EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 October 2012
EMA/2086/2012
Information and Communications Technology

Electronic Application Form Data Exchange Standard 3.0

Supplementary Specification Annex 1 “Initial Human Application Form” v.1.6.0

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1. Introduction

1.1. How to read this document

In association with this document the **maa_human.xsd** file contains the description of the structure of all the concepts used for this annex. This will enable you to construct a data extraction/generation script to populate the relevant information to/from your systems.

The “Chapters” refer to the paragraph number of the paper application form. The “Sections” refer to the paragraph numbering of this document.

Some diagrams are too large to describe the whole hierarchy on only one page. Therefore, the diagrams are split in sub sections that might not be in line with the paper document chapters.

In order to find your way back in this document when starting from paper document refer to the chapters’ labels and numbering.

The information provided in this document focuses only on the initial human application form information and how it is mapped with the DES 3.0 standard.

Description and definition of the DES 3.0 Concepts used in this document can be found in the DES 3.0 supplementary specifications document.

1.2. Sections Components

Each section is split in three components that show different aspects of the DES 3.0 standard applied to the application form.

1.2.1. The Elements Mapping Table

This table describes how the mapping between the paper form fields of a specific chapter and the elements of the DES 3.0 Model.

The table consists in 4 columns:

- **Element Id**: The id of the field used in business rules. <paragraph>-<numeric order> Ex: 264-1
- **Label**: The label of the field in the application form is sometimes preceded by a chapter numbering.
- **DES 3.0 Mapping**: It is the corresponding mapped-to element in the DES 3.0 model. It contains at least one mapped-to element. The mapping shows the hierarchy from the root element to the leaf element with the parent-child link represented by the "/" sign.
- **RDM Mapping**: It is the corresponding mapped-to attribute in the RDM Model. The mapping shows how to get the information in the RDM relational model through links between the technical concepts represented by the ">" sign.

The minimal notation is always "<technical concept parent>/" in the common context and "<mapped-to element>" in the DES 3.0 column.

The description of the technical concept parent is in the DES 2.0 supplementary specifications sections 7.1 and 7.2

If there is no mapping, the DES 1.0 element remains in the form specific part of the model.

- **Remarks**: Contains any relevant information concerning the element values, format or business rules.

Colours

Text: Tells that the elements are not part of the RDM 3.0 and can be found only in DES 3.0 with no similarity in terms of definition.

Text: Tells that there is no existing mapping between the DES 3.0 and RDM 3.0. The missing mapping can be of two kinds.

- "ignored" based on the decision of the RDM team not to map the element
- "not mapped": The RDM 3.0 may contain more or less elements because the RDM 3.0 draft came after the DES 3.0.

Text: Tells that the RDM element is an additional linked entity comparing to the DES 3.0 hierarchy.

Note: The EUTCT controlled terms used in the RDM 3 are **not** always published yet. That's why some of the DES lists only provide a "short-name" which does not directly corresponds to a CTL term id in RDM model.

1.2.2. The Business Rules Table

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.

1.2.3. The Element Tree Diagram (ETD)

The data structure constraints are captured in a graphic approach to facilitate the reading and assessment by the business.

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

The model is called “Element Tree Diagram” (ETD)

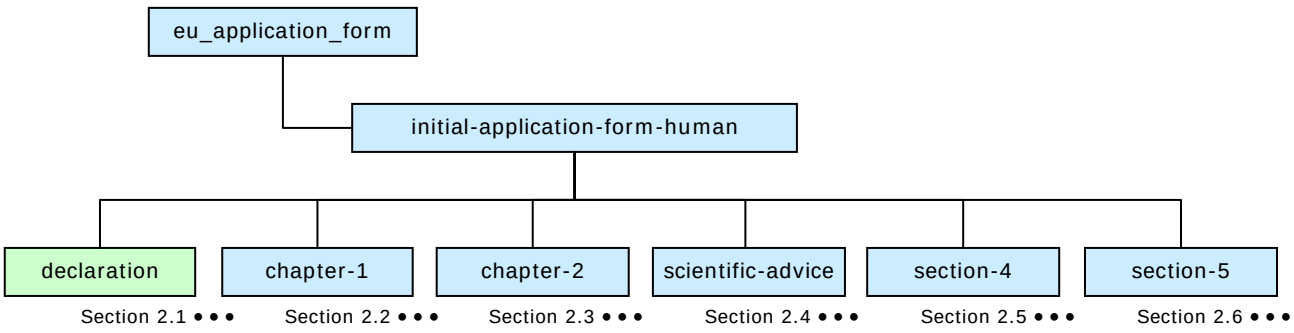
The diagrams of this version reflect the DES 3.0 standard described in the DES 3.0 Supplementary Specifications document. The ETD shows which are the concepts involved in the mapping of all the application form fields in the Element Mapping Table and the hierarchical constrains between them.

2. Initial Application form

The “initial-application-form-human” is the highest level of the form specific model that represents the paper form. All sections are fully mapped to the Reference Data Model core concepts and common application form concepts.

