

**ELECTRONIC APPLICATION FORM**  
**SUPPLEMENTARY SPECIFICATION**  
**DATA EXCHANGE STANDARD 2.0**  
**ITERATION 4**  
**[DRAFT]**

15.4, CURRENT, LOGO

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## ABSTRACT

The Data Exchange Standard (DES) document was written in the context of the electronic Application Form (eAF) project sponsored by the EMEA. This initiative is part of the eCTD program.

The DES describes the framework in which eAF authoring tool, eAF validation tools and eAF receiving tools were developed to support the Application Forms submission process.

DES should help facilitate communication between heterogeneous audiences (Applicants, NCA's, NtA's, EMEA, etc...) for future modifications to the supported Application Forms and to the DES itself.

DES is also a framework for IT audience for tools development and design. and as a reference for the business to gather business rules and requirements..

## 1. DOCUMENT PURPOSE

The purpose of this document is to describe the Data Exchange Standard version 2.0 supporting the electronic Application Form (eAF) for all application forms used between the applicants and the EMEA. The first release of the standard will support the following forms:

- “Application Form for Medicinal Product for human use” (released may 2008),
- “Application form for Medicinal Product for Veterinary Use” (released October 2008),
- “Application for Variation to a Marketing Authorisation” (released may 2008) and
- “Application for Renewal of a Marketing Authorisation” (released February 2007).

This document also contains partial information about the DES 2.0 to provide the reader with some trends of the next release of this document to be in line with RDM V3.

The Data Exchange Standard defines the way to structure an Application Form information, using a standard model specification and describes the all the concepts that may be used to structure the information to be exchanged between parties.

### 1.1. How to read this document.

sections 1 to 4 give the big picture of the DES 2.0 and how it is built.

Section 5 gives a high level description of the different models involved in the DES 2.0

Section 6 gives a detailed descriptions of the elements you may use, about their definition, data types and the related common business rules when occurs.

You may use this document as-is or with the annexes when you have to analyse a supported form (see document purpose).

The annexes are form specific and indicate:

- how the model elements are mapped to the application form fields
- what are this document technical concepts involved
- what are the business main rules to apply for that specific form.

## 2. ACTORS

The table below lists potential audience interested in the DES.

Industry – Pharmaceutical Companies
EMEA / NCAs – Central Information Group (CIG)
EMEA / NCAs – Product Review Team
EMEA / NCAs – Scientific / Business Stakeholders
EMEA / NCAs – Data Administrator
EC – DG ENTR
EMEA – Project Management (PM)
EMEA – IT

*[DES 2.0: add the picture of the group and their responsibilities outside for the project and after DES 2.0 delivery]*

### 3. CONTEXT

Currently information provided as part of the various Application Forms is submitted in PDF or MS Word format. The absence of structured data in these files reduces the chances of automation regarding the validation and review, and raises issues in terms of interoperability with other systems (i.e. need to manually copy data from application forms to other systems).

The main rationale of the eAF systems is to capture, submit, validate, review and store such information in structured format, for the entire submission chain. To do so, the application form needs to be structured the same way for information producers (i.e. applicants) and consumers (i.e. regulators). This common structure is assured by defining a unique Data Exchange Standard (a global framework) for all application forms, assuring the features of the architecture framework described below.

### 3.1. Legislation

The legislative bases for the implementation of the Electronic Application Form project lie mainly in the following Directives and Regulations:

- Directive 2001/82/EC of the European Parliament and of the Council of 06/11/2001 on the /Community code relating to veterinary medicinal products
- Directive 2001/83/EC of the European Parliament and of the Council of 06/11/2001 on the Community code relating to medicinal products for human use
- Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16/12/1999 on orphan medicinal products
- Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31/03/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency
- Regulation (EC) No 847/2000 of 27/04/2000 laying down the provisions for implementation of the criteria for designation of a medicinal product as an orphan medicinal product
- Regulation (EC) No 1084/2003 of 03/06/2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products granted by a competent authority of a Member State
- Regulation (EC) No 1085/2003 of 03/06/2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products falling within the scope of Council Regulation (EEC) No 2309/93
- Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12/12/2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004
- Regulation (EC) No 1902/2006 of the European Parliament and of the Council of 20/12/2006 amending Regulation 1901/2006 on medicinal products for paediatric use
- Regulation (EC) No 2309/93 of 22/07/1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products
- Regulation (EEC) No 2377/90 of 26/06/1990 laying down a Community procedure for the establishment of maximum residue limits for veterinary medicinal products in foodstuffs of animal origin.

### **3.2. EU Telematics Strategy**

The European Union Telematics Strategy for pharmaceuticals is agreed between Member States, the EMEA, and the European Commission. In order to implement European pharmaceutical policy and legislation, the various initiatives aim to increase efficiency, enhance transparency, and support and facilitate the operation of procedures established by legislation.

The "Telematics Master Plan" document details the objectives and requirements for information technology (IT) tools to implement European pharmaceutical policy and legislation.

The objective of the Electronic Application Form project is to better support the review process of the administrative data of medicinal product submitted, and to increase the coherence between those data so as to assure the interoperability of information within the European Regulatory Medicine Network, with the Pharmaceutical Industry and ultimately the Public.

### **3.3. Transparency policy**

One of the principal drivers underlying the EU Telematics Strategy is a requirement for greater transparency. The proposed Electronic Application Form system is one of the tools to be employed in achieving this objective by collecting together and making available authoritative data to stakeholders.

### **3.4. Support for regulatory activities**

The EU Telematics Strategy also foresees practical support for the operation of procedures through electronic networking, coordination and management. The proposed Electronic Application Form system will support the regulatory activities by providing a controlled and secured environment for the review process of administrative data.

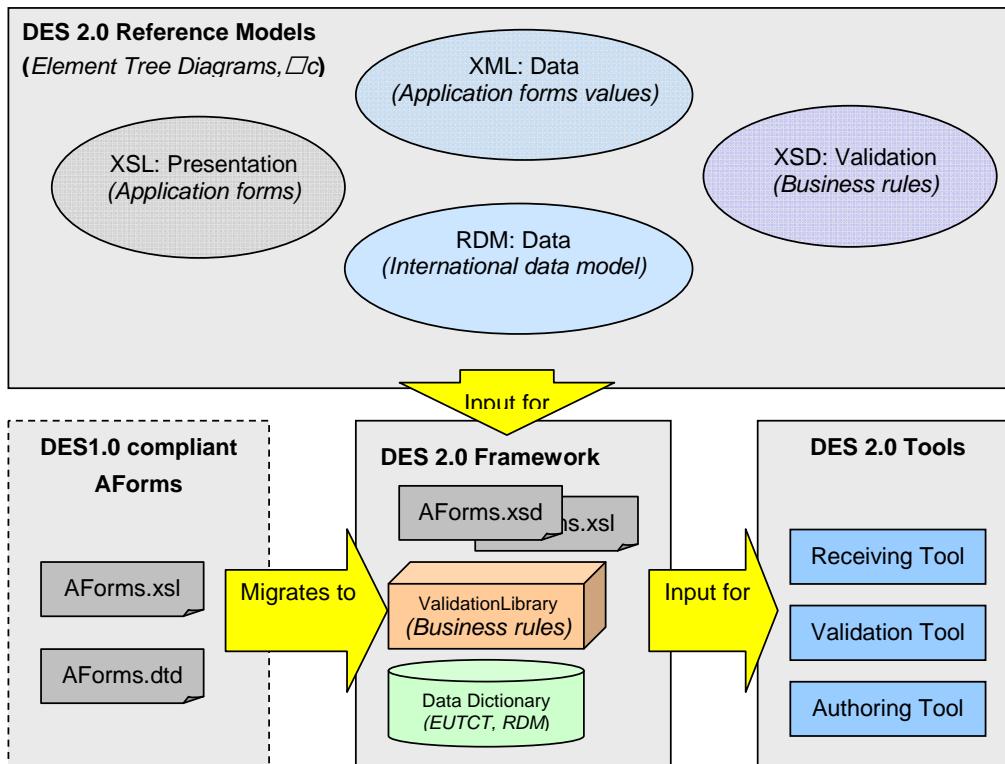
## 4. ARCHITECTURE FRAMEWORK

### 4.1. Definition

This DES 2.0 encompass all the necessary objects to build the eAF model. The DES 2.0 framework is built upon the Reference Data Model and the Common Application form Model.

- DES 2.0 Documents describe
  - The data and architecture models used as a base for the framework (Reference models are described in this document and in the annexes)
  - The constraints and rules for both data and architecture information. They are described in the Reference models and implemented in the XSD and validation libraries.
  - The common approved way of managing data and architecture information. (see LifeCycle management)
- The other deliverables composing the Framework (libraries, configuration files,...)
  - Data libraries:: Contains the data information used for authoring and validation (EUTCT lists,...)
  - Validation libraries:: Contains all the business rules used to validate the structure, some values and formats the supported eAFs See graphic below:

The following diagram describes the different constituents of the DES2.



## 4.2. Paper form compliance

The first release of this document supports a series of application forms:

Form Name	Version
Marketing Authorisation (Human)	May 2008
Marketing Authorisation (Veterinary)	October 2008
Variation (Human and veterinary)	July 2007
Renewal (Human and veterinary)	July 2007

To assure the compliance of form standard model with its paper counterpart, it seems more efficient to design a standard model per application form. However, as the electronic application forms will all be handled by the same set of tools, it is also important to base the standard models on the same framework. This framework determine the way to approach common topics, like [the inclusion of controlled terms \(cf. next section\)](#), [the alignment to RDM](#), or technical concerns like the storage of dates, Boolean values... [The way to support identification, tracking and life cycle management should be addressed at the framework level as well.](#)

Compliance will be guaranteed if standard models are accompanied with style-sheet that allows the rendition of the application form similar to the paper form. At the level of the Data Exchange Standard, the style-sheet is designed to be run from within a standard browser, Microsoft Internet Explorer (IE) and Mozilla FireFox (FF) at least.

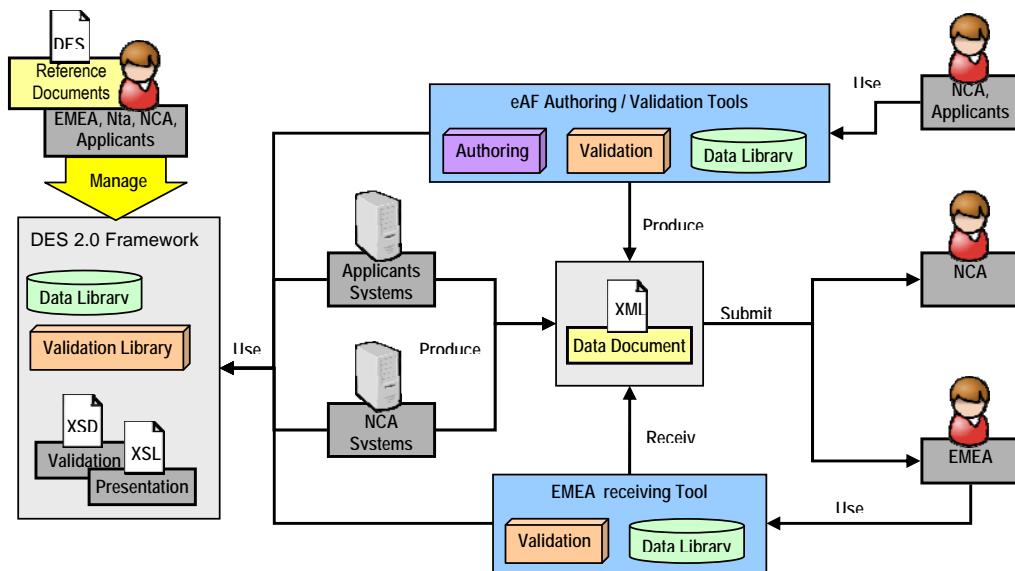
### 4.3. Interaction with eAF Systems

The eAF Systems, i.e. Authoring Tools, Validation Tool and EMEA Receiving Tool, will have to be able to use (import and export) information compliant to the Data Exchange Standard (DES)

The effective storage of the information and the structure of the information within systems (i.e. to run their processes) can be different than the DES. This is a matter of system design. At least the boundaries of each system must be compliant to the DES, when exchanging information between stakeholders (applicants and regulators).

Defined standards that can be used (produced and consumed) by the eAF systems: see (paragraph 4.1.)

The DES plays a role at all levels of the exchange and management of the information (see below)



## 4.4. Interoperability

Current DES interoperability with other systems and databases

*Interoperability with other systems and databases is guaranteed by the validation module composed of an XML Schema and a set of business.*

*To assure the interoperability of information within the EMRN, it is essential to base the standards on RDM V2.2 and EUTCT.*

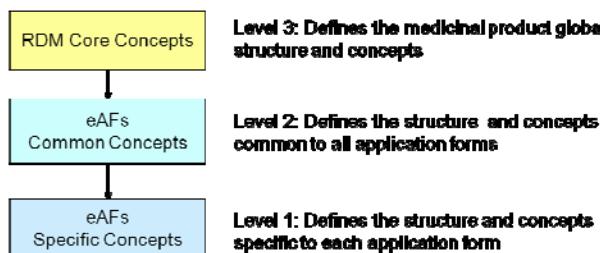
- RDM provides a reference structure of the standard models so that it can be used the same way within the EMRN (semantic interoperability). See [to be added] application form concepts to the Core Concepts of RDM
- EUTCT will provide a set of controlled terminologies to be used within the application forms, limit the use of free texts, and then increase the quality of data within the EMRN.

Note

*There have been concerns about the possibility to retrieve for a given applicant non-public terms that have been entered by that applicant. Such approach would require authentication of the applicant, which is not foreseen (and necessary) at the moment. Also the cases when such circumstances would appear are deemed to be quite rare, as terms would quickly become public for patent reasons.*

levels of interoperability

- Level 3: High interoperability is required for the concepts describing the medicinal product (RDM core concepts) and the major processes linked to it (Pharmacovigilance, Clinical-trials, GMP,...)  
The Level 1 information is recognized by other systems than the eAF.
- Level 2: Medium interoperability is required for the concepts describing the concepts used in most application form (declaration, legislation, references,...)  
The Level 2 information is recognized only by eAF systems
- Level 1: No interoperability is required for the information used only in a specific application form.



## 4.5. Life Cycle Management

The following points should be addressed to manage the delivery of the DES2.0 constituents. Lifecycle would be different for the Reference documents than for the technical deliverables (Libraries and tools)

Following aspects of each lifecycle will be addressed: Version Control, Decision process, Activities, Timelines

## 4.6. Information Tracking

The approach of the eAF DES is to rely on a single system to receive different application forms. Therefore, features must be provided to easily identify application forms and track them over time.

Such information should be provided as part of the framework, within an envelope (i.e. metadata for the electronic application form). The envelope should contain:

- Type of application form
- Identification of the application form to manage amendments (version number or release date)
- Identification of sender and receiver(s)
- High-level identification of the medicinal product (name, form, strength, substance; possibly according to IDMP principles)
- Identification of the procedure type (CP, MRP, DCP, or NP) and application type (e.g. New, Variation IA...)

Tracking information is very important to provide necessary metadata on the application form, so as to support the storage at the correct location, the easy retrieval from the Receiving Tool, e.g. by filtering one or several constituents of the tracking information.

## 4.7. Relation with World-wide Standards

The standard used for DES is the XML (eXtended Markup Language) that is a subset of SGML (Standard Generalized Markup Language (ISO 8879:1986 SGML)), designed so as to make the parser much easier to implement than a full SGML parser. A consequence of the ease of implementation is that XML, rather than SGML, is widely used for deriving document specifications.

Information submitted along the application form should be compliant with RDM but also with the IDMP message (identification of medicinal products).

The eAF standard models should adopt the same structure, which is deemed to also be in line with RDM.

The eAF standard models should also adopt the identification foreseen in IDMP, for medicinal products (MedID) and for pharmaceutical products (PhPIDs). These would facilitate the interoperability within the EMRN and beyond.

## 5. THE STANDARD MODELS

### 5.1. The W3C Element Tree Diagram

The standard model used refers to the one used by W3C (World Wide Web Consortium XML Specification DTD ("XMLspec") for its publication standard issued in 1998.

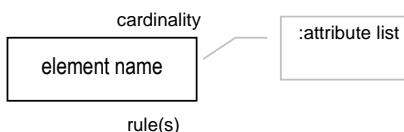
#### 5.1.1 Elements

Any piece of information that is relevant for the communication of information between the sender and the receiver should be included in the ETD. The smallest piece of information having a semantic signification is called an "element" (e.g. "invented-name").

An element may also have sub-elements with a more specialised signification.

Note: An element is also referred to as a "tag" in an XML file.

##### 5.1.1.1 General notation



**element name** represents the name of an element. The element is represented by a square box

**cardinality** tells what is the occurrence of the element in a specific structure. It can be optional, mandatory, unique or repeatable

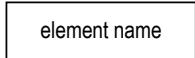
**attributes list** indicate the business requirement for the following:

- attribute value data type
- attribute value format

**rules** indicate the business requirement for the following:

- element value data type
- element value format
- element dependencies with other elements

##### 5.1.1.2 Default representation



**element name** is mandatory

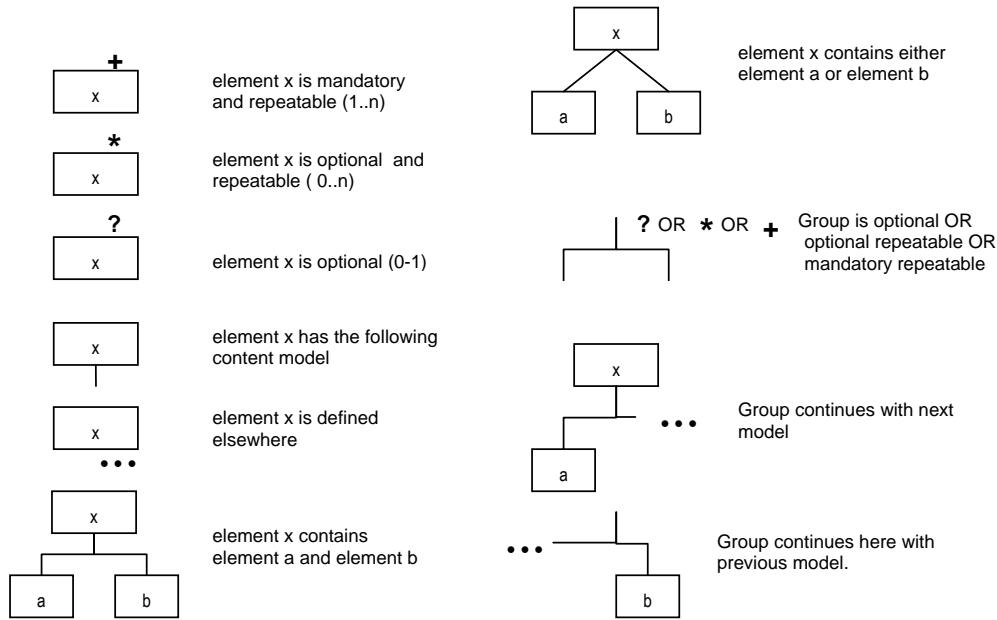
**cardinality** is left blank: means "one and only one"

**attribute list** is left blank: means "no attributes"

**rules** are left blank: means the element MUST be empty (no value and no attribute(s))

## 5.1.2 The W3C model

This model is fixed and may not be changed as it is part of an existing public model.



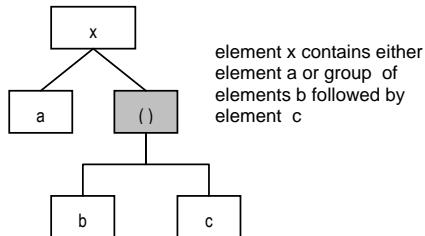
### 5.1.3 Customized patterns of the eAF

The standards have been tailored to the eAF modelling needs and the legend of the model is described below.

The patterns for rules are described in paragraph below.

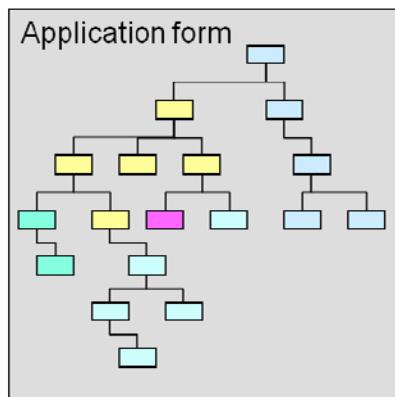
#### Customized patterns

	Element x must be empty and has no attribute.
	Element x is used only as a node.
	element x has been moved between versions
	element x is a new element .
	element x has been deleted .in the new version



#### Element backgrounds patterns

	Light Yellow: Level 3 RDM Core concepts
	Light Purple: Level 3 RDM Clinical Trials
	Cyan: Level 3 RDM GMP
	Light Green: Level 2 Common Application Form (CAF)
	Light blue: Level 1 Specific Application Form (SAF)

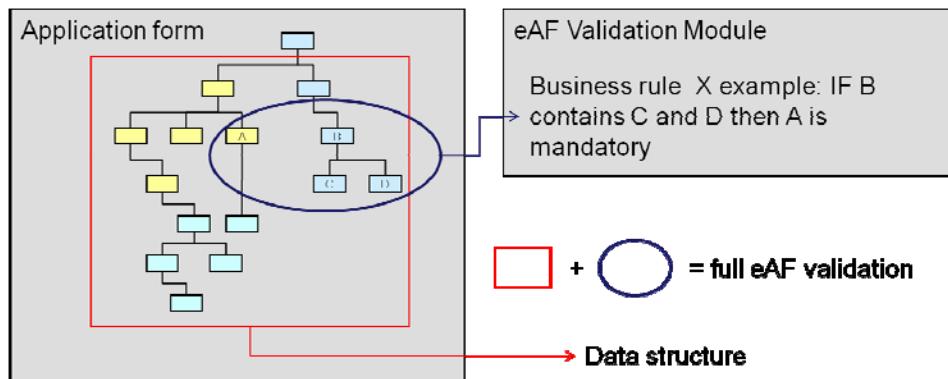


## 5.1.4 Business Rules

The business rules bring specific business constraints to the model of information:

- Business rules cover only conditional constraints between elements or element values.
- The business rules are apart from the data structure which is defined in the "XML schema"

There are 2 levels of business rules. As defined in the picture below.



