 254      **5.4 Second Level Folder Naming Requirements**

255      In **general**, for the second level folder name, the sequence number will be used.

256

257      For **grouping or worksharing** regulatory activities, several sequences can be  
258      included in the submission unit;; the second level folder name should be in the format  
259      of 999900. For additional submission units related to this regulatory activity the  
260      second level folder name will take the form, 999901, 999902 etc. This second level  
261      folder naming convention will be used for all subsequent groupings or worksharing  
262      activities along the life cycle of the products (applications).

263

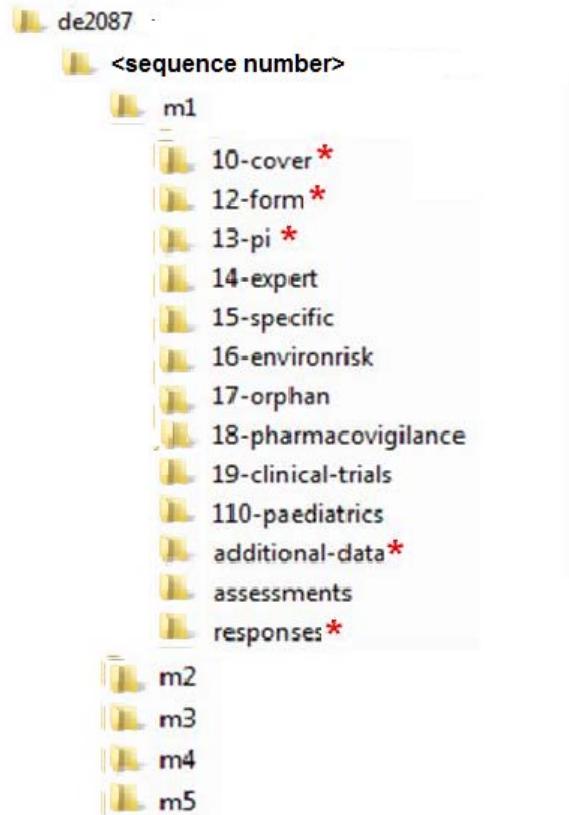
#### 264      **5.5 Pathname Conventions and Best Practices**

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

266

#### 267      **5.6 Folder Hierarchy**

268      To comply with the naming and pathname conventions outlined above, the actual  
269      physical structure of the folder hierarchy will be the following (Figure 1):

**Figure 1: Folder Hierarchy of Module 1 Screenshot**

\* In these folders the CC- or LL-folder are no longer required. Instead, keywords must be applied for country at contextOfUse level. Controlled terms will be introduced at document level to specify the document type. Language is included as attribute of the document element.

273    **5.7       File Formats**

274    In general, for messages to competent authorities in the EU<sup>6</sup> the ICH M2  
275    recommendations on file format<sup>7</sup> and the specification for submission formats<sup>8</sup> of  
276    ICH M8 need to be considered. However in the EU Module 1 files of formats as detailed  
277    below are acceptable:

278    **Table 1: 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 depending from the receiving agency. Currently, there is no common position adopted by the regulatory network in regard to signatures in PDF documents.
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.

279

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

281

282    \*\* = In line with the general principles of the ICH eCTD Implementation Guide, it is intended that  
283    XML will eventually become the *de facto* submission format for administrative forms (because they  
284    contain structured data and a long-term goal of this development is the normalisation of data in  
285    Module 1).

286

287    \*\*\* = SmPC, Package Leaflet and labelling

288

289    **5.8       Checksums**

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

291

292

---

<sup>6</sup> The regional implementation agreed for the EU will apply in the same way to the EEA countries Iceland, Norway and Lichtenstein according to the general agreement in regard to the legislation on medicinal products.

<sup>7</sup> <http://estri.org/recommendations/index.htm>

<sup>8</sup> <http://estri.org/new-eCTD/index.htm>

293      **6. CONTROLLED VOCABULARIES**

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

***Notes to Implementers:***



- *The controlled vocabulary required enables system to system communications and is not always the ideal way to display concepts in a system graphical user interface (GUI). Be cautious not to apply the technical codes in the GUI, instead use the business friendly terms that are specified by Competent Authorities.*
- *During Step 2, the controlled vocabulary will be provided using OID assigned specifically. All EU regionally required controlled terms are available at <http://eutct.ema.europa.eu/eutct/displayWelcome.do>.*

300

301      **6.1 Keywords and Controlled Vocabularies for EU Purpose**

302      Keywords need be used to support a reader friendly presentation of content within the  
303      same context of use either by sender defined **keywordDefinition** or using a controlled  
304      vocabulary, i.e. for document type, language, country. In EU Module 1 for documents  
305      in “10-cover”, “12-form”, “13-pi”, “additional-data”, and “responses” the use of  
306      keywords for country code is required. Depending on the product, additional sender  
307      defined keywords can be used to specify the pharmaceutical form or strength a  
308      product information text is dedicated for. These user defined keywords should be used  
309      for Module 3 purpose at the same time.



***Note to Implementers:*** *The previously required language folder in “13-pi” will be replaced by documentLanguage.code (see: [Section 9.7](#))*

310

311      The controlled vocabularies specified for the EU Module 1 part of the eCTD v4.0  
312      message are provided below with a brief description of the terminology and location  
313      for obtaining detailed information.

314

315

**Table 2: Controlled Vocabularies for EU purpose**

CV list name	Purpose	Source
<b>Context of Use Codes</b>	Examples of enhancement features and the re-use of data are in the contents of use which will allow one piece of data to be used across many applications, avoiding the need for duplication of data elements. More details can be found in the ICH Implementation Guide.	<a href="http://eutct.ema.europa.eu/eutct/viewListDisplay.do?listId=100000155719">http://eutct.ema.europa.eu/eutct/viewListDisplay.do?listId=100000155719</a>
<b>Keyword Definition Codes</b>	Keyword codes for the type of keywords that are defined by the keywordDefinition CTD structure for EU Module 1	Will apply to document type (see Document Type Code), language, country (see <a href="#">Section 6.3</a> )
<b>Application Codes</b>	Type of application the product can be categorised	<a href="http://eutct.ema.europa.eu/eutct/viewListDisplay.do?listId=100000000012">http://eutct.ema.europa.eu/eutct/viewListDisplay.do?listId=100000000012</a>
<b>Application Reference Reason Codes</b>	Reasons, for which a reference to an already authorised medicinal product is used, e.g. in case of a generic product	<a href="http://eutct.ema.europa.eu/eutct/viewListDisplay.do?listId=100000154440">http://eutct.ema.europa.eu/eutct/viewListDisplay.do?listId=100000154440</a>
<b>Contact Party Codes</b>	Details of the legally defined contact person(s) of the sponsor, i.e. the roles, which a contact person of the sponsor can have by submitting an eCTD	<a href="http://eutct.ema.europa.eu/eutct/viewListDisplay.do?listId=100000154441">http://eutct.ema.europa.eu/eutct/viewListDisplay.do?listId=100000154441</a>
<b>Document Type Codes</b>	Type of keyword that is applied to a product information document. This Controlled Term List contains the types of product information documents, which are part of the eCTD Module 1.3.1	<a href="http://eutct.ema.europa.eu/eutct/viewListDisplay.do?listId=100000155531">http://eutct.ema.europa.eu/eutct/viewListDisplay.do?listId=100000155531</a>
<b>Mode Codes</b>	Indicate whether the regulatory activity will be handled as a group or in a single or work shared manner	<a href="http://eutct.ema.europa.eu/eutct/viewListDisplay.do?listId=100000155533">http://eutct.ema.europa.eu/eutct/viewListDisplay.do?listId=100000155533</a>
<b>Ingredient Role Codes</b>	Role of each of the ingredients in the composition of a medicinal product	<a href="http://eutct.ema.europa.eu/eutct/viewListDisplay.do?listId=100000072050">http://eutct.ema.europa.eu/eutct/viewListDisplay.do?listId=100000072050</a>
<b>Manufactured Product Codes</b>	Type of the product under review based on the pharmaceutical form	<a href="http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/03/WC500123648.xls">http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/03/WC500123648.xls</a>
<b>Product Category Codes</b>	Type of the product category. This Controlled Term List is used to indicate the overall category of a human medicinal product based on its active ingredients, e.g. chemical, herbal or biotech product	<a href="http://eutct.ema.europa.eu/eutct/viewListDisplay.do?listId=100000155526">http://eutct.ema.europa.eu/eutct/viewListDisplay.do?listId=100000155526</a>
<b>Substance Codes</b>	Used to name the ingredient based on its role of an active ingredients. The	<a href="http://www.ema.europa.eu/docs/en_GB/docume">http://www.ema.europa.eu/docs/en_GB/docume</a>

	proposed EUTCT Controlled Term List ID is 100000072072.	<a href="#">nt_library/Other/2013/04/WC500142231.xlsx</a>
<b>Place Codes</b>	Used to name the territorial area for which the competent authority's decision will apply to	This is a subset of the EEA country codes derived from the ISO two letter country code list (see <a href="#">Section 6.3</a> )
<b>Regulatory Status Codes</b>	Status of the review of a regulatory activity	<a href="http://eutct.ema.europa.eu/eutct/viewListDisplay.do?listId=100000072049">http://eutct.ema.europa.eu/eutct/viewListDisplay.do?listId=100000072049</a>
<b>Review Procedure Codes</b>	Type of regulatory authorisation procedure in the European Union	<a href="http://eutct.ema.europa.eu/eutct/viewListDisplay.do?listId=100000154442">http://eutct.ema.europa.eu/eutct/viewListDisplay.do?listId=100000154442</a>
<b>Submission Codes</b>	Type of regulatory activity constituted by one or several submission units and referring to at least one application	<a href="http://eutct.ema.europa.eu/eutct/viewListDisplay.do?listId=100000155688">http://eutct.ema.europa.eu/eutct/viewListDisplay.do?listId=100000155688</a>
<b>Applicant's submission unit type Codes</b>	Types of content of submission unit items to be provided by an applicant	<a href="http://eutct.ema.europa.eu/eutct/viewListDisplay.do?listId=100000155046">http://eutct.ema.europa.eu/eutct/viewListDisplay.do?listId=100000155046</a>
<b>Regulating Authority's submission unit type Codes</b>	Types of content of submission items to be provided by a regulating Authority	<a href="http://eutct.ema.europa.eu/eutct/viewListDisplay.do?listId=100000155552">http://eutct.ema.europa.eu/eutct/viewListDisplay.do?listId=100000155552</a>
<b>EU Procedural Authority Role Codes</b>	Role of a regulating party involved in a regulatory activity depending from the procedure type	<a href="http://eutct.ema.europa.eu/eutct/viewListDisplay.do?listId=">http://eutct.ema.europa.eu/eutct/viewListDisplay.do?listId=</a>
<b>Territorial Authority Codes</b>	Competent Authorities responsible for Medicinal Product authorisation in the European Union and the European Economic Area, including name of the country and its domain of expertise. In case of eCTD the usage is restricted to Competent Authorities responsible for human medicinal products.	<a href="http://eutct.ema.europa.eu/eutct/viewListDisplay.do?listId=100000160680">http://eutct.ema.europa.eu/eutct/viewListDisplay.do?listId=100000160680</a>

317  
318  
319

320 **6.2 Controlled Vocabulary specified by HL7**

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

323  
324

325 **6.3 Controlled Vocabulary specified by ISO**

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

- **International Organisation for Standardization (ISO) - Two-Letter Language Code:** This is a two letter code that is specified for the language as specified in the ISO 639.1 standard. This vocabulary is used to define the *text@language* attribute. For EU Module 1 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 Module 1 purposes a constrained list will be used.
- **ISO Health informatics – Identification of Medicinal Products – Structures and Controlled Vocabularies for Ingredients (Substances)** (prEN ISO 11238).

338  
339

340 **6.4 Maintenance of Controlled Vocabularies**

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

344 Maintenance of Controlled Vocabularies from outside the EU region will be handled by the M2  
345 Working Group.

346 All other controlled vocabularies will be handled by EUTCT for the purpose of EU Module 1 use.

347  
348

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

350 There are no principles deviating from the ICH eCTD IG for using the EU part of the XML  
351 schema.

352

353

354 **8. eCTD 4.0 XML MESSAGE**

355 There are no principles deviating from the ICH Implementation Guide for creating the EU part of  
356 the XML message. Especially, in regard to the header of the message the same elements/attributes  
357 apply as outlined in the ICH eCTD IG. Nevertheless, additional regional specific requirements  
358 need to be considered for other elements/attributes as outlined below.

359 All information in this section is organised in order that the eCTD v4.0 XML components appear  
360 within the schema.

**Table 3: XML Structure**

XML Structure
<p>The eCTD v4.0 begins by identifying the <i>subject</i> element of the XML message. The payload message starts with the <i>submissionUnit</i> element and relates the rest of the elements to the Submission Unit being sent. The <i>submissionUnit</i> element contains the following elements and their attributes:</p> <ul style="list-style-type: none"> <li>• <i>component4contextOfUse</i> <ul style="list-style-type: none"> <li>◦ <i>priorityNumber</i></li> <li>◦ <i>replacementOf.relatedContextOfUse</i></li> <li>◦ <i>derivedFrom.documentReference</i></li> <li>◦ <i>subject5.submissionReference</i></li> <li>◦ <i>referencedBy.keyword</i></li> <li>◦ <i>primaryInformationRecipient.TerritorialAuthority</i></li> </ul> </li> <li>• <i>component1.submisison</i></li> </ul> <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;component4&gt;       &lt;priorityNumber value="" /&gt;       &lt;contextOfUse&gt;         &lt;id&gt;&lt;/id&gt;         &lt;code&gt;&lt;/code&gt;         &lt;statusCode&gt;&lt;/statusCode&gt;         &lt;primaryInformationRecipient&gt;           &lt;territorialAuthority&gt;             &lt;governingAuthority&gt;               &lt;/governingAuthority&gt;             &lt;/territorialAuthority&gt;           &lt;/primaryInformationRecipient&gt;         &lt;replacementOf typeCode="RPLC"&gt;           &lt;relatedContextOfUse&gt;             &lt;id&gt;&lt;/id&gt;           &lt;/relatedContextOfUse&gt;         &lt;/replacementOf&gt;         &lt;derivedFrom&gt;           &lt;documentReference&gt;             &lt;id&gt;&lt;/id&gt;           &lt;/documentReference&gt;         &lt;/derivedFrom&gt;       &lt;/component4&gt;     &lt;/submissionUnit&gt;     &lt;subject5 negationInd="" /&gt;     &lt;submissionReference&gt;       &lt;id xsi:type="DSET_II"&gt;         &lt;item&gt;&lt;/item&gt;     &lt;/submissionReference&gt;   &lt;/subject&gt;</pre> <p>The diagram illustrates the hierarchical structure of the XML elements and their corresponding sections and descriptions. The XML code is on the left, and the right side shows boxes with arrows pointing to specific elements, each containing a section number and a description.</p> <ul style="list-style-type: none"> <li><b>submissionUnit (Section 9.1)</b> as a supplement to the ICH eCTD IG</li> <li><b>priorityNumber (Section 9.2)</b> as a supplement to the ICH eCTD IG</li> <li><b>contextOfUse (Section 9.3)</b> as a supplement to the ICH eCTD IG</li> <li><b>primaryInformationRecipient.territorialAuthority (Section 9.4)</b> specific for EU Module 1 IG</li> <li><b>replacementOf.relatedContextOfUse (Section 9.5)</b> as a supplement to the ICH eCTD IG</li> <li><b>derivedFrom.documentReference (Section 9.6)</b> as a supplement to the ICH eCTD IG</li> <li><b>submissionReference (Section 9.7)</b> specific for EU Module 1 IG</li> </ul>

## XML Structure

```
</id>
</submissionReference>
</subject5>
<reference1 typeCode="REFR">
  <keyword>
    <code></code>
  </keyword>
</reference1>
</contextOfUse>
</component4>
```

**Keyword** (Section [9.8](#))  
as a supplement to the ICH eCTD IG  
and specific for EU Module 1 IG

This section of the XML relates to specifying the **Submission** element. The following elements may follow the Submission:

- **sequenceNumber** (included as an element of the relationship between **submissionUnit** and **Submission**)
- **callBackContact.contactParty**
- **subject4.review**
- **subject6.regulatoryReviewTime**
- **subject7.submissionGroup**
- **subject9.mode**

```
<component1>
  <sequenceNumber></sequenceNumber>
  <submission>
    <id></id>
    <code></code>
    <callBackContact>
      <contactParty>
        <id></id>
      </contactParty>
    </callBackContact>
    <subject4>
      <review>
        <...>
      </review>
    </subject4>
    <subject6>
      <regulatoryReviewTime>
        <code></code>
      </regulatoryReviewTime>
    </subject6>
    <subject7>
      <submissionGroup>
        <id></id>
      </submissionGroup>
    </subject7>
    <subject9>
      <mode>
        <code></code>
      </mode>
    </subject9>
```

**sequenceNumber.submission** (Section [9.9](#))  
as a supplement to the ICH eCTD IG

**submission** (Section [9.10](#))  
specific for EU Module 1 IG

**callBackContact** (Section [9.11](#))  
specific for EU Module 1 IG

**review** (Section [9.22](#))  
see separate section below

**regulatoryReviewTime** (Section [9.12](#))  
not required

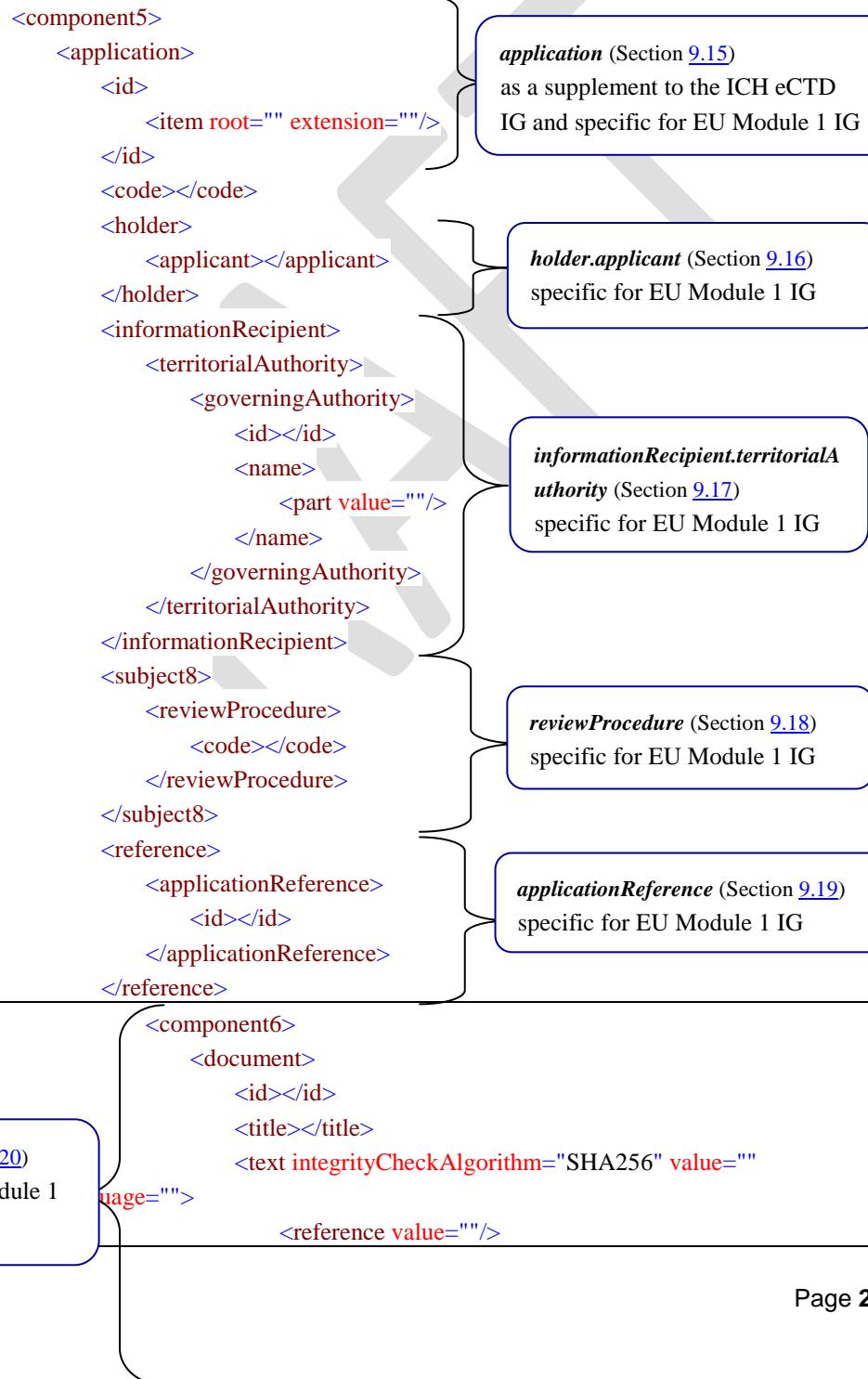
**submissionGroup** (Section [9.13](#))  
specific for EU Module 1 IG