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-human/			
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2.1	APPLICATION FORM : ADMINISTRATIVE DATA			
E2.2	DECLARATION AND SIGNATURE	maa:declaration	Application	See Section 2.1
E2.3	1. TYPE OF APPLICATION	maa:chapter-1	MP Procedure	See section 2.2
E2.4	2. MARKETING AUTHORISATION APPLICATION PARTICULARS	maa:chapter-2		See Section 2.3
E2.5	3. SCIENTIFIC ADVICE	maa:scientific-advice	App Scientific Advice	See Section 2.4
E2.6	4. OTHER MARKETING AUTHORISATION APPLICATIONS	maa:section-4		See Section 2.5
E2.7	5. ANNEXED DOCUMENTS (WHERE APPROPRIATE)	maa:section-5		See Section 2.6

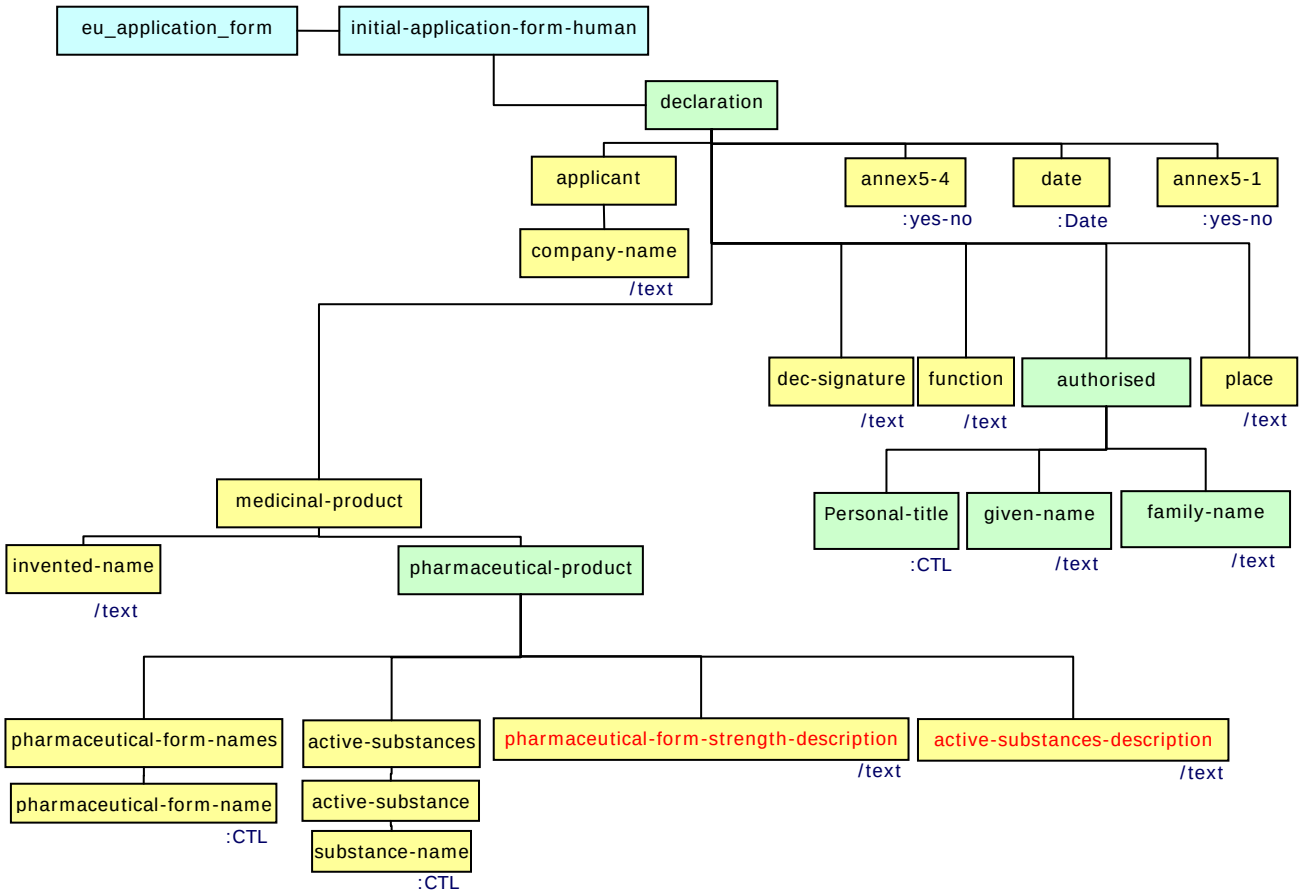
Element Tree Diagram



2.1. DECLARATION AND SIGNATURE

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-human/maa:declaration/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E21-1	Product (invented) name	rdm:medicinal-product/rdm:invented-name	Medicinal Product > Medicinal Product Group > invented name	
E21-2	Pharmaceutical form(s)	rdm:medicinal-product/rdm:pharmaceutical-product/rdm:pharmaceutical-form-names/rdm:pharmaceutical-form-name	Pharmaceutical Dose Form CTL > term id	
E21-3	Strength(s)	rdm:medicinal-product/rdm:pharmaceutical-product/rdm:pharmaceutical-form-strength-description		
E21-4	Active Substance(s)	rdm:medicinal-product/rdm:pharmaceutical-product/rdm:active-substances-description		
E21-5	Active Substance	rdm:medicinal-product/rdm:pharmaceutical-product/rdm:active-substances/rdm:active-substance/rdm:substance-name	Ingredient > Substance CTL, Ingredient > IngredientRole CTL	
E21-6	Applicant details:			
E21-7	Name	maa:applicant/company-name	Role > Party > Organisation > Name	
E21-8	Person authorised for communication*, on behalf of the Applicant:			
E21-9	Title	maa:authorised/rdm:personal-title	Role > Party > Person > Personal title	
E21-10	First name	maa:authorised/rdm:given-name	Role > Party > Person > given name	