### 5.1.4.1 Business Rules Notation

All the rules are gathered with their corresponding Element Tree Diagram (ETD) and are defined as follows

**Element:** The name of the element mentioned in the (ETD)

**Default Cardinality:** Cardinality that applies by default. It corresponds to the cardinality of the concerned element in the ETD

**Rule:** Description of the condition to be evaluated.

**Effect:** if the condition is evaluated to true then the effect is applied

Example:

Business Rules			
Element	Default Cardinality	Rule	Effect(s)
declaration	optional	If the product is the root element.	mandatory

## 5.1.5 Validation

The validation is based on rules derived from the interpretation of the business rules present in the application forms and defined by legislations and the business. Validation brings boundaries for form structure and how it should be filled.

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Validation does not verify the values semantic. This is the responsibility of the business to verify the application form values.

Validation is built on a three tier concept.

Level 1: Element validation (data structure)

The validation is done only on an element or on the relationship between two elements. This includes the following validations:

- The existence (non-existence) of an element
- The family hood of an element (parent, ancestor, child, brother).
- The logical link (XOR, OR, AND) between two or more elements

Level 2 : Core values, formats & constants (basic business rules)

Core list of values and formats are defined for the electronic application form only and used only inside or across the supported forms. (e.g. Yes/No; numeric; >0 ;...).

eAF only means that the validation is controlled and managed within the eAF with no business link to another model or standard (like RDM).

This includes the following validations:

- The eAF only predefined lists (Yes/No; Checked, Not Checked, not applicable;...)
- The eAF only predefined formats (numeric; Date;...)
- The eAF only predefined constants (ZERO(0), EMPTY(""), LARGE(500), MEDIUM(50), LOW (10);...)
- The relation between one of the rule above and the level 1 validation.

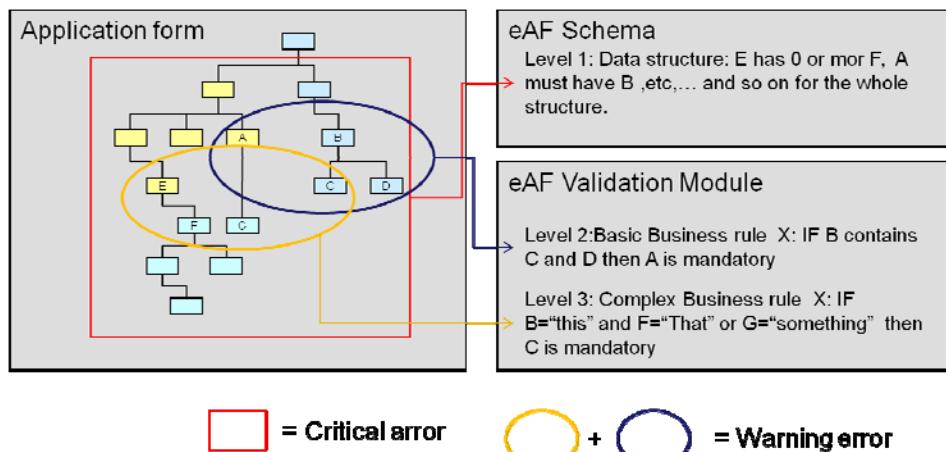
Level 3: Internally managed CTLs values (complex business rules)

The validation is done based on public CTLs and between .

This includes the following validation.

- The logical link (XOR, OR, AND) between 2 CTL values
- The relation between the rule above and the level 1 validation.
- The relation between one of the rules above and the level 2 validation.

Illustration example:



#### 5.1.5.1 Data type rules for Elements or Attributes values

Rules for values only	Value in XML file
/ text(number of characters)	The value must be characters with a maximum length of "number of characters")
/ :<common attribute(s)>	The value must be of the format of the specified common attribute(s)

#### 5.1.5.2 Presentation

The presentation is the way the data information (XML values) is displayed to the user by means of visual media. In the context of the electronic application form, the presentation should reflect the last published version of the paper application form. The media is an internet Browser or Adobe acrobat reader.

## 5.2. How to apply the DES 2.0 standards

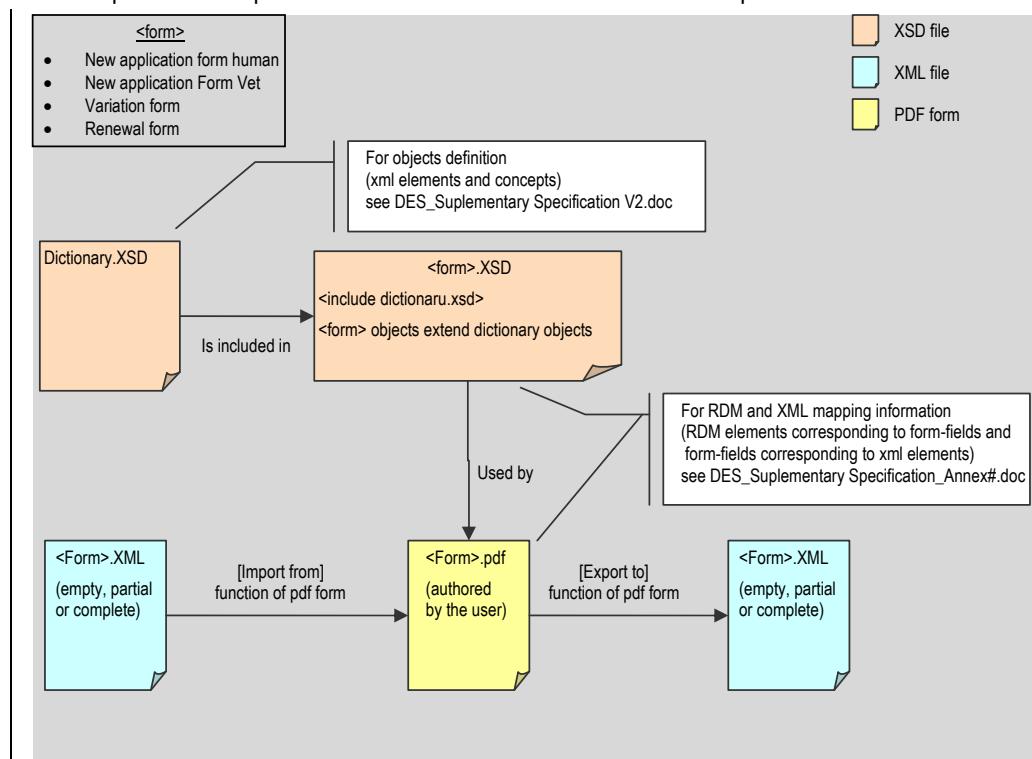
The DES 2.0 is provided with a tool and additional files.

The Dictionary.xsd contains the definition of all the RDM objects that can be extended by any of the supported forms.

The Dictionary.xsd is included in each <form>.xsd.

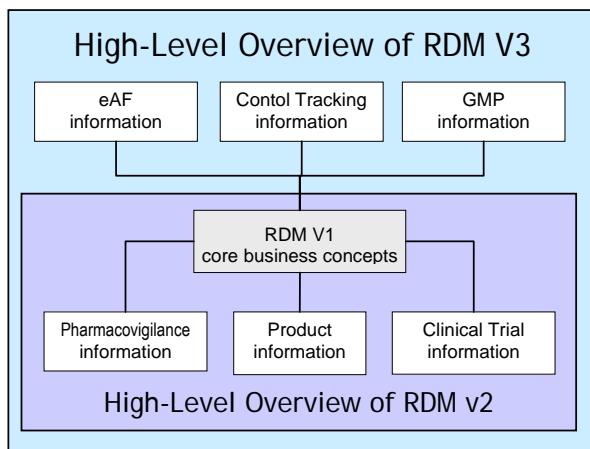
Some objects of the dictionary.xsd are extended for the needs of the form specific fields.

The XML file (partially populated) corresponding to the form.xsd can be imported into a <form>.pdf to be completed or authored from scratch and then be exported as form.xml.



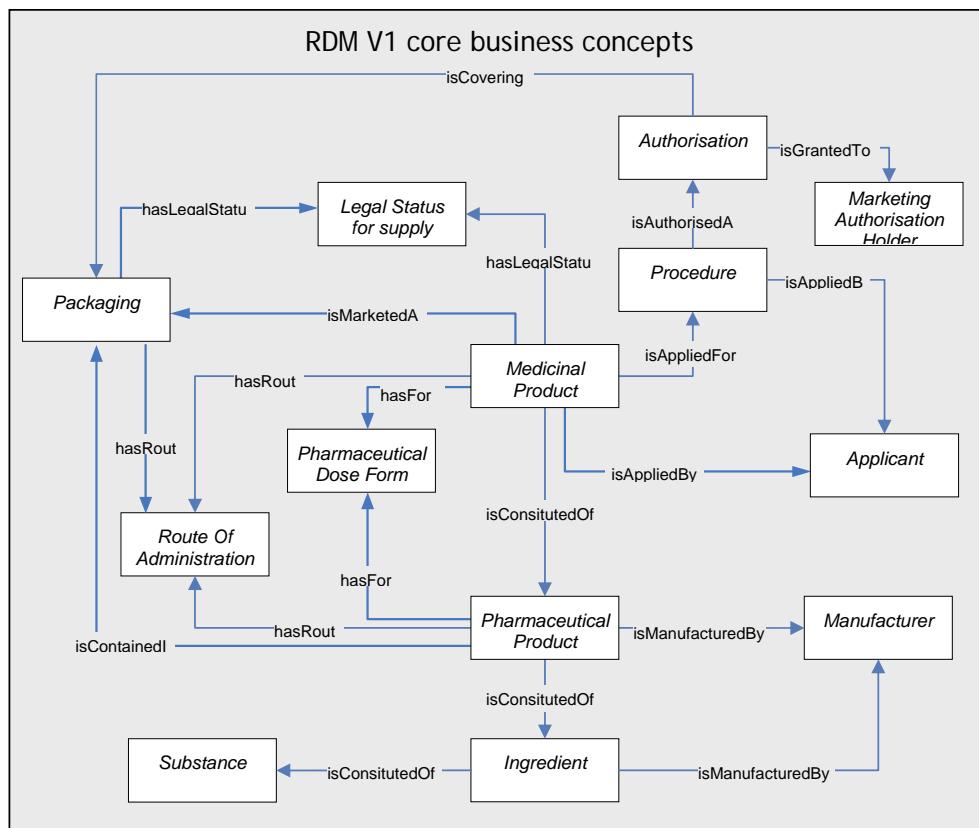
### 5.3. The RDM model

The RDM model is based on the RDM V1 with extended RDM versions containing specific business information.



The RDM core concepts model describes the relationships between the different core business components.

#### RDM V1 core business concepts model

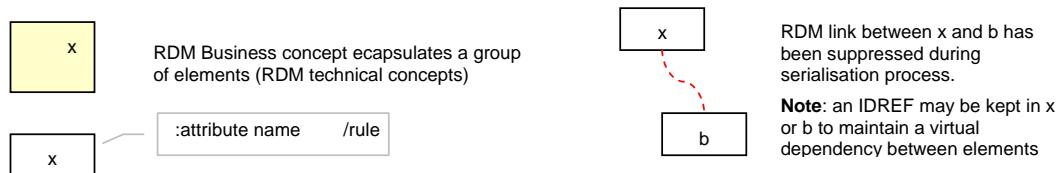


The core business concepts are composed of technical concepts describing the information type and format that can be exchanged. Technical concepts are referred to be elements in the Element Tree Diagrams (ETD's.).

As this model cannot be applied directly to the ETD's it needs a serialisation process described in the sections below. As it is interesting to keep a track of the decisions taken during the process, some new features where added in ETD notation.

#### Customised patterns for RDM serialisation

The serialisation is the action to transform a relational model (database) into a hierarchical model (text) that keeps most of the constraints and structure of the relational model.



### 5.3.1 Controlled term lists

The RDM model is tightly linked to the EUTCT. Terms coming from EUTCT are always encoded with both term ID attribute and a term value. All controlled term list (CTL) element template has been created and is described in the section below along with the list of used EUTCT lists for eAF.

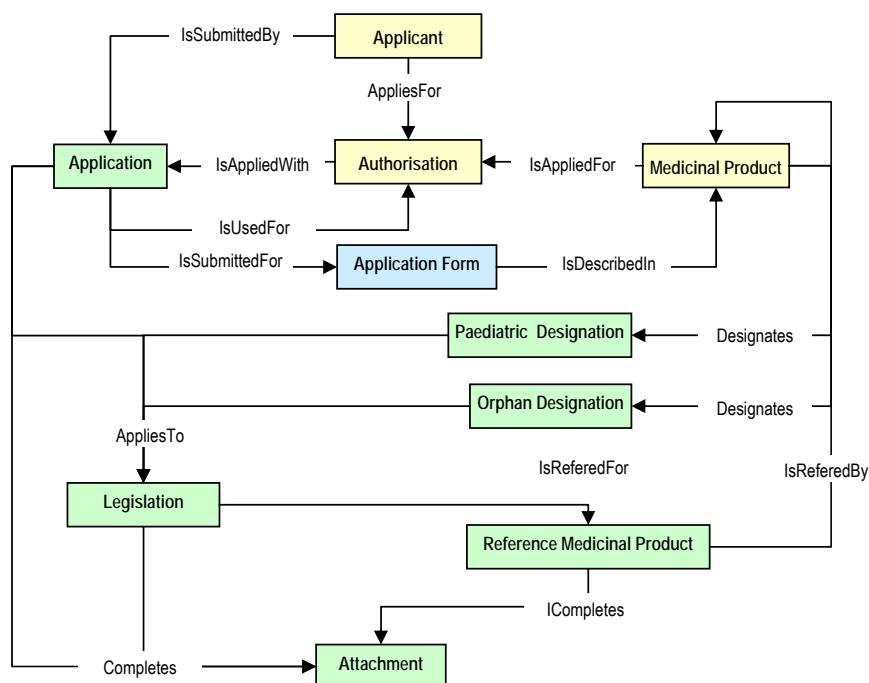
## 5.4. The Common Application Form model

The Common Application Form model is not based on any existing model. It tries to meet the following rules:

- Decouple the questions asked in the form from the model. Keep question as an attribute of a paragraph element of the Specific Application Form model. Unless the question can be modelled by a property of a common application form concept.
- Optimise the field mapping by re-use of business concepts in an across forms.

The Common Application Form business concepts (green) are linked to the RDM code concept by the Authorisation (mp-procedure) and the Medicinal Product.

The application form resides just between the procedure and the authorisation.

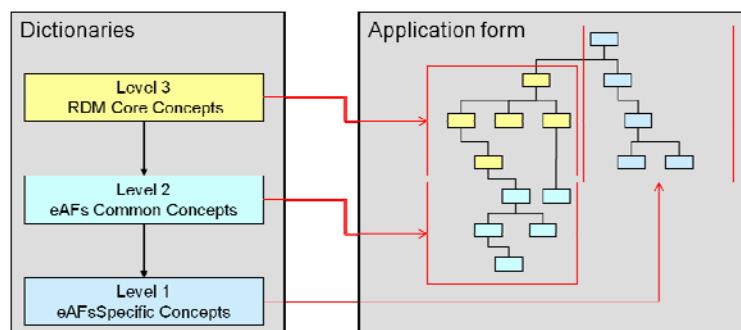


## 5.4.1 Information architecture

The information structure is based on components (single or group of element definition) gathered in dictionaries structured by levels of interoperability that can be reused across forms

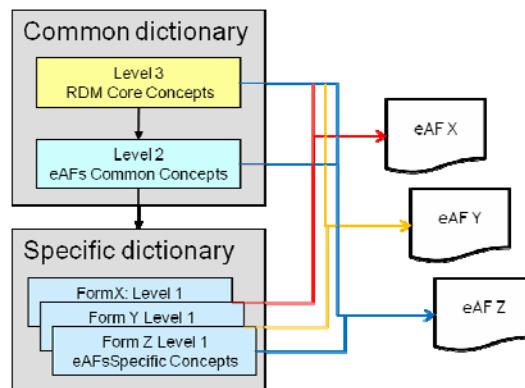
- All forms refers to the same dictionary for level 3 (RDM core concepts) and level 2 (Common AF concepts)

Example:



- Each form will have its own level 1 dictionary of concepts (Specific AF Concepts).

Example:

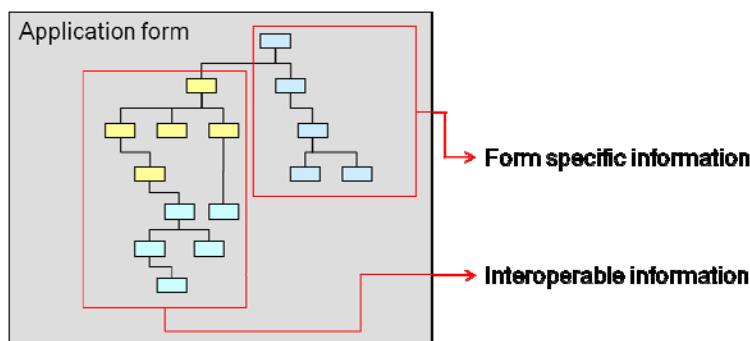


**Remark:** In order to keep the level of interoperability at its highest possible rate, the model tries to reduce the level 1 dictionary elements as much as possible.

### **The specific Application Form information structure**

The Specific Application Form information tries to meet the following rules

- Keep the information structure as close as possible to the paper form.
- Keep the number of business concept as low as possible.
- It separate interoperable information from specific form information like:
  - Questions where a specific form answer is required. ("no" versus forget to answer)
  - Information only needed for the process of the form itself (form approval status).
  - Information that could not be modelled at level 3 or level 2. (should be moved at term)



## 6. THE REFERENCE DATA MODELS

The reference data models contain the necessary data (information) to feed the business processes and information about the data structure and organization of the supported electronic application forms.

They are based on the business rules captured in a graphic approach to facilitate the reading and assessment by the business.

The standard model used for XML data structure modelling is called "Element Tree Diagram" (ETD)

The diagrams of this version reflects the RDM V2 core concepts described below and is implemented in the validation library and XSD file.

All ETD's for the different forms are described in Annexes 1 to 4. and are based on the model described in this section.

### 6.1. RDM V3 Serialisation

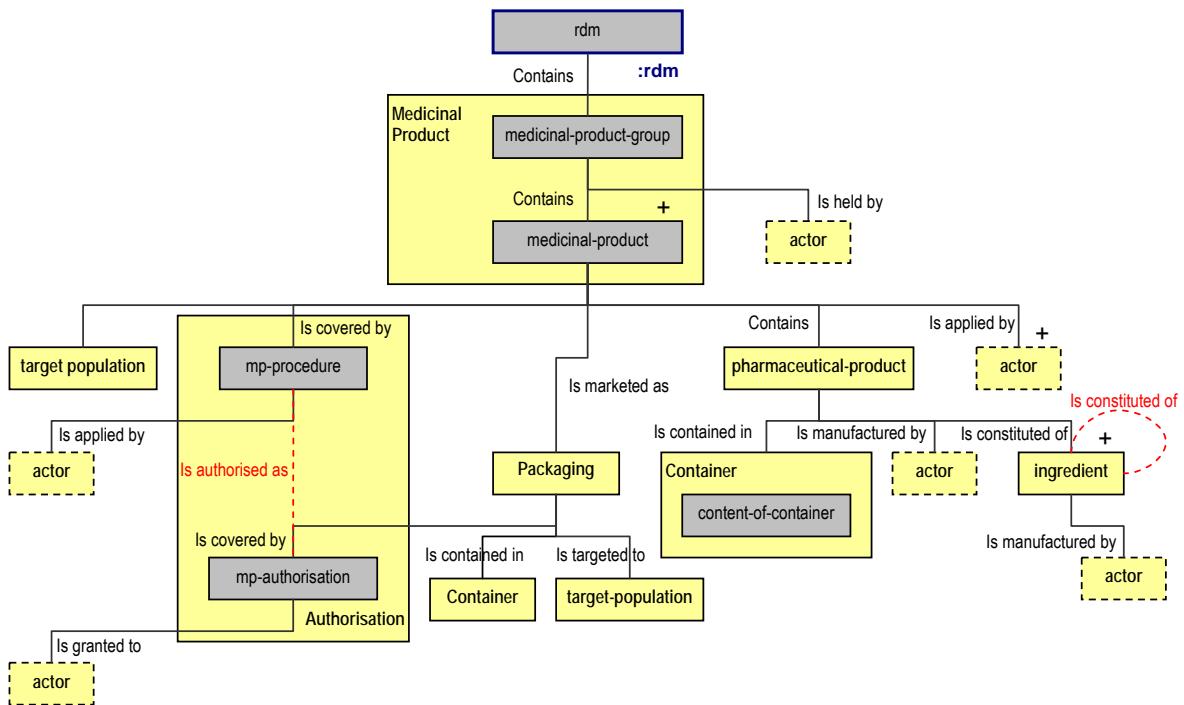
Serialization is the action to build a hierarchical structure (XML) from a relational structure (RDM core business concepts). It will be the base for all the forms to be supported.

