Electronic Common Technical Document (eCTD) v4.0
EU Practical Document

Version 1.0
December 2025

DOCUMENT CHANGE HISTORY

Version	Date	Comments
1.0	December 2025	Creation of practical document to be used in combination with EU Implementation Guide v1.2 The guidance includes practical information to the applicant submitting an eCTD v4.0 Marketing Authorisation Applications for Centralised Procedure.

Table of Contents

NOTICE TO READER

Please use the practical document in conjunction with the EU Implementation guide Version 1.2 and the current ICH Guidance.

INSTRUCTIONS TO READER

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

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

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

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

For the colour coding used in the XML snippets, please consult the ICH Implementation Guide.

Note: *All UUIDs and OIDs used in the XML samples and snippets are only for illustrational purposes, to demonstrate how the respective XML section will look. They cannot be used for testing. They will be replaced by real values once these are available.*

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

Table 1: Legend of Symbols used in Document

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

1. PURPOSE AND SCOPE

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

The RPS standard defines the message for exchanging regulatory information electronically between Competent Authorities and the Pharmaceutical Industry as well as between Competent Authorities in general and needs to be detailed by implementation guides. This document only summarises key points related to the EU regional implementation for the Centralised Procedures. The focus is to outline the essential components of the message which are required for EU Module 1 in addition to and/or differently from the common CTD Modules 2 – 5.

The content of eCTD v4.0 Modules 2 - 5, being shared across all regions represented in the International Council of Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), is not included in this document, although some principles need to be repeated in the document to assure a better understanding. This document therefore should be read together with the EU eCTD 4 IG and ICH eCTD IG to prepare a valid eCTD Submission Unit in the EU.

Please note, this Practical Guidance will be updated regularly as we roll out with future Pilots related to the Forward Compatibility and different Procedure types.

[1] The ICH IG is accessible at www.estri.org

Regional Business Processes Covered by the initial optional use for Centralised Procedures

This document will address the following regional business processes:

- **Application Management/Submission Life Cycle** – includes practical information to the applicant submitting an eCTD v4.0 Marketing Authorisation Applications for Centralised Procedure.

SUBMISSION CONTENTS, FOLDER AND FILE STRUCTURE

Although the eCTD v4.0 specification does not require a specific folder and file structuring or naming convention, the following rules will provide recommended practises for naming the contents of the packages.

1.1. Submission Unit Content in eCTD v4.0 Messages

The Submission Unit consists of:

1. a *First Level Folder* (for example: ema001234, where 1234 is the EMA product Number EMA/H/C/001234)
2. the *Second Level Folder*
3. the eCTD v4.0 XML Message for that individual Submission Unit, named "*submissionunit.xml*"
4. the text file providing the checksum (sha256) of the submissionunit.xml file, named "*sha256.txt"*,
5. the folder m1 and, as appropriate, m2 to m5
6. working-documents, if applicable; they are not subject to eCTD v4.0 rules, and they will always be sent outside the eCTD v4.0 package

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

1.2. Naming Conventions

The naming conventions for files and folders for EU Module 1 will be replaced by keywords using controlled vocabularies at the level of ***submissionUnit.component.contextOfUse***, which is also required for selective display of information. This also includes language and country information. Additional guidance is outlined in the ICH eCTD IG section 5.2.

The EMA recommends that the current file naming conventions as detailed in eCTD v3.2.2 validation criteria 8.2 worksheet File&Folder structure and filenames and the Appendix 2 in the Implementation Guide continue to be followed, for the purposes of documents/files being used outside of the eCTD review tools.

5.2 Naming Conventions

The naming convention for folders was modified for the eCTD v4.0 implementation. Refer to Section 11 for the complete folder naming conventions for Modules 2 – 5.

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

- Folder and file names should be written in lower case only.
- All file names should be unique within the folder. When files have specific naming requirements, additional folders may need to be added[14].
- All files should have one and only one file extension.
- The file extension should be used to indicate the format of the file.
- The First Level Folder should follow details of the respective Regional/Module 1 Implementation Guide.

5.2.1 Allowable Characters

All implementations shall follow the IETF rules for Uniform Resource Locators (URLs) (except for period and asterisk) for file or folder name. All alphanumeric characters are acceptable, and special characters should be limited to those in the table below.

Table 5: Allowable Special Characters

Special Character	Description
$	Dollar sign, Peso sign
-	Hyphen, Dash
_	Underscore, understrike, low line, low dash
+	Plus sign
!	Exclamation mark
'	Apostrophe, Single quotation mark
(	Left parentheses, Left bracket (UK)
)	Right parentheses, Right bracket (UK)

There are no additional requirements other than those outlined in the ICH eCTD IG for the length of names and the path.

1.3. First Level Folder Naming Recommendation

The first level folder structure is required to identify the content within it e.g. when on portable electronic media or after extracting compressed content from a container. The name of the folder should be the application number allocated by the EMA. Any punctuation (such as hyphens, slashes, underscore) should be removed from this name and the text should be in lower case. This first level folder naming convention is optional and should be at applicant discretion. Some examples are shown below:

- **ema000123** in case of the Centralised procedures EMEA/H/C/000123.

Error! Reference source not found.

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

1.4. Second Level Folder Naming Requirements

The second level folder name is the sequence number. The sequence number is a positive whole number between "1" and "999999". The first submission in eCTD v4.0 format will have sequence number "1". This allows storing incoming sequences on the file share in a simple way.

1.5. Pathname Conventions and Best Practices

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

1.6. Folder Hierarchy

Module 1 will be a single folder with no additional folder structure. Country, dosage, and strength information will be defined using keywords for Controlled Vocabulary and ContextofUse rather than folder structure.