**mode** (Section [9.14](#))  
specific for EU Module 1 IG

## XML Structure

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

- ***holder.applicant***
- ***informationRecipient.territorialAuthority***
- ***subject8.reviewProcedure***
- ***reference.applicationReference***
- ***component6.document***
  - ***referencedBy.keyword***
- ***referencedBy.keywordDefinition***



## XML Structure

```
<integrityCheck></integrityCheck>
</text>
</document>
</component6>
<referencedBy>
  <keywordDefinition>
    <code></code>
    <statusCode></statusCode>
    <value>
      <item>
        <displayName></displayName>
      </item>
    </value>
  </keywordDefinition>
</referencedBy>
```

**keywordDefinition**  
(Section [9.21](#))  
specific for EU  
Module 1 IG

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

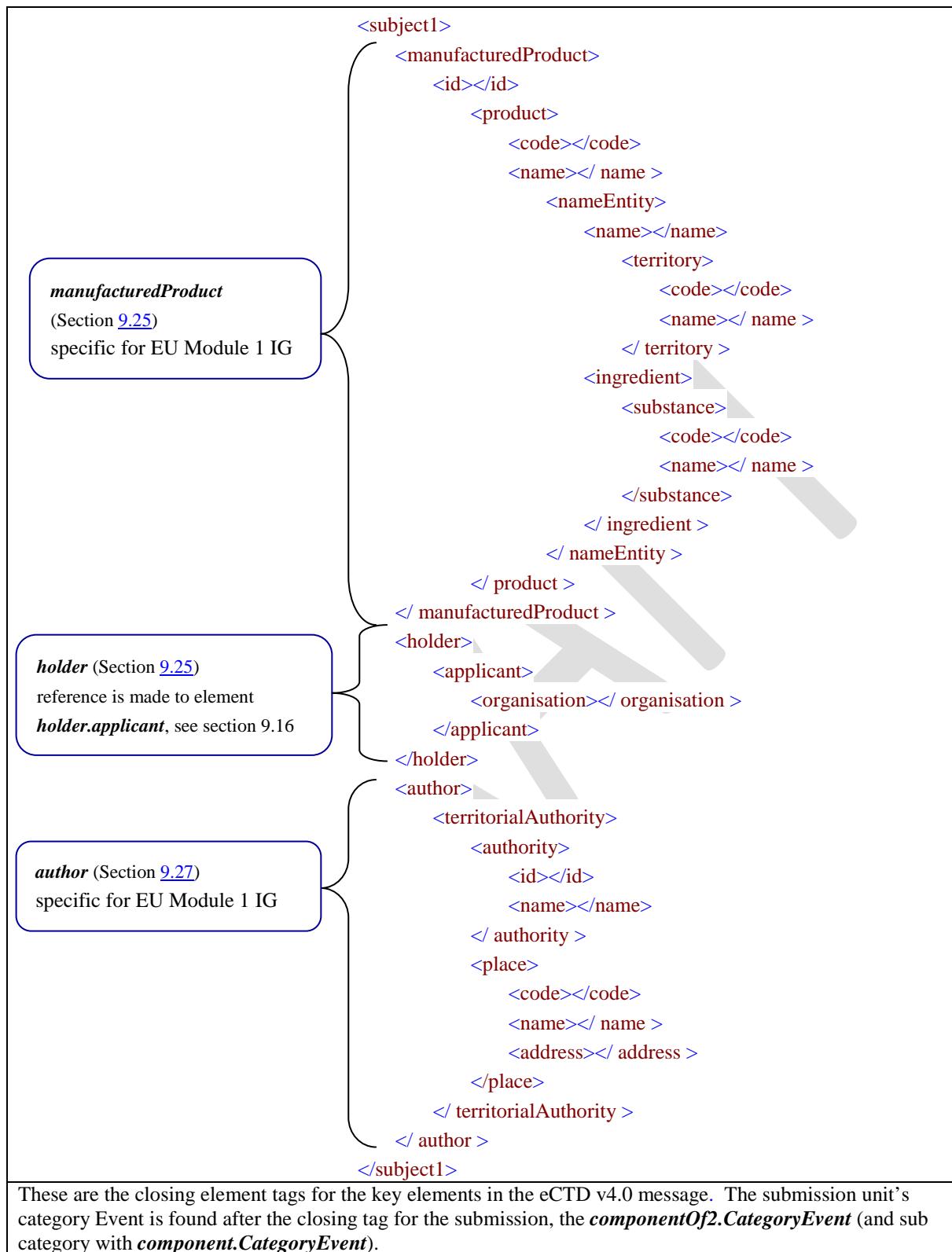
- **subject2.productCategory**
- **subject3.RegulatoryStatus**
- **subject1.manufacturedProduct**
- **holder.applicant**
- **author.territorialAuthority**

**review** (Section [9.22](#))  
specific for EU Module 1 IG

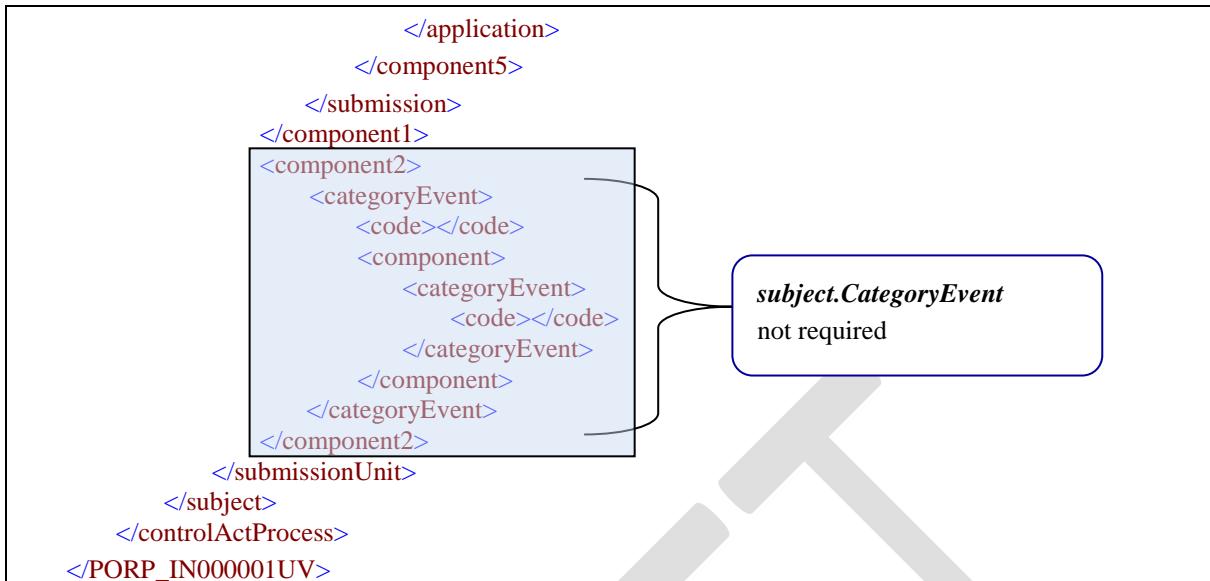
**productCategory** (Section [9.23](#))  
specific for EU Module 1 IG

**regulatoryStatus** (Section [9.24](#))  
specific for EU Module 1 IG

```
<subject4>
  <review>
    <id></id>
    <statusCode></statusCode>
    <effectiveTime></effectiveTime>
  </review>
  <subject2>
    <productCategory>
      <code></code>
    </productCategory>
  </subject2>
  <subject3>
    <regulatoryStatus>
      <code></code>
      <effectiveTime></effectiveTime>
    </regulatoryStatus>
  </subject3>
</subject4>
```



These are the closing element tags for the key elements in the eCTD v4.0 message. The submission unit's category Event is found after the closing tag for the submission, the **componentOf2.CategoryEvent** (and sub category with **component.CategoryEvent**).



364

365

## 366 9. EU REGIONAL SPECIFIC REQUIREMENTS FOR ELEMENTS

367

### 368 9.1 Submission Unit

369 The Submission Unit is a collection of documents provided to the Regulatory Authority at one  
 370 time or to the Applicant in case the Regulatory Authority will send their list of question or  
 371 assessment report using the same messaging standard. A submission unit always relates to a  
 372 regulatory activity specified by the submission that is related to a specified application.

373 Only one submission unit can be sent at a time, this Submission unit may be in response to one or  
 374 more lists of questions from a Regulatory Authority with respect to the specified application and  
 375 submission unit.

376 In case of regulatory activities executed in a grouping or workshare mode, the submission unit will be  
 377 referenced for multiple applications as needed through a submission element each time providing the  
 378 respective sequence number. The submission element connects the submission unit and the  
 379 application.

380 In case a submission unit needs to be withdrawn by the applicant a new message needs to be sent  
 381 just providing the new status code “nullified” of that previously submitted unit. In this case,  
 382 content references are not required as the status code of document elements will not change and  
 383 also CoU elements are not affected. In consequence, the documents will no longer be displayed for  
 384 the application the submission unit was withdrawn, but they can still be used and will be displayed  
 385 when referenced by other applications they have been referenced as well.

#### 386 9.1.1 Location in XML

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

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

389 Refer to [Table 3](#): XML Structure for the XML representation.

390

### 391       **9.1.2      XML details**

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

#### 393       **XML Elements**

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

397

#### 398       **XML Sample:Submission Unit**

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

```
400 <subject_typeCode="SUBJ">
401   <submissionUnit>
402     <id root="78965412-3214-5698-7856-985412563254"/>
403     <code code=" Applicant's submission unit type " codeSystem="12365478-9874-5632-
404       11235-951268473654"/>
405     <title="initial" codeSystem="12311898-4574-5122-99435-94321434564"/>
406     <statusCode code="active"/>
407     .....
408     [Additional information may appear after the addition of the statusCode (if one exists,
409      otherwise this will follow the title or code elements. For example, depending on the type of
410      submission unit the additional elements may be available to select from the submission unit-
411      component, callBackContact, componentOf or subject elements)]
412     ...
413     <component1>
414       <sequenceNumber value="1"/>
415       <submission>
416         ...
417         [Additional information will follow for the submission and application elements.]
418         ...
419       </submission>
420     </component1>
421   </submissionUnit>
422 </subject>
```

423

424

### 425       **9.2      Priority Number**

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

427



*Note: The life cycle will be executed by inserting a new contextOfUse element including the respective combination of keywords and by assigning the appropriate priority number. All life cycle considerations outlined in the*

ICH eCTD IG will apply to EU Module 1 in the same manner.

428

429

430 **9.3 Context of Use**

431 The Context of Use provides a linkage between the table of contents heading of the CTD and the  
432 referenced document that is associated to that heading. There are no additional technical  
433 requirements than outlined in the ICH eCTD IG. In the sections below, the examples will be  
434 provided for EU Module 1.

435



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

436

437 **9.3.1 Location in XML**

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

- *controlActProcess>>subject>>submissionUnit>>component4>>priorityNumber>contextOfUse*

441 Refer to [Table 3](#): XML Structure for the XML representation.

442

443 **9.3.2 XML Details**

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

445

446 **9.3.3 Terminology**

447 The Context of Use codes will be provided by EU-specific controlled vocabularies (see [Section 6.1](#)).

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

450

451

452 **9.4 Territorial Authority (as primary information recipient related to contextofUse)**

454 The elements *primaryInformationRecipient* and *informationRecipient* (see [Section 9.17](#)) will  
455 provide names of *territorialAuthority*. For Centralised procedure this does mean the EMA will be  
456 stated in both cases. In case of DCP the Reference Member State, i.e. France, will be named by  
457 using the *primaryInformationRecipient* element and the *informationRecipient* element, all  
458 Member States involved, i.e. The Netherlands, France, Germany (BfArM), will be named by  
459 using only the *informationRecipient* element. This element will be provided once as always only  
460 one agency will serve as a primary recipient.

461

462     **9.4.1       Location in XML**

463     The *author.territorialAuthority* element in the XML message is in the following location:

- *controlActProcess>>subject>>submissionUnit>>component4>>contextOfUse>>primaryInformationRecipient>>territorialAuthority*

464     Refer to [Table 3](#): XML Structure for the XML representation.

465

466     **9.4.2       XML details**

467       **XML Elements**

468     The following tables provide a complete set of XML elements and attributes required for the *manufacturedProduct* element in case it is provided, and any special instructions.



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

472

473

474     **TerritorialAuthority.place**

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>id</i>		[1..1]		This is a container element for a reference to the place of the governing authority
<i>id.item</i>		[1..1]		The <i>place</i> attribute of the <i>territory</i> element provides the physical location of the territorial authority (e.g., regulatory authority) for which the respective agency is responsible for
	<i>code</i>	[1..1]	Alpha Numeric e.g., DE	The code will be provided by the EU Territorial Authority Code list
	<i>root</i>	[1..1]	Valid OID or UUID	

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
	<i>name</i>	[0..1]	Alpha Numeric e.g., Germany	The <i>name</i> element will display the name of the country / territory
	<i>address</i>	[0..1]	Alpha Numeric e.g., Kurt-Georg-Kiesinger-Allee 3; 53175 Bonn	The <i>address</i> element will provide the display value of address details of the respective authority
<i>Conformance</i>	The <i>id</i> element and <i>root</i> attribute are required.			
<i>Business Rules</i>	This element provides the referencing point for the competent authority responsible for the assessment procedure and indicates for which territory the respective agency is responsible for.			
<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@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>			

475

476

#### 477 *TerritorialAuthority.governingAuthority*

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>id</i>		[1..1]		This is a container element for a reference to the name of the governing authority
<i>name</i>		[1..*]		This is the container element of the following attributes by which the name of the regulating authority is provided.

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
	<b>code</b>	[1..1]	Alpha Numeric e.g., BfArM or 276	The <b>code</b> element will provide the unique identifier of the authority
	<b>codeSystem</b>	[1..1]	Valid OID or UUID	This is the <b>codeSystem</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>name</b>	[1..1]	Alpha Numeric e.g., Bundesinstitut für Arzneimittel und Medizinprodukte	The <b>name</b> element will display the name of the authority
<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 competent agency receiving the message as a primary recipient, e.g. the EMA in case of a Centralised procedure, the RMS in DCP or MRP or the respective NCA in case of a purely national procedure.			
<b>Excluded Elements and Attributes</b>	The following attributes are not required by eCTD 4.0: <ul style="list-style-type: none"> <li>• <b><i>id@extension</i></b></li> <li>• <b><i>id@identifierName</i></b></li> <li>• <b><i>id@scope</i></b></li> <li>• <b><i>id@reliability</i></b></li> <li>• <b><i>id@displayable</i></b></li> </ul>			

478

479

480 **XML sample**

481

482 &lt;primaryInformationRecipient&gt;

483 <!-- Specific Health Authority and/or country to which this CoU is for (if needed to be  
484 specified) -->

485 &lt;territorialAuthority&gt;

```
486 <territory>
487   <code code="FR" codeSystem="4.33.650.1.723354.0.121.230" />
488   <name>
489     <part value = "National Agency for the Safety of Medicine and Health Products"
490 language="en"/>
491   </name>
492   <addr xsi:type="AD">
493     <part value="Saint-Denis" type="CTY" />
494     <part value="143-147 Bld Anatole France" type="STR"/>
495     <part value="93200" type="ZIP" />
496   </addr>
497 </territory>
498 <governingAuthority>
499   <id root="52345678-1234-1234-1234-12345678901" />
500   <name>
501     <part value="ANSM" code="FR-ANSM" />
502   </name>
503 </governingAuthority>
504 </territorialAuthority>
505 </primaryInformationRecipient>
506
507
```

508

## 509 **9.5 Related Context of Use (Context of Use Life Cycle)**

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

511

512

## 513 **9.6 Document Reference**

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

515

516

## 517 **9.7 Submission Reference**

518 The Submission Reference provides the option to refer to a submission sent by applicant in case  
519 the authority will use two-way communication. The *submissionReference* element indicates the  
520 previously started regulatory activity to which the authority response relates. The  
521 *submissionReference* element will be used by regulators only.

522

### 523 **9.7.1 Location in XML**

524 The *submissionReference* element follows the *subject* element next to *contextOfUse* element:

- 525 • *controlActProcess*>>*subject*>>*submissionUnit*>>*component4*>>
- 526 *contextOfUse*>>*subject5*>>*submissionReference*

527 Refer to [Table 3](#): XML Structure for the XML representation.

528

529    **9.7.2     XML details**

530    **XML Elements**

531    The following tables provide a complete set of XML elements and attributes required for the  
532    **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.*

533

534    **SubmissionReference.id**

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<b><i>Id</i></b>		[1..1]		This is the container element of the following elements and attributes by which it uniquely identifies the application.
<b><i>Id.item</i></b>		[1..*]		This is a container element for the <b>SubmissionReference</b>
	<b><i>root</i></b>	[1..1]	Valid OID or UUID	This is the root attribute that provides the global unique identifier for the <b>SubmissionReference</b> element
<b>Conformance</b>	The <b><i>id.item@root</i></b> is a required element			
<b>Business Rules</b>	More than one <b><i>item</i></b> element may be provided.			