The serialization process focus on the RDM core business concepts only. During this serialization process a series of decisions have been taken, like for instance, the split of cyclic relationships or the duplication of elements having relationships with several business concepts.

The following approach has been taken:

- o The removed link between Medicinal product and package can be found back through the medicinal product.
- o The recursive relation on the Ingredient has not been implemented. This raises an issue however on the way to identify an Ingredient (See findings).
- o The Authorisation information has been attached to the Package, and split from the Procedure, so as to assure the identification of a procedure for a medicinal product before approval.
- o The Container and Pharmaceutical Product concepts have been split in the XML Schema, and the link (i.e. what pharmaceutical product is in the container) has been implemented with a reference.
- o As there is no information at the Role level (except the role per se), the Schema has been developed with the Role being a repeatable field of the concept Party.

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### RDM V3 future changes

- Historical data for procedures will be added.

## 6.1.1 Common attributes

### 6.1.1.1 Unit

Notation: **:unit**

Element	RDM Specific Format	Definition	Remarks for Structure/type/rule/format or other
unitVersion	TEXT(10)	The "Unit" controlled term revision number	
unitId	IDENTIFIER	The "Unit" controlled term identifier (term-id)	
Unit		The "Unit" controlled term value	

### 6.1.1.2 Identifier

Notation: **“:ID”**

Identifier attribute is a unique name used to identify any element in the XML form. When specified it force the user to fill in a unique identifier for that element.

### 6.1.1.3 Reference

Notation: **“:reference”**

The reference attributes refers to additional data in the document by using the *ID* of that element.

In other words, a reference attributes forces the user to fill in an *ID* of another element in the same document..

It is mandatory when used by an element. It stands for **:IDREFS /ID**

### 6.1.1.4 Date

Notation is **“:date”**

Internal Date entity is the reference for the use of a date format YYYY-MM-DD for all date alike elements.

If an element declared in the validation form uses this entity then it forces any element in the XML form using this entity to have year, month and day attributes with their corresponding values.

It is mandatory when used by an element. It stands for:

```
:year    / text
:month   / text choice (01-12)
:day     / text choice (01-31)
```

### 6.1.1.5 External link

External link (XLink) is used to link an element to an external reference document like annexes. The XLink entity refers to the W3C XLink format standard.

The notation is “**xlink**” and stands for.

```

  : xmlns:xlink / text http://www.w3.org/1999/xlink
  : xlink:type / text ?
  : xlink:role / text ?
  : xlink:href / text
  : xlink:title / text
  : xlink:show / text choice (new | replace | embed | other | none) ?
  : xlink:actuate / text choice (onLoad | onRequest | other | none) ?
  : id / ID

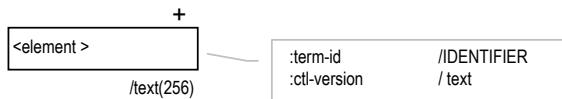
```

## 6.1.2 Control Term Lists (CTL)

### 6.1.2.1 CTL Template

What we consider that it is mandatory from applications to store is actually 2 elements: CT ID and CT revision number. In addition to this applications can decide to also store other elements like name, status etc..

Element	RDM Specific Format	Definition	Remarks for Structure/type/rule/format or other
<element>	TEXT(256)	The element representing the name of the controlled terms	The element name may be the controlled term list friendly name
:term-id	IDENTIFIER	The term identifier (term-id)	
:ctl-version		The term revision number	



Remark: As Web Services are not yet exposed by EUTCT group, the structure of the Controlled Term List is a draft and will be subject to changes to comply with web services specifications.

### 6.1.2.2 Used CTLs

Only CTLs used by more than one Technical concept are defined here. The other CTLs are defined at the Technical concepts level where they belong to.

Highlighted yellow are the new CTLs.

The colours correspond to the model where they were created from:

Yellow: RDM Core concepts

Green: Common Application form

Cyan: RDM GMPC

Grey: Not directly mapped by in the current supported electronic application forms but may be used in others

Element <CTLName>	CTL #Range	Definition	Offline availability
Active Substance Form	see substance	The list of possible forms that an active substance may have. Example(s):(Ether; Ester; Acid; Salt)	? (Shared)
Administration Device	See container (filter container type) 38	The list of devices intended for the correct administration of a medicinal product [CEN 12610: 3.2]. Example(s):(Spoon)	
Age Range	10	The list of age ranges that can be used according to guidelines and regulations in application, namely: <ul style="list-style-type: none"> <li>The guidelines ICH E7 (elderly patients) and ICH E11 (age groups of paediatric population)</li> <li>The guideline EMEA/CHMP/EWP/147013/2004 on the role of pharmacokinetics in the development of medicinal products in the paediatric population (adolescents)</li> <li>The guideline E2B (R2) for Individual Case Safety Reports (ICSRs)</li> <li>The guidance on European clinical trials (in utero)</li> </ul> Example(s):(Less than 18 years; In-Utero; Preterm-Newborn-Infants (up to gestational age <37 weeks); Newborn (0-27 days); Infant-And-Toddler (28 days – 23 months); Children (2-11 years); Adolescent (12-17 years); Adult (18-65 years); Elderly (>65 years))	Yes (Internal)
Application recipients	2	The list of application recipients where the applicant has submitted a request: NCA (National Competent Authority) or IEC (Independent Ethics Committee). Example(s): (Application to NCA; Application to IEC)	Yes (internal)
Application status (same as authorisation status)?	10	The status of an authorisation (Authorised, Pending, Refused, Withdrawn by applicant before authorisation, Withdrawn by applicant after authorisation, Suspended, revoked)	Yes (internal)
Application type	150	The type of application submitted. :MA initial"   "MA renewal"   "MA variation"   "MA pre-submission"   "Scientific advice"   "PIP	Yes (internal)
ATC	> 9000	The Anatomical Therapeutic Chemical Classification used to group medicinal products according to their indications of use for human use or veterinary use [CEN 12610:5.4.1]. Examples: A03FA (Propulsive), C01BC (Antiarrhythmic, class Ic), V04CF (Tuberculosis Diagnostics)	? (external)
ATC-status		The status of an atc request. (pending, assigned)	
Attachment-type		The term id that identifies the attachment or document ex: "letter of consent", "GMP certificate", "letter of authorization", "CV of qualified person", etc.	
Authorisation Status	15	The list of statuses that describe the legal situation of the marketing authorisation or any application for a marketing authorisation. Example(s): Valid; Expired; Not renewed; Withdrawn by MAH; Withdrawn, unspecified	Yes (internal)
Business category	?	The business category in which the party has is social reason. Examples: Association/Federation, EU Institutions, Hospitals or Clinics, Hotel, International Organisations, Media Institutions, National Authority in member states, National authority outside EU, Parallel Distributors, Pharmaceutical Companies, Regional Authority in EU member states, Supplier, University and education or research, unspecified.	
Contact detail type	2	Types of contacts to get in touch with the party. Example(s): Work, Home	
Container	72	The list for containers and closures, where <ul style="list-style-type: none"> <li>a container is a physical holder, which is in direct contact with a pharmaceutical product [CEN 12610: 3.15 modified]</li> <li>a closure is a material used to close the container.</li> </ul> Example(s): (Vial; Ampoule; Pouch; Prefilled syringe; Blister)	? (External)
Country	250	Geographical, political or economic area in which the identification of an ingredient, medicinal product or medicinal product package is valid [CEN 12610: 3.40]. ISO 3166 is used to store country codes (numeric IDs, alpha-2, alpha-3, including values EL and UK < <a href="http://publications.eu.int/code/pdf/37000en.htm">http://publications.eu.int/code/pdf/37000en.htm</a> >), names (short and full), and groups of countries. Example(s): Argentina; Japan; Canada	Yes (external)
Currency	200	The currency in which a payment is done	

Element <CTLName>	CTL #Range	Definition	Offline availability
Declaration condition	<20	<p>The list of conditions assessed by the applicant in the declaration of an application form</p> <p>Examples for variation ("There are no other changes than those identified in this application";, "Where applicable, national fees have been paid"; "This application has been submitted simultaneously in RMS and all CMSS"; "for worksharing only the MAs concerned belong to the same MAH"; Where applicable, all conditions as set for the variation(s) concerned are fulfilled"; "For type 1A notifications, the required documents as specified for the changes concerned have been submitted").</p>	
difference	+-100	Difference or changes between the reference medicinal product and the application product (change of bioavailability, change of pharmacokinetics, change or addition of a new strength / potency, change or addition of a new pharmaceutical form, change or addition of a new route of administration, change(s) in the raw material(s), change(s) in the manufacturing process(es), change in therapeutic indication(s), change in pharmaceutical form(s), change in strength (quantitative change to the active substance(s)), change in route of administration(s), other)	
Domain	3	<p>The list of areas where a medicinal product or a term can be used.</p> <p>Example(s): (Human use; Veterinary use; Human and Veterinary use)</p>	Yes (internal)
Electronic contact type	< 10	<p>The type of electronic contact associated to the contact detail concept</p> <p>Examples: Phone, Fax, Email, Web, Mobile</p>	
Gender	7	<p>The list of values for the gender distinction between male and female for both human and veterinary purposes.</p> <p>Example(s): ( Male; Female; Male and Female; Male-neutered; Female-neutered; Not known; Not applicable)</p>	Yes (internal)
GMP activity		<p>This list contains the activities that can be performed in a GMPC or a MIA site after authorisation is granted.</p> <p>(ex: Manufacture of active substance intermediate, Manufacture of active substance, Quality control of active substance, Sterilisation of active substance (or excipients), Manufacture of finished products intermediate, Manufacture of finished products, Quality control of finished products, Primary packaging, Secondary packaging, Batch certification, Import, Storage and distribution, Manufacture of finished products: solvent / diluents, Others)</p>	
Gmp-category		<p>This list shows whether the certificate is GMP Certificate, Non Compliance, Distance Assessment or MRA GMP Certificate.</p>	
ingredient-origin		<p>The origin of the ingredient ("synthetic"; "vegetal"; "animal"; "human"; "fungus") with a classification of the tissue for veterinary application and human advanced therapies</p>	
Ingredient Role	3	<p>The list of roles an ingredient may have within a medicinal product composition.</p> <p>Example(s) (Active; Excipient; Adjuvant)</p>	Yes (internal)
Inspection-authority	3	<p>The type of inspection authority that perform the inspection of the current site. (EEA, Other)</p>	
Language	180	<p>The list of codes and names for languages [ISO 639].</p> <p>Examples: ( English; Japanese; Greek)</p>	Yes (external)
Legal Status for the Supply	7	<p>The list of classifications on the supply of the medicinal product/package according to Dir 2001/83/EC, Dir 2004/27/EC: article 70. It describes the way that a medicinal product/package can be supplied to the end user.</p> <p>Example(s)</p> <p>Class:(subject to medical prescription;not subject to medical prescription;subject to other controls)</p> <p>Prescription: (veterinary product on prescription which may be renewed veterinary product on prescription which may not be renewed; veterinary product on special prescription;veterinary product on restricted prescription)</p> <p>Non-prescription:(supply through pharmacies only; supply through non-pharmacy outlets and pharmacies supply/administration by veterinary surgeons only; supply by pharmacies and/or veterinary surgeons for animals under their care; supply through authorised distributor;general sale)</p> <p>Administration: (only by a veterinary surgeon; by a veterinary surgeon or under their direct responsibility)</p> <p>Promotion:(promotion to health care professionals only; promotion to the general public and health care professionals)</p>	Yes (internal)
Legislation Code	> 1000	<p>The legislation code of a specific legislation that applies in the application context</p>	
Legislation Type		<p>Defines the type of legislation: directive"   "regulation"   "national"</p>	
Legislation usage		<p>The usage context of the legislation or legislation article element if the code is not sufficient to determine the context of application..</p> <p>Directive 2001/83 / article 8(3) ("new active substance"; "known active substance"),</p> <p>Directive 2001/83 / article 71: "renewable delivery", "not renewable delivery")</p> <p>regulation1768/92/Article 8 ("supplementary protection"; "protected by patent"; "other triggering procedure")</p>	filtered by legislation / article code

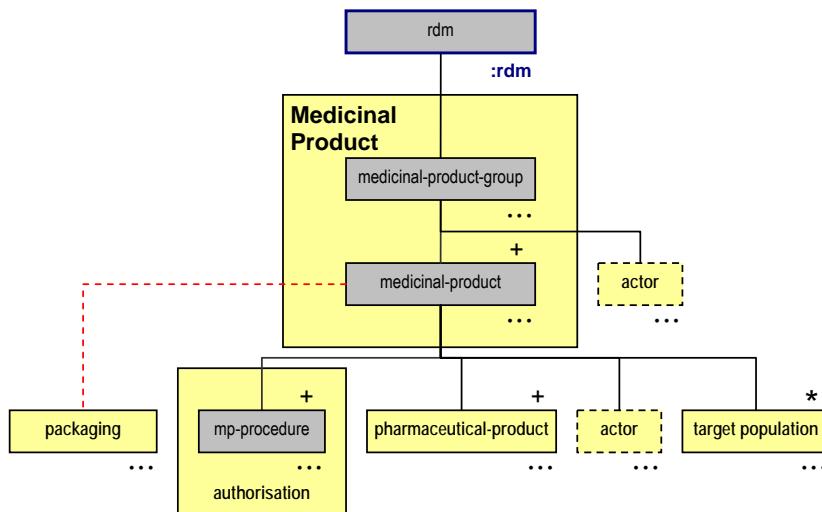
Element <CTLName>	CTL #Range	Definition	Offline availability
Material		Constituent of an outer/immediate container. Ex: Plastic, aluminium, carton, glass...	
Medicinal Product Type	50	The list of medicinal product types so as to identify the ones that may require specific provisions and/or that may need to be identified for statistical purposes. Examples( Cell-Therapy; Radiopharmaceutical; Immunological; Plasma-Derived)	Yes (internal)
MRL Classification	6	<p>The list of the annexes of Regulation (EEC) No 2377/90 to which the MRL may belong and so as to provide the distinction between an active substance for which final/provisional maximum residue limits can/have been fixed or not and an active substance which is not included/subject to the Regulation.</p> <p>Example(s):( Pharmacologically active substances for which maximum residue limits have been fixed.; List of substances not subject to maximum residue limits.; List of pharmacologically active substances used in veterinary medicinal products for which provisional maximum residue limits have been fixed.)</p>	Yes (internal)
MRL Provision	55	<p>The list of values that indicate extra conditions as imposed on the MRL value.</p> <p>Example(s):(Not for use in animals from which milk is produced for human consumption; Not for use in animals from which eggs are produced for human consumption)</p>	Yes (internal)
<u>Party identification type</u>			
Party relationship type		Identifies the type of relationship the party has with its parent.(role and/or party) Examples: Site, Employee, Sub Organisation, Subsidiary	
Party type		The list of values that describe the legal standing of a party. Examples: Organisation, Person	
Payment status	5	The status of the payment transaction (not applicable, not-payed, in-process, payed, refused)	
Pharmaceutical Dose Form (Dosage Form?)	350	<p>The list of forms in which a pharmaceutical product may be presented in a medicinal product. [CEN 12610:5.4.8]</p> <p>Note: The pharmaceutical form has to be distinguished from the dosage form in which a medicinal product is intended to be administered to the patient, even if pharmaceutical form and dosage form are often the same</p> <p>Example(s): (Tablet; Syrup; Oral Suspension; Cream)</p>	? (shared)
Procedure Type	10	The list of Procedure types that describe the legally defined procedures a medicinal product can be subject to during its lifecycle. These procedures refer to different areas of business containing information regarding clinical trials, marketing applications, scientific opinion, etc. Information referring to compassionate use and parallel import may be available in the future. Example(s): Centralised procedure; Mutual Recognition Procedure; Decentralised procedure; National procedure	Yes (internal)
Quantity Operator	8	The list indicating how to relate quantity value(s) of a substance in the pharmaceutical product. Example(s): (equal to; range (Two or Four values needed); less than (One value needed); more than (One value needed); less than or equal to; more than or equal to; equivalent to; approximately equal to)	Yes (internal)
Race	3	The list of races, which often define populations or groups of people distinguished by different sets of characteristics. The most widely used human racial categories are based on visible traits (especially skin color, facial features and hair texture), and self-identification. The legal basis for this controlled list is ICH E5 (R1) – Ethnic Factors in the acceptability of foreign clinical data. The ICH E5 (R1) document does not include definitions of the different race categories. Example(s): (Asian; Black; Caucasian)	Yes (internal)
Reference-medicinal-product-usage		The usage of reference declared ex ("eu marketing authorisation"; " same community/member state application"; " not less than 6/10 years in the EEA"; "demonstrated bioequivalence";"mutual recognition procedure" ...)	
Reference-monograph-standard		Type of reference to a product monograph that is intended to provide the necessary information for the safe and effective use of a new drug and also to serve as a standard against which all promotion and advertising of the drug can be compared: ("In-house"; "Ph.Eur"; "National Pharmacopoeia" ...)	
Role (=actor)	50	<p>The list contains the possible functions that may be performed by a party (organisations/persons) related to one or more activities (manufacturing, marketing, clinical trials etc) in relation to a medicinal product.</p> <p>Example(s): ( Person or Organisation authorised by the Sponsor; NCA (National Competent Authority); Applicant; MAH (marketing Authorisation Holder); Manufacturer; Manufacturer of biological active substance; Manufacturer of medicinal product; Manufacturer responsible for batch release; Importer; Manufacturer and Importer; CMS (Concerned Member State); RMS (Reference Member State); Responsible person for Eudravigilance; Other)</p>	Yes (internal)
Route of Administration	150	The list of the parts of the body through or into which or the way in which a medicinal product is intended to be introduced [CEN 12610:5.4.15]. Example(s):( Intramuscular use; Oral use; Transferral use; Subcutaneous use)	? (Shared)

Element <CTLName>	CTL #Range	Definition	Offline availability
Scientific Advice Source	2	The list of the sources for scientific advice related to clinical trial and to eAF Example(s): (CHMP (Committee for Medicinal Products for Human use); NCA (National Competent Authority))	Yes (internal)
scientific-advice-type	<10	The type of scientific advice that can be asked by the applicant. (EMEA scientific advice, EMEA protocol assistance, National Competent Authorities advice, FDA written request, other opinion/decision/advice)	Not used in eAF yet but should be with sc. Ad. Form.
scientific-advice-status	<10	The status of the current advice (received, planned, pending)	
Shelf Life Type	5	The list of the description of the condition of the medicinal product under which the given time for the shelf life is applicable. ICH Q1A (R2), CPMP/ICH/2736/99: Definition of shelf life (other name: expiration dating period): The time period during which a drug product is expected to remain within the approved shelf life specification, provided that it is stored under the conditions defined on the container level. See CHMP/ICH Guidelines: CPMP/QWP/122/02, rev 1 corr, CPMP/QWP/609/96/Rev 2, CPMP/ICH/2736/99 Examples (closed package; after first opening; after reconstitution/dilution; from manufacturing time; from time of reference; in unit-dose dispensing; after incorporation)	Yes (internal)
Special Precaution for Storage		The list of the storage conditions of the medicinal product for a particular package. Example(s): (Do not store above 25°C; Do not store above 30°C; Store below 25°C; Store below 30°C)	
Species	250	The list of the groups of animal species or sub species for which the marketing organisation of a medicinal product is approved as indicated in the annexes of Regulation No (EEC) 2377/90. Example(s): (Species: Cattle, Pigs, Horses, Sheep, Salmon fish; Sub-species: new born calves)	Yes (internal)
Substance	>13000	The list of active substances, i.e. any composition of matter that has a discrete existence, irrespective of origin, which may be which may be human, animal, vegetable, or chemical. [ISO 11238]. Examples: (Clonazepam; Human recombinant insulin)	? (shared)
Tissue	12	This Controlled Term List covers the tissue terms that are connected with centralised establishment of Maximum Residue Limits (MRL) (Community procedure) for pharmacologically active substances used in food producing animals and with following determination of withdrawal periods for foodstuff of animal origin (edible tissues) during marketing authorisations of products containing these substances.  According to Regulation (EEC) No 2377/90, MRL is defined as: "The maximum concentration of residue resulting from the use of a veterinary medicinal product (expressed in mg/kg or µg/kg on a fresh weight basis) which may be accepted by the Union to be legally permitted or recognized as acceptable in or on a food".  In Directive 2001/82/EC (2004/28/EC): 9. Withdrawal period is "The period necessary between the last administration of the veterinary medicinal product to animals, under normal conditions of use and in accordance with the provisions of this Directive, and the production of foodstuffs from such animals, in order to protect public health by ensuring that such foodstuffs do not contain residues in quantities in excess of the maximum residue limits for active substances laid down pursuant to Regulation (EEC) No 2377/90." Example(s): (All relevant tissues; Fat; Honey; Liver; Milk)	Yes (internal)
Tissue Type	4	This Controlled Term List classifies the tissue terms as to whether they are connected with centralised establishment of Maximum Residue Limits (MRL) or for foodstuff of animal origin (edible tissues). Example(s): (Edible and MRL Tissue; MRL tissue; Edible tissue; Unspecified)	Yes (internal)
Unit	> 500	The list of the units and measurements. Example(s): (mg; ml; µg/kg; day; month; year)	? (Shared)
Variation grouping	<10	The Grouping indicates whether the application includes one or more variations, including or not the line extensions, or worksharing. Examples (Single Variation, Grouping of variations; grouping of variations including line extension; Worksharing)	
Variation classification	<500	The description of the variation that corresponds to the classification as described in the regulation 1234/2008 annex II. The classification is structured as follows: Guideline Section (A, B, C, D...). Guideline number. Guideline index (Examples "The codes that identifies a variation item. B.a or B.2.C.)	
Variation-type	< 10	Gather all types of variation type in the application as defined in the regulation 1084/2003 article 2 plus additions from the variation guidelines for foreseen and unforeseen variation of type IB and type IA in. Examples (Type IA, Type IA IN, Type IB, Type IB unforeseen, Type IB foreseen, Type II, Type II Art.29.)	
Variation domain	<10	The different domains in which the changes occur. Examples (Indication, Paediatric indication, Safety, Safety following urgent safety restriction, quality, Annual variation for human influenza vaccines, Non-food producing target species, Other)	