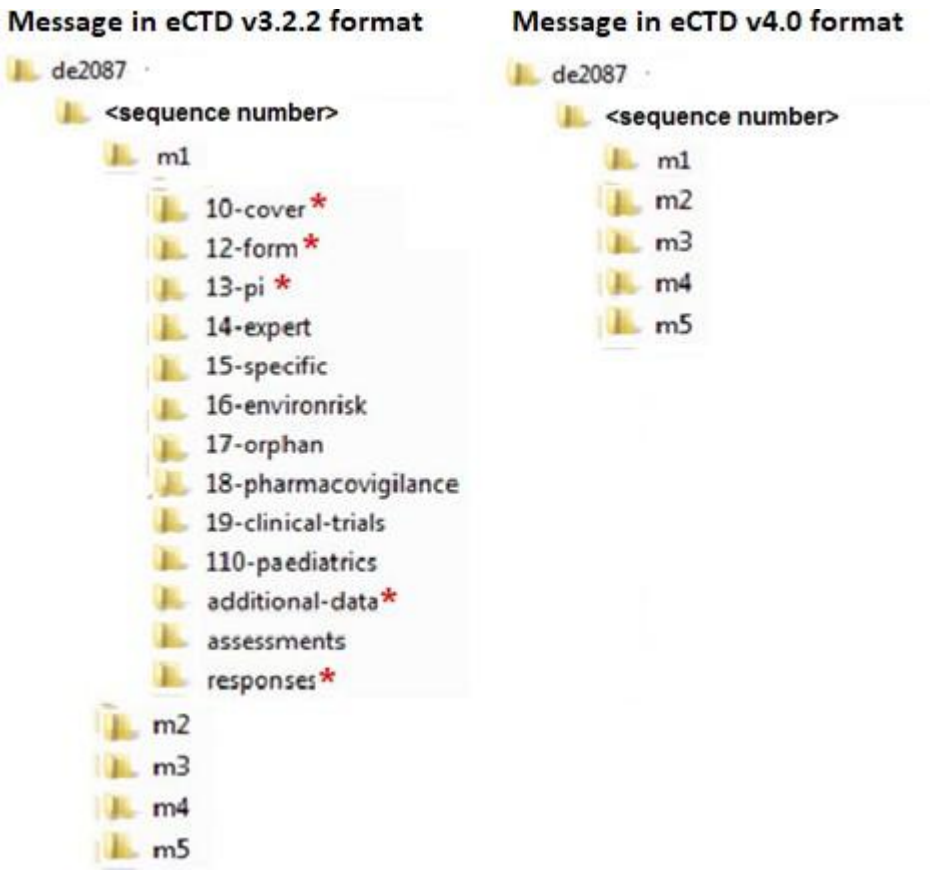


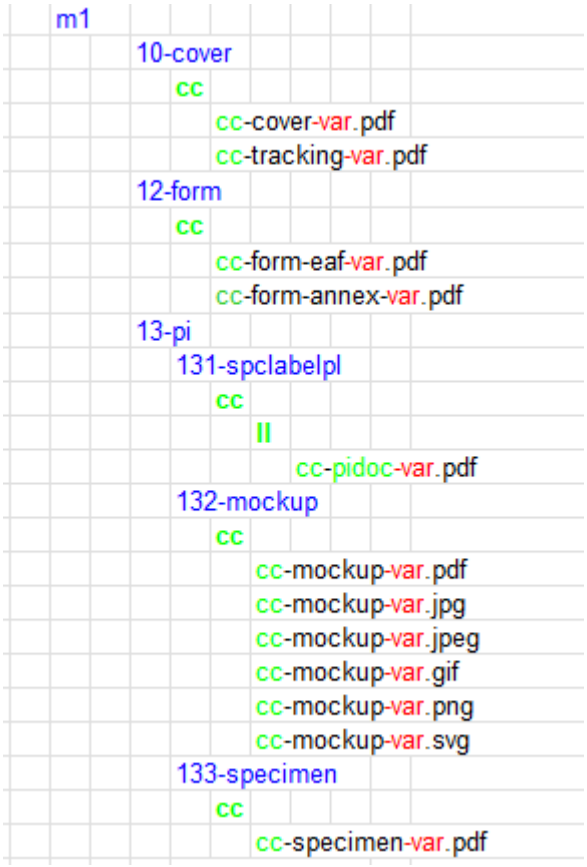
Figure 1 Folder Hierarchy of Module 1 Screenshot

1.7. File names convention

File names as defined in eCTD v3.2.2 on document level are to be followed validation criteria v8.2.

The examples in the annex – examples in blue are only to be used as a visual guidance under which keyword the filenames are to be used. These filenames are recommended to be used to enable the regulators to easily recognise the documents when they are used outside a review tool and context of use keywords are no longer available.

See example below:


m1
10-cover
cc
cc-cover-var.pdf
cc-tracking-var.pdf
12-form
cc
cc-form-eaf-var.pdf
cc-form-annex-var.pdf
13-pi
131-spclabelpl
cc
ll
cc-pidoc-var.pdf
132-mockup
cc
cc-mockup-var.pdf
cc-mockup-var.jpg
cc-mockup-var.jpeg
cc-mockup-var.gif
cc-mockup-var.png
cc-mockup-var.svg
133-specimen
cc
cc-specimen-var.pdf

2. CONTROLLED VOCABULARIES

The applicant should select the submission type “initial Marketing Authorisation” when applying for the Marketing Authorisation in eCTD v4.0 for the first time.

The submission unit: initial (i.e number 1) must contain a review identifier as stated in section “ 9.12 - Reviewer” (xml element 9.12.2.) of the European Implementation guide.

All related submission units as part of the Initial Marketing Authorisation does not contain a review identifier.

2.1. Keywords and Controlled Vocabularies for EU Purpose

Keywords need to be used to support a reader friendly presentation of content within the same context of us

2.1.1. Guidelines for Using Manufacturer Keywords and Document Reuse

Keywords

Keywords are optional. If one document applies to multiple contexts of use (e.g., multiple manufacturers), maintain a one-to-one relationship between the context of use and the keyword. Do not use generic keywords such as “all”. When needed, list the specific names directly in a single keyword field by concatenating them (e.g. for manufacturers: Uranus Ltd + Jupiter GmbH + Neptune Oy).

Using Keywords with Document Reuse

You can manage keywords in two ways:

1. Concatenate the applicable names in one keyword field, or
2. **Use the document reuse functionality, which allows you to:**
   - Share the same document across different contexts of use.
   - **Assign different keywords for the same document without physically duplicating** it in the submission unit (sequence) or application (dossier).

In the example 3.2.P.3 Manufacturer

Keywords are optional, using the keyword 'all' is not recommended, instead concatenate the names of the manufacturers in the same keyword (example: Uranus Ltd + Jupiter GmbH + Neptune Oy).

Optionally, the reuse of document functionality can be used to share document across different context of use elements where specific manufacturers can be used for each context of use.