E21-11	Surname	maa:authorised/rdm:family-name	Role > Party > Person > family name	
E21-12	Signature(s)	maa:dec-signature	Not mapped	
E21-13	Title	maa:signature/rdm:personal-title	Role > Party > Person > Personal title	
E21-14	First name	maa:signature/rdm:given-name	Role > Party > Person > given name	
E21-15	Surname	maa:signature/rdm: family-name	Role > Party > Person > family name	
E21-16	Function	maa:function	Manufacturer MP> functions performed	
E21-17	Place	maa:place	signature place	
E21-18	Date	maa:date	signature date	
E21-19	*Note: please attach letter of authorisation for communication/signing on behalf of the applicant in annex 5.4*	maa:annex5-4		
E21-20	*Note: if fees have been paid, attach proof of payment in Annex5.1 - see information on fee payments in the Notice to Applicants, Volume2A, chapter 7.*	maa:annex5-1		

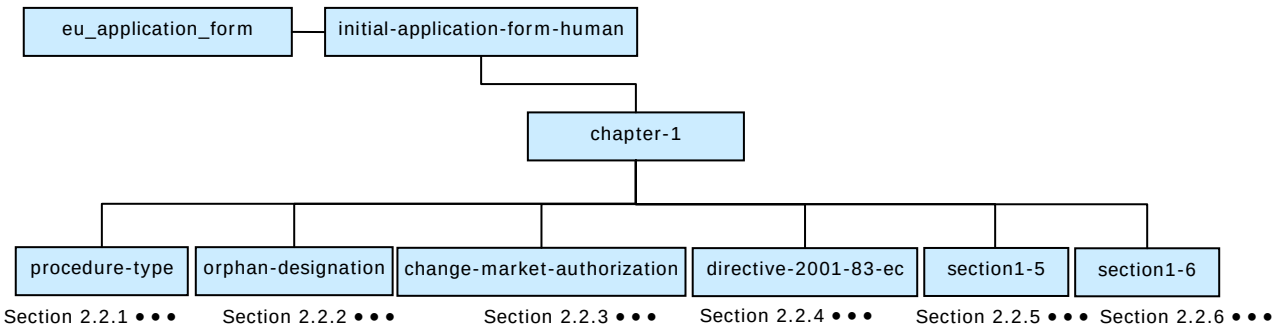
Element Tree Diagram



2.2. TYPE OF APPLICATION

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-1/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E22-1	1.1 THIS APPLICATION CONCERNS	maa:procedure-type		See section 2.2.1
E22-2	1.2 ORPHAN MEDICINAL PRODUCT INFORMATION	maa:orphan-designation		See section 2.2.2
E22-3	1.3 IS THIS AN APPLICATION FOR A CHANGE TO YOUR EXISTING MARKETING AUTHORISATION LEADING TO AN EXTENSION AS REFERRED TO IN ANNEX II OF REGULATIONS (EC) NO 1084/2003 OR 1085/2003, OR ANY NATIONAL LEGISLATION, WHERE APPLICABLE?	maa:change-market-authorization		See section 2.2.3
E22-4	1.4 THIS APPLICATION IS SUBMITTED IN ACCORDANCE WITH THE FOLLOWING ARTICLE IN DIRECTIVE 2001/83/EC	maa:directive-2001-83-ec		See section 2.2.4
E22-5	1.5 CONSIDERATION OF THIS APPLICATION IS ALSO REQUESTED UNDER THE FOLLOWING ARTICLE IN DIRECTIVE 2001/83/EC OR REGULATION (EC) No 726/2004	maa:section1-5		See section 2.2.5
E22-6	REQUIREMENTS ACCORDING TO REGULATION (EC) No 1901/2006 ('PAEDIATRIC REGULATION')	maa:section1-6		See section 2.2.6