## 6.1.3 Medicinal Product

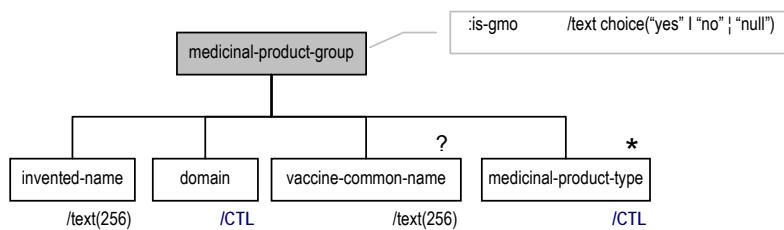
### 6.1.3.1 Medicinal Product (Business Concept)

Element	Definition	Remarks for Structure/type/rule/format or other
rdm	A Medicinal Product consists of a substance, a combination of substances or a preparation of substance(s), which may be used in or administered to human beings or animals, with a view to treat, prevent or diagnose diseases- Directive 2004/27/EC (See Articles 1b, 1c); Directive 2004/28/EC (See Article 1b)	
medicinal-product-group	The grouping of all medicinal products marketed by the same marketing authorisation holder with the same active substance(s) under one name or several closely related names. A group can be considered as a family of products. A group is often what people refer to when they refer to a medicine.	
actor	See Actor business concept	Role="Holder"
medicinal-product	<ul style="list-style-type: none"> <li>• Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or</li> <li>• Any substance or combination of substances which may be used in or administered to human beings with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis. [Dir 2004/27/EC: 1.b].</li> <li>• Any substance or combination of substances presented as having properties for treating or preventing disease in animals; or</li> <li>• Any substance or combination of substances which may be used in or administered to animals with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis [Dir 2004/28/EC: 1.b].</li> <li>• Any medicinal product prepared from substances called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopeias currently used officially in the Member States. A homeopathic medicinal product may contain a number of principles. [Dir 2004/27/EC:1.c].</li> <li>• Any medicinal product, exclusively containing as active ingredients one or more herbal substances or one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations [Dir 2004/24/EC:1.30].</li> </ul>	
authorisation	See Authorisation business concept	
packaging	See Packaging business concept	Packaging keeps link with pharmaceutical product only
actor	See Actor business concept	Role="Applicant"
pharmaceutical-product	See Pharmaceutical product business concept	



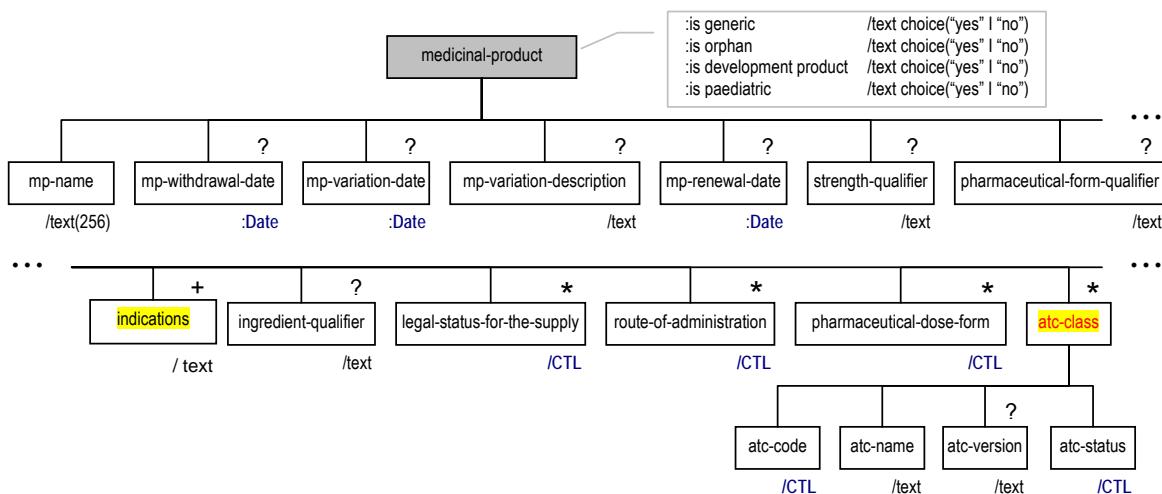
### 6.1.3.2 Medicinal product group (Technical Concept)

Element	RDM Specific Format	Definition	Remarks for Structure/type/rule/format or other
medicinal-product-group	-	See Medicinal product group technical concept	
is-gmo	Boolean	Flag to indicate whether the medicinal product group belongs to genetically modified organisms (GMO) or not. If this flag is true, the medicinal product group is GMO.	As a general principle, if some information is not known by all systems, a field is set optional. Should the "is-gmo" field be optional? The XML Schema has encoded the field as optional.
invented-name	NAME	The family name used to describe all the products in the group. E.g. Actos, Humalog, Fendrix, Optaflu.	
domain	IDENTIFIER + TERMNAME	See used CTLS	
vaccine-common-name	NAME	Common name for the vaccines. E.g. Hepatitis B (rDNA) vaccine (adjuvanted, adsorbed), Influenza vaccine (surface antigen, inactivated, prepared in cell cultures).	
medicinal-product-type	IDENTIFIER + TERM NAME	See used CTLS	The Medicinal Product Type (in Medicinal Product Group) contains different types of information (usually connected to the substance) while EudraPharm only uses "Medicinal Product". In the examples, the only type used is "Medicinal Product".



## 6.1.3.3 Medicinal Product (Technical Concept)

Element	RDM Specific Format	Definition	Remarks for Structure/type/rule/format or other
medicinal-product (mp)*	-	-	
:is generic	Boolean undefined	If this flag is true (generic), it refers to the innovative medicinal product	
:is-orphan	Boolean undefined	If true, the medicinal product is the orphan drug.	RDM: See AF "orphan-designation"
:is-development product	Boolean undefined	If true, the medicinal product is under the clinical trial prior to marketing authorisation.	
:is-pediatric	Boolean undefined	If true, the medicinal product is also for paediatrics	
mp-name	NAME	Name of the medicinal product. E.g. Actos, Humalog Basal.	
mp-withdrawal-date	Date	Date when the Medicinal Product was withdrawn from the authorised market.	Is it valuable to store the dates (authorisation, variation, renewal, withdrawal) at both Package and Medicinal Product levels? Would the Package level be enough (and repeat if the same for all packages)? What about parallel procedures for the same MP?
mp-variation-date	Date	Date when the latest variation became effective.	
mp-renewal-date	Date	Date on which the latest renewal of the marketing authorisation was granted.	
mp-variation-description	DESCRIPTION	Explanation about the latest variation of a Medicinal Product.	
strength-qualifier	DESCRIPTION	Free text to describe the strength associated with the medicinal product. E.g. pioglitazone 15 mg (Actos), amlodipine / valsartan 10 mg/160 mg (Dafiro).	
pharmaceutical-form-qualifier	DESCRIPTION	Free text to describe the pharmaceutical form. E.g. Tabs, Capsule Rigid.	
indications	DESCRIPTION	The indications of the medicinal product	
ingredient-qualifier	DESCRIPTION	Free text to describe the ingredient(s) of the medicinal product. Examp(s):. pioglitazone hydrochloride equivalent to pioglitazone 15 mg (Actos).	
legal-status-for-the-supply	IDENTIFIER + TERM NAME	See used CTL	
route-of-administration	IDENTIFIER + TERM NAME	See used CTL	The Route of Administration has been attached to the Pharmaceutical Product and to the Medicinal Product so as to cover reconstituted and diluted products.
pharmaceutical-dose-form	IDENTIFIER + TERM NAME	See used CTL	The Pharmaceutical Dosage Form has been attached to the Pharmaceutical Product and to the Medicinal Product so as to cover reconstituted and diluted products
atc-class	-	The medicinal product classification.	
atc-code	IDENTIFIER + TERM NAME	See ATC CTL	"
atc-name	DESCRIPTION	The corresponding name to the classification code	
atc-version	-	-	
atc-status		See atc-status CTL	

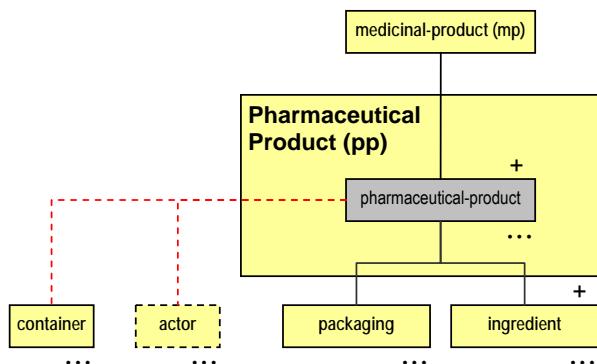
Element tree diagram


Complex Business Rules			
Element	Default BR	Rule	Effect(s)
pharmaceutical-product / pharmaceutical-dose-form	optional to many	If the pharmaceutical-product/pharmaceutical-dose-form is empty	medicinal-product/pharmaceutical-dose-form is mandatory (+)
medicinal-product/ pharmaceutical-dose-form	optional to many	If the medicinal-product/pharmaceutical-dose-form is empty	the pharmaceutical-product/pharmaceutical-dose-form is mandatory (+)

## 6.1.4 Pharmaceutical product

### 6.1.4.1 Pharmaceutical product (Business concept)

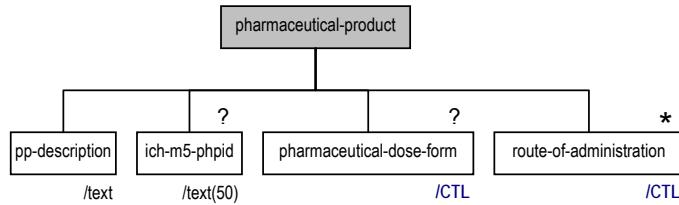
Element	Definition	Remarks for Structure/type/rule/format or other
pharmaceutical-product	A Pharmaceutical Product reflects the active ingredient(s), strength(s), pharmaceutical dosage form(s) and routes of administration(s) that constitute a medicinal product - ICH M5: Data Elements and Standards for Drug Dictionaries (See Section 2.3.5)	
packaging	See packaging business concept	Packaging keeps link with pharmaceutical product only
ingredient	See ingredient business concept	Role="Applicant"
actor	See actor business concept	?
container	See container business concept	The Container and Pharmaceutical Product concepts have been split in the XML Schema, and the link (i.e. what pharmaceutical product is in the container) has been implemented with a reference.



## 6.1.4.2 Pharmaceutical Product (Technical concept)

Element	RDM Specific Format	Definition	Remarks for Structure/type/rule/format or other
pharmaceutical-product (pp)*	-		
pp-description	DESCRIPTION	Text to give pharmaceutical product description. Examples: Gastro-resistant tablet, Concentrate containing the active substance clonazepam and several excipients, Diluent consisting of water	
ich-m5-ppid	ICH M5 ID	An identifier assigned at the level of the pharmaceutical product based on the active ingredient(s), the strength(s) of the ingredient(s) and the pharmaceutical dose form. Methodology: PhPIDs represent the pharmaceutical product at four levels as defined as follows: - PhPID4 = Ingredient(s) – Strength(s) – Strength unit(s) – Pharmaceutical Dose Form - PhPID3 = Ingredient(s) – Pharmaceutical Dose Form - PhPID2 = Ingredient(s) – Strength(s) – Strength unit(s) - PhPID1 = Ingredient(s) Each PhPID is a unique, non-semantic, alphanumeric code and is derived from the ICH M5 data elements, but is not part of these data elements.	
pharmaceutical-dose-form	IDENTIFIER + TERM NAME	See used CTLS	
route-of-administration	IDENTIFIER + TERM NAME	See used CTLS	

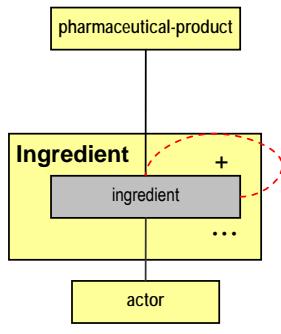
\* Abbreviation pp has to be replaced by the full name when using XML.



## 6.1.5 Ingredient

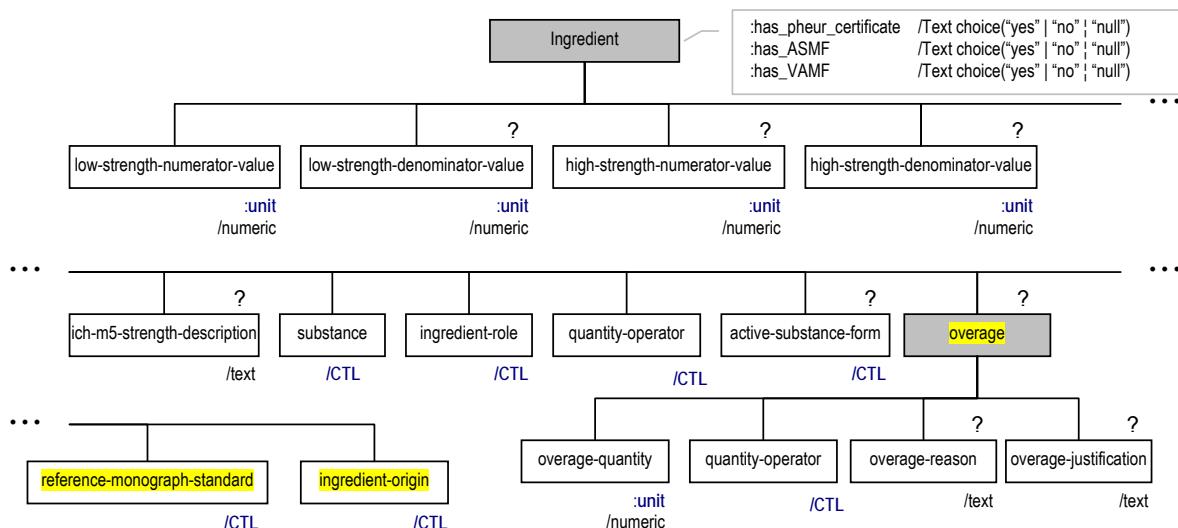
### 6.1.5.1 Ingredient (Business concept)

Element	Definition	Remarks for Structure/type/rule/format or other
ingredient	An Ingredient is a substance, active or not, that is included as a component in a pharmaceutical product. - CEN 12610:3.16  HALOFUGINONE 0.050 g (For medicinal product Halocur – Oral solution HALOFUGINONE 0.5 mg/ml)	The presence of a recursive relation on the Ingredient concept requires a proper way to identify Ingredient. Should it rely on a PK or on a business identifier, ingredient or CTL?
actor	See Actor business concept	



## 6.1.5.2 Ingredient (Technical concept)

Element	RDM Specific Format	Definition	Remarks for Structure/type/rule/format or other
ingredient	-		
:has_asmf	TEXT		"yes", "No", "Null"
:has_vamf	TEXT		
:has_pheur-certificate	TEXT		
low-strength-numerator-value	QUANTITY	Strength value for low numerator.	See Note 1
low-strength-denominator-value	QUANTITY	Strength value for low denominator.	
high-strength-numerator-value	QUANTITY	Strength value for high numerator.	
high-strength-denominator-value	QUANTITY	Strength value for high denominator.	
ich-m5-strength-description	DESCRIPTION	Strength description as given by ICH M5.	
substance	IDENTIFIER + TERM NAME	See used CTLS	
ingredient-role	IDENTIFIER + TERM NAME	See used CTLS	
quantity-operator	IDENTIFIER + TERM NAME	See used CTLS	
active-substance-form	IDENTIFIER + TERM NAME	See used CTLS	
overage	-	An overage is a fixed amount of the drug substance in the dosage form that is added in excess of the label claim.	
overage-quantity	QUANTITY	Quantity of substance overage	
quantity-operator	IDENTIFIER + TERM NAME	See used CTLS	
overage-reason	DESCRIPTION	reason for the overage (e.g., to compensate for expected and documented manufacturing losses),	
overage-justification	DESCRIPTION	Any overages in the manufacture of the drug product, whether they appear in the final formulated product or not should be justified considering the safety and efficacy of the product	
Reference-monograph-standard	IDENTIFIER + TERM NAME	Type of reference to a product monograph that is intended to provide the necessary information for the safe and effective use of a new drug and also to serve as a standard against which all promotion and advertising of the drug can be compared. ("In-house", "Ph.Eur", "National Pharmacopoeia", ...)	
ingredient-origin	IDENTIFIER + TERM NAME	The origin of the ingredient ("synthetic", "vegetal", "animal"; "human"; "fungus")	

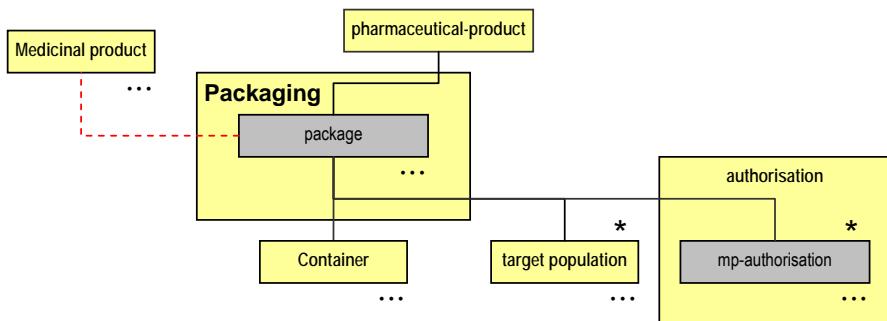


Business Rules		
Element	Default BR	Rule
*-Strength*	-	<ul style="list-style-type: none"> <li>• No strength value can be zero or less.</li> <li>• Low strength value (numerator/denominator) must be less than high strength value (numerator/denominator).</li> <li>• No strength value can be provided without units.</li> <li>• If quantity operator is 'equal to', 'equivalent to' or 'approximately equivalent to' then elements low strength numerator value and low strength denominator value should be used to describe strength.</li> <li>• If quantity operator is 'range' then <ul style="list-style-type: none"> <li>◦ elements low strength numerator value and low strength denominator value should be used to describe the low strength.</li> <li>◦ elements high strength numerator value and high strength denominator value should be used to describe the high strength.</li> <li>◦ Units provided must be same for low and high strengths</li> </ul> </li> <li>• If quantity operator is 'less than' or 'less than or equal to' then elements high strength numerator value and high strength denominator value should be used with their strengths.</li> <li>• If quantity operator is 'more than or equal to' then elements low strength numerator value and low strength denominator value should be used with their strengths.</li> </ul>