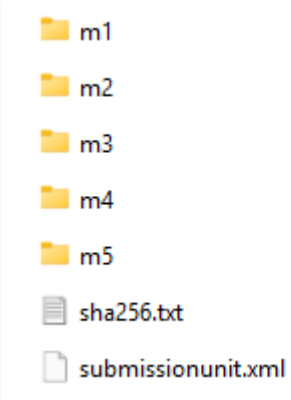
Please note that the upcoming M4Q reorganisation of modules 2 and 3 may suggest a revision of this section.

3. ECTD V4.0 XML MESSAGE

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

In eCTD 4.0, there is **no separate regional envelope data**, the only document applicant should submit is the submissionunit.xml.

Information such as regulatory activity, sequence, and product is tracked via **UUIDs** at different levels.



Please refer to the sample submissionunit.xml in this document and to the European Implementation Guide and validation criteria.

4. EU REGIONAL SPECIFIC REQUIREMENTS FOR ELEMENTS

4.1. Submission Unit

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

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

If a regulatory activity is withdrawn, fully or partially or rejected fully or partially, then the documentation must be updated accordingly with a **consolidation** submission unit. Context of Use elements and documents that are no longer relevant should be suspended, and context of use elements and documents where the content needs to be adjusted to reflect the withdrawal or rejection be replaced. The application form and cover letter should always be retained to keep the history. A consolidation submission unit should be submitted to restore the current view of the application to what it was before the rejected activity was submitted. This would also apply where documentation needs to be adjusted as a result of a commitment or a partially rejected variation. The submission type should be '**consolidating'**.
Note, in EU region it is not possible to delete/suspend a submission unit from the life cycle to accommodate the withdrawal or rejection.

4.2. Context of Use

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

*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.*

4.3. Territorial Authority (as primary information recipient related to contextofUse)

The optional element ***primaryInformationRecipient*** will provide names of ***territorialAuthority.governingAuthority*** in case a single ***contextOfUse*** element is dedicated to one agency separately. **For Centralised procedures** and in cases the Submission Unit contains documents for just one Concerned Member State, this means **the element should be ignored** as all documents will be relevant for all recipients of the message. In case of DCP or MRP, e.g. France may be named by using the ***primaryInformationRecipient*** element to restrict the display of the fee payment notification from ANSM to France.

4.4. Submission Reference

The Submission Reference is designed to permit the sender to specify that a ***contextOfUse element*** does not apply to that submission (regulatory activity). The ***submissionReference*** element indicates the previously started regulatory activity to which the ***contextOfUse*** element must not be assigned.

The ***submissionReference*** element applies when using Grouped Submissions functionality

Note: ***The SubmissionReference cannot be used for the Initial Marketing Authorisation application***

Note: The Submission Reference is only to be used with the Grouped submissions functionality and only when all the submitted documents do not apply to all applications included in the submissionUnit.xml

4.5. Keyword

The ***keyword*** element is used for the purpose of transmitting additional information about a ***contextOfUse*** element. In the EU M1, the Country Code will be used to specify commonly used or nationally used documents including the referenced files. The keywords to identify types of product information texts will be used for ***contextOfUse*** elements related to Module 1.

The ***keyword*** is either defined by an external controlled vocabulary, e.g. Document Type Code, Language Code or Country Code, or it may be defined within the message as ***keywordDefinition***. For EU M1, the latter principle will apply to ***contextOfUse*** elements referencing product information texts in order to sort them according to pharmaceutical form or strength if relevant.

The only keyword definition allowable for EU M1 is the one for strength (**eu_keyword_definition_type_2** in the EU CoU Keyword Definition Type controlled vocabulary). Please consult the controlled vocabulary package for further details on how the definition of the keyword is recommended to be built.

Note: The life cycle will be executed by inserting a new contextOfUse element including the respective combination of keywords and 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.

4.6. Submission

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

A Submission Unit may contain more than one submission, each referring to one application. This is relevant in the case of grouped variations or workshare procedures.

A Submission cannot be "suspended"

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

Remark: In the initial submission unit for an MAA, the regulatory activity number should be provided in the id.item@extension attribute. This is the expected format of the number: H0006213 (In the future IRIS number EMA/MAA/0000XXXXXX).

4.7. Contact Party

The ***callBackContact*** element is to be used for a person or department (***contactParty***) to contact if there are any questions. At least one Contact Party needs to be named per each Submission Unit.

When submitting an initial eCTD v4.0 submission unit for an application, a person (technical or non-technical) responsible for eCTD submissions communication should be included for the purpose of troubleshooting any issues (with for example the forward compatibility feature). The information should be sent for each technical or non-technical contact.

It can also be the person authorised for communication on behalf of the applicant during the regulatory activity (running procedure) (as detailed in the eAF), regardless of whether this is a member of staff of the applicant or of a third party acting on behalf of the applicant.

A submission should have one or more contacts provided. Contact(s) should be provided for each new regulatory activity and should include the appropriate regulatory and technical contacts. Only changes to the contact parties (additions, suspensions, or modifications (deletion is not possible)) should be provided in future submission units of the regulatory activity. Only the elements listed for the Contact Party are expected for each contact. If additional information is sent, it will be ignored by the receiving system.

4.7.1. Contact party lifecycle

The Contact Party for a Submission should be provided in the initial Submission Unit and any time the Contact Party is added, removed or contact information needs to be updated. To change the contact's type, suspend the previous contact and send a new contact party element with the new type. To assign more than one contact type for an individual, send multiple contact party elements. For Grouped Submissions, only one set of contacts should be provided under the primary application.

The following sections describe how to life cycle a contact's information for a Submission – i.e., suspending and updating one or more parts of the contact party's information.

Suspending a Contact

The contacts for a regulatory activity may change during the course of the submission review. If that happens and a contact is no longer active, the contact should be suspended.

When suspending a contact, the **contactParty** element should use the same **id@root** attribute value to identify the contact party and change to the status code from active to suspended using the **updateMode** attribute. The sample below shows the required elements and attributes:

```
<callBackContact>
        <contactParty>
                <id root="417e5c25-2001-40d1-af34-f1f285614187"/>
                <code code="200000043407" codeSystem="2.16.840.1.113883.3.6905.1.6.1"/>
                <statusCode code="suspended" updateMode="R" />
        </contactParty>
<callBackContact>
```

Note: Only the required elements for the contact party are sent when suspending a contact.