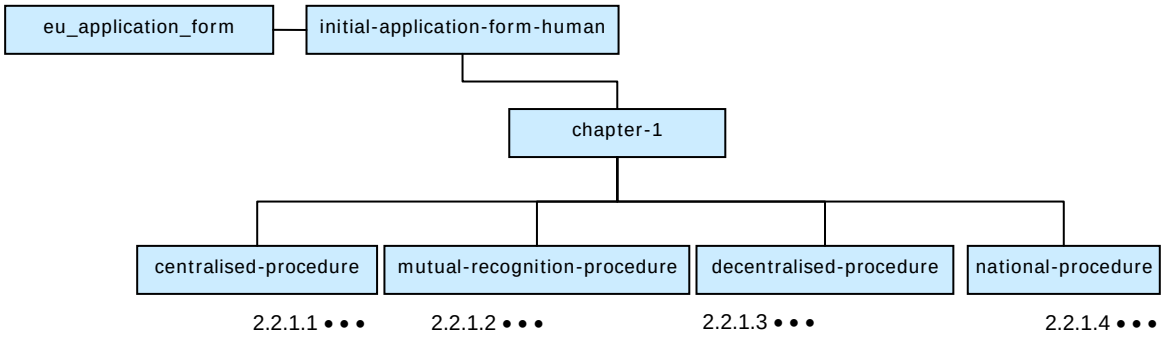
Element Tree Diagram



2.2.1. THIS APPLICATION CONCERNS

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-1/maa:procedure-type/		Application > MP Procedure	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E221-1	1.1.1 A CENTRALISED PROCEDURE	maa:centralised-procedure/rdm:selected	Procedure Type CTL (Value="centralised")	B221-1, See section 2.2.1.1
E221-2	1.1.2 A MUTUAL RECOGNITION PROCEDURE	maa:mutual-recognition-procedure/rdm:selected	Procedure Type CTL (Value=" mutual-recognition ")	B221-1, See section 2.2.1.2
E221-3	1.1.3 A DECENTRALISED PROCEDURE	maa:decentralised-procedure/rdm:selected	Procedure Type CTL (Value="decentralised")	B221-1, See section 2.2.1.3
E221-4	1.1.4 A NATIONAL PROCEDURE	maa:national-procedure/rdm:selected	Procedure Type CTL (Value="national")	B221-1, See section 2.2.1.4

Element Tree Diagram

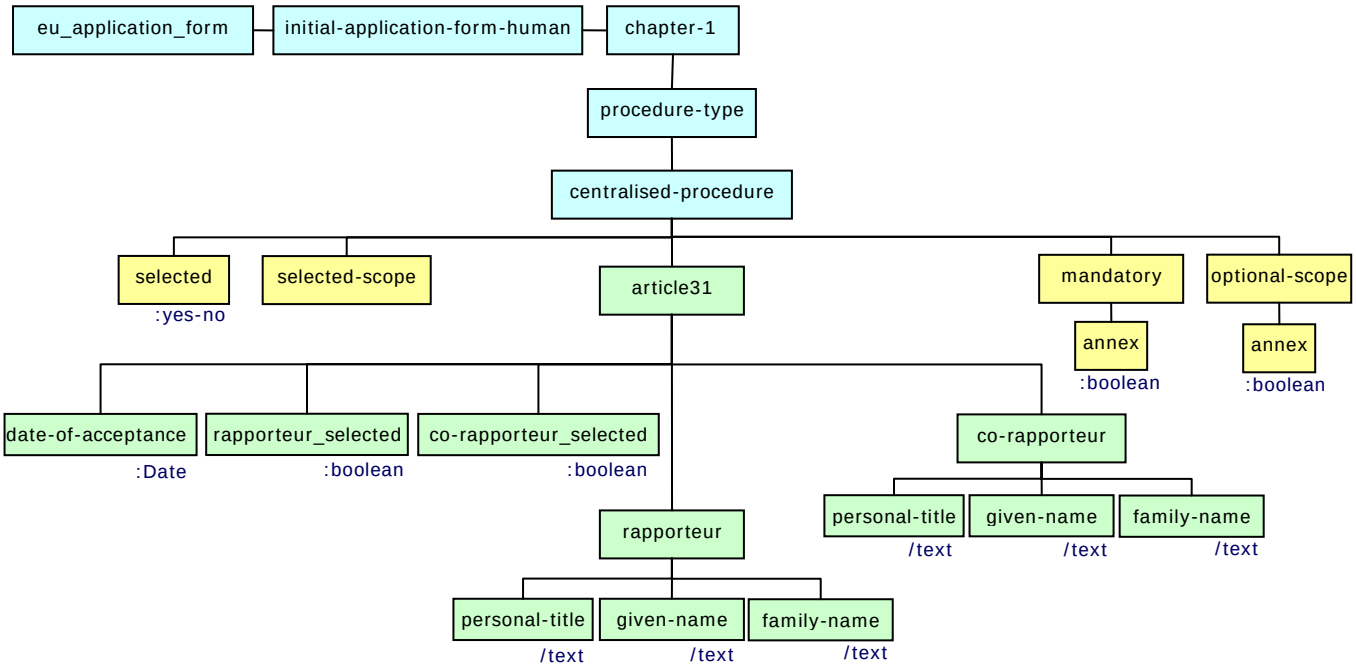


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B221-1	E221-1 to E221-4	Mandatory.	The specific element ids are mutually exclusive.	Only one of these can be selected.