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</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.item@identifierName</i></li> <li>• <i>id.item@scope</i></li> <li>• <i>id.item@reliability</i></li> <li>• <i>id.item@displayable</i></li> <li>• <i>id@validTimeLow</i></li> <li>• <i>id@validTimeHigh</i></li> <li>• <i>id@controlInformationRoot</i></li> <li>• <i>id@controlInformationExtension</i></li> <li>• <i>id@nullFlavor</i></li> <li>• <i>id@flavorId</i></li> <li>• <i>id@updateMode</i></li> </ul>	

535

536

### 537 **XML Sample: Submission Reference**

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

539



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

540



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

541

### 542 **9.7.3 Terminology**

543 There is no further terminology foreseen.

544

545

### 546 **9.8 Keyword**

547 The *keyword* element is used for the purposes of transmitting additional information about a *contextOfUse* element. In the EU M1, the Country Code will be used to specify commonly used  
548 or nationally used documents including the referenced files. The keywords to identify types of  
549 product information texts will be used for *contextOfUse* elements related to Module 1.3.1.  
550

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

553 For EU M1, the latter principle will apply to *contextOfUse* elements referencing product  
554 information texts in order to sort them according to pharmaceutical form or strength.  
555



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

### 556 **9.8.1 Location in XML**

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

- *controlActProcess>> subject>> submissionUnit>>component4>>priorityNumber> contextOfUse >> reference1>> keyword*

559 Refer to [Table 3](#): XML Structure for the XML representation.

560

### 561 **9.8.2 XML Details**

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

563

### 564 **9.8.3 Terminology**

565 For EU Module 1 controlled vocabularies are provided via EUTCT (see [Section 6.1](#)).

566

567

568

## 569 **9.9 Sequence Number**

570 There are no additional requirements than outlined in the ICH eCTD IG. In case more than one  
571 sequence number need to be provided (in case of grouped variations and work share procedures)  
572 the sequence number needs to be stated as required next to the application involved in the  
573 grouping or work shared procedure.

574

575

## 576 **9.10 Submission**

577 The *submission* is the representation of a regulatory activity constituted by several submission  
578 units and referring to exactly one application. The respective controlled vocabulary is EU specific.  
579 However, for the purposes of the Current View Transition message the ICH Controlled  
580 Vocabulary should be used.

581 A submission unit may contain more than one submission referring each to one application (see  
582 [Section 5](#)), relevant in case of grouped variations or workshare procedures.



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.

### 583 **9.10.1 Location in XML**

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

- 585       • *controlActProcess>>subject>>submissionUnit>>component1>>*  
 586       *sequenceNumber>>submission*

587       Refer to [Table 3](#): XML Structure for the XML representation.

588

## 589      **9.10.2     XML Details**

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

### 591      ***XML Elements***

592       The following tables provide a complete set of XML elements and attributes required for the  
 593       ***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.*

### 594      ***Submission.id***

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>id</i>		[1..1]		This is a container element that provides a unique identifier for the submission
<i>id.item</i>		[1..1]		This is the container element of the following attributes by which it uniquely identifies the application. <i>Note: This is a regional constraint.</i>
	<i>root</i>	[1..1]	Valid OID or UUID	This is the root attribute that uniquely identifies the submission
	<i>extension</i>	[1..n]	alpha-numeric e.g. DE/H/1234/0 01-003/II/013	The <b><i>extension</i></b> attribute of the <b><i>id</i></b> element provides a location to specify the EU procedure number including specific extensions related to the regulatory activity.

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<b>Conformance</b>	The <i>id.item@root</i> attribute is required for the <b>submission</b> element.			
<b>Business Rules</b>	Only one <i>item</i> element should be provided for a Submission. The <i>id@extension</i> is the extended procedure number for the regulatory activity. This value will stay the same for all submission units within the regulatory activity.			
<b>Excluded Elements and Attributes</b>	<p>The following attributes are not required by eCTD 4.0:</p> <ul style="list-style-type: none"> <li>• <i>id.item@identifierName</i></li> <li>• <i>id.item@scope</i></li> <li>• <i>id.item@reliability</i></li> <li>• <i>id.item@displayable</i></li> <li>• <i>id@validTimeLow</i></li> <li>• <i>id@validTimeHigh</i></li> <li>• <i>id@controlInformationRoot</i></li> <li>• <i>id@controlInformationExtension</i></li> <li>• <i>id@nullFlavor</i></li> <li>• <i>id@flavorId</i></li> <li>• <i>id@updateMode</i></li> </ul>			

595

596

### **Submission.code**

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<b>code</b>		[0..1]		This is a container element for the submission
	<b>code</b>	[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>
	<b>codeSystem</b>	[1..1]	Valid OID or GUID	This is the codeSystem attribute
<b>Conformance</b>	There must be one and only one <i>code@code</i> attribute specified for a submission.			
<b>Business Rules</b>	<b>Submission</b> codes may vary for different product types. In case of eCTD for human medicinal product the relevant code list is referenced in section 6.1.18.			

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</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.displayName</i></li> <li>• <i>code.originalText</i></li> <li>• <i>code.translation</i></li> <li>• <i>code.source</i></li> <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@codingRationale</i></li> <li>• <i>code@validTimeLow</i></li> <li>• <i>code@validTimeHigh</i></li> <li>• <i>code@controlInformationRoot</i></li> <li>• <i>code@controlInformationExtension</i></li> <li>• <i>code@nullFlavor</i></li> <li>• <i>code@flavorId</i></li> <li>• <i>code@updateMode</i></li> </ul>	

597

598

**Submission.statusCode**

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<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, suspended	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>			

599

600

601 **XML samples:**

602 **Submission**



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

603

604

605 **Submission componentOf Application**



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

606



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

607

608 **9.10.3 Terminology**

609 The **submission** element code values will be provided by EU-specific controlled vocabularies (see  
610 [Section 6.1](#)).

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

612

613 **9.10.4 Related Elements**

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

- 615     ○ **subject4.review** (see [Section 9.22](#))
- 616     ○ **subject6.regulatoryReviewTime** (see [Section 9.12](#))
- 617     ○ **subject7.submissionGroup** (see [Section 9.13](#))
- 618     ○ **subject9.mode** (see [Section 9.14](#))

619

620

621 **9.11 Contact Party**

622 The **callBackContact** element is to be used for a person or department (**contactParty**) to call if  
623 there are any questions. At least one Contact Party needs to be named per each submission unit.  
624 Therefore, it will always be the person authorised for communication on behalf of the applicant  
625 during the regulatory activity (running procedure) (code 2.4.2)

626 In case of the Transition Mapping submission file a technical contact party should be included for  
627 the purposes of troubleshooting any issues with the forward compatibility file. The following  
628 information should be sent for each technical contact.

629

630    **9.11.1    Location in XML**

631    The *callBackContact* element in the XML message is in the following location:

- *controlActProcess>> subject>> submissionUnit>>component1>>*
- submission>>callBackContact>>contactParty*

634    Refer to [Table 3](#): XML Structure for the XML representation.

635

636    **9.11.2    XML details**

637    There are no additional requirements than outlined in the ICH eCTD IG. The sample provided  
638    there is applicable for other contact party roles as well.

639

640    **9.11.3    Terminology**

641    The *ContactParty* element requires codes for the *code* element (see [Section 6.1](#)) and the  
642    *statusCode* element.

643

644

645    **9.12    Regulatory Review Time**

646    The *regulatoryReviewTime* element will not be used in the EU.



*This class will not be used in EU Module 1 eCTD v4.0 message, because the review time is already defined by legislation and does not need to be stated in the message.*

647

648

649    **9.13    Submission Group**

650    The Submission Group represents an option to process regulatory activities together in case the  
651    assessment will cover same content and the regulatory activity concerns more than one variation  
652    for the same product or applies to more than one product, e.g several generic applications with  
653    different product names but identical pharmaceutical composition and properties which can  
654    otherwise not be assessed like grouped variations or other formal workshare procedures in one go.  
655    A submission group needs to be defined per regulatory activity and is required to be stated within  
656    each submission unit submitted during that course of assessment.

657    The *submissionGroup* element can be used in case same regulatory activity will be processed the  
658    same way but formally not running under the same procedure number or can be grouped or shared  
659    according legal rules. The UUID will connect the different applications for this submission  
660    (regulatory activity) in the submission group, e.g. id=0987.997.

661

662    **9.13.1    Location in XML**

663    The *submissionGroup* element follows the *submission* element, which follows the *subjectOf*  
664    element.

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

- 666     • *controlActProcess>>subject>>submissionUnit>>component1>>*  
 667       *sequenceNumber>>submission>>subject7>>submissionGroup*

668 Refer to Table 3: XML Structure for the XML representation.

669

### 670   **9.13.2   XML details**

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

#### 672   **XML Elements**

673 The following tables provide a complete set of XML elements and attributes required for the  
 674 **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.*

675

#### 676   **SubmissionGroup.id**

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>id</i>		[1..1]		This is a container element that provides a unique identifier for the submission group of which the submission is part of
<i>id.item</i>		[1..*]		This is the container element of the following attributes by which it uniquely identifies the referenced submission.
	<i>root</i>	[1..1]	Valid UUID	The <b>root</b> attribute of the <i>id</i> element provides a global unique identifier for the submission reference.
<b>Conformance</b>		The <i>id.item@root</i> is a required attribute.		

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<b>Business Rules</b>	More than one <i>item</i> element may be provided. This will indicate a group of applications the regulatory activity applies to but not formally as a grouping or worksharing, but in case of duplicates processed together but as independent products.			
<b>Excluded Elements and Attributes</b>	<p>The following attributes are not required by eCTD 4.0:</p> <ul style="list-style-type: none"> <li>• <i>id.item@identifierName</i></li> <li>• <i>id.item@scope</i></li> <li>• <i>id.item@reliability</i></li> <li>• <i>id.item@displayable</i></li> <li>• <i>id@validTimeLow</i></li> <li>• <i>id@validTimeHigh</i></li> <li>• <i>id@controlInformationRoot</i></li> <li>• <i>id@controlInformationExtension</i></li> <li>• <i>id@nullFlavor</i></li> <li>• <i>id@flavorId</i></li> <li>• <i>id@updateMode</i></li> </ul>			

677

678 **XML Sample: SubmissionGroup derived from Submission**

```

679 <subject7>
680   <submissionGroup>
681     <idroot="UUID for the submissionGroup" extension="0987.997" />
682   </submissionGroup>
683 </subject7>
684 <componentOf>
685   <application>
686     <id>
687       - <!-- Application ID -->
688       - <!-- ===== -->
689       - <!-- Should EU use this item to store the number used by an agency to track the
690         submission, in any procedure, in relation to a particular product. -->
691       - <!-- This could be a MRP Number, the EMEA application number, or any other number
692         used by an agency to track a submission. -->
693       - <!-- ===== -->
694       <item root="fr-2082-001-dc" />
695       <item root="fr-2083-001-dc" />
696       <item root="fr-2084-001-dc" />
697       <item root="fr-2085-001-dc" />
698     </id>
699   ...

```

700 [Additional information may appear after the addition of the *Application.code*, for  
701 example any of the following elements related to *Application – component*,  
702 *referencedBy*, *informationRecipient*, *reference*, *subject*, or *holder*]  
703 ...  
704 </application>  
705 </componentOf>  
706



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

707

### 708 9.13.3 Terminology

709 There is no further terminology foreseen.

710

711

## 712 9.14 Mode

713 The high-level handling of the information submitted as part of variation(s) and extension  
714 applications will be indicated by this element. The **mode** element should only be used in variation  
715 or line extension regulatory activities and must be included in every sequence of that activity. The  
716 following are the valid modes: a single regulatory activity (e.g. a Type II variation), a grouped  
717 activity (e.g. several variations grouped into a single submission, a periodic report of type IA  
718 variations applicable to one or more marketing authorisations or a PSUR single assessment  
719 procedure) and an activity subject to a worksharing agreement (e.g. a Type II variation applicable  
720 to more than one marketing authorisation).

### 721 9.14.1 Location in XML

722 The **mode** element in the XML message is in the following location:

- *controlActProcess>>subject>>submissionUnit>>component1>>sequenceNumber>>submission>>subject9>>mode*

723 Refer to [Table 3](#): XML Structure for the XML representation.

724

### 725 9.14.2 XML details

#### 726 **XML Elements**

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



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

730

731

732

733 **Mode.code**

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

734

735 The following is an example of the XML for the *mode* element.736 **XML Sample : Mode**

```

<componentOf>
  <sequenceNumber value="2" />
  <submission>
    ...
  </submission>

```

```
740      <id>
741          <item root="0F7650B5-F126-424C-8AC6-75E11B08C202" />
742      </id>
743      <code code="100000155689" codeSystem="9.16.330.1.113884.2.800.2"/>
744      <subject9>
745          <mode>
746              <!--The mode element should only be used in variation or line extension regulatory
747 activities and must be included in every sequence of that activity -->
748              <code code="worksharing" codeSystem="3.12.850.1.223354.0.121.1" />
749          </mode>
750      </subject9>
751      ...
752          [Additional information may appear]
753          ...
754      </submission>
755  </componentOf>
756
```



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

757  
758

#### 759 **9.14.3 Terminology**

760 The **mode** element requires codes for the code element (see [Section 6.1](#)).

761  
762

### 763 **9.15 Application**

764 The **application** element represents a request from Regulated Industry to a Regulatory Authority
765 for the approval to market of a medicinal product for human use. The application in this context
766 typically will cover all dosage forms and strengths of a product. In the Centralised procedure, this
767 will be equivalent to all dosage forms and strengths covered by an EMA application number (e.g.
768 EMEA/H/C/000123). In MRP/DCP, a single eCTD application should preferably be used for the
769 procedure (e.g. DE/H/2087/001-sss/DC or MR). However, if an applicant decides not to apply for
770 all strengths and dosage forms in every member state in the procedure, the possibility of having
771 one eCTD application per strength/dosage form should be considered. The RPS standard used for
772 eCTD v4.0 provides the opportunity to refer across applications. However, it is not allowed to
773 make use of this option for the initial submission unit applying for a marketing authorisation and
774 eCTDv4.0 identifier cannot be used for previously submitted eCTD v 3.2.2 sequences as long as
775 the transition messages has not been submitted. Submissions and submission units for regulatory
776 activities after this initial one may refer to several applications at the same time.

777 An application will consist over time of multiple submissions or regulatory activities (e.g., initial
778 marketing authorisation application, variations or PSURs). For example a marketing application
779 may consist of one or more regulatory decisions - e.g., the collection of all approvals is related to
780 the application. Each regulatory submission (for details refer to section 6.1. controlled vocabulary

781 of submission types) will have its own regulatory action, and most likely will be composed of one  
782 or more submission units.

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

786

### 787 **9.15.1 Location in XML**

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

- 789 • ***controlActProcess>>subject>>submissionUnit>>component1>>***
- 790       ***submission>>component5>>application***

791 Refer to [Table 3](#): XML Structure for the XML representation.

792

### 793 **9.15.2 XML details**

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

795

### 796 **9.15.3 Terminology**

797 The controlled terminology for the ***application*** element includes codes for ***productCategory*** (e.g.  
798 Full Dossier, Bibliographic, Biosimilar, Generic) (refer to [Section 6.1](#)).

799

### 800 **9.15.4 Related Elements**

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

- 802     ○ ***holder.applicant*** (see [Section 9.12](#))
- 803     ○ ***informationRecipient.territorialAuthority*** (see [Section 9.17](#))
- 804     ○ ***subject8.reviewProcedure*** (see [Section 9.18](#))
- 805     ○ ***reference.applicationReference*** (see [Section 9.19](#))

806

807

## 808 **9.16 Applicant**

809 The Applicant element is presenting the role of the sponsor of the initiation of a marketing  
810 authorisation application and is mentioned in relation to ***applicant*** element.

811

### 812 **9.16.1 Location in XML**

813 The ***applicant*** element in the XML message is in the following location:

- 814     • ***controlActProcess>>subject>>submissionUnit>>component1>>***
- 815       ***submission>>component5>>application>>holder>>applicant***

816 Refer to [Table 3](#): XML Structure for the XML representation.

817

## 818 9.16.2 XML details

### 819 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.*

### 820 XML Sample: Applicant

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

```
823 <holder>
824   <applicant>
825     <sponsorOrganisation>
826       <name xsi:type="BAG_EN">
827         <item>
828           <!--Code - 123456789 is the DUNS Number for the company Name-->
829           <part value="Good Drugs" code="123456789" codeSystemVersion="OID for
830 DUNandBradstreet"/>
831         </item>
832       </name>
833     </sponsorOrganisation>
834   </applicant>
835 </holder>
836 ...
837 ...
```



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

838

839

## 840 9.17 Territorial Authority (as information recipient related to application)

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

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

### 848 9.17.1 Location in XML

849 The **territorialAuthority** element in the XML message is in the following location:

- 850     • *controlActProcess>>subject>>submissionUnit>>component1>>*  
851       *submission>>component5>>application>>informationRecipient>>territorialAuthority*

852 Refer to [Table 3](#): XML Structure for the XML representation.

853

## 854   **9.17.2   XML details**

### 855   **XML Elements**

856 For the complete set of XML elements and attributes required for the *territorialAuthority* element  
857 see [Section 9.4](#).



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

### 858   **XML Sample: Territorial Authority**

```
859 <informationRecipient>
860   <territorialAuthority>
861     <territory>
862       <code code="FR" />
863     </territory>
864     <governingAuthority>
865       id root="52345678-1234-1234-1234-12345678901" />
866     <name>
867       <part value="ANSM" code="FR-ANSM" />
868     </name>
869     <governingAuthority>
870   </territorialAuthority>
871 </informationRecipient>
872 <informationRecipient>
873   <territorialAuthority>
874     <territory>
875       <code code="NL" />
876     </territory>
877     <governingAuthority>
878       id root="62345678-1234-1234-1234-12345678901" />
879     <name>
880       <part value=" MEB " code=" NL-MEB " />
881     </name>
882     <governingAuthority>
883   </territorialAuthority>
884 </informationRecipient>
885 <informationRecipient>
886   <territorialAuthority>
887     <territory>
888       <code code="DE" />
```

```
889     </territory>
890     <governingAuthority>
891         id root="72345678-1234-1234-1234-12345678901" />
892     <name>
893         <part value=" BFARM " code=" DE-BFARM " />
894     </name>
895     </governingAuthority>
896     </territorialAuthority>
897   </informationRecipient>
898
```

### 899 **9.17.3 Terminology**

900 The name of the territory is provided in the respective controlled vocabulary (see [Section 6.1](#)).

901

902

## 903 **9.18 Review Procedure**

904 The **reviewProcedure** defines the type of procedure to assess the marketing authorisation  
905 application whether it is a Centralised, decentralised, mutual recognition or purely national  
906 procedure

907

### 908 **9.18.1 Location in XML**

909 The **reviewProcedure** element in the XML message is in the following location:

- 910 • **controlActProcess>>subject>>submissionUnit>>component1>>**
- 911       **submission>>component5>>application>>subject8>>reviewProcedure**

912 Refer to [Table 3](#): XML Structure for the XML representation.

913

### 914 **9.18.2 XML details**

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

#### 916 **XML Elements**

917 The following tables provide a complete set of XML elements and attributes required for the  
918 **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.

919

920 **ReviewProcedure.code**

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

921

922 **XML Sample: ReviewProcedure**

923



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

924



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

### 925    9.18.3 Terminology

926    The *reviewProcedure* element requires codes for the *code* element (see [Section 6.1](#)).

927  
928

## 929    9.19 Application Reference

930    The *applicationReference* element is presenting the type of reference in specific application  
931    types, e.g. generic products. The element is not required in case a reference does not need to be  
932    provided. In case of an informed consent application or a generic product the reference product is  
933    mandated to be named.