## 6.1.6 Packaging

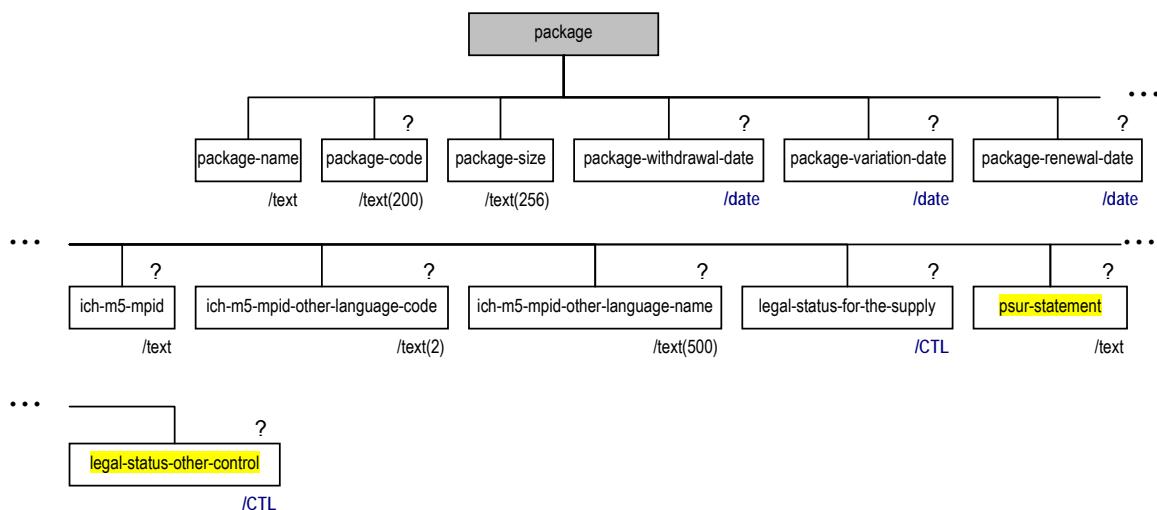
### 6.1.6.1 Packaging (Business Concept)

Element	Definition	Remarks for Structure/type/rule/format or other
package	Packaging covers the delivery units of a medicinal product, in an outer container, including the container information in those packages. [CEN 12610: 3.26]  Example(s): (Actos – 28, blister (alu/alu) ; 1 box of Karvea containing 2 x 14-tablet blisters; 1 box with 60 vials of Fuzeon powder + 60 vials solvent + 60 3ml syringes + 60 1ml syringes + 180 alcohol swabs)	
target-population	See Target population business concept	
authorisation	See Authorisation business concept	
container	The container information in a particular package	



## 6.1.6.2 Package (Technical Concept)

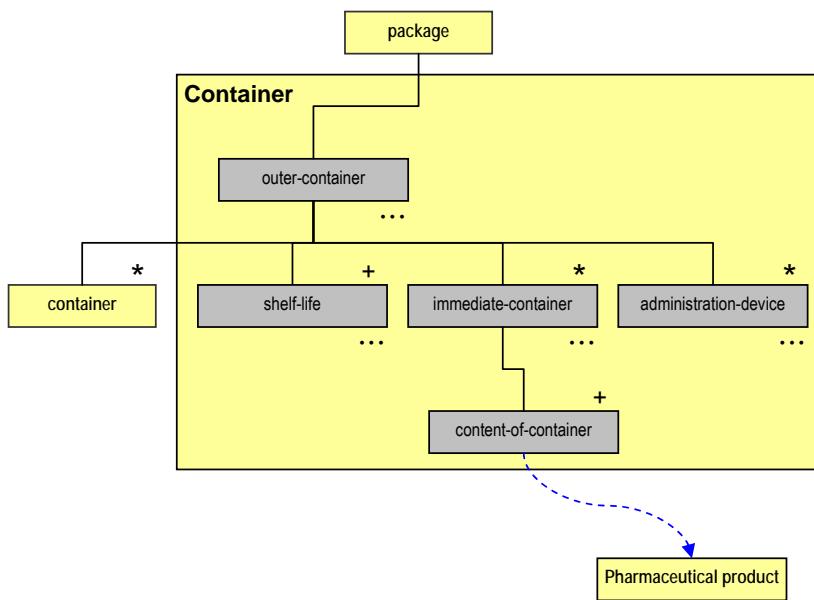
Element	RDM specific Format	Definition	Remarks for Structure/type/rule/format or other
package-name	NAME	Contains the name of the package. E.g. Actos, Actraphane 10 Penfill.	It is difficult to determine what goes into package code vs. package name (especially when the code is quite long)
package-code	-	Designation in the form of a code value that within a given coding scheme identifies the medicinal product package [CEN 12610: 5.5.1]	
package-size	-	Size of the package including the number of tablets or size of package having vials. E.g. 28, blister (alu/alu)	
package-withdrawal-date	DATE	Date when the package was withdrawn from the authorised market.	
package-variation-date	DATE	Date on which the latest variation became effective.	
package-renewal-date	DATE	Date on which the latest renewal of the marketing authorisation was granted.	
ich-m5-mpid	ICH M5 ID	An identifier assigned to a medicinal product by the regulator of the country/territory of authorisation. E.g. EU-EU/1/02/209/008-3939AF75.	
ich-m5-mpid-other-language-code	-	Language code of the other language (Japanese).	
ich-m5-mpid-other-language-name	-	Name of the package in other language (Japanese).	
legal-status-for-the-supply	IDENTIFIER + TERM NAME	See used CTLS	
psur-statement	DESCRIPTION	Specification of the requirements only if they are different from the normal PSUR cycle in Annex II.	



## 6.1.7 Container

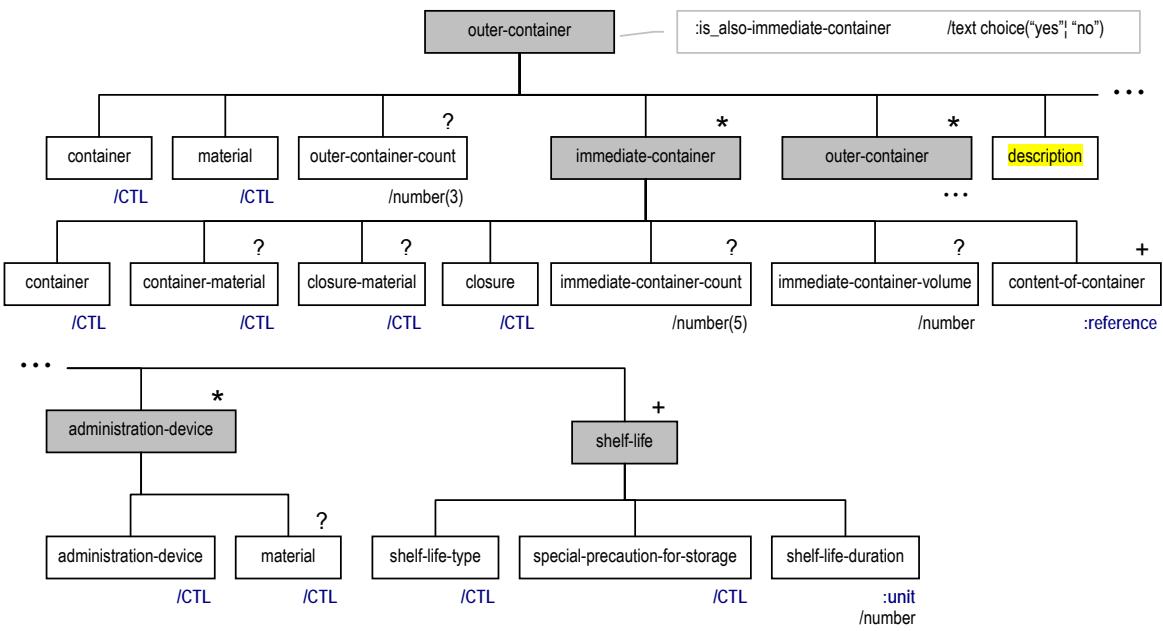
### 6.1.7.1 Container (Business concept)

Element	RDM specific Format	Definition	Remarks for Structure/type/rule/format or other
outer-container	-	Physical delivery unit of the medicinal product or any container that is not in direct contact with the pharmaceutical product.	
immediate-container	-	Inner/Immediate container is defined as: Container which is in direct contact with the pharmaceutical product [ENV 12610:1997 – 3.14]	
shelf-life	-	This entity contains the information about time of usage of the outer container.  Example: Medicinal product 'Halocur – Oral solution HALOFUGINONE 0.5 mg/ml' has the shelf life information as 'Shelf-life of the veterinary medicinal product as packaged for sale: 3 years. Shelf-life after first opening the container: 6 months'. This entity contains two shelf lives as 3 years while the package remains closed and 6 months after first opening	
content-of-container	-	Reference to one or more pharmaceutical-product contained in the package.	
administration-device	-	This entity contains the administration devices information in the package:	



### 6.1.7.2 Container(Technical Concept)

Element	RDM specific Format	Definition	Remarks for Structure/type/rule/format or other
outer-container	-	-	
:is_also-immediate-container	BOOLEAN		
description	DESCRIPTION	Textual description of the package	Initial-application-form
outer container count	-	Number of containers in the outer container.	
container	IDENTIFIER + TERM NAME	See list of CTL	
immediate-container	-	-	
immediate-container-container-count	-	Number of inner containers per category in the outer container. For example, 10 blisters and 2 bottles in a folded box.	
immediate-container volume	QUANTITY	Volume of pharmaceutical product that the inner container can hold. This field is useful for containers that may hold the liquid pharmaceutical products.	
container-material	IDENTIFIER + TERM NAME	See materiel CTL	
closure	IDENTIFIER + TERM NAME	a closure is a material used to close the container. (ex: Aluminium cap) See container CTL	
closure-material	IDENTIFIER + TERM NAME	See materiel CTL	
content-of-container	:	This entity contains the reference to the contents (i.e. pharmaceutical product) present in the immediate container	
shelf-life	-	-	
shelf-life-duration	QUANTITY		
shelf-life-type	IDENTIFIER + TERM NAME	See list of CTL	
special-precaution-for-storage	IDENTIFIER + TERM NAME	See list of CTL	
administration-device	-		
administration-device	IDENTIFIER + TERM NAME	See list of CTL	
material	IDENTIFIER + TERM NAME	See list of material CTL	

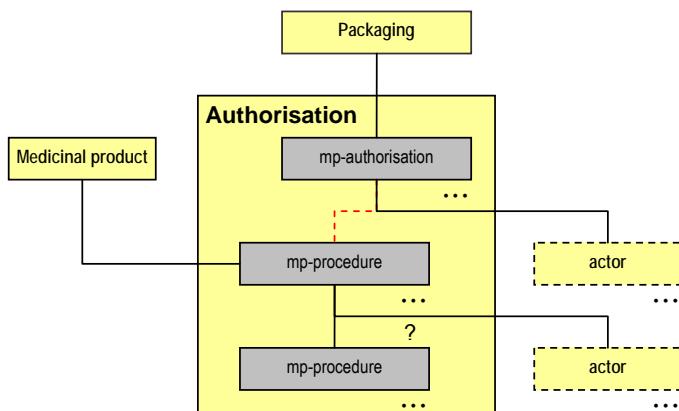


## 6.1.8 Authorisation

### 6.1.8.1 Authorisation (Business Concept)

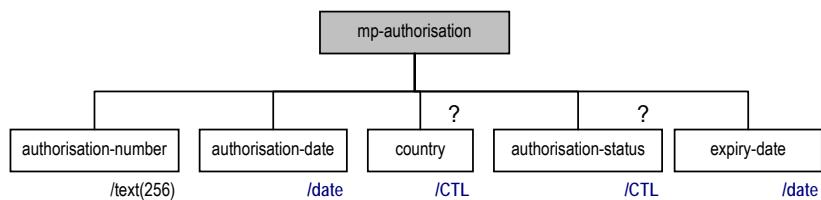
Definition	Sources
Authorisation covers the information on procedure and authorisation related to the marketing of medicinal products.	Regulation (EEC) N° 2309/93 (see article 3)

Element	Definition	Remarks for Structure/type/rule/format or other
mp-authorisation	<p>The authorisation information of the medicinal products.</p> <p>Example(s): For a centralized Human Medicinal Product</p> <ul style="list-style-type: none"> <li>• Authorisation number: EU/1/00/150/001</li> <li>• Date: 13 October 2000</li> <li>• Status: Authorised by Marketing Authorisation Holder</li> </ul>	The Authorisation information has been attached to the Package, and split from the Procedure, so as to assure the identification of a procedure for a medicinal product before approval.
actor	See Actor business concept	Role = "marketing authorisation holder"
mp-procedure	<p>The Authorisation procedure followed for the granting of the marketing authorisation. The procedure number corresponds to a common identification.</p> <p>Examples: EMEA/H/C/000285 (For a centralised procedure)</p>	The mp-procedure may contain itself for historical data purposes in case of an MRP.
actor	See Actor business concept	Role="applicant", "rapporteur", "co-rapporteur"
medicinal product	See Medicinal Product business concept	



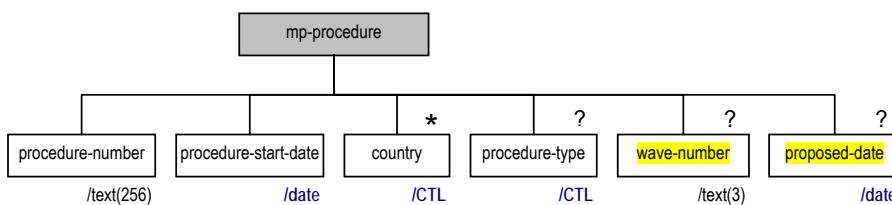
**6.1.8.2 authorisation (Technical Concept)**

Element	RDM Specific Format	Definition	Remarks for Structure/type/rule/format or other
authorisation-number	-	Authorisation number granted by the relevant authority (EMEA, NCAs). E.g. EU/1/00/150/001.	
authorisation-date	DATE	Date on which the marketing authorisation was granted, either in a centralised or in a national procedure	The RDM field "authorised on" has been renamed to "authorisation date" for coherence purposes. Does the field "authorised on" correspond to the first approval date (as in EudraPharm) or the latest one?
country	IDENTIFIER + TERM NAME	See used CTL  The country for which the authorisation is given. The country may be the reference member state or the concerned member state depending on the application.	The relation to the Country CTL has been encoded as mandatory, as a MP is always authorised for a country.
authorisation-status	IDENTIFIER + TERM NAME	See used CTL	
expiry-date	DATE	Date of expiration of the current authorisation	



## 6.1.8.3 procedure(Technical Concept)

Element	RDM Specific Format	Definition	Remarks for Structure/type/rule/format or other
procedure-number	-	The procedure number corresponds to a common identification of the procedure. E.g. EMEA/H/C/000071 is a centralised procedure number.	is "Procedure Number" the core number or the full one with the procedure type and sequence ?
procedure-start-date	DATE	Date on which the procedure was started.	the field "procedure started on" has been renamed to "procedure-start-date" for coherence purposes
country	IDENTIFIER + TERM NAME	See country CTLS The concerned member state	Filter="EEA"
procedure-type	IDENTIFIER + TERM NAME	See procedure-type CTLS	
wave-number	NUMBER	The sequence number of the procedure for the same medicinal product	Range for 0 (first authorization) to n
proposed-date	DATE	The common agreed proposed date. This date depends on the type of procedure (ex: proposed date for type "renewal" is the proposed renewal date")	

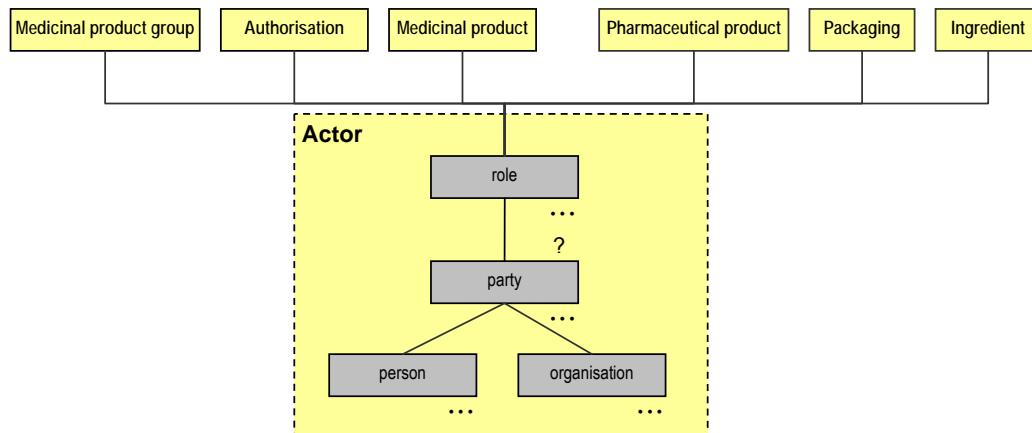


Business Rules				
ID	Element	Default BR	Rule	Effect(s)
1	procedure-start-date	optional	application-type="initial application human" OR application-type="initial-application vet"	Mandatory
2	country	Optional multiple	If procedure-type = "national" or "centralized" => one and only one	Single (?)
2.1	country	?	If procedure-type = "centralised"	Value= 'EU'

## 6.1.9 Actor

### 6.1.9.1 Actor (Business Concept)

Element	definition	Remarks for Structure/type/rule/format or other
Actor	Actor is any individual or organisation that is involved in or affected by any activities relating to human and veterinary medicinal products. Examples of Actor are: marketing authorisation holder, manufacturer, sponsor... [Regulation (EC) N° 726/2004 (see article 2)]	
role	The role played by a given party (organisation/person) in one or more activities (manufacturing, marketing authorisation, clinical trials etc.) related to a medicinal product. This entity combines the parties with their roles for a particular activity. Example(s): <ul style="list-style-type: none"><li>• Ranbaxy Laboratories Ltd with role Manufacturer of active substance to medicinal product Sertraline Omega 50 mg coated tablet</li><li>• Aventis Pharma Deutschland GmbH with role Marketing Authorisation Holder to the different Insulman products</li><li>• Boehringer Ingelheim AB with role Local Representative to the different Buscopan medicinal products</li><li>• Pharmacia Ltd with role Manufacturer of the pharmaceutical product to medicinal product Celebra.</li></ul>	
party	Any individual or organisation that is involved in or affected by any activities relating to human and veterinary medicinal products. This entity contains the identifiers for the parties. This entity has a recursive relationship to cover the parent and child parties. For example, a marketing authorisation holder having representatives in various countries, a sponsor having a contact person, a manufacturer having various manufacturing sites etc. In the examples, marketing authorisation holder, sponsor and manufacturer are the parent parties while local representatives, contact person and manufacturing sites are the child parties respectively.	
Person	This entity contains the additional information for the party if party is of type Person	
Organisation	This entity contains the name for the party if party is of type Organisation. Examples: Ranbaxy Laboratories Ltd , Aventis Pharma Deutschland GmbH, Boehringer Ingelheim AB, Pharmacia Ltd	



## 6.1.9.2 Actor (Technical Concept)

Element	RDM Specific Format	Definition	Remarks for Structure/type/rule/format or other
role	-	See business concept	
role	IDENTIFIER + TERM NAME	See used CTLs	Merged with the party technical concept
role-country	IDENTIFIER + TERM NAME	See used CTLs	Renamed to role-country in the merged role + party technical concept
party	-	See business concept	Merged with the role and the organisation or the person
party-identification			
party-identification-type	IDENTIFIER + TERMNAME	Indicate by which kind of information the party can be uniquely identified.  Examples: Tax Number, Social Security Number, VAT Number, Duns Number (Number assigned to the site as per Data Universal Numbering System), GS1 Number, WHO Number, ISO/IEC-7 Identifier ????	Value: Reference is used in the af renwal.
identification-number		The number that uniquely identifies the party	
party-relationship-type	IDENTIFIER + TERMNAME	See Party relationship type CTL	
business-category		See Business category CTL	
party-type	IDENTIFIER + TERM NAME	See Party type CTLs	
role-country	IDENTIFIER + TERM NAME	See country CTLs The country for which the role is used. Ex: the site is in Italy but the	
person	-	See business concept	Merged with the role and the party
personal-title	CHARACTER(50)	Personal title of the person.	
job-title	CHARACTER(500)	Research Analyst, Pharmacist	Replaces function?
given-name	CHARACTER(500)	Given name of the person.	
middle-name	CHARACTER(500)	Middle name of the person.	
family-name	CHARACTER(500)	Family name of the person.	
initials	CHARACTER(500)	Person's initials.	
qualification		See qualification CTL	
gender		See Gender CTL	
organisation	-	See business rules	Merged with the role and the party
name		Name of the party	if party is of type 'Public Agency', 'Private Limited Company' or 'Academic Institute'
contact-details		See contact detail technical concept	
party		Sub organisation or person of this party (recursive concept)	



To simplify the use of this structure the party has been removed because a party is mandatory in the eAF and as a one to one relationship.

The person and organisation element have been removed because their respecting fields can be identified by using the party-type.