2.2.1.1. A Centralised Procedure

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-1/maa:procedure-type/maa:centralised-procedure/		Application > MP Procedure >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2211-2	« Mandatory scope » (Article 3(1))	rdm:selected_scope (Value=1)	Basis for Eligibility CTL	B2211-1
E2211-3	Annex (1) (Biotech medicinal product)	rdm:mandatory/rdm:annex (Value=1)	Basis for Eligibility CTL	B2211-2
E2211-4	Annex (3) (New active substance for mandatory indications)	rdm:mandatory/rdm:annex (Value=2)	Basis for Eligibility CTL	B2211-2
E2211-5	Annex (4) (Orphan designated medicinal product)	rdm:mandatory/rdm:annex (Value=3)	Basis for Eligibility CTL	B2211-2
E2211-6	« Optional scope » (Article 3(2))	rdm:selected_scope (Value=2)	Basis for Eligibility CTL	B2211-1
E2211-7	Annex 3(2)(a) (New active substance)	rdm:optional-scope/rdm:annex (Value=1)	Basis for Eligibility CTL	B2211-3
E2211-8	Annex 3(2)(b) (Significant innovation or interest of patients at community level)	rdm:optional-scope/rdm:annex (Value=2)	Basis for Eligibility CTL	B2211-3
E2211-9	« Generic of a Centrally Authorised Medicinal Product » (Article 3(3))	rdm:selected_scope (Value=3)	Basis for Eligibility CTL	B2211-1
E2211-10	« Marketing Authorisation including paediatric indication » (Article 28 of Regulation (EC) No 1901/2006)	rdm:selected_scope (Value=4)	Basis for Eligibility CTL	B2211-1
E2211-11	« Article 29 application » (Article 29 of Regulation (EC) No 1901/2006)	rdm:selected_scope (Value=5)	Basis for Eligibility CTL	B2211-1
E2211-12	« Paediatric Use Marketing Authorisation (PUMA) » (Article 31 of Regulation (EC) No 1901/2006)	rdm:selected_scope (Value=6)	Basis for Eligibility CTL	B2211-1
E2211-13	Date of acceptance/confirmation by CHMP:	rdm:article31/ rdm:date-of-acceptance	chmp acceptance date	
E2211-14	Rapporteur	rdm:article31/ rdm:rapporteur_selected	Role > Party> Party Type CTL (Value="Person")	B2211-4
E2211-15	Title	rdm:article31/rdm:rapporteur/ rdm:personal-title	Role > Party > Person > Personal Title	B2211-4
E2211-16	First name	rdm:article31/rdm:rapporteur/ rdm:given-name	Role > Party > Person > Given Name	B2211-4
E2211-17	Surname	rdm:article31/rdm:rapporteur/ rdm:family-name	Role > Party > Person > Family Name	B2211-4
E2211-18	Co-Rapporteur:	rdm:article31/ rdm:co-rapporteur_selected	Role > Party> Party Type CTL (Value="Person")	B2211-5
E2211-19	Title	rdm:co-rapporteur/ rdm:personal-title	Role > Party > Person > Personal Title	B2211-5
E2211-20	First name	rdm:co-rapporteur/ rdm:given-name	Role > Party > Person > Given Name	B2211-5
E2211-21	Surname	rdm:co-rapporteur/ rdm:family-name	Role > Party > Person > Family Name	B2211-5