934

### 935    9.19.1 Location in XML

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

- *controlActProcess>>subject>>submissionUnit>>component1>>submission>>component5>>application>>reference>>applicationReference*

939    Refer to [Table 3](#): XML Structure for the XML representation.

940

### 941    9.19.2 XML details

#### 942    XML Elements

943    The following tables provide a complete set of XML elements and attributes required for the  
944    *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.*

945

#### 946    ApplicationReference.id

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>id</i>		[1..1]		This is a container element of the following attributes by which it uniquely identifies the application being referenced.

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
	<i>root</i>	[1..1]	Valid OID or UUID	This attribute is for a global unique identifier.
	<i>extension</i>	[1..1]	Alpha Numeric <i>e.g.,FR/H/123 4/001/MR</i>	The <i>extension</i> attribute of the <i>id</i> element provides a location to specify the application number being referenced.
<i>Conformance</i>	The <i>id</i> is a required element required for the <i>applicationReference</i> element if to be submitted.			
<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>	<p>The following attributes are not required by eCTD 4.0:</p> <ul style="list-style-type: none"> <li>• <i>id.item@identifierName</i></li> <li>• <i>id.item@scope</i></li> <li>• <i>id.item@reliability</i></li> <li>• <i>id.item@displayable</i></li> <li>• <i>id@validTimeLow</i></li> <li>• <i>id@validTimeHigh</i></li> <li>• <i>id@controlInformationRoot</i></li> <li>• <i>id@controlInformationExtension</i></li> <li>• <i>id@nullFlavor</i></li> <li>• <i>id@flavorId</i></li> <li>• <i>id@updateMode</i></li> </ul>			

947

948

***ApplicationReference.reasoncode***

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<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>code</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>			

949

## 950 **XML Sample: application reference**

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

952 ...

```

953 <reference>
954   <!--Reference to an originator product-->
955   <applicationReference>
956     <id root=" 5.993452.56789.12345" extension=" ema002156-001"/>
957     <reasonCode>
958       <!-- Reference medicinal product chosen for the demonstration of bioequivalence -->
959       <item code="BE-Ref-Product" codeSystem="OID for EU Application Reference
960 Codes"/>
961     </reasonCode>
962   </applicationReference>
963 </reference>
964
965

```



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

966

### 967 9.19.3 Terminology

968 The **applicationReference.reasonCode** element requires codes for the **code** element, e.g. expiry of  
969 data protection period (see [Section 6.1](#)).

970

971

## 972 9.20 Document

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

979 **Document** elements (e.g., PDF files) are prepared by the Applicant for review by the Regulatory  
980 Authority. In case of a Regulatory Authority that will send a submission unit to Applicants, the  
981 **document** elements are prepared by the Regulatory Authority. A **document** element will be  
982 submitted with a reference to one file and is referenced by one **contextOfUse** element. Documents  
983 can be grouped using a group title provided with the **contextOfUse**. Documents can be referenced  
984 by multiple **contextOfUse** elements, and may be used in multiple submission units.<sup>14</sup>



*Note to Implementers: For simple documents, the text element should be provided. For compound documents, the component element should be used instead to indicate the documents that make up the compound document.*

985

### 986 9.20.1 Location in XML

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

- **controlActProcess>>subject>>submissionUnit>>component1>>submission>>component5>>application>>component6>>document**

988

989 Refer to [Table 3](#): XML Structure for the XML representation.

990

991

---

<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.

992 **9.20.2 XML details**993 **XML Elements**

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

997

998 **Document.id**

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<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
<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>			

999

1000

1001 **Document.title**

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>title</i>		[0..1]		This is a container element that provides the title for the document in the associated assignment
	<i>extension</i>	[0..1]		.....
<i>Conformance</i>	The <i>title</i> is an optional element			

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>Business Rules</i>				
<i>Excluded Elements and Attributes</i>	The following attributes are not required by eCTD 4.0: • <i>title@displayable</i>			

1002

1003

1004

#### ***Document.text***

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>text</i>		[0..1]		This is a container element that provides additional information about the document, including but not limited to: relative file path of the file in the submission contents, language, media type and integrity checksum information.....
	<i>integrityCheckAlgorithm</i>	[1..1]	Alpha Numeric <i>e.g., SHA256</i>	This is the type of <i>integrityCheckAlgorithm</i> that was used for the checksum values provided in <i>integrityCheck</i> element.
	<i>mediaType</i>	[0..1]	Alpha Numeric <i>Refer to Section 4.</i>	This is the <i>mediaType</i> attribute that specifies the usage of the file where it is regionally requested.

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>language</i>		[0..1]		This is the container element that organises the coded value for the language.
	<i>code</i>	[1..1]	Alpha Numeric	The <i>code</i> attribute is a unique value that indicates the type of language controlled vocabulary (e.g., en, de, fr, etc.) see <a href="#">Section 6.3</a>
	<i>codeSystem</i>	[1..1]	Valid OID	The <i>codeSystem</i> attribute is a unique identifier that indicates the controlled vocabulary system.  <i>This should be the OID registered for the code system.</i>
<i>text.reference</i>		[0..1]		This is the container element within the <i>text</i> element for a document.
	<i>value</i>	[1..1]	Alpha Numeric  File path of the document <i>e.g., “./m3/32-body-data/32s-drug-sub/32s1-gen-info.pdf”</i>	This is the <i>value</i> attribute of the <i>text</i> element that provides the location of the document with the relative path and filename of the document.

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>text.integrityCheck</i>		[1..1]	Alpha Numeric  <i>e.g.,</i> “618102bf070 65bcc125059 4201fe448515 f0fa61”	This is the integrity check element, which has the checksum value.
<i>Conformance</i>	Documents require the following elements/attributes:			
	<ul style="list-style-type: none"> <li>• The <i>text</i> element             <ul style="list-style-type: none"> <li>○ The <i>text@IntegrityCheckAlgorithm</i> attribute</li> <li>○ The <i>reference@value</i> attribute</li> <li>○ The <i>text.integrityCheck</i> element</li> </ul> </li> </ul>			
<i>Business Rules</i>	<p>The <i>text</i> element should be used when sending a document.</p> <p>The <i>text@language</i> should be provided for document elements referenced by the EU M1 CoU codes m1-3-1.</p> <p>The <i>text@mediaType</i> should be provided if there is a special file format.</p> <p>For file reuse, the <i>text</i> element must indicate the same <i>reference@value</i>, <i>text@IntegrityCheckAlgorithm</i> and <i>text.integrityCheck</i> values of the previously submitted <i>document</i> element.</p>			
<i>Excluded Elements and Attributes</i>	No other elements than indicated in the ICH eCTD v4.0 IG will be excluded.			

1005

1006

1007

### ***Document.confidentialityCode***

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>code</i>		[0..1]		This is a container element that provides .....
	<i>root</i>	[1..1]	Valid OID or UUID	This is the code attribute that .....

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>cnfidentialityCode</i> is an optional element			
<i>Business Rules</i>	If the element is provide a code and a root is required.			
<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.displayName</i></li> <li>• <i>code.originalText</i></li> <li>• <i>code.translation</i></li> <li>• <i>code.source</i></li> <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@codingRationale</i></li> <li>• <i>code@validTimeLow</i></li> <li>• <i>code@validTimeHigh</i></li> <li>• <i>code@controlInformationRoot</i></li> <li>• <i>code@controlInformationExtension</i></li> <li>• <i>code@nullFlavor</i></li> <li>• <i>code@flavorId</i></li> <li>• <i>code@updateMode</i></li> </ul>			

1008

1009

## 1010 **XML Samples**

1011 The following are examples of the XML for *document* elements The Document is a component of  
1012 an Application.

1013 <component>  
1014 <document>  
1015 <id root="OCE22887-210F-472C-B318-9E9FB7E7BOBC"/>

```

1016    <!--Code is only used for further identifying simple documents that are part of a compound
1017    document and for which the controlled vocabulary has been defined-->
1018    <code code="b12345" codeSystem="8.13.850.1.223354.0.121.322"/>
1019    <title value="General Information"/>
1020    <text integrityCheckAlgorithm="SHA256" <text language="en" />
1021    <text reference value="../../m1/eu/16-environrisk/161-nongmo/nongmo-
1022    var.pdf"/>
1023    <integrityCheck>56df6492f724ee2e76e12cb4b001bd2fdc43603fb15
1024    d70afc89813398739fb9c</integrityCheck>
1025    </text>
1026    <statusCode code="active"/>
1027    <setIdroot="12345678-4321-4321-4321-123456789987"/>
1028    <versionNumber value="1"/>
1029    ...
1030    [Additional information may appear after the addition of the text (if one exists, otherwise this will
1031    follow the component. For example, depending on the type of document the following elements
1032    may be available to select from the Document – component, sequelTo, referencedBy)
1033    ...
1034    </document>
1035    </component>
1036
1037    <component>
1038        <document>
1039            <id root="9CF93E08-5C28-4D6D-B907-BFBE34F4119D" />
1040            <title value="Cover Letter for DE" />
1041            <text integrityCheckAlgorithm="SHA256" language="de">
1042                <reference value="../../m1/eu/10-cover/de/de-cover.pdf" />
1043                <integrityCheck>b9a6aff775736cf100505af68da859a941432a9f9e56d245ac3e
1044        daa4235df0ac</integrityCheck>
1045        </text>
1046        <!-- ===== -->
1047        <!-- Commercial Confidential Informationand Protected Personal Data-PPD in EU: -->
1048        <!-- L =Low -->
1049        <!-- M=Moderate -->
1050        <!-- N=Normal -->
1051        <!-- U=Unrestricted -->
1052        <!-- R=Restricted -->
1053        <!-- V=Very Restricted -->
1054        <!-- ===== -->
1055        <confidentialityCode code="L"/>
1056    </document>
1057    </component>
1058

```



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



*Note to Implementers: For documents (i.e., representing each a single file), the text element will be provided along with the other required elements. Documents will have a keyword code to further specify the file tags for the document, e.g., smpc, according to the respective controlled vocabulary (see Section 6.1)*

1059    **9.20.3    Terminology**

1060    The **document** element has one coded terminology for language (the ISO language codes) (see  
1061    [Section 6.3](#)) . Regarding the document type code (see [Section 6.1](#)). in Module 1.3.1 only,  
1062    **document** elements must provide this type of information by using the respective keyword  
1063    definition.

1064  
1065

1066    **9.21    Keyword Definition**

1067    The **keywordDefinition** element is used to define a keyword by the sender that is referenced by  
1068    identifier in other parts of the message. For details see ICH Implementation guide. The usage of  
1069    this element is expected to be helpful in EU Module 1 for product information text to separate  
1070    different pharmaceutical forms or strengths and the document type.

1071  
1072

1073    **9.22    Review**

1074    The **review** element is related to the regulatory activity (as defined by the submission), is  
1075    associated with the holder and an author in the meaning of the Reference Member State or  
1076    responsible authority, e.g. EMA in Centralised procedures, and refers to the product and the  
1077    product category.

1078    Optionally, additional information about the reference member state and the applicant can be  
1079    provided, but will not be required for the EU.

1080

1081    **9.22.1    Location in XML**

1082    The **application** element in the XML message is in the following location:

- **controlActProcess>>subject>>submissionUnit>>component1>>  
1083        submission>>subject4>>review**

1084    Refer to [Table 3](#): XML Structure for the XML representation.

1085

1086    **9.22.2    XML details**

1088    **XML Elements**

1089    The following tables provide a complete set of XML elements and attributes required for the  
1090    **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.

1091

#### 1092 **Review.id**

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<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
<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>			

1093

#### 1094 **Review.statusCode**

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<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>			

1095

1096 **XML Sample: Review**

1097 The following is an example of the XML for the *review* element.



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

1098



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

### 1099 **9.22.3 Terminology**

1100 The *review* element requires codes for the *statusCode* element.

1101 The desired status codes will be used in line with ICH eCTD IG definitions.

1102

### 1103 **9.22.4 Related Elements**

1104 The *following* elements are related to *review* and require additional information:

1105     ○ *subject2.productCategory* (see [Section 9.23](#))

1106     ○ *subject3.RegulatoryStatus* (see [Section 9.24](#))

1107     ○ *subject1.manufacturedProduct* (see [Section 9.25](#))

1108     ○ *holder.applicant* (see [Section 9.26](#))

1109     ○ *author.territorialAuthority* (see [Section 9.27](#))

1110

1111

## 1112 **9.23 Product Category**

1113 The *productCategory* is used to indicate the overall category of human medicinal product based  
1114 on the active ingredients, e.g. chemical, herbal or biotech product.

1115

### 1116 **9.23.1 Location in XML**

1117 The *productCategory* element in the XML message is in the following location:

- 1118     • *controlActProcess>>subject>>submissionUnit>>component1>>*
- 1119         *submission>>subject4>>review>>subject2>>productCategory*

1120 Refer to [Table 3](#): XML Structure for the XML representation.

1121

### 1122 **9.23.2 XML details**

#### 1123 **XML Elements**

1124 The following tables provide a complete set of XML elements and attributes required for the  
1125 *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.

1126

1127 **ProductCategory.code**

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

1128

1129

1130 The following is an example of the XML for **ProductCategory**.

1131 <subject2>

1132    <**productCategory**>  
1133      <!-- Product Category: Medicinal product containing chemical substance -->  
1134      <**code code**=**"chemical"** **codeSystem**=**"ProductCategory Code system OID"**/>  
1135     </**productCategory**>  
1136 </**subject2**>

1137



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

### 1138    **9.23.3 Terminology**

1139    The **productCategory** element requires codes for the **code** element (see [Section 6.1](#)).

1140

1141

## 1142    **9.24 Regulatory Status**

1143    The **regulatoryStatus** element defines the outcome of regulatory action on a submission.

1144    The **RegulatoryStatus** element is to assign the status of a regulatory activity applied for once the  
1145    authority has decided to respond to the applicant. This element will be used by Competent  
1146    Authorities only and supports therefore two-way communication.

### 1147    **9.24.1 Location in XML**

1148    The **regulatoryStatus** element in the XML message is in the following location:

- **controlActProcess>> subject>> submissionUnit>>component1>>**  
**submission>>subject4>>review>>subject3>> regulatoryStatus**

1149    Refer to [Table 3](#): XML Structure for the XML representation.

1150

### 1151    **9.24.2 XML details**

1152    The following is an example of the XML for the **regulatoryStatus** element.

#### 1153    **XML Elements**

1154    The following tables provide a complete set of XML elements and attributes required for the  
1155    **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.*

1156

1159 **RegulatoryStatus.code**

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<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
	<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>	This element should be used by the responsible competent authority only, e.g. EMA in case of Centralised procedures or the RMS in case of DCP or MRP.			

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</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.displayName</i></li> <li>• <i>code.originalText</i></li> <li>• <i>code.translation</i></li> <li>• <i>code.source</i></li> <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@codingRationale</i></li> <li>• <i>code@validTimeLow</i></li> <li>• <i>code@validTimeHigh</i></li> <li>• <i>code@controlInformationRoot</i></li> <li>• <i>code@controlInformationExtension</i></li> <li>• <i>code@nullFlavor</i></li> <li>• <i>code@flavorId</i></li> <li>• <i>code@updateMode</i></li> </ul>	

1160

1161

### ***RegulatoryStatus.effectiveTime***

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

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

1162

1163 **XML Sample: regulatoryStatus**

```
1164 <subject3>
1165   <regulatoryStatus>
1166     <code code="100000072097">
1167       <displayName value="Application for Marketing Authorisation received."/>
1168     </code>
1169   </regulatoryStatus>
1170 </subject3>
1171
```



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

1172

1173 **9.24.3 Terminology**

1174 The *regulatoryStatus* element requires codes for the *code* element (see [Section 6.1](#)).

1175

1176

1177 **9.25 Manufactured Product**

1178 This element must be selected in case of an eCTD v4.0 message concerning the initial application  
 1179 for a human medicinal product. This determines the role of a product in the national context  
 1180 within a DCP or MRP. Subsequent submission units related to authorised products do not need to  
 1181 provide this type of information repeatedly.

1182 The *manufacturedProduct* element collects the name of the product by country and the active  
 1183 ingredients. This element may support internal workflow mechanisms but will not replace the  
 1184 annex 5.15 to the application form of the current Module 1.2 in the EU.

1185 **9.25.1 Location in XML**

1186 The *manufacturedProduct* element in the XML message is in the following location:

- *controlActProcess>>subject>>submissionUnit>>component1>>*
- submission>>subject4>>review>>subject1>>manufacturedProduct*

1189 Refer to [Table 3](#): XML Structure for the XML representation.

1190

1191 **9.25.2 XML details**1192 **XML Elements**

1193 The following tables provide a complete set of XML elements and attributes required for the  
 1194 *manufacturedProduct* element in case it is provided, and any special instructions.



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

1195

1196 **ManufacturedProduct.id**

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>id</i>		[1..1]		This is a container element for a reference to the manufactured product
	<i>root</i>	[1..1]	Valid OID or UUID	This attribute is for a global unique identifier of the <i>manufactured product</i> being referenced
	<i>extension</i>	[0..1]	Alpha Numeric <i>e.g., Wonderpil 200 mg coded tablets</i>	The <i>extension</i> attribute of the <i>id</i> element provides a location to specify a region-specific name of the manufactured product.
<b>Conformance</b>	The <i>id</i> element and <i>root</i> 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. In case of <u>initial</u> MAA, these elements may provide the respective name of the manufactured product as proposed for the country the authorisation is applied for.			
<b>Excluded Elements and Attributes</b>	The following attributes are not required by eCTD 4.0: <ul style="list-style-type: none"> <li>• <i>id@exrenson</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>			

1197  
1198  
1199 **XML Sample: manufacturedProduct**  
1200 The following is an example of the XML for the *ManufacturedProduct* element.

1201 <subject1>  
1202 <manufacturedProduct>  
1203 <id/>  
1204 <manufacturedProduct>  
1205 <asNamedEntity>  
1206 <assigningTerritory>  
1207 <code code="NL" />  
1208 <name>  
1209 <!-- Product name type and value -->  
1210 <part value="Wonder Drug" language="nl" />  
1211 </name>  
1212 </assigningTerritory>  
1213 </asNamedEntity>  
1214 <ingredient>  
1215 <activeIngredientSubstance>  
1216 <name>  
1217 <!-- Substance name type and value -->  
1218 <part code="IND01" codeSystem="Active ingredient code system OID"  
1219 value="Pioglitazone hydrochloride" />  
1220 <part code="IND02" codeSystem="Active ingredient code system OID"  
1221 value="Metformin hydrochloride" />  
1222 </name>  
1223 </activeIngredientSubstance>  
1224 </ingredient>  
1225 </manufacturedProduct>  
1226 </manufacturedProduct>  
1227 </subject1>  
1228  
1229

### 1230 **9.25.3 Related Elements**

1231 The following element is related to *manufacturedProduct* and requires additional information:

1232  
1233 **Product with attributes on ingredients and territory the product name is valid for**  
1234 The *product* element provides the information about the name of the product as used per territory  
1235 and its ingredient(s) depending on how many pharmaceutical active ingredients contained. The  
1236 following is an example for one relevant product name (case 1) and two different product names  
1237 per each country in use for the same manufactured product (case 2):

1238 **Case 1**

```
1239 <subject1>
1240   <manufacturedProduct>
1241     <manufacturedProduct>
1242       <name>
1243         <item>
1244           <part code="Product Name Type code" codeSystem="Product Name Type code system OID"
1245 value="Product Name" language="en"/>
1246         </item>
1247       </name>
1248     <asNamedEntity>
1249       <name>
1250         <item>
1251           <part value="authority name"/>
1252         </item>
1253       </name>
1254     <assigningTerritory>
1255       <code code="country code"/>
1256     </assigningTerritory>
1257   </asNamedEntity>
1258   <ingredient>
1259     <activeIngredientSubstance>
1260       <name>
1261         <part code="Substance Name Type(INN, USAN, etc)" codeSystem="Substance Name Type
1262 code system OID" value="Substance Name"/>
1263       </name>
1264     </activeIngredientSubstance>
1265   </ingredient>
1266   </manufacturedProduct>
1267 </manufacturedProduct>
1268 </subject1>
```

1269  
1270 **Case 2**

1271 To have multiple product names (e.g., Refludan and Refludin), the product.name.item.part can be  
1272 repeated, and alternatively, <subject1> can be repeated as well.