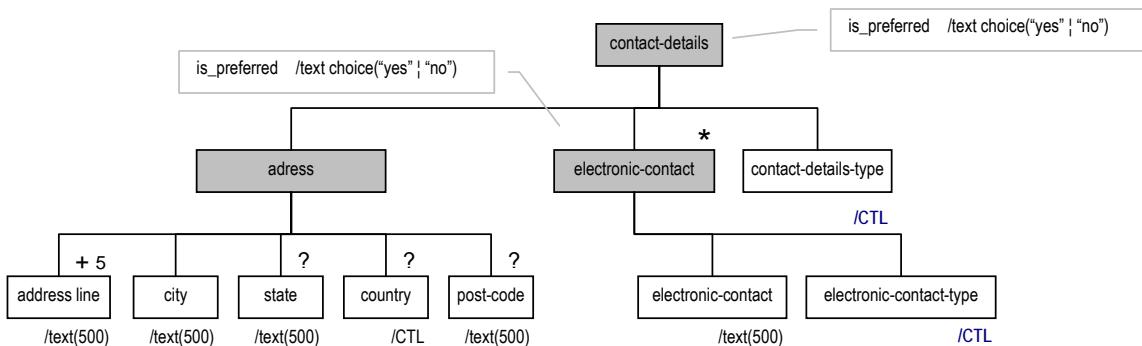
The XML could look like this

Example: contact details required from a person in a company.

```
< person-com-during-procedure >
  <party-type>organisation<party-type>
  <name> WonderProducts <name>
  <party-relationship-type> headquater </party-relationship-type> CTL
  <business-category> pharmacy </business-category>
</ person-com-during-procedure >
< person-com-during-procedure >
  <party-type>person<party-type>
  <party-relationship-type> employee </party-relationship-type> CTL
  <party-identification>
    <party-identification-type> social security card </party-identification-type> CTL
    <identification-number> 999-234342-11 </identification-number>
  </party-identification>
  <contact-details>
    ...see contact detaild section
  </contact-details>
<personal-title> Rr. </personal-title>
<job-title> Vaccines department director</job-title>
<given-name> John <given-name>
<middle-name/>
<family-name> Doe </family-name>
<initials> m </initials>
<qualification/> CTL
<gender> M </gender> CTL
</ person-com-during-procedure >
```

## 6.1.9.3 Contact details (Technical Concept)

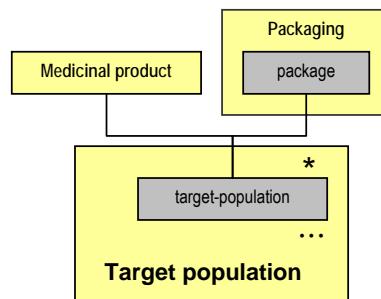
Element	RDM Specific Format	Definition	Remarks for Structure/type/rule/format or other
contact-details	-	This entity contains the identifiers for contact details for the parties. One party will have only one contact detail identifier. This entity serves the purpose of an umbrella for all contact information like Address, Phone, Fax and Email.	
:is_preferred		Tells which contact detail is preferred	
contact-details-type		See Contact details type CTL	
adress		Postal/Street address line 1 of the party. E.g. Address of party 'Pfizer Limited' is 'Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom'.	
address-line	CHARACTER(500)	Address of the contact.	
city	CHARACTER(500)	Town or city of the contact.	
state	CHARACTER(500)	State or province	
post-code	CHARACTER(500)	Post code of the party. E.g. post code for 'Pzifer Limited' is 'CT13 9NJ'	
electronic-contact			
:is_preferred		Tells which electronic contact is preferred	
electronic-contact-type	IDENTIFIER + TERMNAME	See Electronic contact type CTL	
electronic-contact			



## 6.1.10 Target population

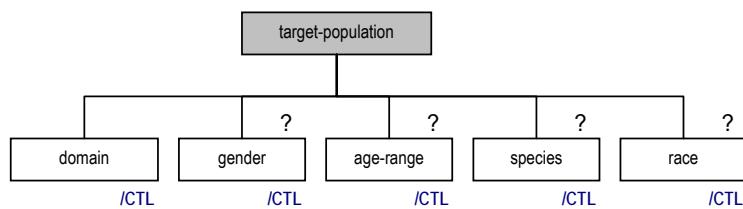
### 6.1.10.1 Target population (Business Concept)

Element	Definition	Remarks for Structure/type/rule/format or other
Medicinal product	The group of patients/animals described by domain, gender, age range, race and/or species who might be treated by the medicinal product.	
Packaging	See packaging business concept	
Target population	See target population business concept	



## 6.1.10.2 target-population (Technical Concept)

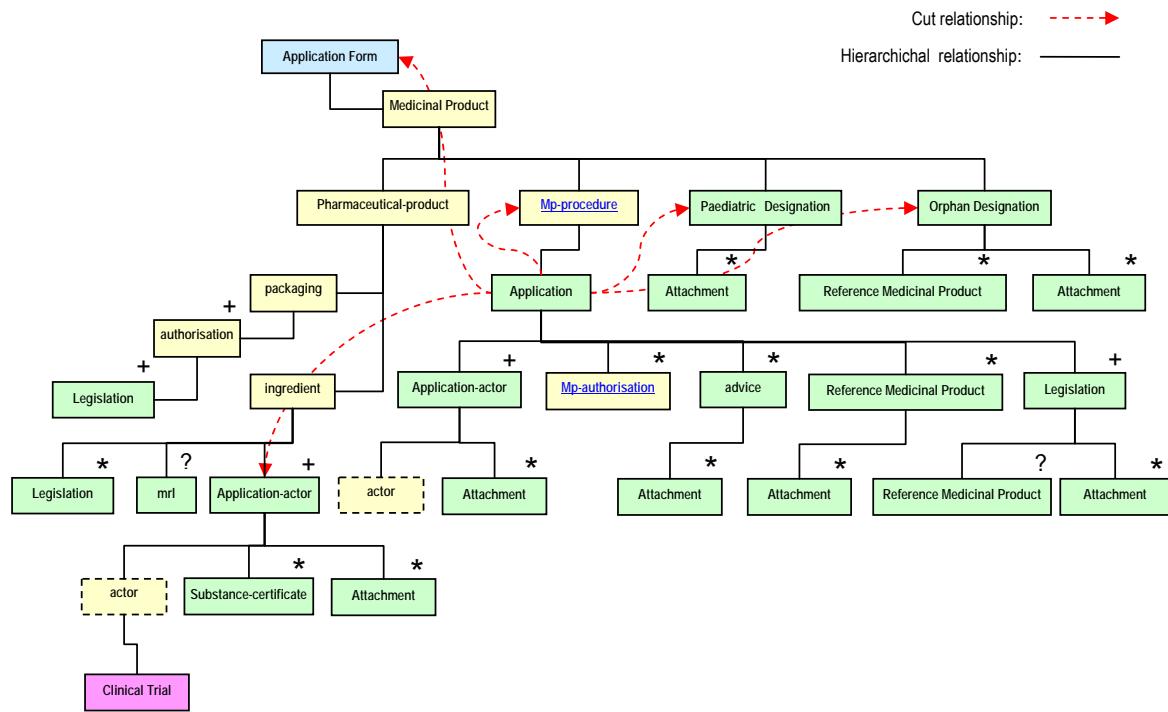
Element	RDM Specific Format	Definition	Remarks for Structure/type/rule/format or other
target-population	-		
domain	IDENTIFIER + TERM NAME	The list of areas where a medicinal product or a term can be used (Human use, Veterinary use, Human and Veterinary use,...)	
gender	IDENTIFIER + TERM NAME	See used CTLS	
age-range	IDENTIFIER + TERM NAME	See used CTLS	
species	IDENTIFIER + TERM NAME	See used CTLS	
race	IDENTIFIER + TERM NAME	See used CTLS	



## 6.2. Common Application Form

### 6.2.1 Common Application Form model serialization

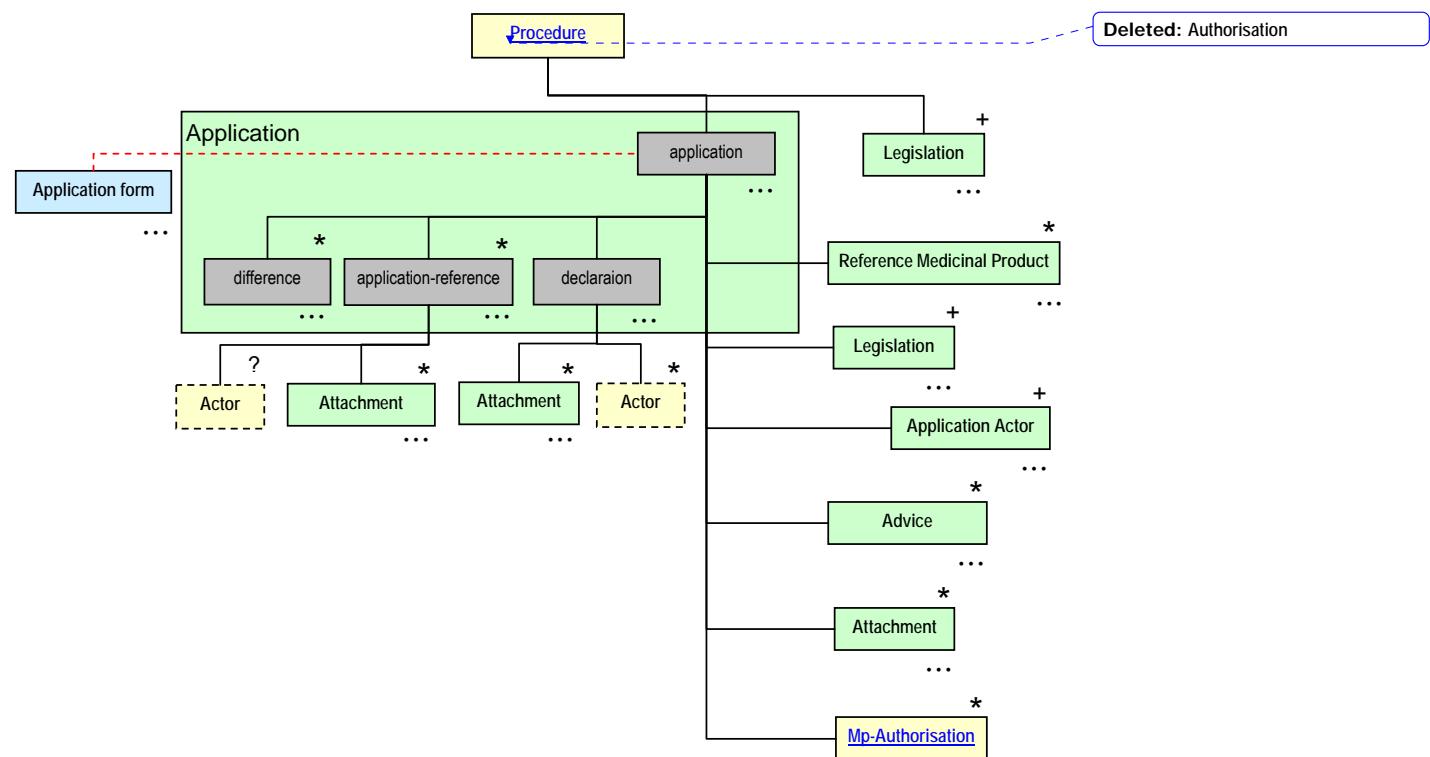
The application form ETD provides structure for all currently supported application form.



## 6.2.2 Application

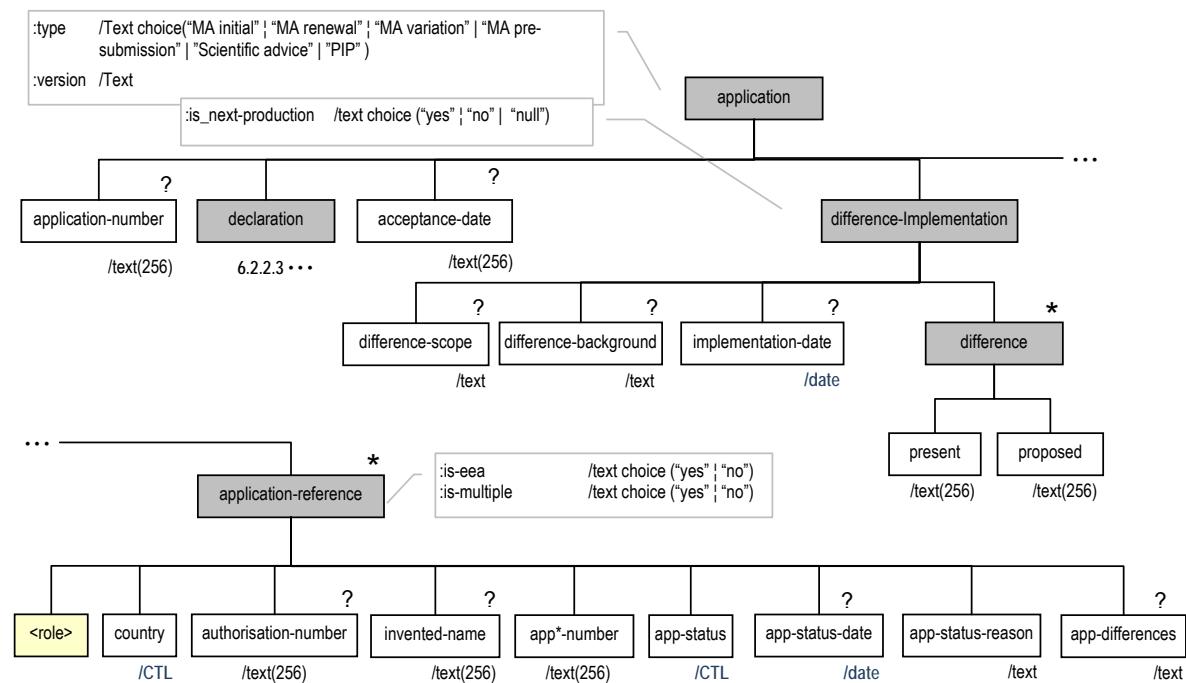
### 6.2.2.1 Application (Business concept)

Element	RDM Specific Format	Definition	Remarks for Structure/type/rule/format or other
Application	-	The application is the process steps that defines the all the information requested by the regulator to get an authorisation.	application technical concept is linked to the mp-procedure technical concept
Authorisation	-	See authorisation concept	
Attachment	-	See Attachment concept	
Declaration	-	The declaration identifies who applies for the application and what are their responsibilities.	



## 6.2.2.2 Application (Technical concept)

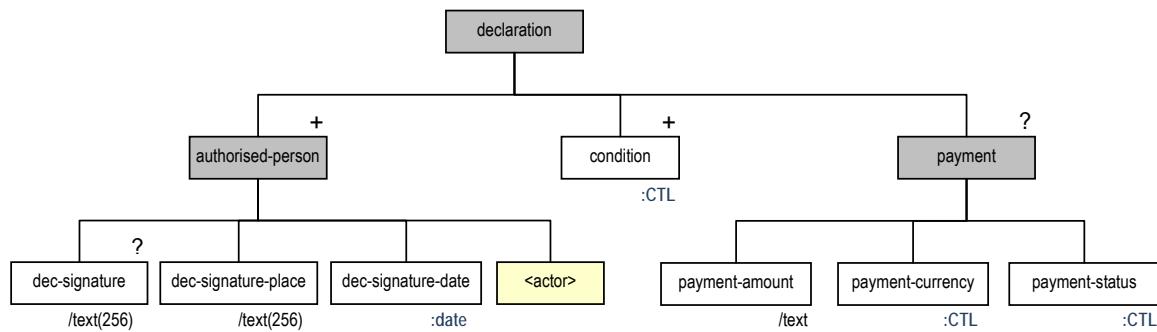
Element	RDM Specific Format	Definition	Remarks for Structure/type/rule/format or other
Application	-	An application is done for only one medicinal product except for a centralised procedure where multiple medicinal product are tolerated	This is valid in the context of the initial-application form human and vet.
:type	IDENTIFIER + TERMNAME	Saa application-type CTL The type of application submitted by the applicant. It stands for the form title.	
:version		The DES version with which the message was built.	
application-number		The number used as a reference for the reference application	
acceptance-date	DATE	The date of acceptance of the application by the CHMP or CVMP	
application-reference	-	The other marketing authorization applications for the same medicinal product inside or outside the eea.	
:is-eea	BOOLEAN	Refer to region where other applications are submitted by the applicant for the same medicinal product.	
:is-multiple	BOOLEAN	Refer to multiple or duplicate applications made for the same product.	
<role>		The party to be mentioned in the referenced application	Value="marketing-authorisation-holder"
country	IDENTIFIER + TERMNAME	Country filter inside or outside eea	
authorisation-number		The number of the authorisation	
application-number		The number used as a reference for the reference application	
application-status		See authorisation-status CTL	Deleted: To be checked.
application-status-date			
invented-name		The most common invented name	
application-status-reason	DESCRIPTION		
application-differences	DESCRIPTION		
declaration	-	The declaration provides the identification and authentication information of the application  See section 6.2.2.3	
difference-implementation	-	The implementation of the differences contains the information on how to implement the changes/differences mentioned in the application (renewal or variation)	
ls_next-production	Boolean unknown	When the next production run or next printing of the medicinal product	
difference-scope	DESCRIPTION	Scope of the change(s) in a concise way	
difference-background	DESCRIPTION	Brief background explanation for the proposed changes to your MA, as well as a justification in case of consequential changes	
implementation-date	DATE		
difference	-	The differences/changes between current medicinal product and proposed medicinal product that the application covers by its lega.	
present	DESCRIPTION	Description of what is to be changed if the application is authorised	
proposed	DESCRIPTION	Description of the how it will be after the changes is applied.	

Element Tree Diagram


\*app=application

## 6.2.2.3 Declaration (technical concept)

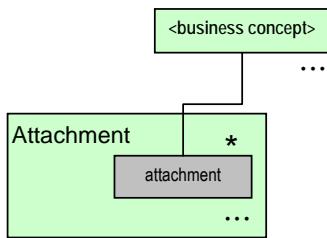
Element	RDM Specific Format	Definition	Remarks for Structure/type/rule/format or other
declaration	-	The declaration provides the identification and authentication information of the application	
authorised-person			
dec-signature		The digital signature of the applicant if any	
dec-place-signature		The geographical place where the signature took place	
dec-date-signature		The date when the application was signed	
<actor>		The role assigned to the authorised-person element	Values: "applicant"; "main-signatory"; "second-signatory"
payment	-	The payment associated to the application which is subject to various tarifications depending on the sme-status.	
payment-amount		The amount to be paid for the application processing	
payment-currency		The currency in which the payment is done	
payment-status		See payment status CTL The status of the payment transaction (not-payed, in-process, payed, refused)	CTL to be defined (optional -> mandatory if payment-amount is <> 0)
condition	TERMID + TERMNAME	See declaration condition CTL The list of condition fulfilled or not in a application declaration	Used in variation application

Element tree diagram


## 6.2.3 Attachment

### 6.2.3.1 Attachment (business concept)

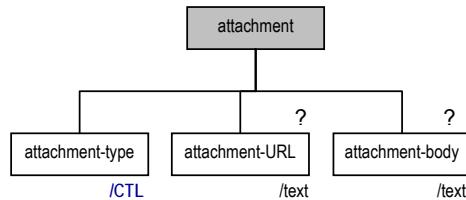
Element	RDM Specific Format	Definition	Remarks for Structure/type/rule/format or other
Attachment	-	The declaration identifies who applies for the application and what are their responsibilities.	
<business concept>		Any business concept	



### 6.2.3.2 Attachment (technical concept)

Element	RDM Specific Format	Definition	Remarks for Structure/type/rule/format or other
Attachment	-	Any document that need to be added with the application form	The name of the control term value
Attachment-type	IDENTIFIER + TERMNAME	The term id that identifies the attachment or document ex: "letter of consent", "GMP certificate", "letter of authorization", "CV of qualified person", etc. see attachment-type CTL	
Attachment-URL		The URL/URI to the document	
Attachment-body		Base 64 encoded attachment body	Note: Foreseen in case of base 64 encoding

#### Element Tree Diagram



## 6.2.4 Reference Medicinal Product

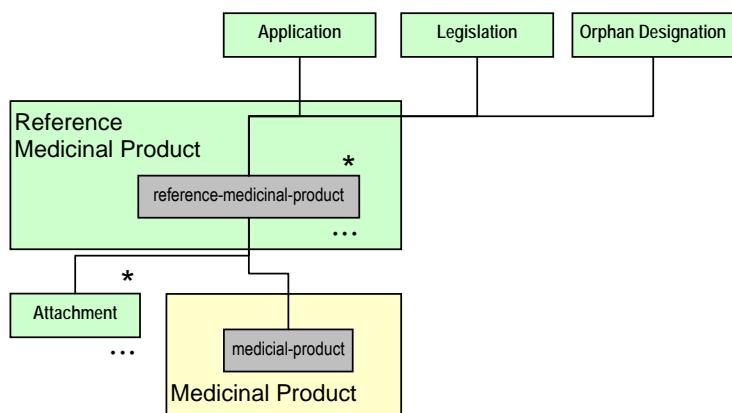
### 6.2.4.1 Reference Medicinal Product (Business Concept)

Element	RDM Specific Format	Definition	Remarks for Structure/type/rule/format or other
Reference Medicinal Product	-	represent the medicinal product that already comply with the E.U or National legislation And is used a reference in the context of the application.	The link to the medicinal product is kept through an internal reference id.
Orphan Designation	-	See Orphan Designation concept	The link is defined by the regulation EC 847/2000 for "similar" medicinal product definition
Legislation	-	See Legislation concept	The Reference Medicinal Products link to a specific legislation are defined in the annexes.

#### Element Tree Diagram

The Reference medicinal product may be used by (under) any common application form concept if the reference medicinal product clearly linked to that concept.