Element Tree Diagram

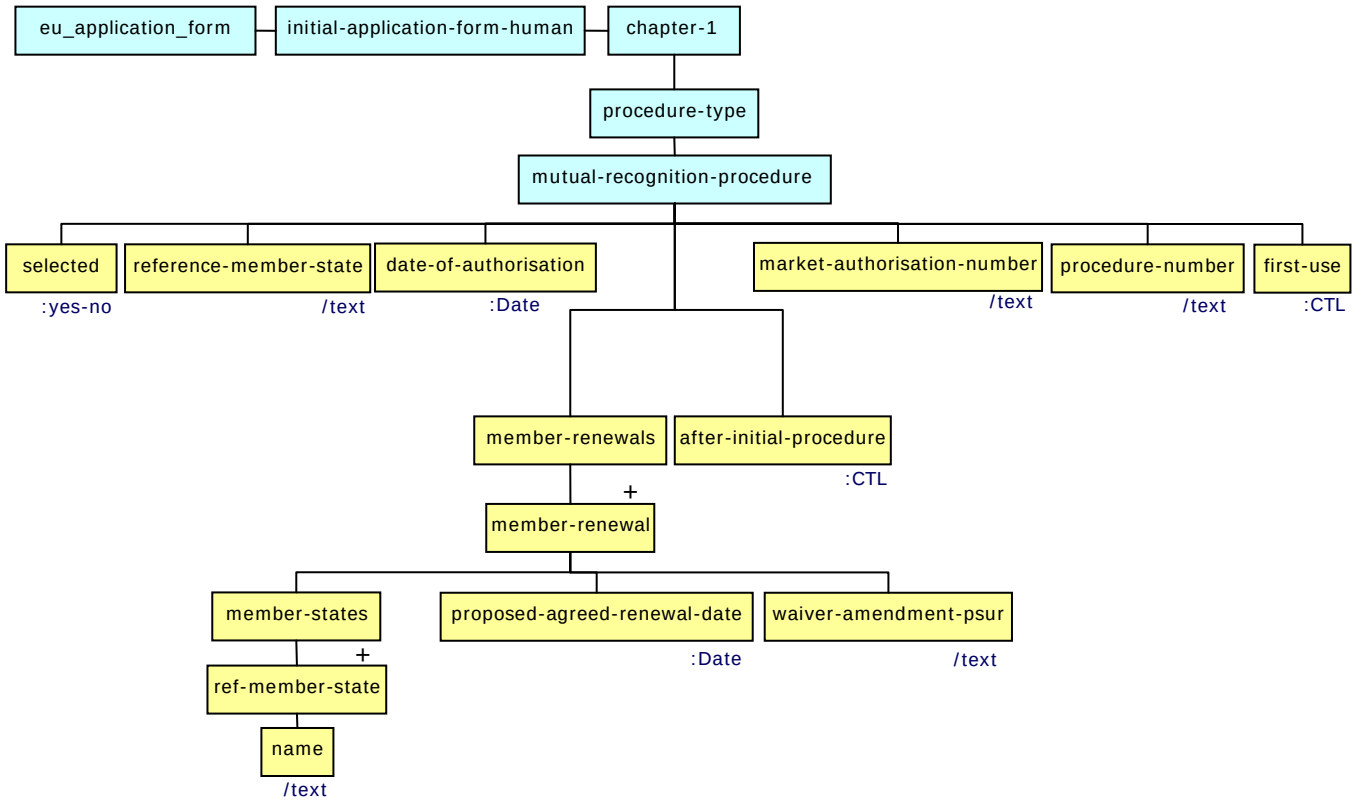


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2211-1	E2211-2, E2211-6, E2211-9 to E2211-12	Mandatory.	Fields are mutually exclusive.	Can only have one of them active at a time.
B2211-2	E2211-3 to E2211-5	Mandatory if E2211-2 is selected.	Fields are mutually exclusive.	Can only have one of them active at a time.
B2211-3	E2211-7, E2211-8	Mandatory if E2211-6 is selected.	Fields are mutually exclusive.	Can only have one of them active at a time.
B2211-4	E2211-14, E2211-15 to E2211-17	E2211-14 is mandatory.	If E2211-14, then E2211-15 to E2211-17 are mandatory.	
B2211-5	E2211-18, E2211-19 to E2211-21	E2211-18 is mandatory, rest are optional.	If E2211-18, then E2211-19 to E2211-21 are mandatory.	

2.2.1.2. A MUTUAL RECOGNITION PROCEDURE

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-1/maa:procedure-type/maa:mutual-recognition-procedure/		Application > MP Procedure >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2212-1	1.1.2 A MUTUAL RECOGNITION PROCEDURE	rdm:selected	Procedure Type CTL (Value=" mutual-recognition ")	
E2212-2	Reference Member State	rdm:reference-member-state	Role > Country CTL	
E2212-3	Date of authorisation	rdm:date-of-authorisation	previous auth date	
E2212-4	Marketing authorisation number	rdm: market-authorisation-number	previous auth number	
E2212-5	Procedure number:	rdm:procedure-number	procedure number	
E2212-6	First use	rdm:first-use (Value=1)	Procedure Use CTL	B2212-1
E2212-7	Repeat use (Please also complete section 4.2)	rdm:first-use (Value=2)	Procedure Use CTL	B2212-1, B222-2
E2212-8	After initial decentralised procedure	rdm:after-initial-procedure (Value=1)	Procedure Use CTL	B2212-2
E2212-9	After initial mutual recognition procedure	rdm:after-initial-procedure (Value=2)	Procedure Use CTL	B2212-2
E2212-10	Wave	rdm:member-renewals/rdm:member-renewal	Procedure Use > waive id	B2212-2
E2212-11	Concerned Member State (specify)	rdm:member-renewals/ rmd:member-renewal/ rdm:member-states/ rdm:ref-member-state/rdm:name	Procedure Use > Role > Country CTL	
E2212-12	Proposed/Agreed common renewal date	rdm:member-renewals/ rmd:member-renewal/ rdm:proposed-agreed-renewal-date	Procedure Use > Proposed / agreed common renewal date	
E2212-13	If a waiver or amendment or PSUR-cycle is applied for, to harmonise with a substance birthdate, please specify:	rdm:member-renewals/ rmd:member-renewal/ rdm:waiver-amendment-psur	Procedure Use > psur cycle waiver	