1273  
1274 (1) if you repeat the product.name.item.part;

```
1275 <subject1>
1276   <manufacturedProduct>
1277     <manufacturedProduct>
1278       <name>
1279         <item>
1280           <part code="Product Name Type code" codeSystem="Product Name Type code system OID"
1281 value="Refludan" language="en"/>
1282           <part code="Product Name Type code" codeSystem="Product Name Type code system OID"
1283 value="Refludin" language="es"/>
1284         </item>
1285       </name>.....
1286
```

1287 (2) if you repeat the <subject1>;

```
1288 <subject1>
1289   <manufacturedProduct>
1290     <manufacturedProduct>
```

```
1291      <name>
1292        <item>
1293          <part code="Product Name Type code" codeSystem="Product Name Type code system OID"
1294 value="Refludan" language="en"/>
1295        </item>
1296      </name>
1297      <asNamedEntity>
1298        <name>
1299          <item>
1300            <part value="authority name1"/>
1301          </item>
1302        </name>
1303        <assigningTerritory>
1304          <code code="country code"/>
1305        </assigningTerritory>
1306      </asNamedEntity>
1307      <ingredient>
1308        <activeIngredientSubstance>
1309          <name>
1310            <part code="Substance Name Type(INN, USAN, etc)" codeSystem="Substance Name Type
1311 code system OID" value="Substance Name1"/>
1312          </name>
1313        </activeIngredientSubstance>
1314      </ingredient>
1315    </manufacturedProduct>
1316  </manufacturedProduct>
1317 </subject1>
1318 <subject1>
1319   <manufacturedProduct>
1320   <manufacturedProduct>
1321     <name>
1322       <item>
1323         <part code="Product Name Type code" codeSystem="Product Name Type code system OID"
1324 value="Refludin" language="es"/>
1325       </item>
1326     </name>
1327     <asNamedEntity>
1328       <name>
1329         <item>
1330           <part value="authority name2"/>
1331         </item>
1332       </name>
1333       <assigningTerritory>
1334         <code code="country code"/>
1335       </assigningTerritory>
1336     </asNamedEntity>
1337     <ingredient>
1338       <activeIngredientSubstance>
1339         <name>
1340           <part code="Substance Name Type(INN, USAN, etc)" codeSystem="Substance Name Type
1341 code system OID" value="Substance Name1"/>
1342         </name>
1343       </activeIngredientSubstance>
1344     </ingredient>
1345   </manufacturedProduct>
1346 </manufacturedProduct>
```

1347 </subject1>

1348

1349

1350 **9.26 Holder**

1351 This element is referencing the details of the *applicant* element (see [Section 9.16](#)).

1352

1353

1354 **9.27 Territorial Authority (as author of review)**

1355 This element refers to the author of the review in the meaning of the Reference Member State or  
1356 responsible authority, e.g. EMA in Centralised procedures, and refers to the product and the  
1357 product category and states the respective authority and the territory of responsibility. This  
1358 element will be used if the message is created by Regulatory Authority sending back e.g. the  
1359 Assessment Report or List of Questions.

1360

1361 **9.27.1 Location in XML**

1362 The *author.territorialAuthority* element in the XML message is in the following location:

- *controlActProcess>>subject>>submissionUnit>>component1>>  
submission>>subject4>>review>>subject1>>author>>territorialAuthority*

1363 Refer to [Table 3](#): XML Structure for the XML representation.

1364

1365 **9.27.2 XML details**

1366 **XML Elements**

1367 For the complete set of XML elements and attributes required for the *territorialAuthority* element  
1368 see [Section 9.4](#).



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

1371 **XML Sample: *author.territorialAuthority***

```
1372 <subject2>
1373   <review>
1374     <id></id>
1375     <statusCode><statusCode />
1376     <author>
1377       <territorialAuthority>
1378         <name>
1379           <!--Assessment authoring authority -->
1380           <part code="ansm" value=" L'Agence nationale de sécurité du médica
1381               ment et des produits de santé " codeSystem="Authority Code syst OID" />
1382         </name>
1383       </territorialAuthority>
```

1384           </author>  
1385        </review>  
1386   </subject2>  
1387  
1388

1389 **9.28 Category Event**

1390 The *categoryEvent* element will not be used in the EU.



*This class will currently not be used in EU Module 1 part of an eCTD v4.0 message, because documentation submitted in eCTD format will not be required for event types such as scientific advice or regulatory advice.*

1391

1392

1393

1394 **10. CREATING THE MESSAGE**

1395 With the individual components of the XML message described above, each of those components  
1396 will now be used to demonstrate how to compose multiple components to address a specific  
1397 scenario and to explain how to address the creation and modifications to the content transmitted  
1398 during the lifecycle of a submission focusing on EU Module 1 as recommendations need to differ  
1399 from ICH recommendations to cover EU specific scenarios. Therefore, this section will provide  
1400 samples dealing with elements not used commonly in ICH, e.g. manufacturedProduct,  
1401 submissionMode, territorialAuthority, as well as regulatory activities used specifically in the EU,  
1402 e.g. grouped variation, workshare procedures and submissions in Decentralised and Mutual  
1403 Recognition Procedures.

1404  
1405

1406 **10.1 Individual Components**

1407 **10.1.1 Managing Country Specific Product Names in MRP and DCP**

1408 Different from the centralised and purely national procedures, in MRP and DCP different product  
1409 names per Member State may occur. Not copying content from the annexes of the application  
1410 form, but supporting agency specific processing the product names related to the territory of the  
1411 assigning authority can be stated in ***ManufacturedProduct*** and related elements.

1412

1413 ***XML example for different product names in MRP/DCP:***

```
1414 <subject1>
1415   <!-- to have multiple product name (e.g. WonderMat in Germany, Wonder Drug in NL,
1416   WonderPil in UK and PileWonder in France -->
1417   <manufacturedProduct>
1418     <id />
1419     <manufacturedProduct>
1420       <name>
1421         <item>
1422           <part value="WonderMat" language="de"/>
1423         </item>
1424       </name>
1425       <asNamedEntity>
1426         <name>
1427           <item>
1428             <part value="BfArM" language="de"/>
1429           </item>
1430         </name>
1431         <assigningTerritory>
1432           <code code="DE"/>
1433         </assigningTerritory>
1434       </asNamedEntity>
1435       <ingredient>
1436         <activeIngredientSubstance>
1437           <name>
```

```
1438      <part code="IND01" codeSystem="Substance Name Type code system OID"
1439 value="Pioglitazone hydrochloride"/>
1440      <part code="IND02" codeSystem="Substance Name Type code system OID"
1441 value="Metformin hydrochloride"/>
1442      </name>
1443      </activeIngredientSubstance>
1444      </ingredient>
1445      </manufacturedProduct>
1446      </manufacturedProduct>
1447  </subject1>
1448  <subject1>
1449      <manufacturedProduct>
1450      <id />
1451      <manufacturedProduct>
1452          <name>
1453              <item>
1454                  <part code="Wonder drug" language="NL"/>
1455              </item>
1456          </name>
1457          <asNamedEntity>
1458              <name>
1459                  <item>
1460                      <part value="MEB"/>
1461                  </item>
1462              </name>
1463              <assigningTerritory>
1464                  <code code="NL"/>
1465              </assigningTerritory>
1466          </asNamedEntity>
1467          <ingredient>
1468              <activeIngredientSubstance>
1469                  <name>
1470                      <part code="IND01" codeSystem="Substance Name Type code system OID"
1471 value="Pioglitazone hydrochloride"/>
1472                      <part code="IND02" codeSystem="Substance Name Type code system OID"
1473 value="Metformin hydrochloride"/>
1474                  </name>
1475                  </activeIngredientSubstance>
1476                  </ingredient>
1477                  </manufacturedProduct>
1478                  </manufacturedProduct>
1479  </subject1>
1480  <subject1>
1481      <manufacturedProduct>
1482      <id />
1483      <manufacturedProduct>
1484          <name>
1485              <item>
1486                  <part code="Wonder Pil" language="EN"/>
1487              </item>
1488          </name>
1489          <asNamedEntity>
1490              <name>
1491                  <item>
1492                      <part value="MHRA"/>
```

```
1493      </item>
1494    </name>
1495    <assigningTerritory>
1496      <code code="UK"/>
1497    </assigningTerritory>
1498  </asNamedEntity>
1499  <ingredient>
1500    <activeIngredientSubstance>
1501      <name>
1502        <part code="IND01" codeSystem="Substance" Name Type code system OID"
1503 value="Pioglitazone hydrochloride"/>
1504        <part code="IND02" codeSystem="Substance" Name Type code system OID"
1505 value="Metformin hydrochloride"/>
1506      </name>
1507    </activeIngredientSubstance>
1508  </ingredient>
1509  </manufacturedProduct>
1510  </manufacturedProduct>
1511 </subject1>
1512 <subject1>
1513   <manufacturedProduct>
1514     <id />
1515   <manufacturedProduct>
1516     <name>
1517       <item>
1518         <part code="Pile Wonder" language="EN"/>
1519       </item>
1520     </name>
1521     <asNamedEntity>
1522       <name>
1523         <item>
1524           <part value="ANSM"/>
1525         </item>
1526       </name>
1527       <assigningTerritory>
1528         <code code="FR"/>
1529       </assigningTerritory>
1530     </asNamedEntity>
1531     <ingredient>
1532       <activeIngredientSubstance>
1533         <name>
1534           <part code="IND01" codeSystem="Substance" Name Type code system OID"
1535 value="Pioglitazone hydrochloride"/>
1536           <part code="IND02" codeSystem="Substance" Name Type code system OID"
1537 value="Metformin hydrochloride"/>
1538         </name>
1539       </activeIngredientSubstance>
1540     </ingredient>
1541   </manufacturedProduct>
1542   </manufacturedProduct>
1543 </subject1>
1544
1545
1546
```

1547

1548 **10.1.2 Managing Country Specific Processing Numbers**

1549 Only in case of MRP and DCP multiple national procedure numbers need to be stated in addition  
1550 to the procedure number. The latter is inserted as UUID of the application. The application.id.item  
1551 element will be repeated as many times as needed. The extension provides the container for a  
1552 national procedure number.

1553 **XML example:**

```
1554 <componentOf>
1555   <application>
1556     <id>
1557       <item root="fr-2083-001-dc" extension="de-2189072"/>
1558       <item root="fr-2083-001-dc" extension="nl-456789"/>
1559       <item root="fr-2083-001-dc" extension="uk-341974"/>
1560       <item root="fr-2083-001-dc" extension="fr-234-345"/>
1561     </id>
1562     ...
1563     [Additional information may appear after the addition of the Application.code, for
1564     example any of the following elements related to Application – component, referencedBy,
1565     informationRecipient, reference, subject, or holder]
1566     ...
1567   </application>
1568 </componentOf>
1569
```

1570 **10.1.3 Product Information Texts in EU Module 1.3.1**

1571 Product information texts need to have a set of metadata to specify the country of applicability,  
1572 the language, the type of text and – depending from the product structure – information regarding  
1573 pharmaceutical form or strength this text is dedicated to be used. These metadata will be assigned  
1574 using different elements of the eCTD XML message:

1575 The **document.text** element holds a *language* element

1576 The **document** element holds a **code** element specifying document types like “smpc” or “pl”.

1577 A keyword from the controlled vocabulary of ISO country codes specifies the country of  
1578 applicability.

1579 A keyword value from the sponsor defined **keywordDefinition** of pharmaceutical form or strength  
1580 will allow a presentation of the set of product information texts provided in the QRD template per  
1581 pharmaceutical form or strength.

1582 Note: The keyword value for pharmaceutical form must not use a standard term according  
1583 EDQM. The purpose of this value is just to differentiate the product presentations and could be  
1584 simple as possible.

1585 **XML example:**

```
1586 <component>
1587   <priorityNumber value="1"/>
1588   <contextOfUse> <id root="12345678-1234-5678-3456-127536489712"/>
```

```

1589      <!-- CTD Heading -->
1590      -<code codeSystem="Code system OID " code="m131-smpclabelpl">
1591          <displayName value="1.3.1 SmPC, Label ,PL"
1592      </code>
1593          <statusCode code="active"/>
1594          <setId root="set ID"/>
1595          <versionNumber value="1.0"/>
1596      -<primaryInformationRecipient>
1597          <!-- Specific Health Authority and/or country to which this CoU is for (if needed to be specified) -->
1598          -<territorialAuthority>
1599              <territory>
1600                  <code codeSystem="FR" codeSystemName="country code system name"/>
1601                  </territory>
1602              </territorialAuthority>
1603          </primaryInformationRecipient>
1604      -<derivedFrom>
1605          <documentReference>
1606              <id root="12345678-1234-1234-1234-198765432198" extension="12345"/>
1607          </documentReference>
1608      </derivedFrom>
1609      -<subjectOf negationInd="1">
1610          <!-- The SubmissionReference element is used to indicate when a ContextOfUse is not
1611              relevant to a specific Submission within a submissionUnit.-->
1612          -<submissionReference>
1613              <id>
1614                  <item root="12345678-1234-5678-3456-127536489712"/>
1615              </id>
1616          </submissionReference>
1617          <referencedBy typeCode="REFR">
1618              <keyword>
1619                  <code codeSystem="SmPC Label PL" codeSystemName="cdocument type code
1620 system name"/>
1621                  </keyword>
1622          </referencedBy>
1623      </subjectOf>
1624      </contextOfUse>
1625  </component>
1626
1627
1628

```

## 1629       **10.2       Content Management (contextOfUse and Documents)**

1630 There are no deviating principles to apply in case of an eCTD v4.0 XML message is sent to a  
1631 European Competent Authority in comparison to the general rules set out by ICH. The example  
1632 below shows a short sample of *contextOfUse* and *Document* elements referencing a few EU  
1633 Module 1 files.

### 1634       ***XML example:***

```

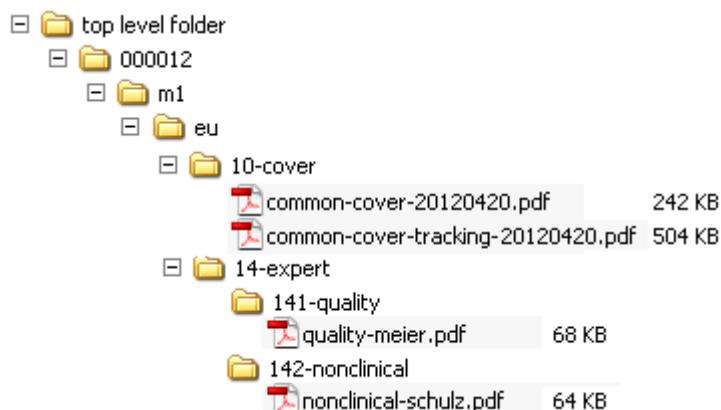
1635      <componentOf>
1636          <application>
1637

```

1638 [Additional information may appear after the addition of the *Application.code*, for  
1639 example any of the following elements related to *holder*, *informationRecipient*,  
1640 *ReviewProcedure*, *Application.Reference*]  
1641  
1642 <component>  
1643 <document>  
1644 <id root="12345678-5555-5555-5555-555555550001"/>  
1645 <title value="Cover Letter"/>  
1646 <text integrityCheckAlgorithm="SHA256">  
1647 <reference value="..../m1/eu/10-cover/common-cover-20120420.pdf"/>  
1648 <integrityCheck>3285a776897425b9a3b87abbaaf163fb261242397997b003efe3201e</integrityCheck>  
1649 </text>  
1650 <statusCode code="active"/>  
1651 <setId root="57694301"/>  
1652 <versionNumber value="1"/>  
1653 </document>  
1654 </component>  
1655 <component>  
1656 <document>  
1657 <id root="12345678-5555-5555-5555-555555550001"/>  
1658 <title value="Tracking Table"/>  
1659 <text integrityCheckAlgorithm="SHA256">  
1660 <reference value="..../m1/eu/10-cover/common-cover-tracking-20120420.pdf"/>  
1661 <integrityCheck>3285a776xv745a25b9a3b87abbaaf163f726ec91242397997b003efe3201e</integrityCheck>  
1662 </text>  
1663 <statusCode code="active"/>  
1664 <setId root="573421301"/>  
1665 <versionNumber value="1"/>  
1666 </document>  
1667 </component>  
1668 <component>  
1669 <document>  
1670 <id root="12345678-5555-5555-5555-555555550002"/>  
1671 <title value="Expert Quality"/>  
1672 <text integrityCheckAlgorithm="SHA256">  
1673 <reference value="..../m1/eu/14-expert/141-quality/quality-meier.pdf"/>  
1674 <integrityCheck>3285a776897425b9a3b877z45abbaaf1726ec91242397997b003efe3202e</integrityCheck>  
1675 </text>  
1676 <statusCode code="active"/>  
1677 <setId root="29872638"/>  
1678 <versionNumber value="1"/>  
1679 </document>  
1680 </component>  
1681 <component>  
1682 <document>  
1683 <id root="12345678-5555-5555-5555-555555550003"/>  
1684 <title value="Expert Non-Clinical"/>  
1685 <text integrityCheckAlgorithm="SHA256">  
1686 <reference value="..../m1/eu/14-expert/142-nonclinical/nonclinical-schulz.pdf"/>  
1687 <integrityCheck>3285a776897425b9a3b87abbaaf16  
1688 3fb2646726ec91242397997b003efe3203e</integrityCheck>  
1689 </text>  
1690 <statusCode code="active"/>  
1691 <setId root="6910897729"/>  
1692 <versionNumber value="1"/>

1693                   </document>  
1694                    </component>  
1695                    </application>  
1696                    </componentOf>  
1697

1698 The respective folder structure is provided below:



1699

**Figure 2: Folder structure related to submission unit message**

1700

1702

### 1703 **10.3 Complex Scenarios**

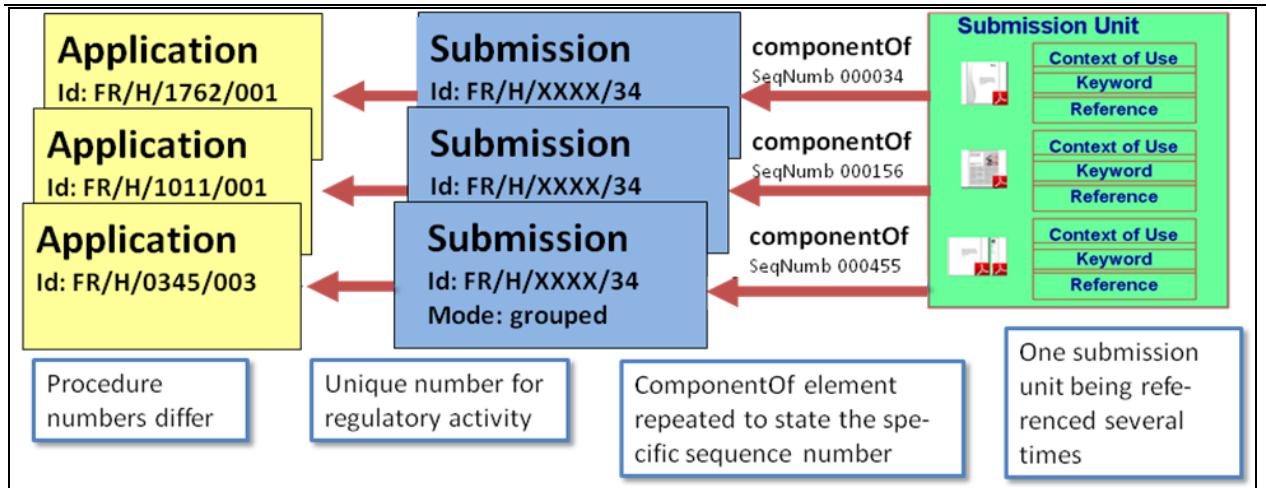
#### 1704 **10.3.1 Referencing Multiple Applications in Case of Grouping or Worksharing 1705 Regulatory Activities (Submissions)**

1706 Grouped and workshared variations are the only business cases for sending a Submission Unit  
1707 with more than one *componentOfSubmission* element (e.g., manufacturing changes that affect  
1708 more than one application) to associate this *submissionUnit* via multiple *submission* elements to  
1709 all *applications* concerned by the grouped variation or workshared procedure.