Updating Contact Information

When updating contact information, use the same **id@root** attribute value to identify the contact party and indicate the changed element by providing the **updateMode** attribute for that element. The following subsections outline the instructions for updating each element of the Contact's information. There is also a complete XML sample to show the use of the **updateMode** attribute.

Contact Person's Name

To make updates to a contact party's information, the entire ***callBackContact*** element should be sent. The values for the ***updateMode*** are indicated below depending on whether there is a change to the ***contactPerson.name*** element.

- For a change – indicate by using an "R" as the ***name@updateMode*** attribute value.
- For no change – indicate by using an "N" as the ***name@updateMode*** attribute value.

Contact Person's Telecom

To make updates to a contact party's information, the entire ***callBackContact*** element should be sent. The values for the ***updateMode*** attribute are indicated below depending on whether or not there is a change to the ***contactPerson.telecom*** element.

- For a change – indicate by using an "R" as the ***telecom@updateMode*** attribute value.
- For no change – indicate by using an "N" as the ***telecom@updateMode*** attribute value.

Represented Organization's Name

To make updates to a contact party's information, the entire ***callBackContact*** element should be sent. The values for the ***updateMode*** attribute are indicated below depending on whether or not there is a change to the ***representedOrganization.name*** element.

- For a change – indicate by using an "R" as the ***name@updateMode*** attribute value.
- For no change – indicate by using an "N" as the ***name@updateMode*** attribute value.

XML Sample – Updating Contact Party

The following XML snippet depicts how to send a change to the contact record. The contact's information should be complete each time it is submitted – i.e., each element of the contact's information is replaced by the update. Note that the ***id*** and ***code*** elements cannot be updated. If the ***id*** or ***code*** element is changed, the contact will not exist and therefore cannot be changed.

```
<callBackContact>
    <contactParty>
            <id root="417e5c25-2001-40d1-af34-1f285614187"/>
```

```
                    <code code="100000155054"
                          codeSystem="2.16.840.1.113883.3.6905.1.6.1"/>
                <statusCode code="active" updateMode="N"/>
            <contactPerson>
                <name updateMode="N">
                    <part type="GIV" value="Jane"/>
                        <part type="GIV" value="Mary" qualifier="MID"/>
                    <part type="FAM" value="Smith"/>
                </name>
                  <telecom xsi:type="BAG_TEL" updateMode="R">
                      <item value="tel:+34-999-999-999" use="WP" capabilities="voice"/>
                          <item value="tel:+44-999-9999-9999" use="MC" capabilities="voice"/>
                      <item value="tel:+33-9-99-99-99-99" use="WP" capabilities="fax"/>
                      <item value="mailto:jane.smith@acme.com"/>
                </telecom>
                <asAgent>
                    <representedOrganization>
                        <name updateMode="N">
                            <part value="Good Drugs"/>
                        </name>
                            </representedOrganization>
                </asAgent>
                </contactPerson>
            </contactParty>
        </callBackContact>
```

4.8. Review

The ***review*** element provides a unique ID and is related to the regulatory activity (as defined by the submission) and is associated with the holder and an author in the meaning of the ReferenceMember State or responsible authority, e.g. EMA in Centralised procedures, and refers to the product and the product category. This ID may be used for a proper connection to a case management system.

For a new marketing authorisation application, details on the product category and the manufactured product are required from the applicant. For any other Submission Unit type and submission types these attributes should be ignored.

4.8.1. Related Elements

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

- ***subject1.manufacturedProduct***
- ***holder.applicant***
- ***subject2.productCategory***

4.9. Manufactured Product

This element must be selected in the case of an eCTD v4.0 message concerning the initial Marketing Authorisation Application for a human medicinal product. This determines the assessment of a product in the national context within a DCP or MRP or may trigger internal

procedural decisions. Subsequent Submission Units related to authorised products do not need to provide this type of information repeatedly.

The ***manufacturedProduct*** element collects the name of the product by country and the active ingredients. This element may support internal workflow mechanisms but will not yet replace the annex 5.19 to the application form of the current Module 1.2 in the EU.

4.9.1. Related Elements

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

- ***manufacturedProduct.name***

  This element needs to be extended to assign the country where the product name is proposed to be used. For the Centralised Procedure this is the only element that is required to mention the invented name of the product in the name.part@value attribute. More information will follow in the cases of MRP and DCP.

- ***manufacturedProduct.ingredient***

  This element is restricted to classCode "ACTI", which means the active ingredient only.

Remark: We are currently clarifying how the update to a product name will be in the future submissions. At the moment update of the review element is not possible.

4.10. Product Category

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

4.11. Mode

The high-level handling of the information submitted as part of variation(s) and extension applications will be indicated by this element. The ***mode*** element should only be used in variation or extension regulatory activities and must be included in every sequence of that activity. The following are the valid modes:

- a single regulatory activity (e.g. a Type II variation),
- a grouped activity (e.g. several variations grouped into a single submission, a periodic report of type IA variations applicable to one or more marketing authorisations),
- an activity subject to a worksharing agreement (e.g. a Type II variation applicable to more than one marketing authorisation) and
- a PSUR single assessment procedure.

4.12. Application

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

this will be equivalent to all dosage forms and strengths covered by an EMA application number (e.g. EMEA/H/C/000123).

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

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

Several types of application can be differentiated as outlined in Annex 1 of the Directive 2001/83/EU and reflected in the ***code*** element .

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


An application cannot be "suspended"

4.13. Applicant

The ***applicant*** element is used to provide the sponsor details of a marketing authorisation application**.**

4.14. Territorial Authority (as information recipient related to application)

This element refers to the applicable recipients receiving the Submission Unit / Submission and being involved in the procedure. The recipients need to be named for each country where the medicinal product is applied to be marketed.

The ***territorialAuthority*** element indicates the country for which the authority decision will be relevant and which NCA is the recipient in cases where more than one is responsible to authorise medicinal products in one country, e.g. PEI for vaccines and BfArM for herbal medicinal products in Germany.

4.15. Review Procedure

The ***reviewProcedure*** element defines the type of procedure to assess the marketing authorisation application whether it is a Centralised, Decentralised, Mutual Recognition or purely National procedure.

4.16. Application Reference

The ***applicationReference*** element provides the type of reference for generic products. Therefore,

the element is required only where a reference need to be provided. The product confirming the data protection period has expired and the reference product being used in the bioequivalence study have to be stated. In all cases the authorisation number should be provided.