Element Tree Diagram

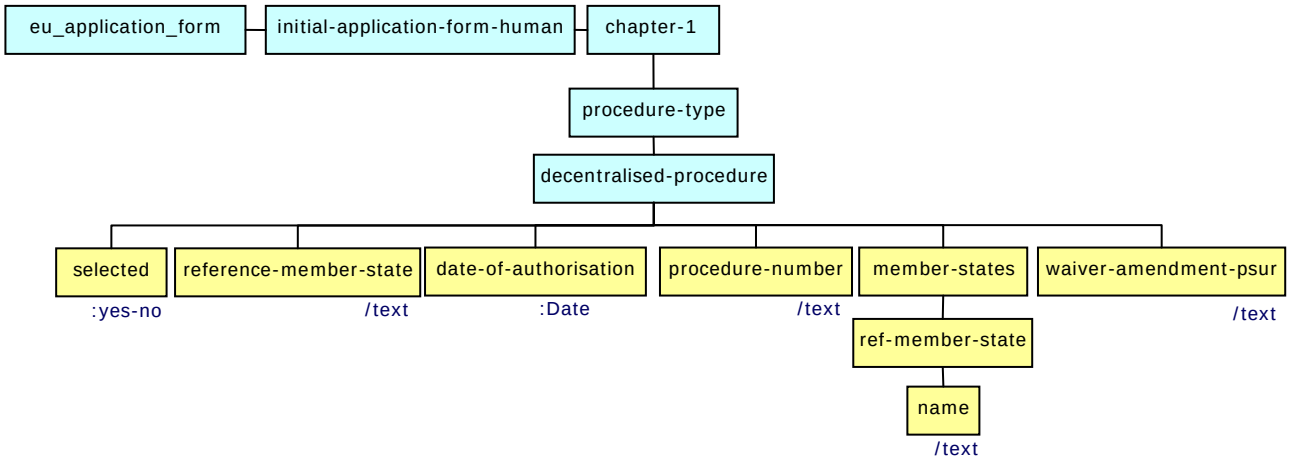


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2212-1	E2212-6 , E2212-7	Mandatory.	Mutually Exclusive.	
B2212-2	E2212-7 to E2212-10	If E2212-7 is selected, then E2212-8 to E2212-10 are mandatory.	E2212-8, E2212-9 are mutually exclusive.	

2.2.1.3. A DECENTRALISED PROCEDURE

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-1/maa:procedure-type/maa:decentralised-procedure/		Application > MP Procedure >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2213-1	1.1.3 A DECENTRALISED PROCEDURE	rdm:selected	Procedure Type CTL (Value="decentralised")	
E2213-2	(according to Article 28(3) of Directives 2001/83/EC)			
E2213-3	Reference Member State	rdm:reference-member-state	Procedure Use > Role > Country CTL	
E2213-4	Procedure number:	rdm:procedure-number	Procedure number	
E2213-5	Concerned Member State (specify)	rdm:member-states/ rdm:ref-member-state/rdm:name	Procedure Use > Role > Country CTL	
E2213-6	If a waiver or amendment or PSUR-cycle is applied for, to harmonise with a substance birthdate, please specify:	rdm:waiver-amendment-psur	Procedure use > psur cycle waiver	
E2213-7	In case of a repeat-use procedure after an initial decentralised procedure, please complete section 1.1.2 - Repeat Use 1st wave			

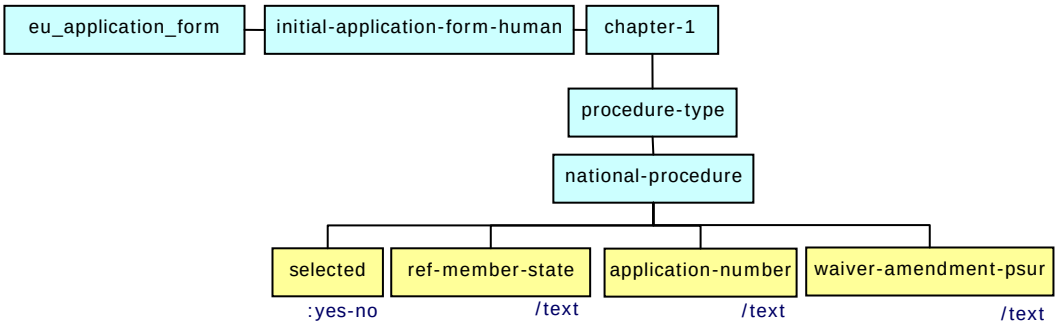
Element Tree Diagram



2.2.1.4. A NATIONAL PROCEDURE

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-1/maa:procedure-type/maa:national-procedure/		Application > MP Procedure >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2214-1	1.1.4 A NATIONAL PROCEDURE	rdm:selected	Procedure Type CTL (Value="national")	
E2214-2	(according to Article 28(3) of Directives 2001/83/EC)			
E2214-3	Member State	rdm:ref-member-state	Role > Country CTL	
E2214-4	Application number (if available)	rdm:application-number	previous app number	
E2214-5	If a waiver or amendment or PSUR-cycle is applied for, to harmonise with a substance birthdate, please specify:	rdm:waiver-amendment-psur	Procedure Use > psur cycle waiver	