1710

1711  
1712

**Figure 3: Referencing multiple applications**



1713

1714 Top level folder will be fr034g.

1715 The second level folder 999900 contains sequence number 34 of application FR/H/1762/001 and  
1716 below that all relevant documents according to structure outline in [Annex 1](#) and ICH eCTD IG.

1717 For sequence number 156 of application FR/H/1011/001 and sequence number 455 of application  
1718 number FR/0345/001 it is not needed to submit files physically. They will be referenced by the  
1719 submission unit xml file and can be displayed as being submitted physically.

1720

1721 In case of a different grouping the top level folder may be named 'fr072g' or in case of a  
1722 worksharing 'de045ws'.

1723 The second level folder 999900 concerning sequence number 000172 of application 1762.

1724

1725 **XML example:**

```
<subject typeCode="SUBJ">
  <submissionUnit>
    <id></id>
    <code></code>
    <title></title>
    <statusCode></statusCode>
    <callBackContact>
      <contactParty>
        ...
        </contactParty>
    </callBackContact>
    <component>
      <priorityNumber value="1"/>
      <contextOfUse>
        ...
        </contextOfUse>
    </component>
    <componentOf>
      <sequenceNumber>
        <sequenceNumber value="34"/>
```

```

1746      </sequenceNumber>
1747      <submission>
1748          <id/>
1749          <item root="Globally unique submission ID" extension="FR/H/XXXX/34" />
1750          <code code="var-type2" codeSystem="Submission Type Code system OID" codeSystemName="Submission
1751      Type Codes " />
1752          <subject1>
1753              <mode>
1754                  <id/>
1755                  < code="grouped" />
1756              </mode>
1757          </subject1>
1758          <subject2>
1759              <review>
1760                  <author>
1761                      ...
1762                  </author>
1763              </review>
1764          </subject2>
1765          ° </submission>
1766      </component>
1767      <componentOf>
1768          <application>
1769              <id xsi:type="DSET_II">
1770                  <item root="fr-1762-001-dc"
1771              </id>
1772          ...
1773      [Additional information may appear after the addition of the Application.code, for example any of the following
1774      elements related to Application – component, referencedBy, informationRecipient, reference, subject, or
1775      holder]
1776      ...
1777          </application>
1778      ° </component>
1779      <component>
1780          <sequenceNumber>
1781              <sequenceNumber value="156"/>
1782          </sequenceNumber>
1783          <submission>
1784              <id/>
1785              <item root="Globally unique submission ID" extension="FR/H/XXXX/34" />
1786              <code code="var-type2" codeSystem="Submission Type Code system OID" codeSystemName="Submission
1787      Type Codes " />
1788          <subject1>
1789              <mode>
1790                  <id/>
1791                  < code="grouped" />
1792              </mode>
1793          </subject1>
1794          <subject2>
1795              <review>
1796                  <author>
1797                      ...
1798                  </author>
1799              </review>
1800          </subject2>
1801          ° </submission>
1802      </component>
1803      <componentOf>
1804          <application>
1805              <id xsi:type="DSET_II">
1806                  <item root="fr-1011-001-dc"
1807              </id>
1808          ...
1809      [Additional information may appear after the addition of the Application.code, for example any of the following
1810      elements related to Application – component, referencedBy, informationRecipient, reference, subject, or
1811      holder]
1812      ...
1813          </application>
1814      </component>
1815      <component>

```

```

1816      <sequenceNumber>
1817      <sequenceNumber value="455"/>
1818      </sequenceNumber>
1819      <submission>
1820      ....
1821      ° </submission>
1822      </component>
1823      <componentOf>
1824      -<application>
1825      ....
1826      </application>
1827      </componentOf>
1828      </submission>
1829      </componentOf>
1830      </submissionUnit>
1831      </subject>
1832

```

1833

### 1834 10.3.2 Update of Product Information Texts (SmPC, PL) in Response to 1835 Regulators Assessment of a Grouped Variation

1836 Due to a PRAC recommendation a Type II variation to update the wording of the SmPC and PL  
1837 for a number of products across a range of MAs is submitted as a Grouped Variation. France is  
1838 the RMS with the UK, Ireland and Netherlands as CMS. The previously submitted documents  
1839 need to be updated.

1840 Set of documents provided:

Grouped ID Mode: Grouped	Virtual variation number (not included in the XML but would be included in the cover letter)	Sequence number per application	Documents separated by product name and member state
id: FR/H/xxxx/II/003G	FR/H/1762/001/II/002/G	0019	Pile Wonder 10mg tablets - FR Wonder Pills 10mg tablets - UK & IR Wonder Drug 10mg tablets - NL
id: FR/H/xxxx/II/003G	FR/H/1762/002/II/002/G	0019	Pile Wonder 20mg tablets - FR Wonder Pills 20mg tablets - UK & IR Wonder Drug 20mg tablets - NL
id: FR/H/xxxx/II/003G	FR/H/1011/001/II/003/G	0054	Pile Wonder 10mg capsules - FR Wonder Pill 10mg capsules - UK & IR Wonder Drug 10mg capsules - NL
id: FR/H/xxxx/II/003G	FR/H/0345/001/II/003/G	0024	Pile Wonder 10mg/ml Solution for Infusion - FR Wonder Pill 10mg/ml Solution for Infusion - UK & IR Wonder Drug 10mg/ml Solution for Infusion - NL

1841

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

1842 **XML sample:**

```
<?xml version="1.0" encoding="UTF=8"?>
<!= ===== Reference Instance for EU =====>
<!= =====>
<PORP_IN00001UV ITSType="XML_1.0" xsi:schemaLocation="urn:hl7-org:v3
RPS_FlatSchema_Jan2012Ballot.xsd" xmlns="urn:hl7-org:v3" xmlns:xsi="http://www.w3.org/2001/XMLSchema-
instance">
<subject typeCode="SUBJ">
  <submissionUnit>
    <id>=78965412-3214-5698-7856-985412563254"/</id>
    <code code="response to questions" codeSystem="Submission Unit code system OID"/>
    <title>Response to Questions</title>
    <statusCode code="active"/>
    <component>
      <priorityNumber value="1" />
      <contextOfUse>
        <id root="12345678-1234-5678-3456-127536489712" />
        <code code=" m1-3-1-spc-label-pl " codeSystem="EU M1 CoU Code system OID for SmPC">
          <displayName value="1.3.1 SmPC" />
        </code>
        <statusCode code="active" />
        <primaryInformationRecipient>
          <territorialAuthority>
            <territory>
              <code code="FR" codeSystem="country code system OID"
codeSystemName="country code system name" />
            </territory>
            <governingAuthority>
              <id root="52345678-1234-1234-1234-12345678901" />
              <name>
                <part value="ANSM" code="FR-ANSM" />
              </name>
            </governingAuthority>
          </territorialAuthority>
        </primaryInformationRecipient>
        <replacementOf="RPLC">
          <relatedContextOfUse>
            <id root="87454521-9874-6541-1236-159842345687" />
            <versionNumber value="1" />
          </relatedContextOfUse>
        </replacementOf>
        <derivedFrom>
          <documentReference>
            <id root="12345678-1234-1234-1234-198765432198" extension="12345" />
          </documentReference>
        </derivedFrom>
        <subject7 />
        <submissionReference>
          <id xsi:type="DSET_II">
            <item root="12345678-1234-5678-3456-127536489712" />
          </id>
        </submissionReference>
      </component>
    </submissionUnit>
  </subject>
</PORP_IN00001UV>
```

This section need to be repeated as often as CoU need to be included, e. g. for cover letter, tracking table, variation form

This section will point to the previous version of the SmPC and will be repeated as many as documents will be replaced.

```

1894     </subject7>
1895     <referencedBy typeCode="REFR">
1896         <keyword>
1897             <code code="" m1-3-1-spc-label-pl " codeSystem="EU M1 CoU system OID"
1898                 codeSystemName="EU M1 CoU Codes " />
1899             </keyword>
1900         </referencedBy>
1901     </contextOfUse>
1902 </component>
1903 <componentOf1 >
1904     <sequenceNumber>
1905         <sequenceNumber value="000019"/>
1906     <submission>
1907         <id></id>
1908             <item root="Globally unique submission ID" extension="FR/H/XXXX/34" />
1909             <code code="var-type2" codeSystem="Submission Type Code system OID"
1910                 codeSystemName="Submission Type Codes " />
1911     </submission>
1912     <callBackContact>
1913         <contactParty>
1914             ...
1915         </contactParty>
1916     </callBackContact>
1917     <subject2>
1918         <review>
1919             <subject1>
1920                 <regulatoryStatus>
1921                     <code></code>
1922                 </regulatoryStatus>
1923             </subject1>
1924         </review>
1925     </subject2>
1926     <subject5>
1927         <mode>
1928             <code="grouped" />
1929         </mode>
1930     </subject5>
1931     <componentOf>
1932         <application>
1933             <id xsi:type="DSET_II">
1934                 <item root="fr-1762-001-dc" extension="fr-2189072"/>
1935                 <item root="fr-1762-001-dc" extension="uk-pl/2012/13"/>
1936                 <item root="fr-1762-001-dc" extension="ie-4523.23.1978"/>
1937                 <item root="fr-1762-001-dc" extension="nl-mb-23419"/>
1938             </id>
1939             ...
1940             [Additional information may appear after the addition of the Application.code, for example any of
1941             the following elements related to Application – component, referencedBy, informationRecipient,
1942             reference, subject, or holder]
1943             ...
1944             <informationRecipient>
1945                 <territorialAuthority>
1946                     <governingAuthority>

```

The sequence number and following attributes including information recipient and application attribute need to be repeated as many as different sequences will be provided. In this example the grouping is related to three applications requiring three different sequence numbers..

This section need to be repeated as often as member states are involved in the procedure

```

1947 <id root="52345678-7890-1234-1234-12345678902" />
1948 <name>
1949   <part value="MHRA" code="UK-MHRA" />
1950 </name>
1951 </governingAuthority>
1952 </territorialAuthority>
1953 </informationRecipient>
1954 <subject8>
1955   <reviewProcedure>
1956     <code>mutual recognition</code>
1957   </reviewProcedure>
1958 </subject8t>
1959 </application>
1960 </componentOf>
1961 <component>
1962   <document>
1963     <id>
1964       <id root="12345678-1234-1234-1234-198765432198" extension="12345" />
1965     </id>
1966     <title>Pile Wonder 10mg tablets </title>
1967     <text integrityCheckAlgorithm="SHA256"
1968       language="en">
1969       <reference value="..../m1/eu/131=SmPC/common=SmPC.pdf" xsi:type="TEL"/>">
1970     <integrityCheck>3285a776897425b9a3b87abbaaf163fb261242397997b003efe3201e</integrityCheck>
1971   </text>
1972   <referencedBy>
1973     <keywordDefinition>
1974       <code>100000155532</code>
1975       <statusCode>active</statusCode>
1976       <value>
1977         <item>
1978           <displayName>SmPC</displayName>
1979         </item>
1980       </value>
1981     </keywordDefinition>
1982   </referencedBy>
1983   </document>
1984 </component>
1985 <referencedBy>
1986   <keywordDefinition>
1987     <code></code>
1988     <statusCode></statusCode>
1989     <value >
1990       <item>
1991         <displayName></displayName>
1992       </item>
1993     </value>
1994   </keywordDefinition>

```

This section need to be  
repeated as often as  
documents need to be  
included, e. g. for cover  
letter, tracking table,  
variation form and PL

In case of  
additional  
keywords this  
section can be  
repeated.

1995           </referencedBy> ...  
1996           </component>  
1997           [A similar entry would be made for the application form]  
1998           ...  
1999

2000   **10.3.3 Managing Duplicates**

2001 In case of submitting duplicates of a new marketing authorisation application (different product  
2002 names but one sponsor using the identical dossier) the assessment and processing of these  
2003 duplicates can be simplified by building a group. This will be managed by the **submissionGroup**  
2004 element. This serves as an indicator in the review system to manage all related MAA as a group  
2005 (see [Section 9.13](#))

2006

2007   **10.3.4 Referencing across submissions and applications of the same  
2008 pharmaceutical company**

2009 The principles of referencing is entirely the same regardless whether a reference should be  
2010 presented within a submission unit, where a document is to be displayed with two different  
2011 context of use, or across submissions, or across applications. Always a **document** element will be  
2012 referenced by the new **contextOfUse** element by its ID. The **document** element provides the link  
2013 to the PDF-file. The **document** element ID needs to be known which might not work, if the  
2014 compiling systems of different companies are not interoperable once the medicinal product was  
2015 transferred to another MAH. In those cases a separate transition sequence is required to allow a  
2016 mapping between the previous and the new document ID via a replacing **contextOfUse** element.  
2017 As a general rule, no **document** elements can be referenced if they are not submitted to all  
2018 member states involved. From technical point of view the rules outlined in the ICH eCTD IG  
2019 apply entirely to EU Module 1 as well.

2020 Remark: Document title corrections will be displayed wherever the document element is  
2021 referenced. This effect is acceptable as no regulatory content will be changed. Further guidance  
2022 when a document title change is allowed or recommended will be provided separately.

2023

2024   **10.4 eCTD XML message from regulators**

2025 As it was the purpose of eCTD improvement version 4.0 to support two way communications,  
2026 XML messages have to be built by regulators as well. These messages should include any type of  
2027 assessment reports and list of questions, but in case of messages at the end of a procedure it  
2028 should provide the updated regulatory statusas well, the authorisation letter and the finally agreed  
2029 product information texts. Several elements relevant for a messages sent by applicants will not be  
2030 needed by regulators. The following tables will illustrate the constrained part.

**Table 4: XML Structure- Submission Unit from Regulators**

XML Structure
<p>The eCTD begins by identifying the <i>subject</i> element of the XML message. The payload message starts with the <i>submissionUnit</i> element and relates the rest of the elements to the Submission Unit being sent. The <i>submissionUnit</i> element in case of a message from regulators contains the following elements and their attributes:</p> <ul style="list-style-type: none"> <li>• <i>component4.contextOfUse</i> <ul style="list-style-type: none"> <li>○ <i>prioritNumber</i></li> <li>○ <i>replacementOf.relatedContextOfUse</i></li> <li>○ <i>derivedFrom.documentReference</i></li> <li>○ <i>subject5.submissionReference</i></li> <li>○ <i>referencedBy.keyword</i></li> <li>○ <i>primaryInformationRecipient.TerritorialAuthority</i></li> </ul> </li> <li>• <i>component1.submisisonpriorityNumber</i></li> </ul> <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;component4&gt;       &lt;prioritNumber value=""&gt;       &lt;contextOfUse&gt;         &lt;id&gt;&lt;/id&gt;         &lt;code&gt;&lt;/code&gt;         &lt;statusCode&gt;&lt;/statusCode&gt;         &lt;primaryInformationRecipient&gt;           &lt;territorialAuthority&gt;             &lt;governingAuthority&gt;               &lt;/governingAuthority&gt;             &lt;/territorialAuthority&gt;           &lt;/primaryInformationRecipient&gt;         &lt;replacementOf typeCode="RPLC"&gt;           &lt;relatedContextOfUse&gt;             &lt;id&gt;&lt;/id&gt;           &lt;/relatedContextOfUse&gt;         &lt;/replacementOf&gt;         &lt;sequelTo&gt;         &lt;derivedFrom&gt;           &lt;documentReference&gt;             &lt;id&gt;&lt;/id&gt;           &lt;/documentReference&gt;         &lt;/derivedFrom&gt;       &lt;/contextOfUse&gt;     &lt;/component4&gt;   &lt;/submissionUnit&gt; &lt;/subject&gt;</pre> <p><b>Mandatory elements in the message</b></p> <p><i>submissionUnit</i> (see Section 9.1)</p> <p><i>prioritNumber</i> (see Section 9.2)</p> <p><i>contextOfUse</i> (see Section 9.3)</p> <p><i>primaryInformationRecipient.territorialAuthority</i> (see Section 9.4) 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> <p><i>replacementOf.relatedContextOfUse</i> (see Section 9.5) A replace can be executed if an update is necessary.</p> <p><i>derivedFrom.documentReference</i> (see Section 9.6) Any assessment report, list of question or letter to the applicant will be referenced here.</p>