4.17. Document

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

Document elements (referencing e.g. PDF files) will be prepared by the sender, i.e. the Applicant, for review by the Regulatory Authority. A ***document*** element is applicable to one file and is referenced by one ***contextOfUse*** element. The same CoU element combinations may be used in multiple Submission Units (re-use of documents)[14]. Document Re-use using Forward Compatibility is detailed in ICH eCTD IG Section 9.2.17.1. Documents can be grouped using a group title provided with the ***contextOfUse*** element. To the ***contextOfUse*** element an additional label can be assigned if the document title is not instructive enough or too general or too detailed.

Coding of documents regarding confidentiality may be applied. For the time being this element remains optional as different business rules may apply in different member states. The confidentiality code is only able to indicate, that the content needs to be checked, and no other restrictions are applied if a document is sent with a specific confidentiality flag.

Remark: *Please do not send an updateMode for a document that contains both updateMode="R" and also includes one or more of the following:*

- *text@integrityCheckAlgorithm*
- *Text.integrityCheck*
- *reference@value*

4.17.1. Document Reuse

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

Document reuse will only be possible if the files has been previously submitted (just submitted and not approved) and are validly retained. Hence this functionality cannot be used widely in all NCAs (and EU procedures) until the Common Repository is set up for his purpose. However, can be used from the beginning for all EMA CAPs.

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

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

All the contents of the reused document, including references and hypertext links to other documents,

should be relevant to the submission that reuses the document.

The ***documentReference*** element provides the UUID of the document element to be re-used.

4.18. Keyword Definition

The ***keywordDefinition*** element is used by the sender to define a keyword that is referenced by an identifier in other parts of the message. For details see the ICH Implementation guide. The usage of this element is expected to be helpful in EU Module 1 for product information text to separate different strengths in addition to the keywords as mentioned earlier.

The purpose is to support presentation of content that shall be displayed together and will provide a meaningful orientation for reviewers.

The only keyword definition allowable for EU M1 is the one for strength (eu_keyword_definition_type_2 in the EU CoU Keyword Definition Type controlled vocabulary). Please consult the controlled vocabulary package for further details on how the definition of the keyword is recommended to be built.

4.18.1. Guidance regarding Keyword Definition values

For EU M1 currently one sender defined keyword type is in use: eu_keyword_definition_type_2. It is describing the strength of the manufactured pharmaceutical form. It consists of a value and the related unit of measurement (to be taken from SPOR-RMS: https://spor.ema.europa.eu/rmswi/#/lists/100000110633/terms if exists already).
The code "FIGURE_UNIT" reflects this concatenation, for example:

- 30_mg, 1_milligram(s)/millilitre
- 2500_anti-Xa activity International Unit(s)/millilitre

XML Samples

The following is an example of the XML for keywordDefinition element at application level and its use for a contextOfUse element at submissionUnit level.

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

<id/>
 <controlActProcess classCode="ACTN" moodCode="EVN">
        <subject typeCode="SUBJ">
                <submissionUnit>
                 <id root="c503dce7-d628-42c1-861a-ab738afe739d"/>
                        <code code="100000155047" codeSystem="2.16.840.1.113883.3.6905.1.8.1"/>
                        <title value="Initial"/>
                        <statusCode code="active"/>
                        <component>
                          <priorityNumber value="1800"/>

                          <contextOfUse>
                                <id root="d55b4f72-4fe7-462b-9720-dcb3b8ed988c"/>
                                <code code="100000164032" codeSystem="2.16.840.1.113883.3.6905.1.17.1">
```

Submission Unit

Context of Use

```
                    <originalText value="m1/131-smpc.pdf"/>
                  </code>
                  <statusCode code="active"/>
                  <derivedFrom>
                   <documentReference>
                     <id root="af90684b-8650-4b8f-aa49-dda2da086e6c"/>
                   </documentReference>
                  </derivedFrom>
                  <referencedBy typeCode="REFR">
                   <keyword>
                     <code code="100000155538" codeSystem="2.16.840.1.113883.3.6905.1.18.1"/>
                   </keyword>
                  </referencedBy>
                  <referencedBy typeCode="REFR">
                    <keyword>
                     <code code="100000000395" codeSystem="2.16.840.1.113883.3.6905.1.1.1"/>
                    </keyword>
                   </referencedBy>
              <referencedBy typeCode="REFR">
               <keyword>
                <code code="fr" codeSystem="2.16.840.1.113883.3.6905.1.16.1"/>
               </keyword>
              </referencedBy>
              <referencedBy typeCode="REFR">
                <keyword>
                  <code code="FIGURE_UNIT" codeSystem="CustomCodes1"/>
                </keyword>
              </referencedBy>
              <referencedBy typeCode="REFR">
               <keyword>
                 <code code="100000073665" codeSystem="2.16.840.1.113883.3.6905.1.14.1"/>

               </keyword>
              </referencedBy>
            </contextOfUse>
          </component>
          <componentOf1>
            <sequenceNumber value="1"/>
            <submission>
             <subject2>
               <review/>
             </subject2>
             <componentOf>
               <application>
                 <id>
<!-- ================================================-->
<!-- Root reflects the UUID introduced in eCTD v3.2.2. -->
<!-- Extension reflects the EU procedure number, in this example FR/H/9001/001/DC -->

<!-- ================================================-->
                    <item root="5f0e8436-e1df-4031-90d3-413deff109e5" extension="fr9001"/>
                  </id>

                  <component>
                   <document>
                    <id root="af90684b-8650-4b8f-aa49-dda2da086e6c"/>
                    <title value="Summary of Product characteristics"/>
                    <text integrityCheckAlgorithm="SHA256" language="en">
                      <reference value="m1/131-smpc.pdf"/>
<integrityCheck>aa3857911141cde703c4473241b7548a88b37ee1376a4dd9a224a9e0c0b5ff81</integrityCheck>
                    </text>
                    <confidentialityCode code="200000004985" codeSystem="2.16.840.1.113883.3.6905.1.15.1
"/>                                    </document>
                  </component>
                  <referencedBy>
                    <keywordDefinition>
          <code code="eu_keyword_definition_type_2" codeSystem="2.16.840.1.113883.3.6905.5.1.1"/>
                    <statusCode code="active"/>
                    <value>
                      <item code="FIGURE_UNIT" codeSystem="CustomCodes1">
                        <displayName value="150_mg" />
                      </item>
                    </value>
```

Document

Keywords for documents properties in its context of use

Keyword on product information document type

Keyword on country

Keyword on language

Sender defined keyword on strength

Keyword on manufactured pharmaceutical form

More details inbetween

More details inbetween

More details inbetween

More details inbetween

Referenced documents

Sender defined keyword definition