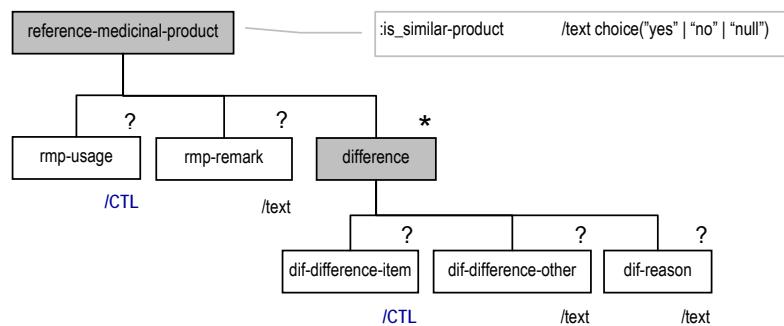
The medicinal product RDM concept is reused under the Reference medicinal product to avoid the proliferation of internal references.



### 6.2.4.2 Reference Medicinal Product (technical concept)

Element/ Attribute	RDM Specific Format	Definition	Remarks for Structure/type/rule/format or other
reference-medicinal-product (rmp)	-	represent an identified part of the E.U or National legislation to which the medicinal product or the application comply with.	
:is_similar-product	Boolean Undefined	Determine if the reference product is "similar" to the current applied product.  'similar medicinal product' means a medicinal product containing a similar active substance or substances as contained in a currently authorised orphan medicinal product, and which is intended for the same therapeutic indication;	Default value is undefined Used in the context of orphan designation market exclusivity
rmp-reference	REFERENCE	Is the xml internal reference to the corresponding medicinal product	
rmp-usage	IDENTIFIER + TERMNAME	The usage of reference declared ex ("eu marketing authorisation"; "same community/member state application"; "not less than 6/10 years in the EEA"; "demonstrated bioequivalence"; "mutual recognition procedure"...) See reference-medicinal-product-usage	
rmp-remark	DESCRIPTION	the remark or comments by the applicant	
difference	-	Represent the differences between the reference medicinal product and the medicinal product for which the application is made. See difference CTL	
dif-reason	DESCRIPTION	The reason to the difference to exists	
dif-difference-item	IDENTIFIER + TERMNAME	Difference or changes between the reference medicinal product and the application product (change of bioavailability, change of pharmacokinetics, change or addition of a new strength / potency, change or addition of a new pharmaceutical form, change or addition of a new route of administration, change(s) in the raw material(s), change(s) in the manufacturing process(es), change in therapeutic indication(s), change in pharmaceutical form(s), change in strength (quantitative change to the active substance(s)), change in route of administration(s), other)	
dif-difference-other	DESCRIPTION	When the difference does not exist in any controlled term list	

#### Element Tree Diagram

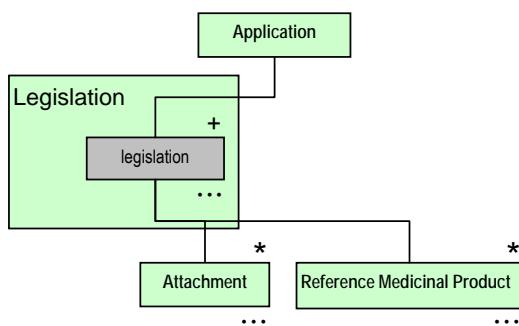


Business Rules			
Element	Default BR	Rule	Effect(s)
dif-difference-other	optional	dif-difference-item = "other"	mandatory

## 6.2.5 Legislation

### 6.2.5.1 Legislation (business concept)

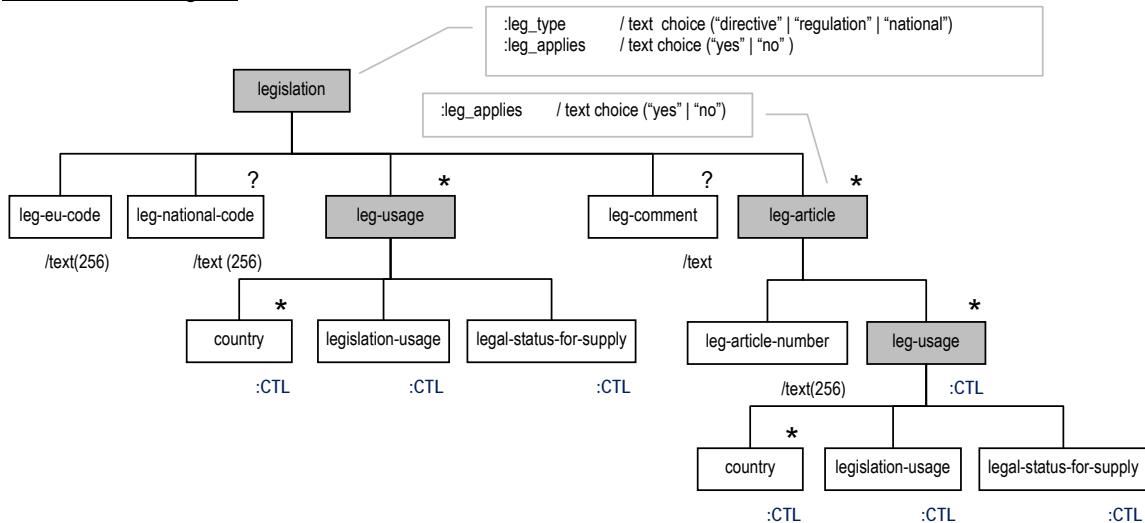
Element	RDM Specific Format	Definition	Remarks for Structure/type/rule/format or other
legislation	-	represent an identified part of the E.U or National legislation to which the medicinal product or the application comply or does not comply with.	



### 6.2.5.2 Legislation (technical concept)

Element	RDM Specific Format	Definition	Remarks for Structure/type/rule/format or other
Legislation (leg)	-		
:leg_type	IDENTIFIER+ TERMNAME	Defines the type of legislation: directive"   "regulation"   "national"	"directive"   "regulation"
:leg_applies	boolean	Determine is the applicants comply or not with the specific legislation.	"yes"   "no"
leg-eu-code		The european code for the law See legislation-code CTL	Format : directive: YYYY/9999/EC or Regulation: 9999/YYYY The format depends on the leg-type
leg-national-code		The national code of the law See legislation-code CTL	
:leg_usage		The usage context of the legislation element if the code is not sufficient to determine the context of application.. Ex ("new active substance", "known active substance" are referred together in one paragraph of the legislation...)	Comment [d3]: The legislation is used to contain term id of the legal status for the supply and the country together in a leg-usage to cover mrp case. Discussed with Robert but there was no solution found. (still under discussion for RDM V3). This is a working proposition.
country	IDENTIFIER+ TERMNAME	The country for which the legislation applies see the Country CTL	
legislation-usage	IDENTIFIER+ TERMNAME	See legislation usage CTL	
legal-status-for-supply	IDENTIFIER+ TERMNAME	Covers the form fields not covered by a legislation article.(pharmacies only,...) See Legal-status-for-the-supply CTL	
leg-comment	DESCRIPTION	Note or comment associated to the legislation in the context of the application	
leg-article	-		
leg-article-number		The article that is part of the legislation if any	Format: article 999.[99] [annex 99]
leg-article-usage	IDENTIFIER+ TERMNAME	The usage context of the legislation article element if the code is not sufficient to determine the context of application. Ex ("renewable delivery", "not renewable delivery" ...)	

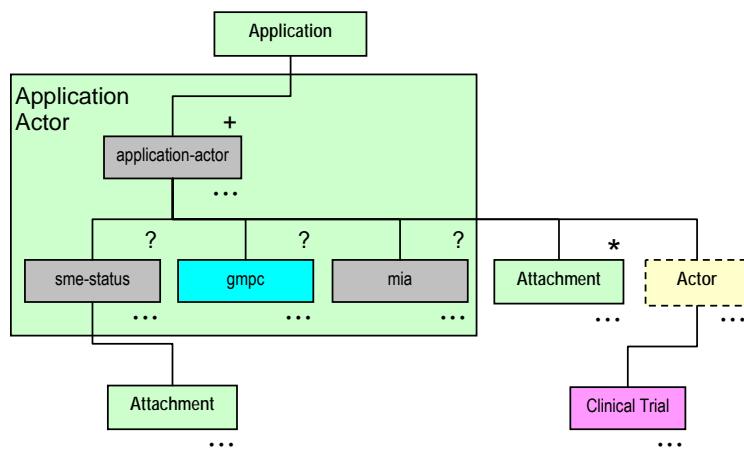
#### Element Tree Diagram



## 6.2.6 Application Actor

### 6.2.6.1 Application Actor (Business concept)

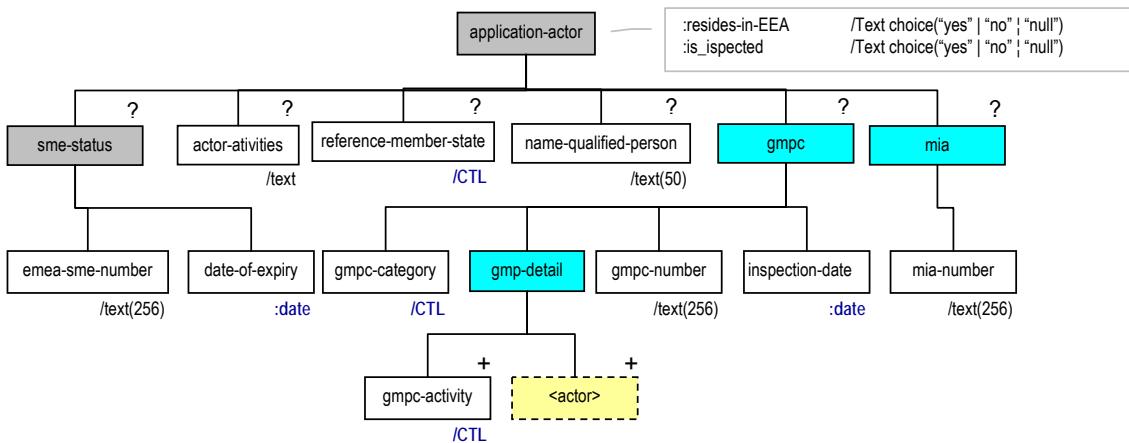
Element	RDM Specific Format	Definition	Remarks for Structure/type/rule/format or other
Reference actor	-	Any actor related to the current application. . .	This is used to - assign the same actor to different roles - refer to an actor already defined elsewhere in the model. - define an actor not foreseen in the RDM model or for which interoperability info is not relevant.
sme-status	-	The small to Medium enterprise status provided by the emea	Defined by the <a href="#">Recommendation 96/280/EC</a> Legislation("Regulation 726/2004")/ article("70.2")/leg_applies="yes"
Gmpc	-	God Manufacturing Process certificate: This entity contains the header level information for a GMP Certificate issued by a National Competent Authority to some company site	
Mia	-	This entity contains the header level information for a MIA (Manufacturing and Importation Authorisation) issued by a National Competent Authority to some company site(s)	
Clinical trial	-	Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of one or more investigational medicinal product(s), and/or to identify any adverse reactions with the object of ascertaining its (their) safety and/or efficacy.	



### 6.2.6.2 application Actor (Technical concept)

Element	RDM Specific Format	Definition	Remarks for Structure/type/rule/format or other
application-actor	-		
:resides-in-eea	TEXT	Indicates if the application actor resides in EEA or not ("yes"   "no"   "null")	
:is-inspected	TEXT	Indicated if the application actor has been inspected ("yes"   "no"   "null")	Only valid when the application actor is a manufacturer otherwise value is null
reference-member-state	IDENTIFIER + TERMNAME	See country CTL  The reference member state in which the actor has a role. The actor's country may be different from the reference-member-state	By default the reference-country and the actor's country are the same. Examples show sometimes the contrary.
actor-activities	IDENTIFIER + TERM NAME	Activities (test, process functions,...) performed by the actor depending on its role (mainly the Manufacturer)	May be conceived into a list and filtered by type of activity
Inspection-authority	IDENTIFIER + TERM NAME	The type of inspection authority that performs the inspection of the current site. (EEA, Other)	
name-qualified-person	NAME	According to 2001/83/EC The qualified person is responsible in particular for carrying out the duties specified in Article 51 and fulfils the conditions of qualification set out in paragraphs 2 and 3 of article 49.	
gmpc	-	This entity contains the header level information for a GMP Certificate issued by a National Competent Authority to some company site	
gmpc-category		The category is fixed to the value "GMP Certificate"  See gmpc-category	
gmpc-number		GMPC reference number	
inspection-date		Last GMP inspection date	
gmp-detail	-	This entity holds detail level information (authorised dosage forms, activities etc) for a GMP Certificate	
gmp-activity	IDENTIFIER + TERM NAME	category of products and activities inspected  see GMP activity CTL	
mia	-	This entity contains the header level information for a MIA (Manufacturing and Importation Authorisation) issued by a National Competent Authority to some company site(s).	
mia-number		The authorization number delivered by the National Competent Authority	
sme-status	-	The status given by the EMEA in order to get some fee reductions on a application.	
emea-sme-number		The reference by which the SME status is registered by the EMEA	
date-of-expiry	DATE	The expiration date of the sme status	

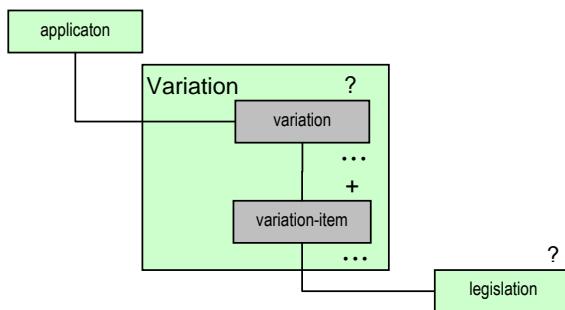
### Element Tree Diagram



## 6.2.7 Variation

### 6.2.7.1 Variation (business concept)

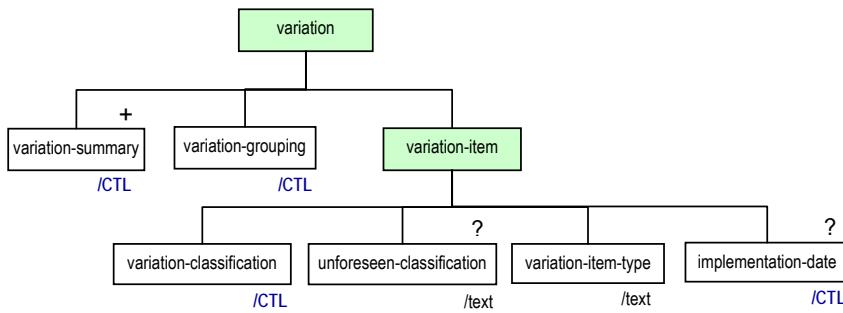
Element	RDM Specific Format	Definition	Remarks for Structure/type/rule/ format or other
Variation	-	<p>'Variation to the terms of a marketing authorisation' or 'variation' means an amendment to the contents of the particulars and documents referred to in:</p> <p>(a) Articles 12(3), 13, 13a, 13b, 13c, 13d and 14 of Directive 2001/82/EC and Annex I thereto, and Article 31(2) of Regulation (EC) No 726/2004 in the case of veterinary medicinal products;</p> <p>(b) Articles 8(3), 9, 10, 10a, 10b, 10c and 11 of Directive 2001/83/EC and Annex I thereto, Article 6(2) of Regulation (EC) No 726/2004, point (a) of Article 7(1) and Article 34(1) of Regulation (EC) No 1901/2006 of the European Parliament and of the Council (2) and Articles 7 and 14(1) of Regulation (EC) No 1394/2007 of the European Parliament and of the Council (3) in the case of medicinal products for human use;</p>	
Variation-item	-	The smallest piece of change possible in a variation having a classification	



## 6.2.7.2 Variation (Technical concept)

Element	RDM Specific Format	Definition	Remarks for Structure/type/rule/ format or other
variation-type-summary	IDENTIFIER + TERM-NAME	See variation type CTL	
variation-grouping	IDENTIFIER + TERM-NAME	See variation-grouping CTL	
variation-domain-summary	IDENTIFIER + TERM-NAME	See variation domain CTL	Rule 1
Variation-item		represent a single variation.	
variation-classification	DENTIFIER + TERM-ID	See variation-classification CTL	Format: class.index.sub-index Just a title may be selected if other variation is to be described
unforeseen-classification	DESCRIPTION	See variation classification CTL	value is z other variation
variation-item-type	ENTIFIER + TERM-ID	See variation type CTL	
implementation-date	DATE	The proposed date of the implementation of the variation	

**Comment [d5]:** To be decided if the (z) is part of the CTL or deducted when the unforeseen-classification is filled or when only a title is selected in the classification-section is selected



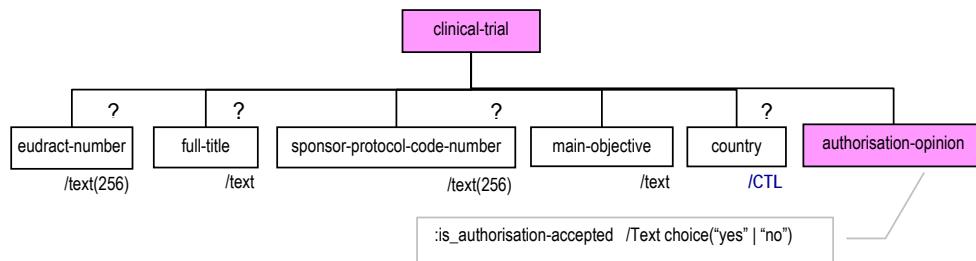
Business Rules			
Element	Default BR	Rule	Effect(s)
1 - variation-class-summary	optional	If variation type summary is IB unforeseen, IB foreseen, II or II art 29	Mandatory

## 6.2.8 Clinical trial

### 6.2.8.1 Clinical Trial (Technical Concept)

Element	RDM Specific Format	Definition	Remarks for Structure/type/rule/format or other
eudract-number	-	EudraCT number for the clinical trial.	
full-title	DESCRIPTION	Full title of the clinical trial.	
sponsor-protocol-code-number	-	The Sponsor's protocol code number.	
main-objective	DESCRIPTION		To be checked
country	IDENTIFIER+TERMNAME		
authorisation-opinion	-	This entity contains information about the authorisations and/or opinions for a particular clinical trial	
Is authorisation accepted	BOOLEAN	Flag to indicate whether authorisation is accepted or opinion given is favourable.	

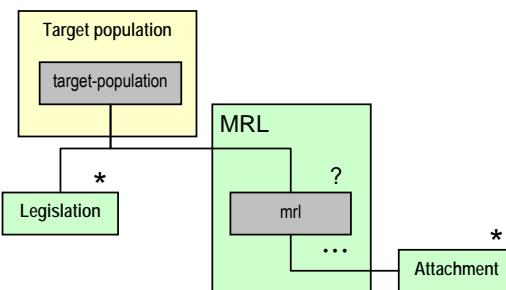
#### Element Tree Diagram



## 6.2.9 Maximum Residue Limit (MRL)

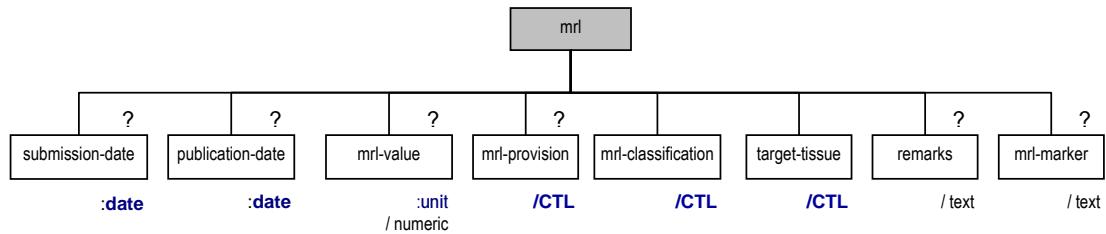
### 6.2.9.1 MRL (business concept)

Element	RDM Specific Format	Definition	Remarks for Structure/type/rule/format or other
Maximum residue limit	-	All pharmacologically active substances, whether active principles, excipients or degradation products, and their metabolites which remain in foodstuffs obtained from animals to which the veterinary medicinal product in question has been administered	according to Council Regulation (EEC) No 2377/90



### 6.2.9.2 MRL (Technical concept)

Element	RDM Specific Format	Definition	Remarks for Structure/type/rule/format or other
maximum residue limit	-		
mrl-value	NUMERIC	Value for maximum residue limit.	
mrl-provision	IDENTIFIER + TERM NAME	See Mrl provision CTL	
mrl-classification	IDENTIFIER + TERM NAME	See Mrl classification CTL	optional
target-tissue		See tissue CTL	
publication-date	DATE	The date when it has been published in the Official Journal of the European Communities	optional
submission-date	DATE	The date when it has been submitted to the agency	optional
remarks	DESCRIPTION	Remark about the mrl status of the ingredient	Optional
Mrl-marker	DESCRIPTION	Active substance or any of its metabolites, or a combination of any of these, the concentration of which decreases in a known relationship to the concentration of the total residues in target tissues (muscle, fat, liver, kidney), eggs, milk or honey. The analytical methods for monitoring of residues are developed to detect the marker residue.	