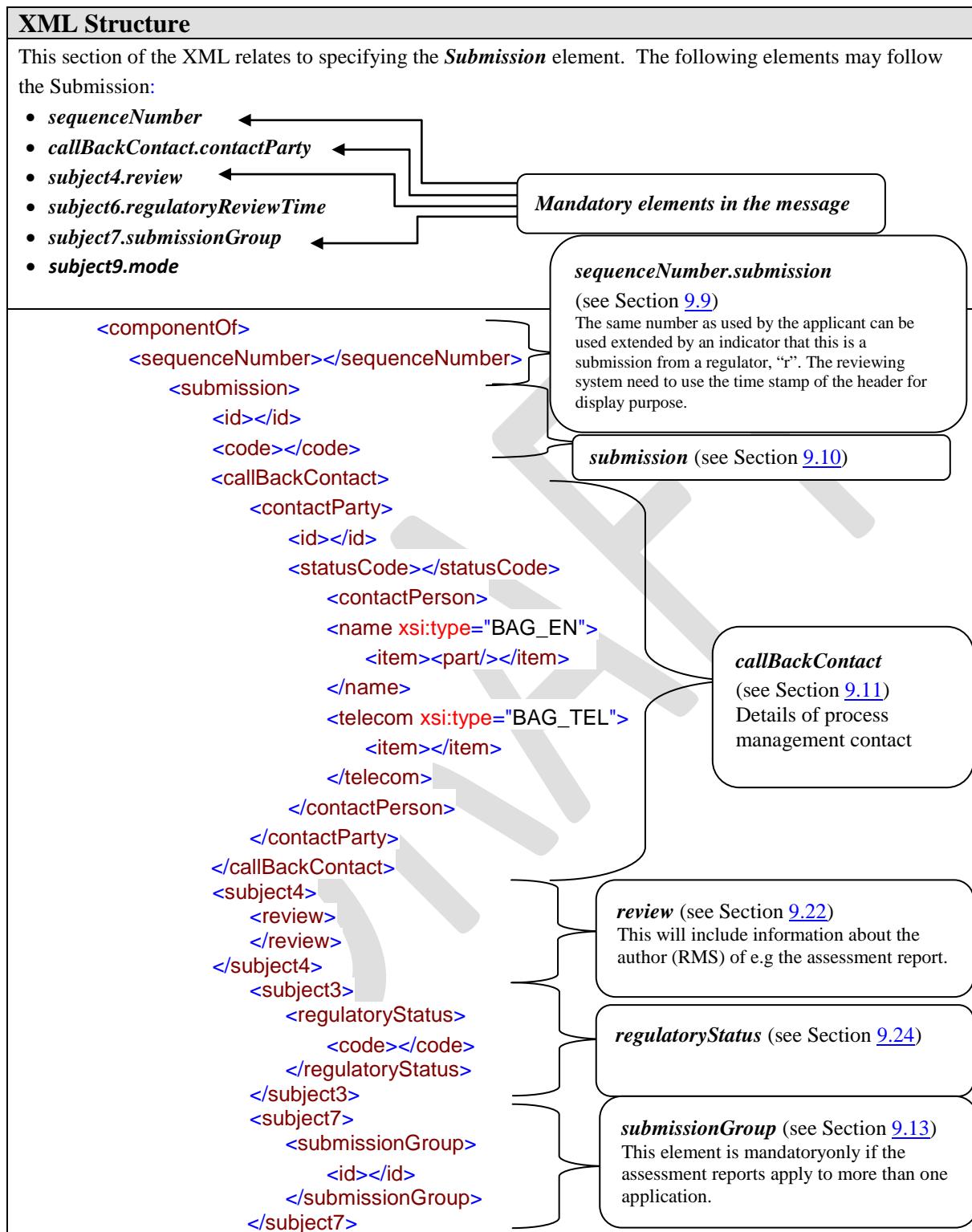
## XML Structure

```
<subject5 negationInd="">
  <submissionReference>
    <id xsi:type="DSET_II">
      <item></item>
    </id>
  </submissionReference>
</subject5>
<reference1 typeCode="REFR">
  <keyword>
    <code></code>
  </keyword>
</reference1>
</contextOfUse>
</component4>
```

*submissionReference*  
see Section [9.7](#)

**Keyword** (see Section [9.8](#))  
as a supplement to the ICH  
Implementation Guide and specific for  
EU Module 1 Implementation Guide

2032

**Table 5: XML Structure – Submission from Regulators**

**Table 6: XML Structure - Application from Regulators**

<b>XML Structure</b>
<p>This section of the XML relates to the <b><i>application</i></b> element. The application section contains the following elements and their attributes in case of a message from regulators:</p> <ul style="list-style-type: none"> <li>• <b><i>holder.applicant</i></b></li> <li>• <b><i>informationRecipient.territorialAuthority</i></b></li> <li>• <b><i>subject8.reviewProcedure</i></b></li> <li>• <b><i>reference.applicationReference</i></b></li> <li>• <b><i>component6.document</i></b> <ul style="list-style-type: none"> <li>◦ <b><i>referencedBy.keyword</i></b></li> </ul> </li> <li>• <b><i>referencedBy.keywordDefinition</i></b></li> </ul> <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <b><i>application</i></b> (see Section <a href="#">9.15</a>)     </div> <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <b><i>informationRecipient.territorialAuthority</i></b> (see Section <a href="#">9.17</a>)        Details of the receiving member states)     </div>

XML Structure	
<p><i>document</i> (see Section <a href="#">9.20</a>) This will reference e.g. the assessment report.</p>	<pre>&lt;component6&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;integrityCheck&gt;&lt;/integrityCheck&gt;     &lt;/text&gt;   &lt;/document&gt; &lt;component6&gt;   &lt;keywordDefinition&gt;     &lt;code&gt;&lt;/code&gt;     &lt;statusCode&gt;&lt;/statusCode&gt;     &lt;value&gt;       &lt;item&gt;         &lt;displayName&gt;&lt;/displayName&gt;       &lt;/item&gt;     &lt;/value&gt;   &lt;/keywordDefinition&gt; &lt;/referencedBy&gt;</pre>
<p><i>keywordDefinition</i> (see Section <a href="#">9.21</a>) specific for EU Module 1 Implementation Guide</p>	

The the closing element tags for the key elements in the eCTD v4.0 message are not displayed..

2037

2038 The most consistant way to make use of a sequence number will be to re-use the same as the  
 2039 sponsor's submission unit to which the regulators message responds extended by an indicator that  
 2040 this is a submission from a regulator, "r". It may be more appropriate to use some header  
 2041 information to allow differentiation between different regulating agencies sending their messages.  
 2042 A respective feature should be developed. The reviewing system needs to use the time stamp of  
 2043 the header for display purposes and to support an appropriate ordering: the incoming message can  
 2044 be presented first (receiving date at agency) and the outgoing message second (sending date by  
 2045 agency).

2046

## 2047      **10.5 Building Regulatory Activities (Submission)**

2048 The following section provides a set of message snippets that highlight the Module 1 content.  
 2049 These XML samples do not include the information that is relevant to Modules 2-5. All samples  
 2050 in this section provide a regulatory activity life cycle within an application.

2051

### 2052    **10.5.1 Marketing Authorisation Application (MAA)**

2053 Examples are provided in [Appendix 2](#)

2054

2055    **10.5.2    Variation**

2056    Examples are provided in [Appendix 2](#)

2057

2058

2059

DRAFT

2060

2061 **11. XML MESSAGE VALIDATION RULES**

2062 The principles of validation rules for eCTD v4.0 messages will not differ between regions. For  
 2063 details please refer to the ICH Implementation Guide. The following table highlights validation  
 2064 rules by elements which are specifically used in the EUAll checks according to the schema will not  
 2065 be repeated here. All code values are expected to be currently valid.

2066

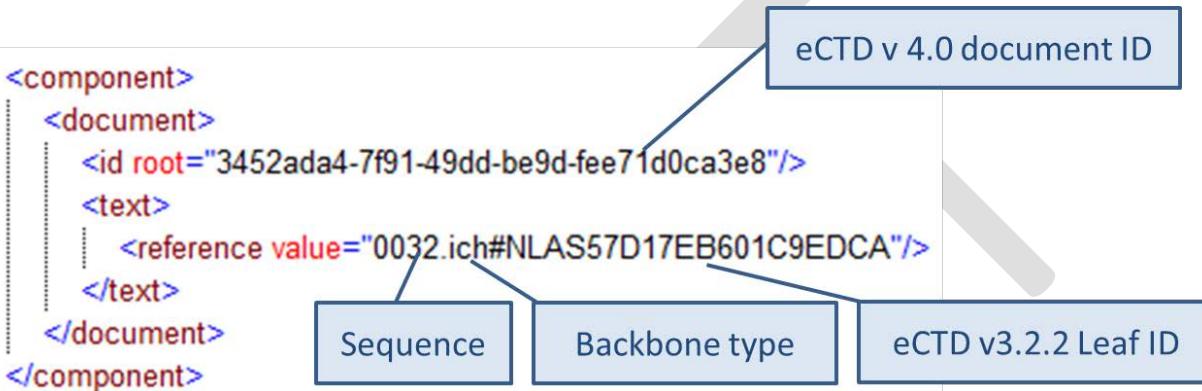
<b>Category</b>	<b>Type/Element</b>	<b>Validation Criteria</b>
Message Validation	<a href="#"><u>Territorial Authority</u></a>	The Authority attribute must have a valid code value.
	<a href="#"><u>Submission Reference</u></a>	A submission unit sent by regulators must provide a Submission Reference stated as a valid code value
	<a href="#"><u>Submission</u></a>	Submission must have a valid code value
	<a href="#"><u>Submission Group</u></a>	Submission Group must have a valid code value.
		Submission Group id root must be a unique identifier
	<a href="#"><u>Mode</u></a>	Mode id root must be a unique identifier
		Mode code must have a valid code value
	<a href="#"><u>Applicant</u></a>	Applicant must have a valid code value
		Applicant status code requires the code attribute “active”
	<a href="#"><u>Review Procedure</u></a>	Review Procedure number must be a whole number
		The Review Procedure must have one and only one value for the Submission element
		Review Procedure for initial submission unit starts with 1
	<a href="#"><u>Application Reference</u></a>	Application Reference identifier is required (1..1)
		Application Reference must have a valid code value
	<a href="#"><u>Review</u></a>	Only one Review element can exist for a message.
		Review code must have a valid OID for the Code System value
		Review status code requires the code attribute “active”
	<a href="#"><u>Product Category</u></a>	Product Category id root must be a unique identifier
		Only one Product Category element can exist for a message.
		Product Category code must have a valid OID for the Code System value

Category	Type/Element	Validation Criteria
	<u>Regulatory Status</u>	Only one Regulatory Status element can exist for a message
		Regulatory Status code must have a valid OID for the Code System value .

2067  
2068

## 2069        **12. COMPATIBILITY AND REFERENCE TO EU MODULE 1 eCTD v2.0**

2070        The principles of forward compatibility will not differ between regions.



2071  
2072

2073        In case of the regional module the backbone type will be changed into 'eu' for the Module 1 of the EU region.

2074

2075        The ICH Implementation Guide describes a onetime transition from v3.2.2 to v4.0 based on the current regulatory view of a dossier. This means that all valid content of a dossier in eCTD format v3.2.2 will be mapped in a way that document elements can be referenced in the future according to the eCTD specification v4.0. This transition will work once the dossier volume is already re-baselined in eCTD v3.2.2. It needs to be carefully considered whether all parts of the dossier need to be included into a baseline. It needs to be noted that those parts which are not yet in eCTD format cannot be transitioned. According to current guidance baselines must not include large-volume modules like module 4 and 5.

2076

2077        The transition workload will definitely depend from a business decision on whether a dossier need to be switched entirely to eCTD v3.2.2 in advance or whether it remains acceptable that only parts of a dossier are switched, or that the use of eCTD can start even with single documents. Transition to eCTD v4.0 will be possible only for those parts already in eCTD format v3.2.2. Any advantage of version 4.0 can be achieved only after transition.

2078

2079        Different from transition – forward compatibility from version 3.2.2 towards version 4.0 of eCTD submissions – guidance need to be established how current dossiers can be switched into eCTD once version 4.0 is implemented. Presumably, the same rules on baselining can be applied as for the switch towards eCTD v3.2.2 at the moment.

2080

2096

2097 **APPENDIX 1 SAMPLE FILES AND FOLDERS FOR EU MODULE 1 LITE FOLDER**  
2098 **STRUCTURE**

2099 **Module 1**

2100 Current Module 1 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

2101

2102

2103 Proposed Lite Module 1 Folder Structure

-  m1

2104 Note: Filenames provide sufficient specificity

2105

2106

2107 **APPENDIX 2 SAMPLE ECTD MESSAGES**

2108 This section includes general examples on marketing authorisation application and variation type  
2109 2 for illustration.

2110

2111 **Marketing Authorisation application**

```
2112 <?xml version="1.0" encoding="UTF-8"?>
2113 <PORP_IN000001UV xsi:schemaLocation="urn:hl7-org:v3 ../multicacheschemas/PORP_IN000001UV.xsd"
2114 ITSTVersion="XML_1.0" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
2115 org:v3">
2116 <id/>
2117 <creationTime/>
2118 <interactionId/>
2119 <processingCode/>
2120 <processingModeCode/>
2121 <acceptAckCode/>
2122 <receiver typeCode="RCV">
2123   <device determinerCode="INSTANCE" classCode="DEV">
2124     <id/>
2125   </device>
2126 </receiver>
2127 <sender typeCode="SND">
2128   <device determinerCode="INSTANCE" classCode="DEV">
2129     <id/>
2130   </device>
2131 </sender>
2132 <controlActProcess classCode="ACTN" moodCode="EVN">
2133   <subject typeCode="SUBJ">
2134     <submissionUnit>
2135       <!-- ===== -->
2136       <!-- This is the root attribute that uniquely identifies the submission -->
2137       <!-- Create a new Decentralised Procedure application and submission -->
2138       <!-- Acme Pharmaceuticals has prepared information relating to its new product - Global Fixit -->
2139       <!-- The submission unit contains documentation that are common to all countries but also documentation -->
2140       <!-- that are specific to individual countries and languages -->
2141     <!-- ===== -->
2142     <!-- ===== -->
2143     <id root="11953B86-AF49-408B-820D-67CF80D41C6A"/>
2144     <!-- ===== -->
2145     <!-- Submission Unit Type = Initial submission to start a regulatory activity" -->
2146     <!-- ===== -->
2147     <!-- EUTCT = "100000155047" short name ="initial" -->
2148     <!-- ===== -->
2149     <code codeSystem="3.16.750.1.223354.0.121.521" code="100000155047"/>
2150     <title value="EU-300 test case – Sequence 1"/>
```

```
2151      <statusCode code="active"/>
2152      <!-- ===== -->
2153      <!-- the Reference Member State : RMS -->
2154      <!-- ===== -->
2155      <component>
2156          <contextOfUse>
2157              <id root="30A7CF17-5204-4C08-A936-JEE8746BE100"/>
2158              <statusCode code="active"/>
2159              <primaryInformationRecipient>
2160                  <!-- RMS -->
2161                  <territorialAuthority>
2162                      <territory>
2163                          <code code="FR"/>
2164                      </territory>
2165                      <governingAuthority>
2166                          <name>
2167                              <part codeSystem="4.33.650.1.723354.0.121.230" code="FR-ANSM" value="ANSM"/>
2168                          </name>
2169                      </governingAuthority>
2170                  </territorialAuthority>
2171              </primaryInformationRecipient>
2172          </contextOfUse>
2173      </component>
2174      <!-- ===== -->
2175      <!--Reference Document: Document ID -->
2176      <!-- eCTD EU Context of Use -->
2177      <!-- ===== -->
2178      <component>
2179          <priorityNumber value="1000"/>
2180          <contextOfUse>
2181              <id root="50C7BF17-6204-4C08-A936-CEE7746BE293"/>
2182              <code codeSystem="2.16.840.1.113883.3.989.0" code="eu-m1-2"/>
2183              <statusCode code="active"/>
2184          <!--Reference Document: Application Form-->
2185          <derivedFrom>
2186              <documentReference>
2187                  <id root="4967C88D-1803-4879-9805-79EBCC17FAAB"/>
2188                  </documentReference>
2189              </derivedFrom>
2190          </contextOfUse>
2191      </component>
2192      <component>
2193          <priorityNumber value="1000"/>
2194          <contextOfUse>
2195              <id root="80D7BF17-6204-4C08-A936-CEE7746BE172"/>
2196              <code codeSystem="2.16.840.1.113883.3.989.1" code="eu-m1-0"/>
```

```
2197      <statusCode code="active"/>
2198      <!--Reference Document: Cover Letter for DE -->
2199      <derivedFrom>
2200      <documentReference>
2201          <id root="9CF93E08-5C28-4D6D-B907-BFBE34F4119D"/>
2202          </documentReference>
2203      </derivedFrom>
2204      </contextOfUse>
2205      </component>
2206      <component>
2207          <priorityNumber value="1000"/>
2208          <contextOfUse>
2209              <id root="90E7BF17-6204-4C08-A936-CEE7746BE220"/>
2210          <!-- ===== -->
2211          <!-- ich code = "ich-2-5" description = "m2.5 clinical overview" -->
2212          <!-- ===== -->
2213              <code codeSystem="2.16.840.1.113883.3.989.3" code="ich-2-5"/>
2214          <statusCode code="active"/>
2215      <!--Reference Document: Clinical Overview -->
2216      <derivedFrom>
2217      <documentReference>
2218          <id root="22222222-4C2B-4570-9093-46885129AF97"/>
2219          </documentReference>
2220      </derivedFrom>
2221      </contextOfUse>
2222      </component>
2223      <component>
2224          <priorityNumber value="1000"/>
2225          <contextOfUse>
2226              <id root="55A7BF17-6204-4C08-A936-CEE7746BA700"/>
2227          <!-- ===== -->
2228          <!-- code = "ich-3-3" description = "m3.3 literature references" -->
2229          <!-- ===== -->
2230              <code codeSystem="2.16.840.1.113883.3.989.4" code="ich-3-3"/>
2231          <statusCode code="active"/>
2232      <!--Reference Document:Literature References -->
2233      <derivedFrom>
2234      <documentReference>
2235          <id root="33333333-7BDE-43A5-A3C8-1381E225C279"/>
2236          </documentReference>
2237      </derivedFrom>
2238      </contextOfUse>
2239      </component>
2240      <component>
2241          <priorityNumber value="1000"/>
2242          <contextOfUse>
```

```

2243         <id root="66F7BF17-6204-4C08-A936-CEE7746CE400"/>
2244     <!-- ===== -->
2245     <!-- code = "ich-4-3" description = "m4.3 literature references" -->
2246     <!-- ===== -->
2247         <code codeSystem="2.16.840.1.113883.3.989.5" code="ich-4-3"/>
2248         <statusCode code="active"/>
2249     <!--Reference Document: Literature References 1 -->
2250         <derivedFrom>
2251             <documentReference>
2252                 <id root="44444444-2486-484B-A6D8-D509B5A4E306"/>
2253             </documentReference>
2254         </derivedFrom>
2255     </contextOfUse>
2256     </component>
2257     <component>
2258         <priorityNumber value="1000"/>
2259     <contextOfUse>
2260         <id root="88B8BF17-6204-4C08-A936-CEE7746BE293"/>
2261     <!-- ===== -->
2262     <!-- code = "ich-5-2" description = "m5.2 tabular listing of all clinical studies" -->
2263     <!-- ===== -->
2264         <code codeSystem="2.16.840.1.113883.3.989.6" code="ich-5-2"/>
2265         <statusCode code="active"/>
2266     <!-- Reference Document: Tabular Listing of all clinical studies -->
2267         <derivedFrom>
2268             <documentReference>
2269                 <id root="55555555-3B0E-4B61-9B6D-689A02CC8A40"/>
2270             </documentReference>
2271         </derivedFrom>
2272     </contextOfUse>
2273     </component>
2274     <!-- ===== -->
2275     <!-- Reference Document : Information on the manufacturer -->
2276     <!-- manufacturer(s) (name, manufacturer) -->
2277     <!-- ===== -->
2278         <component>
2279             <priorityNumber value="1000"/>
2280         <contextOfUse>
2281             <id root="63M8NF18-3304-4C08-C916-AA2446QE1900"/>
2282     <!-- ===== -->
2283     <!-- CTD Heading - Manufacturer(s) (name, manufacturer) -->
2284     <!-- ich-3-2-s-2-1 - m3.2.s.2.1 manufacturer(s) - substance (R), manufacturer (R), group title (O) -->
2285     <!-- ===== -->
2286         <code codeSystem="2.16.840.1.113883.3.989.7" code="ich-3-2-s-2-1"/>
2287         <statusCode code="active"/>
2288     <!-- ===== -->