```
                    </keywordDefinition>
                  </referencedBy>
                </application>
              </componentOf>
            </submission>
          </componentOf1>
        </submissionUnit>
      </subject>
    </controlActProcess>
</PORP_IN000
```

Note to Implementers: It is not foreseen to re-submit keywordDefinition values in each sequence. However, sender defined keywords can be modified but will executed then for all applications making use of them.

5. Content Life Cycle Management (contextOfUse and Documents)

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

XML example:

```
<componentOf>
 <application>
        <!--  ================================================-->
        <!-- Additional information may appear after the Application.code, for example any-->
        <!-- of the following elements related to holder, informationRecipient, -->
        <!-- ReviewProcedure, Application.Reference-->
        <!--  ================================================-->
 <component>
  <document>
       <id root="88c5b0a4-8042-4110-a0c2-af8e51d87e26"/>
       <title value="Cover Letter"/>
       <text integrityCheckAlgorithm="SHA256" language="en" charset="utf-8">
        <reference value="../m1/common-cover-20120420.pdf"/>
        <integrityCheck>3285a776897425b9a3b87abbaaf163fb261242397997b003efe3201e</integrityCheck>
       </text>
       <confidentialityCode code="200000004985" codeSystem="2.16.840.1.113883.3.6905.1.15.1"/>
  </document>
 </component>
 <component>
     <document>
       <id root="b4db2ef3-cb0a-4fd7-be1c-2875e0ae7193"/>
       <title value="Tracking Table"/>
       <text integrityCheckAlgorithm="SHA256" language="en" charset="utf-8">
        <reference value="../m1/common-cover-tracking-20120420.pdf"/>
        <integrityCheck>3285a776xv745a25b9a3b87abbaaf163f726ec912423979
 97b003efe3201e</integrityCheck>
        <description value="Sender can describe the document in this field"/>
       </text>
  </document>
 </component>
 <component>
  <document>
       <id root="3bd2276d-fa45-47c7-9360-fa833cffbb1f"/>
       <title value="Expert Quality"/>
       <text integrityCheckAlgorithm="SHA256" language="en" charset="utf-8">
       <reference value="../m1/quality-meier.pdf"/>
       <integrityCheck>3285a776897425b9a3b877z45abbaaf1726ec912423979
 97b003efe3202e</integrityCheck>
```

```
        </text>
        <confidentialityCode code="200000004985" codeSystem="2.16.840.1.113883.3.6905.1.15.1"/>
    </document>
  </component>
  <component>
    <document>
        <id  root="0b4229b0-6c98-4fe9-9575-556019c12fc5"/>
        <title value="Expert Non-Clinical"/>
        <text  integrityCheckAlgorithm="SHA256"  language="en"  charset="utf-8">
        <reference  value="../m1/nonclinical-schulz.pdf"/>
        <integrityCheck>3285a776897425b9a3b87abbaaf163fb2646726ec912423979
   97b003efe3203e</integrityCheck>
        </text>
    </document>
  </component>
  </application>
</componentOf>
```

Appendix: XML Sample

Sample Submission Unit 1 for Centralised Procedure:

```
<?xml version="1.0" encoding="utf-8"?>
<PORP_IN000001UV xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:xsd="http://www.w3.org/2001/XMLSchema" xsi:schemaLocation="urn:hl7-org:v3 PORP_IN000001UV.xsd"
ITSVersion="XML_1.0" xmlns="urn:hl7-org:v3">
  <id />
  <creationTime />
  <interactionId />
  <processingCode />
  <processingModeCode />
  <acceptAckCode />
  <receiver typeCode="RCV">
    <device classCode="DEV" determinerCode="INSTANCE">
      <id>
        <item identifierName="ICH eCTD v4.0 IG v1.6" root="2.16.840.1.113883.3.989.2.2.1.11.5" />
        <item identifierName="EU M1 IG v1.2" root="2.16.840.1.113883.3.989.5.1.1.6.1.2" />
      </id>
    </device>
  </receiver>
  <sender typeCode="SND">
    <device classCode="DEV" determinerCode="INSTANCE">
      <id>
        <item />
      </id>
    </device>
  </sender>
  <controlActProcess classCode="ACTN" moodCode="EVN">
    <subject typeCode="SUBJ">
      <submissionUnit classCode="ACT" moodCode="EVN">
        <id root="31d77ef3-1846-4649-7dda-08de2032a0dc" />
        <code code="100000155047" codeSystem="2.16.840.1.113883.3.6905.1.8.1">
          <displayName value="Initial" />
        </code>
        <title value="Initial MAA" />
        <statusCode code="active" />
        <component typeCode="COMP">
          <priorityNumber value="1000" />
          <contextOfUse classCode="DOC" moodCode="EVN">
            <id root="8fa8f501-a815-4803-8227-08de2032a0dc" />
            <code code="ich_2.3.p" codeSystem="2.16.840.1.113883.3.989.2.2.1.1.5" />
            <statusCode code="active" />
            <derivedFrom typeCode="DRIV">
              <documentReference classCode="DOC" moodCode="EVN">
                <id root="7919ba12-5a04-43cf-8225-08de2032a0dc" />
              </documentReference>
            </derivedFrom>
            <referencedBy typeCode="REFR">
              <keyword classCode="OBS" moodCode="EVN">
                <code code="11e1e18c7101467e922650573e31481b" codeSystem="577f3b87c05e40048caa3bf9a6dea145" />
              </keyword>
            </referencedBy>
            <referencedBy typeCode="REFR">
              <keyword classCode="OBS" moodCode="EVN">
                <code code="455ea91770fe4390a504a9f8af470a81" codeSystem="48e5fed8b7b844aaa190ccc287c00220" />
              </keyword>
            </referencedBy>
          </contextOfUse>
        </component>
        <component typeCode="COMP">
          <priorityNumber value="1000" />
          <contextOfUse classCode="DOC" moodCode="EVN">
            <id root="1c2f90a3-8d17-4fcf-82cc-08de2032a0dc" />
            <code code="ich_2.3.s" codeSystem="2.16.840.1.113883.3.989.2.2.1.1.5" />
            <statusCode code="active" />
            <derivedFrom typeCode="DRIV">
              <documentReference classCode="DOC" moodCode="EVN">
                <id root="99f93263-2e98-4487-82ca-08de2032a0dc" />
              </documentReference>
            </derivedFrom>
```

Submission Unit elements