Element Tree Diagram


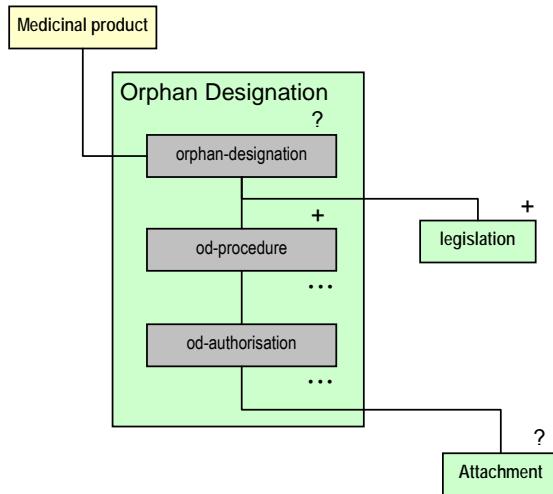
Business Rules				
Element	Default BR	Rule	Effect(s)	
mrl	optional	Ingredient / Legislation: type="Regulation (EC) 2377/90" :leg_applies="yes"		mandatory
Date of submission	optional	If the publication does not exist		mandatory
Date of publication	optional	If the submission does not exist		mandatory

### 6.2.10 Orphan designation

### 6.2.10.1 Orphan designation (business concept)

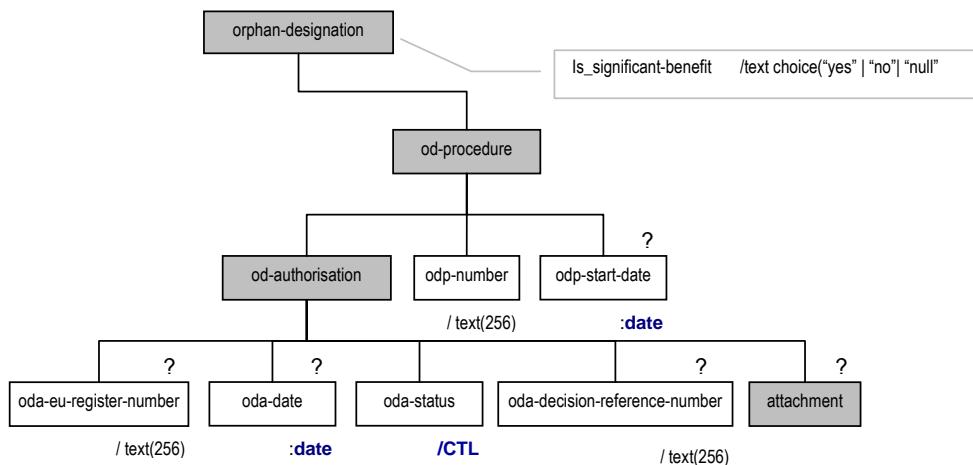
Element	RDM Specific Format	Definition	Remarks for Structure/type/rule/format or other
Orphan designation	-	<p>The designation criteria are laid down in Article 3(1) of Regulation (EC) No 141/2000</p> <p>A medicinal product shall be designated as an orphan medicinal product if its sponsor can be established:</p> <ul style="list-style-type: none"> <li>a) not more than five in 10 thousand persons in the Community when the application is made or would not generate sufficient return to justify the necessary investment;</li> <li>b) that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorised in the Community or, if such method exists, that the medicinal product will be of significant benefit to those affected by that condition</li> </ul>	Designation as an orphan medicinal product is governed by Articles 3 and 5 of Regulation (EC) No 141/2000
Legislation	-	<p>Legislation="Regulation (EC) 141/2000"/article="3(1)(b)" and</p> <p>"that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorised in the Community or, if such method exists, that the medicinal product will be of significant benefit to those affected by that condition"</p>	Determine if the orphan designation is a significant benefit.
Legislation	-	<p>Legislation="Regulation (EC) 141/2000"/article="8.1":</p> <p>"...the Community and the Member States shall not, for a period of 10 years, accept another application for a marketing authorisation, or grant a marketing authorisation or accept an application to extend an existing marketing authorisation, for the same therapeutic indication, in respect of a similar medicinal product"</p>	Determine the market exclusivity terms according to the different regulations.
Legislation		<p>Legislation="Regulation (EC) 141/2000"/article="5.1":</p> <p>In order to obtain the designation of a medicinal product as an orphan medicinal product, the sponsor shall submit an application to the Agency at any stage of the development of the medicinal product before the application for marketing authorisation is made.</p>	Used to determined if a OD was submitted..
Legislation		<p>Legislation="Regulation (EC) 141/2000"/article="5.9"</p> <p>"The designated medicinal product shall be entered in the Community Register of Orphan Medicinal Products."</p>	

### Element tree diagram



### 6.2.10.2 Orphan designation (technical concept)

Element	RDM Specific Format	Definition	Remarks for Structure/type/rule/format or other
orphan designation	-	The designation criteria are laid down in Article 3(1) of Regulation (EC) No 141/2000	Designation as an orphan medicinal product is governed by Articles 3 and 5 of Regulation (EC) No 141/2000
ls_significant-benefit	Boolean Undefined	"that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorised in the Community or, if such method exists, that the medicinal product will be of significant benefit to those affected by that condition"	Note: from "Regulation (EC) 141/2000" article 3(1)(b) Determine if the orphan designation is a significant benefit.
or-procedure	-	The procedure number associated to the application for or eu orphan designation.	
odp-number		EMEA procedure number	Format=" EMEA/OD/XXX/yyyy"
odp-start-date	DATE	Date on which the procedure was started.	
or-authorisation	-	The orphan designation authorisation associated to the medicinal product	
oda-eu-register-number		the Number in the Community Register of Orphan Medicinal Products	Format="EU/X/XX/XXX"
oda-date	DATE	The date of one of the final status ("granted", "refused", "withdrawn")	
oda-status	IDENTIFIER+ TERMINAME	The current status of the authorisation. See the authorisation status CTL	
oda-decision-reference-number		The reference number from the copy of the Commission Decision on orphan designation	
attachment	-	copy of the Orphan Designation Decision	
attachment-type		The type of attachment	"5.18.001"

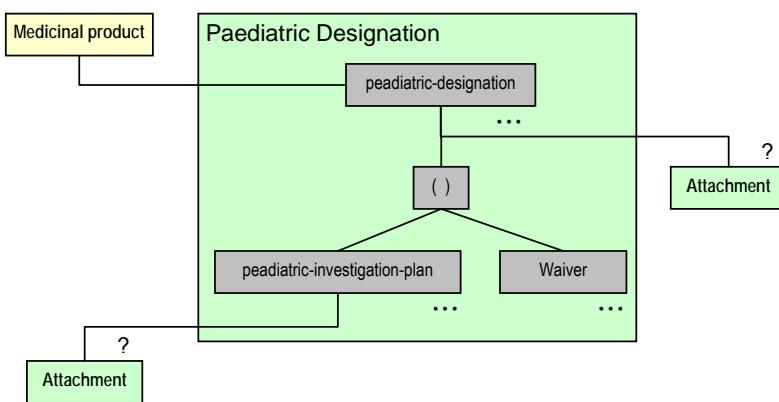
Element Tree Diagram


Business Rules				
Rule ID	DES 2.0 Element	Default BR	Rule	Effect(s)/ Remarks
1	oda-decision-reference-number	optional	TRUE(oda-status == "refused")	Mandatory
2	attachment	optional	TRUE(oda-status == "granted")	Mandatory
3	oda-date	optional	TRUE(oda-status != "pending")	Mandatory
5	oda-eu-register-number	optional	TRUE(oda-status == "granted")	Mandatory
	n/orphan-designation Legislation	mandatory	VALUE(Legislation="Regulation (EC) 141/2000"/article="8":leg_applies) = VALUE(application/orphan-designation:has_market-exclusivity)	
	/orphan-designation /Legislation	mandatory	TRUE(VALUE(Legislation="Regulation (EC) 847/2000"/article="3":applies="yes") = VALUE(application/orphan- designation:is_similar-product)="yes")	Yes: modules 1.7.1 and 1.7.2 to be completed No: modules 1.7.1 to be completed

### 6.2.11 Paediatric Designation

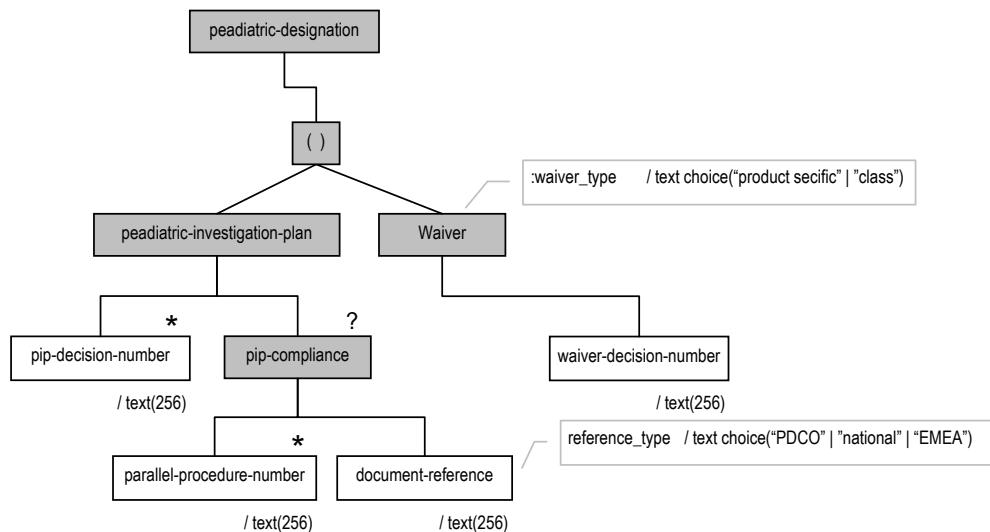
#### 6.2.11.1 Paediatric designation (business concept)

Element	RDM Specific Format	Definition	Remarks for Structure/type/rule/format or other
Paediatric designation	-	REQUIREMENTS ACCORDING TO REGULATION (EC) N° 1901/2006 ('PAEDIATRIC REGULATION'):	This Regulation lays down rules concerning the development of medicinal products for human use in order to meet the specific therapeutic needs of the paediatric population, without subjecting the paediatric population to unnecessary clinical or other trials and in compliance with Directive 2001/20/EC



## 6.2.11.2 Paediatric designation (technical concept)

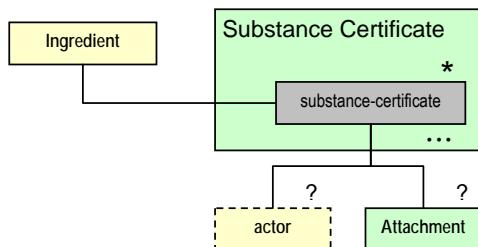
Element	RDM Specific Format	Definition	Remarks for Structure/type/rule/format or other
paediatric-investigation-plan	-	Procedure by which the PDCO gives his decision on paediatric use for specific medicinal product indications	
pip-decision-number		PDCO decision number of the pip decision document	
waiver	-	Procedure by which the PDCO gives his decision on a prohibited paediatric use specific medicinal product indications	
waiver-decision-number			

Element Tree Diagram


## 6.2.12 Substance Certificates

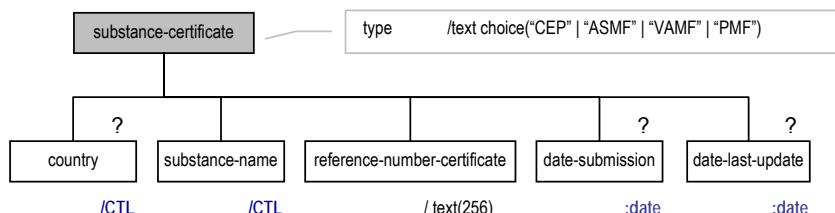
### 6.2.12.1 Substance Certificate (Business Concept)

Element	RDM Specific Format	Definition	Remarks for Structure/type/rule/format or other
Substance Certificate	-	<p>The substance certificates supports the following certificates for the interoperable information of MAA to be transmitted between parties</p> <ul style="list-style-type: none"> <li>- An Active Substance Master File (ASMF), also known as the European Drug Master File (EDMF), is the active substance section of dossiers for a marketing authorisation application.</li> <li>- Vaccines Antigen Master File (VAMF): One given VAMF contains all relevant information of biological, pharmaceutical and chemical nature for one given vaccine antigen, which is common to several vaccines from the same MA applicant or MAH</li> <li>- The European Pharmacopoeia (the CEP) can be used by the manufacturer of medicinal product in its application for marketing authorisation to demonstrate the compliance of the substance used with the monographs of the European Pharmacopoeia as referred in Directive 2001/83/EC</li> <li>- The Plasma Master File (PMF) is a compilation of all the required scientific data on the quality and safety of human plasma relevant to the medicines, medical devices and investigational products that use human plasma in their manufacture. These data cover all aspects of the use of plasma, from collection to plasma pool.</li> </ul>	



### 6.2.12.2 Substance Certificate (technical concept)

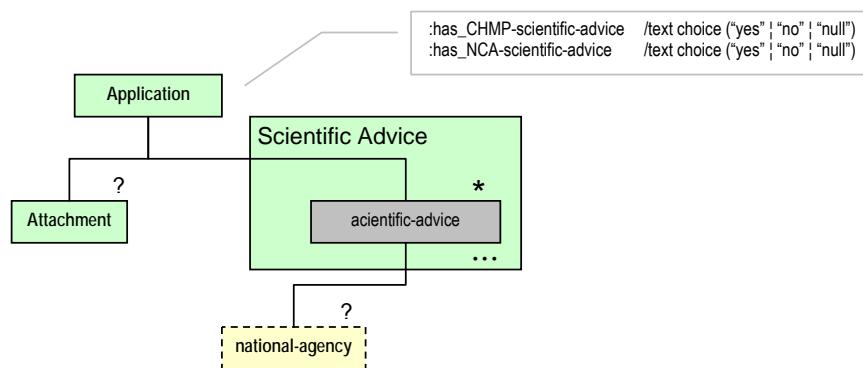
Element	RDM Specific Format	Definition	Remarks for Structure/type/rule/format or other
substance-certificate	-		
country	IDENTIFIER+ TERM NAME	See country CTL The country in which the certificate is issued	Found in an example for initial application human
substance-name	IDENTIFIER+ TERM NAME	Name of the substance referenced by the certificate See substance CTL	Note 1
reference-number-certificate	-		
date-submission	DATE		
date-last-update	DATE		



## 6.2.13 Scientific advice

### 6.2.13.1 Scientific advice (business concept)

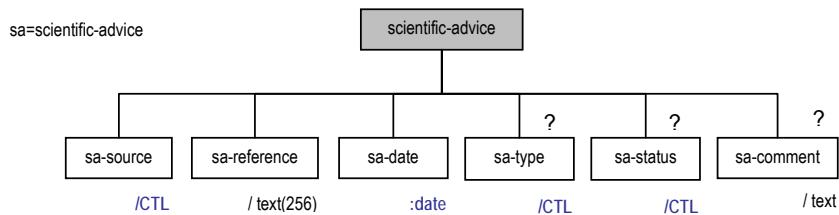
Element	RDM Specific Format	Definition	Remarks for Structure/type/rule/format or other
scientific-advice	-	<p>The applicant should list in this section all advice(s) received, or pending or planned, from any regulatory authorities, which is relevant to the application; this includes advice(s) received for the adult population which may be of relevance for children. Advice received is classified by category (EMEA scientific advice, EMEA protocol assistance, National Competent Authorities advice, FDA written request, other opinion/decision/advice)</p> <p>Any legal or natural person developing a medicine for human use may request scientific advice from the EMEA or by a similar member state agency .</p> <p>Advice will be given on the design and conduct of trials necessary to demonstrate the quality, safety and efficacy of the medicine in the target population</p>	



### 6.2.13.2 Scientific advice (technical concept)

Element	RDM Specific Format	Definition	Remarks for Structure/type/rule/format or other
scientific-advice	-	-	
scientific-advice-source	IDENTIFIER+TERMNAME	The list of the sources for scientific advice related to clinical trial: CHMP (Committee for Medicinal Products for Human use), NCA (National Competent Authority) See scientific-advice-source CTL	
scientific-advice-reference	TEXT	The registered number of the scientific advice	
scientific-advice-country	IDENTIFIER + TERMNAME	The country of the national agency, source of the scientific advice	
scientific-advice-date	DATE	The date the scientific advice was issued by the medical agency (EMEA or National).	
scientific-advice-type	IDENTIFIER+TERMNAME	The type of scientific advice that can be asked by the applicant. (EMEA scientific advice, EMEA protocol assistance, National Competent Authorities advice, FDA written request, other opinion/decision/advice) See scientific-advice-type CTL	
scientific-advice-status	IDENTIFIER + TERMNAME	The status of the current advice (received, planned, pending) see scientific-advice-status CTL	

#### Element Tree Diagram

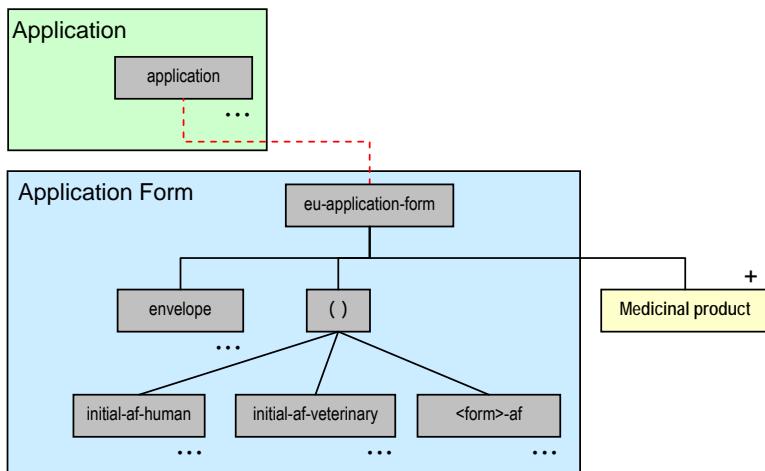


Business Rules				
Rule ID	DES 2.0 Element	Default BR	Rule	Effect(s)/ Remarks
1	scientific-advice	optional	application/ :has_CHMP-scientific-advice="yes"	mandatory
1.1	scientific-advice-source	mandatory	Value="CHMP"	
2	scientific-advice	optional	application/ :has_NCA-scientific-advice="yes"	Mandatory
2.1	scientific-advice-source	mandatory	Value="NCA"	
2.2	scientific-advice/national-agency	optional	-	Mandatory.

## 6.3. Specific Application Form

This section makes the link between the common application concepts and the specific application form concepts.

Element	Label	Remarks for Structure/type/rule/format or other
application-form (af)	-	
Initial-af-human	Module 1: Administrative information Application form	
initial-af-veterinary	VOLUME 6B Presentation and content of the dossier-Part 1 Summary of the dossier Part 1A Application form	
variation-af	APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION	
renewal-af	APPLICATION FOR RENEWAL OF A MARKETING AUTHORISATION	
scientific-advice-af		
<form>-af	Is the template for form to be supported in the future	



## 7. ANNEXED DOCUMENTS

Description	Filename	Version
EDT for "Medicinal Product for Human Use Volume 2B Module 1: Administrative Information Application Form"	DES20_Suplementary Specification_Annex1	[draft]
ETDf for "Medicinal Product for Veterinary Use Volume 6B Module 1: Administrative Information Application Form"	DES20_Suplementary Specification_Annex4	[draft]
EDT for "Application for Variation to a marketing authorisation"	DES20_Suplementary Specification_Annex2	[draft]
ETDf for "Application for renewal of marketing authorisation"	DES20_Suplementary Specification_Annex3	[draft]

## 8. RELATED DOCUMENTS

Description	Filename	Version
eAF Project Definition document	eAF High-Level Architecture v0 2.doc	V 0.2
eAF High level architecture document	<i>[to be filled]</i>	[draft]

## 9. ABOUT THIS DOCUMENT

### 9.1. Document location

The document is located in the following folder on EDMS: \_\_\_\_\_

### 9.2. Definitions, Acronyms, and Abbreviations

Acronym / Abbreviation	Description
DES	Data Exchange Standard
DTD	Data Type Definition
eAF	electronic Application Form
SGML	Standard Generalized Markup Language
XML	eXtended Markup Language
XSL	Xml Style Sheet

### 9.3. Open Issues

### 9.4. Referenced documents

Doc ID	Title	Locator

### 9.5. Document Approval

Date	Submitted by	Approved by	Approver Role

### 9.6. Document history

Version	Who	Date	What
[draft]	Philippe Deblire	04-03-2009	Review paragraphs 1 to 4, abstract, version.
[draft]	Philippe Deblire	22-04-2009	Review document
1.8	Philippe Deblire	03-08-2009	Review document
1.9	Philippe Deblire	10-08-2009	Review document: 7.1.7 ; 7.2.1; 7.2.2; 7.2.3; 7.2.; 7.2.7; 7.2.9
1.9	Philippe Deblire	12-11-2009	Concepts reviewed: - Application/acceptance-date - Actor