```

```

2289 <!-- Reference document="Information on the manufacturer" -->
2290 <!-- ===== -->
2291     <derivedFrom>
2292         <documentReference>
2293             <id root="36987451-3B0E-4B61-9B6D-689A02CC8A40"/>
2294         </documentReference>
2295     </derivedFrom>
2296     <referencedBy typeCode="REFR">
2297         <keyword>
2298             <code codeSystem="3.26.840.1.113884.2.900.1" code="MANU001">
2299                 <displayName value="rinkydink"/>
2300             </code>
2301         </keyword>
2302     </referencedBy>
2303     </contextOfUse>
2304 </component>
2305     <componentOf1>
2306         <sequenceNumber value="1"/>
2307 <!-- ===== -->
2308 <!-- Application Submission Type : Controlled Vocabularies -->
2309 <!-- EUTCT code = "100000155689" short name = "initial-maa" -->
2310 <!-- Description : Initial Marketing Authorisation Application -->
2311 <!-- ===== -->
2312     <submission>
2313         <id>
2314             <item root="3EDF1AD3-7338-479E-9F6C-BE20E5BA95FO"/>
2315         </id>
2316         <code codeSystem="9.16.330.1.113884.2.800.2" code="initial-maa"/>
2317 <!-- ===== -->
2318 <!-- the contact party: a person to call if there is any questions -->
2319 <!-- ===== -->
2320     <callBackContact>
2321         <contactParty>
2322             <id root="12B4562-1312-31C1-2F74-1234E6789125"/>
2323             <code codeSystem="8.13.850.1.223354.0.121.322" code="2.4.2"/>
2324             <statusCode code="active"/>
2325         <contactPerson>
2326             <name>
2327                 <part value="Pierre" type="GIV"/>
2328                 <part value="Raynaud" type="FAM"/>
2329             </name>
2330             <telecom>
2331                 <item value="+33155873010" capabilities="voice" use="WP"/>
2332                 <item value="+33155873001" capabilities="fax" use="WP"/>
2333                 <item value="pierre.raynaud@acmepharmaceuticals.com"/>
2334         </telecom>

```

```

2335      <addr>
2336          <part value="Paris" type="CTY"/>
2337          <part value="75012" type="ZIP"/>
2338      </addr>
2339      </contactPerson>
2340      </contactParty>
2341  </callBackContact>
2342  <subject2>
2343      <review>
2344          <id root="8COE9431-A1CB-9832-80C3-713CEFF1M9V8"/>
2345          <statusCode code="active"/>
2346      <!-- ===== -->
2347      <!-- Product name and Substance -->
2348      <!-- ===== -->
2349      <subject1>
2350          <manufacturedProduct>
2351              <manufacturedProduct>
2352                  <name>
2353                      <part code="GF5000" value="Global Fixit"/>
2354                  </name>
2355                  <ingredient classCode="INGR">
2356                      <ingredientSubstance>
2357                          <name>
2358                              <part code="S803" value="subst1"/>
2359                          </name>
2360                      </ingredientSubstance>
2361                  </ingredient>
2362              </manufacturedProduct>
2363          </manufacturedProduct>
2364      </subject1>
2365  </review>
2366  </subject2>
2367  <componentOf>
2368      <application>
2369          <id>
2370          <!-- ===== -->
2371          <!-- procedure number FR/H/01-->
2372          <!-- ===== -->
2373          <item root="5FOE8436-E1DF-4031-90D3-413DEFF109E5" extension="FR/H/01"/>
2374      </id>
2375      <!-- ===== -->
2376  <!-- Application type = New active substance (Article 8(3) of Directive N° 2001/83/EC -->
2377  <!-- ===== -->
2378  <code codeSystem="eu-application-type" code="100000116047"/>
2379      <holder>
2380          <applicant>

```

```

2381      <sponsorOrganization>
2382          <name>
2383          <!-- codeSystem = OID - DUNS number -->
2384              <part code="88858" value="Acme Pharmaceuticals"/>
2385          </name>
2386          <telecom>
2387              <item value="+33155873000" capabilities="voice" use="WP"/>
2388              <item value="+33155873002" capabilities="fax" use="WP"/>
2389              <item value="info@acmepharmaceuticals.com"/>
2390          </telecom>
2391          <addr>
2392              <part value="Paris" type="CTY"/>
2393              <part value="75012" type="ZIP"/>
2394          </addr>
2395      </sponsorOrganization>
2396  </applicant>
2397 </holder>
2398 <!-- ===== -->
2399 <!-- Regulatory Authorities - countries -->
2400 <!-- ===== -->
2401      <informationRecipient>
2402          <territorialAuthority>
2403              <territory>
2404                  <code codeSystem="eu-country" code="FR"/>
2405              </territory>
2406              <governingAuthority>
2407                  <name>
2408                      <part language="fr" codeSystem="4.33.650.1.723354.0.121.230" code="FR-ANSM">
2409                          value="Agence Nationale de Sécurité du Médicament et des Produits de Santé"/>
2410                      </name>
2411                  </governingAuthority>
2412              </territorialAuthority>
2413          </informationRecipient>
2414          <informationRecipient>
2415              <territorialAuthority>
2416                  <territory>
2417                      <code codeSystem="eu-country" code="DE"/>
2418                  </territory>
2419                  <governingAuthority>
2420                      <name>
2421                          <part language="de" codeSystem="5.49.650.1.623351.0.121.660" code="DE-BFARM">
2422                          value="Bundesinstitut für Arzneimittel und Medizinprodukte"/>
2423                      </name>
2424                  </governingAuthority>
2425              </territorialAuthority>
2426          </informationRecipient>

```

```
2427 <informationRecipient>
2428   <territorialAuthority>
2429     <territory>
2430       <code codeSystem="eu-country" code="BE"/>
2431     </territory>
2432     <governingAuthority>
2433       <name>
2434         <part language="fr" codeSystem="6.32.650.1.423350.0.121.350" code="BE-FAMHP"
2435 value="Agence Fédérale des Médicaments et des Produits de Santé">
2436   </name>
2437   </governingAuthority>
2438 </territorialAuthority>
2439 </informationRecipient>
2440 <informationRecipient>
2441   <territorialAuthority>
2442     <territory>
2443       <code codeSystem="eu-country" code="SE"/>
2444     </territory>
2445     <governingAuthority>
2446       <name>
2447         <part language="sv" codeSystem="7.46.650.1.423350.0.121.350" code="SE-MPA"
2448 value="Medical Products Agency"/>
2449   </name>
2450   </governingAuthority>
2451 </territorialAuthority>
2452 </informationRecipient>
2453 <informationRecipient>
2454   <territorialAuthority>
2455     <territory>
2456       <code codeSystem="eu-country" code="UK"/>
2457     </territory>
2458     <governingAuthority>
2459       <name>
2460         <part language="en" codeSystem="8.44.650.1.423350.0.121.800" code="UK-MHRA"
2461 value="Medicines and Healthcare products Regulatory Agency"/>
2462   </name>
2463   </governingAuthority>
2464 </territorialAuthority>
2465 </informationRecipient>
2466 <!-- ===== -->
2467 <!-- Review Procedure -->
2468 <!-- ===== -->
2469 <subject8>
2470   <!-- Procedure type=DCP -->
2471   <!-- EUTCT code for DCP is 100000155060 short name = "DCP" -->
2472 <code codeSystem="2.44.120.2.123370.0.141.879" code="DCP"/>
```

```

2473      </reviewProcedure>
2474      </subject8>
2475      <!-- ===== -->
2476      <!-- common application form for all Member States involved -->
2477      <!-- Cover letter specific for Germany in German language -->
2478      <!-- ===== -->
2479      <component>
2480          <document>
2481              <id root="4967C88D-1803-4879-9805-79EBCC17FAAB"/>
2482              <text language="en" integrityCheckAlgorithm="SHA256">
2483                  <reference value="m1/eu/12-form/common/common-form.pdf"/>
2484                  <integrityCheck>56df6492f724ee2e76e12cb4b001bd2fdc43603fb15d70afc8
2485 9813398739fb9c</integrityCheck>
2486                  </text>
2487                  <confidentialityCode code="" />
2488          </document>
2489      </component>
2490      <component>
2491          <document>
2492              <id root="9CF93E08-5C28-4D6D-B907-BFBE34F4119D"/>
2493              <text language="de" integrityCheckAlgorithm="SHA256">
2494                  <reference value="m1/eu/10-cover/de/de-cover.pdf"/>
2495                  <integrityCheck>b9a6aff775736cf100505af68da859a941432a9f9e56d245ac3eda
2496 a4235df0ac</integrityCheck>
2497                  </text>
2498                  <!-- ===== -->
2499                  <!-- Commercial Confidential Information-CCI and Protected Personal Data-PPD in the EU: -->
2500                  <!-- L=Low -->
2501                  <!-- M=Moderate -->
2502                  <!-- N=Normal -->
2503                  <!-- U=Unrestricted -->
2504                  <!-- R=Restricted -->
2505                  <!-- V=Very Restricted -->
2506                  <!-- ===== -->
2507                  <confidentialityCode code="L"/>
2508          </document>
2509      </component>
2510      <!-- ===== -->
2511      <!-- CTD sections defined by ICH (Modules 2-5) -->
2512      <!-- Document ="..\m2\25-clin-over\clinical-overview.pdf" -->
2513      <!-- Document ="..\m3\33-lit-ref\aaami-2001.pdf" -->
2514      <!-- Document= "..\m4\43-lit-ref\reference-1.pdf" -->
2515      <!-- Document= "..\m5\52-tab-list\tabular-listing.pdf" -->
2516      <!-- Document= "..\m3\32-body-data\32s-drug-sub\subst1-rinkydink\32s2-
2517 manuf\manufacturer.pdf" -->
2518      <!-- ===== -->
```

2519           <component>  
2520            <document>  
2521            <id root="22222222-4C2B-4570-9093-46885129AF97"/>  
2522            <text language="en" integrityCheckAlgorithm="SHA256">  
2523            <reference value="m2/25-clin-over/clinical-overview.pdf"/>  
2524            <integrityCheck>3b4f545c0e0f57c5a971c5e6015548ffa02f0f2fc9646dd28c7faa9  
2525            19b7ed06b</integrityCheck>  
2526            </text>  
2527            </document>  
2528          </component>  
2529          <component>  
2530            <document>  
2531            <id root="33333333-7BDE-43A5-A3C8-1381E225C279"/>  
2532            <text language="en" integrityCheckAlgorithm="SHA256">  
2533            <reference value="m3/33-lit-ref/aami-2001.pdf"/>  
2534            <integrityCheck>2d7eb3613b926514cc75b8900f1b9f893d3189975942040e68b123  
2535            bbac9504d6</integrityCheck>  
2536            </text>  
2537            </document>  
2538          </component>  
2539          <component>  
2540            <document>  
2541            <id root="44444444-2486-484B-A6D8-D509B5A4E306"/>  
2542            <text language="en" integrityCheckAlgorithm="SHA256">  
2543            <reference value="m4/43-lit-ref/reference-1.pdf"/>  
2544            <integrityCheck>58dbba78175122c32e10b593992115a8cb3eee4cf4de1d59f503e  
2545            615f2e2a568</integrityCheck>  
2546            </text>  
2547            </document>  
2548          </component>  
2549          <component>  
2550            <document>  
2551            <id root="55555555-3B0E-4B61-9B6D-689A02CC8A40"/>  
2552            <text language="en" integrityCheckAlgorithm="SHA256">  
2553            <reference value="m5/52-tab-list/tabcular-listing.pdf"/>  
2554            <integrityCheck>be7068c8ccb21d2112fb17a0e51b124fea342df8129cc173454ae1d1d  
2555            e17730a</integrityCheck>  
2556            </text>  
2557            </document>  
2558          </component>  
2559          <component>  
2560            <document>  
2561            <id root="36987451-3B0E-4B61-9B6D-689A02CC8A40"/>  
2562            <text language="en" integrityCheckAlgorithm="SHA256">  
2563            <reference value="m3/32-body-data/32s-drug-sub/subst1-rinkydink/32s2-  
2564            manuf/manufacturer.pdf"/>

```
2565      <integrityCheck>e5f61cdcac26ce21f99bc0578ce9b55e6d223566f324f05ee2a757  
2566 6ca82ab2a6</integrityCheck>  
2567      </text>  
2568      <confidentialityCode code="R"/>  
2569      </document>  
2570      </component>  
2571      </application>  
2572      </componentOf>  
2573      </submission>  
2574      </componentOf1>  
2575      </submissionUnit>  
2576      </subject>  
2577      </controlActProcess>  
2578  </PORP_IN000001UV>  
2579
```

## 2580 Variation type 2

```
2581      <id root="87454521-9874-6541-1236-159842345687" />  
2582      <code code="var-type2" codeSystem="Submission Code System OID" />  
2583          <title value="Variation Type II" />  
2584          <statusCode code="active" />  
2585  
2586          -<review>  
2587              <id />  
2588              <statusCode code="active" />  
2589              -<holder>  
2590                  -<applicant>  
2591                      -<sponsorOrganisation>  
2592                          -<name xsi:type="BAG_EN">  
2593                              -<item>  
2594                                  <part value="PharmaCompany" code="888528" codeSystemVersion="OID for  
2595 Duns" />  
2596                                  </item>  
2597                              </name>  
2598                          -<telecom xsi:type="BAG_TEL">  
2599                              <item value="tel: +33 1 55 87 31 80" use="WP" />  
2600                              <item value="tel: +33 6 25 30 31 80" use="MC" />  
2601                              <item value="mailto:richard.dumont@pharmaccompany.com" />  
2602                          </telecom>  
2603                          -<addr xsi:type="BAG_AD">  
2604                              -<item xsi:type="AD">  
2605                                  <part type="ZIP" value="93285" />  
2606                                  <part type="STR" value="143-147 Bld Anatole France" />  
2607                                  <part type="CTY" value="Saint-Denis" />  
2608                              </item>  
2609                          </addr>
```

```

2610          </sponsorOrganisation>
2611      </applicant>
2612      </holder>
2613  - <author>
2614      - <territorialAuthority>
2615          - <territory>
2616              <code code="FR" codeSystem="Country Code system OID" />
2617          </territory>
2618          - <governingAuthority>
2619              - <name>
2620                  <part code="ANSM" value="Agence nationale de sécurité du médicament et des
2621 produits de santé" codeSystem="Authority Code system OID" />
2622          </name>
2623          </governingAuthority>
2624      </territorialAuthority>
2625  - <author>
2626  - <subject2>
2627      - <productCategory>
2628          <code code="chemical" codeSystem="ProductCategory Code system OID" />
2629      </productCategory>
2630  - <subject2>
2631 </review>
2632
2633
2634  - <callBackContact typeCode="CALLBCK">
2635      - <contactParty>
2636          <id root="32568794-789874" identifierName="Mycontact" />
2637          <code code="c2125" codeSystem="contactParty Event Code System OID" />
2638          <statusCode code="active" />
2639      - <contactPerson>
2640          - <id>
2641              <item root="Globally unique contact ID" />
2642          </id>
2643          - <name xsi:type="BAG_EN">
2644          - <item>
2645              <part value="Richard" type="GIV" />
2646              <part value="Dumont" type="FAM" />
2647          </item>
2648          </name>
2649      - <telecom xsi:type="BAG_TEL">
2650          <item value="tel: +33 1 55 87 31 80" use="WP" />
2651          <item value="tel: +33 6 25 30 31 80" use="MC" />
2652          <item value="mailto:richard.dumont@pharmaccompany.com" />
2653      </telecom>
2654  - <asAgent classCode="AGNT">
2655      - <representedOrganisation>

```

```

2656     _ <name xsi:type="BAG_EN">
2657     _ <item>
2658         <part value="Organisation name" />
2659     </item>
2660   </name>
2661   </representedOrganisation>
2662   </asAgent>
2663 </contactPerson>
2664 </contactParty>
2665 </callBackContact>
2666 _ <component>
2667     <priorityNumber value="1" />
2668 _ <contextOfUse>
2669     <id root="12345678-1234-5678-3456-127536489712" />
2670     _ <code code="m10cover" codeSystem="Code system OID for Cover Letter">
2671         <displayName value="1.0 Cover Letter" />
2672     </code>
2673     <title value="1.0 Cover Letter" />
2674     <statusCode code="active" />
2675     <setId root="set ID" />
2676     <versionNumber value="1.0" />
2677 _ <primaryInformationRecipient>
2678     _ <territorialAuthority>
2679         _ <territory>
2680             <code code="DE" codeSystem="country code system OID" codeSystemName="country code
2681 system name" />
2682             </territory>
2683             _ <governingAuthority>
2684                 <id root="DE-BFARM" value="BFARM" />
2685                 </governingAuthority>
2686             </territorialAuthority>
2687         </primaryInformationRecipient>
2688 _ <sequelTo typeCode="RPLC">
2689     _ <relatedContextOfUse>
2690         <id root="87454521-9874-6541-1236-159842345687" />
2691         <versionNumber value="1" />
2692     </relatedContextOfUse>
2693     </sequelTo>
2694 _ <derivedFrom>
2695     _ <documentReference>
2696         <id root="12345678-1234-1234-1234-198765432198" extension="12345" />
2697         </documentReference>
2698     </derivedFrom>
2699 _ <subjectOf>
2700     _ <submissionReference>
2701         _ <id xsi:type="DSET_II">

```

```
2702      <item root="12345678-1234-5678-3456-127536489712" />
2703      </id>
2704      </submissionReference>
2705      </subjectOf>
2706      </contextOfUse>
2707      </component>
2708      -<component>
2709          <priorityNumber value="1" />
2710      -<contextOfUse>
2711          <id root="Context of Use ID" />
2712          -<code code="m12form" codeSystem="Code system OID for Application Form">
2713              <displayName value="1.2 application form" />
2714          </code>
2715          <title value="1.2 application form" />
2716          <statusCode code="active" />
2717          <setId root="set ID" />
2718          <versionNumber value="1.0" />
2719          -<primaryInformationRecipient>
2720          ....
2721          </primaryInformationRecipient>
2722          -<derivedFrom>
2723              -<documentReference>
2724                  <id root="12121212-1234-1234-1234-98765432198" extension="23456" />
2725                  </documentReference>
2726              </derivedFrom>
2727          </contextOfUse>
2728      </component>
2729      -<componentOf>
2730
2731
```

2732

2733 **APPENDIX 3 ABBREVIATIONS, TERMS AND DEFINITIONS**

2734 The following table defines some common terms in this document and specific to eCTD v4.0.  
2735 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 eCTD IG
<b>Payload</b>	See ICH eCTD IG

2736

2737

2738 **APPENDIX 4 REFERENCES**

2739 [This section will include references to procedures described in the IG (e.g., The SHA256  
2740 Message-Digest Algorithm).]

2741

DRAFT