```
    <referencedBy typeCode="REFR">
      <keyword classCode="OBS" moodCode="EVN">
        <code code="5b5163b1700f4f9b8a163a5e5739ac7b" codeSystem="8598740322c644a29972ad53fe14ce07" />
      </keyword>
    </referencedBy>
    <referencedBy typeCode="REFR">
      <keyword classCode="OBS" moodCode="EVN">
        <code code="b67ebff3f5854f7bb549fb523f053a21" codeSystem="a1f51eaf16f54040bea88568affbc32d" />
      </keyword>
    </referencedBy>
  </contextOfUse>
</component>

    <!--  ================================================-->
    <!-- Additional Context of Use -->
    <!--  ================================================-->

<component typeCode="COMP">
  <priorityNumber value="1000" />
  <contextOfUse classCode="DOC" moodCode="EVN">
    <id root="d95a5a46-c11e-4cc6-ae2d-08de2032a0dc" />
    <code code="ich_3.2.s.1" codeSystem="2.16.840.1.113883.3.989.2.2.1.1.5" />
    <statusCode code="active" />
    <derivedFrom typeCode="DRIV">
      <documentReference classCode="DOC" moodCode="EVN">
        <id root="7f2fd88d-6d6b-4165-ae2b-08de2032a0dc" />
      </documentReference>
    </derivedFrom>
    <referencedBy typeCode="REFR">
      <keyword classCode="OBS" moodCode="EVN">
        <code code="5b5163b1700f4f9b8a163a5e5739ac7b" codeSystem="8598740322c644a29972ad53fe14ce07" />
      </keyword>
    </referencedBy>
    <referencedBy typeCode="REFR">
      <keyword classCode="OBS" moodCode="EVN">
        <code code="b67ebff3f5854f7bb549fb523f053a21" codeSystem="a1f51eaf16f54040bea88568affbc32d" />
      </keyword>
    </referencedBy>
  </contextOfUse>
</component>
<component typeCode="COMP">
  <priorityNumber value="2000" />
  <contextOfUse classCode="DOC" moodCode="EVN">
    <id root="bfd19655-6fb8-488c-b39e-08de2032a0dc" />
    <code code="ich_3.2.s.1" codeSystem="2.16.840.1.113883.3.989.2.2.1.1.5" />
    <statusCode code="active" />
    <derivedFrom typeCode="DRIV">
      <documentReference classCode="DOC" moodCode="EVN">
        <id root="aca1c64b-798c-41e3-b39c-08de2032a0dc" />
      </documentReference>
    </derivedFrom>
    <referencedBy typeCode="REFR">
      <keyword classCode="OBS" moodCode="EVN">
        <code code="5b5163b1700f4f9b8a163a5e5739ac7b" codeSystem="8598740322c644a29972ad53fe14ce07" />
      </keyword>
    </referencedBy>
    <referencedBy typeCode="REFR">
      <keyword classCode="OBS" moodCode="EVN">
        <code code="b67ebff3f5854f7bb549fb523f053a21" codeSystem="a1f51eaf16f54040bea88568affbc32d" />
      </keyword>
    </referencedBy>
  </contextOfUse>
</component>
<component typeCode="COMP">
  <priorityNumber value="3000" />
  <contextOfUse classCode="DOC" moodCode="EVN">
    <id root="4301dc00-246c-4792-b93f-08de2032a0dc" />
    <code code="ich_3.2.s.1" codeSystem="2.16.840.1.113883.3.989.2.2.1.1.5" />
    <statusCode code="active" />
    <derivedFrom typeCode="DRIV">
      <documentReference classCode="DOC" moodCode="EVN">
        <id root="df0c78eb-8a97-41ab-b93d-08de2032a0dc" />
      </documentReference>
```

```
    </derivedFrom>
    <referencedBy typeCode="REFR">
      <keyword classCode="OBS" moodCode="EVN">
        <code code="5b5163b1700f4f9b8a163a5e5739ac7b" codeSystem="8598740322c644a29972ad53fe14ce07" />
      </keyword>
    </referencedBy>
    <referencedBy typeCode="REFR">
      <keyword classCode="OBS" moodCode="EVN">
        <code code="b67ebff3f5854f7bb549fb523f053a21" codeSystem="a1f51eaf16f54040bea88568affbc32d" />
      </keyword>
    </referencedBy>
  </contextOfUse>
</component>

    <!-- ================================================-->
    <!-- Additional Context of Use -->
    <!-- ================================================-->

<componentOf1 typeCode="COMP">
  <sequenceNumber value="1" />
  <submission classCode="ACT" moodCode="EVN">
    <id>
      <item extension=" H0001234" root="9f020845-b2fa-4005-7dd8-08de2032a0dc" />
    </id>
    <code code="100000155689" codeSystem="2.16.840.1.113883.3.6905.1.11.1">
      <displayName value="Initial Marketing Authorisation Application" />
    </code>
    <callBackContact typeCode="CALLBCK">
      <contactParty classCode="CON">
        <id root="13885fad-7521-449b-7ec0-08de2032a0dc" />
        <code code="100000155054" codeSystem="2.16.840.1.113883.3.6905.1.6.1">
          <displayName value="Proposed Marketing Authorisation Holder/Person" />
        </code>
        <statusCode code="active" />
        <contactPerson classCode="PSN" determinerCode="INSTANCE">
          <id />
          <name>
            <part value="Dr.Academic" qualifier="AC" type="FAM" />
          </name>
          <telecom xsi:type="BAG_TEL">
            <item value="contact@domain.com" />
          </telecom>
          <asAgent classCode="AGNT">
            <representedOrganization classCode="ORG" determinerCode="INSTANCE">
              <id />
              <name>
                <part value="Organisation name" />
              </name>
            </representedOrganization>
          </asAgent>
        </contactPerson>
      </contactParty>
    </callBackContact>
    <subject2 typeCode="SUBJ">
      <review classCode="REV" moodCode="RQO">
        <id root="f6569c3c-6d8b-4f63-7f12-08de2032a0dc" />
        <statusCode code="active" />
        <subject1 typeCode="SBJ">
          <manufacturedProduct classCode="MANU">
            <id root="61b30ec9-015f-45d2-7f13-08de2032a0dc" />
            <manufacturedProduct classCode="MMAT" determinerCode="KIND">
              <code code="100000073380" codeSystem="2.16.840.1.113883.3.6905.1.14.1">
                <displayName value="Coated tablet" />
              </code>
              <name>
                <part language="en" value="WonderDrug" />
              </name>
              <ingredient classCode="ACTI">
                <ingredientSubstance classCode="MAT" determinerCode="KIND">
                  <name>
                    <part code="123456" codeSystem="2.16.840.1.113883.3.6905.2.1" value="Paracetamol" />
                  </name>
                </ingredientSubstance>
```

Submission elements with the regulatory activity number

Contact party elements

Review element

Manufactured product element

Manufactured product invented name

Ingredient elements

```
        </ingredient>
       </manufacturedProduct>
      </manufacturedProduct>
     </subject1>
     <author typeCode="AUT">
      <territorialAuthority classCode="TERR">
       <governingAuthority classCode="PUB" determinerCode="INSTANCE">
        <id root="40ea9fd2-9622-4af9-7f19-08de2032a0dc" />
        <name>
         <part code="100000160628" codeSystem="2.16.840.1.113883.3.6905.1.12.1" />
        </name>
       </governingAuthority>
      </territorialAuthority>
     </author>
     <subject2 typeCode="SUBJ">
      <productCategory classCode="CATEGORY" moodCode="EVN">
       <code code="100000155527" codeSystem="2.16.840.1.113883.3.6905.1.9.1">
        <displayName value="Chemical Medicinal Product" />
       </code>
      </productCategory>
     </subject2>
    </review>
   </subject2>
   <subject3 typeCode="SUBJ">
    <mode classCode="POLICY" moodCode="EVN">
     <code code="100000155554" codeSystem="2.16.840.1.113883.3.6905.1.10.1">
      <displayName value="Single Regulatory Activity" />
     </code>
    </mode>
   </subject3>
   <componentOf typeCode="COMP">
    <application classCode="ACT" moodCode="EVN">
     <id>
      <item extension="EMEA/H/C/001234" root="5dc66589-d24f-406d-9aba-3e5796024330" />
     </id>
     <code code="100000116047" codeSystem="2.16.840.1.113883.3.6905.1.4.1">
      <displayName value="New active substance (Article 8(3) of Directive No 2001/83/EC)" />
     </code>
     <holder typeCode="HLD">
      <applicant classCode="SPNSR">
       <sponsorOrganization classCode="ORG" determinerCode="INSTANCE">
        <id>
         <item extension="123456789" root="213456789" />
        </id>
        <name>
         <part value="Org Name" />
        </name>
       </sponsorOrganization>
      </applicant>
     </holder>
     <informationRecipient typeCode="IRCP">
      <territorialAuthority classCode="TERR">
       <territory classCode="PLC" determinerCode="INSTANCE">
        <code code="100000000390" codeSystem="2.16.840.1.113883.3.6905.1.1.2">
         <displayName value="European Union" />
        </code>
       </territory>
       <governingAuthority classCode="PUB" determinerCode="INSTANCE">
        <id root="efde1eac-f0b3-472d-7e56-08de2032a0dc" />
        <name>
         <part code="100000160628" codeSystem="2.16.840.1.113883.3.6905.1.12.1" value="EU-EMA" />
        </name>
       </governingAuthority>
      </territorialAuthority>
     </informationRecipient>
     <subject typeCode="SUBJ">
      <reviewProcedure classCode="POLICY" moodCode="EVN">
       <code code="100000155059" codeSystem="2.16.840.1.113883.3.6905.1.7.1">
        <displayName value="Centralised Procedure" />
       </code>
      </reviewProcedure>
     </subject>
     <component typeCode="COMP">
```

Application elements with the sample application number

Applicant elements

Information recipient as part of the application – For CP: Territory code for European Union) and Governing Authority (code for EU-EMA)

Review procedure elements

Sample Document element

```
            <document classCode="DOC" moodCode="DEF">
              <id root="7919ba12-5a04-43cf-8225-08de2032a0dc" />
              <title value="2.3.P Drug Product - Non-granular - Tablet - Pharm - 2" />
              <text integrityCheckAlgorithm="SHA256">
                <reference value="m2/2-3-p-drug-product---non-granular---tablet.pdf" />
                <integrityCheck>C791A8A068A69CCC54B5F3D320F7F8C6455283C7598F263CE18A2DD2888DD5EF
</integrityCheck>
              </text>
            </document>
          </component>
          <component typeCode="COMP">
            <document classCode="DOC" moodCode="DEF">
              <id root="99f93263-2e98-4487-82ca-08de2032a0dc" />
              <title value="2.3.S Drug Substance - Non-granular -CHFT" />
              <text integrityCheckAlgorithm="SHA256">
                <reference value="m2/2-3-s-drug-substance---non-granular--chft.pdf" />
                <integrityCheck>D093775C7EFE583E93648F4B8A9D6603500E9D227E551E91A7D78A99296FF78C</integrit
yCheck>
              </text>
            </document>
          </component>

        <!--  ================================================-->
        <!-- Additional documents-->
        <!--  ================================================-->
```

Sample Keyword definition element

```
          <referencedBy typeCode="REFR">
            <keywordDefinition classCode="OBS" moodCode="DEF">
              <code code="ich_keyword_type_2" codeSystem="2.16.840.1.113883.3.989.2.2.1.5.4" />
              <statusCode code="active" />
              <value>
                <item code="5b5163b1700f4f9b8a163a5e5739ac7b"
codeSystem="8598740322c644a29972ad53fe14ce07">
                  <displayName value="Paracetamol" />
                </item>
              </value>
            </keywordDefinition>
          </referencedBy>

        <!--  ================================================-->
        <!-- Additional keyword definitions-->
        <!--  ================================================-->

          </application>
        </componentOf>
      </submission>
    </componentOf1>
  </submissionUnit>
 </subject>
</controlActProcess>
</PORP_IN000001UV>
```