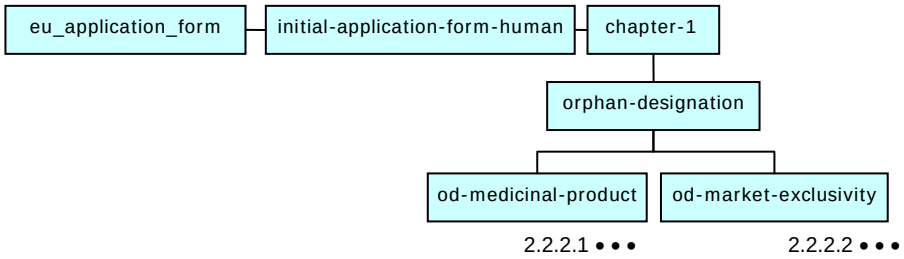
Element Tree Diagram



2.2.2. ORPHAN MEDICINAL PRODUCT INFORMATION

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-1/maa:orphan-designation/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E222-1	1.2.1 HAS ORPHAN DESIGNATION BEEN APPLIED FOR THIS MEDICINAL PRODUCT?	maa:od-medicinal-product	Orphan Designation	See Section 2.2.2.1
E222-2	1.2.2 INFORMATION RELATING TO ORPHAN MARKET EXCLUSIVITY Has any medicinal product been designated as an Orphan medicinal product for a condition relating to the indication proposed in this application?	maa:od-market-exclusivity		See Section 2.2.2.2

Element Tree Diagram



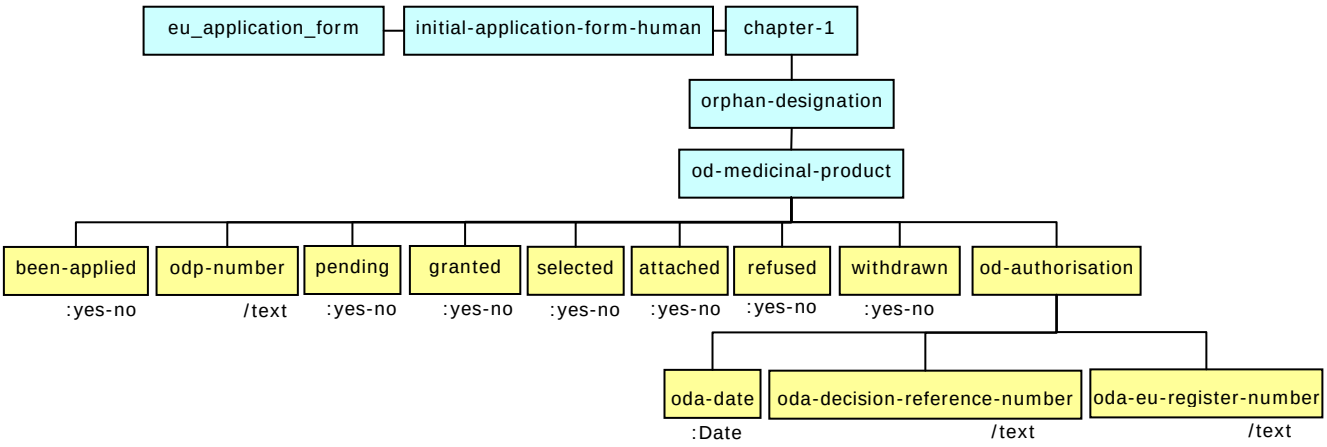
Business Rules

Rule ID	Element id(s)	Default BR	Rule	Effect(s)
B2221-1	E2221-1, E2221-2	Mandatory.	Mutually exclusive.	
B2221-2	E2221-1, E2221-3 to E2221-5, E2221-12,E2221-15	E2221-1 is mandatory, rest are optional.	If E2221-1, then the rest is mandatory, else they are optional.	
B2221-3	E2221-4, E2221-5, E2221-12, E2221-15	Optional.	Mutually exclusive.	
B2221-4	E2221-5, E2221-6 to E2221-11	Optional.	If E2221-5 is selected, the rest are mandatory.	
B2221-5	E2221-7, E2221-8	Optional.	Mutually Exclusive.	
B2221-6	E2221-12 to E2221-14	Optional.	If E2221-12 is selected, the rest is mandatory.	
B2221-7	E2221-15, E2221-16	Optional.	If E2221-15, then E2221-16 is mandatory.	

2.2.2.1. HAS ORPHAN DESIGNATION BEEN APPLIED FOR THIS MEDICINAL PRODUCT?

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-1/maa:orphan-designation/ maa:od-medicinal-product/		Application > Orphan Designation >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2221-1	Yes	rdm:been-applied (Value=1)	has od applied	B2221-1, B2221-2
E2221-2	No	rdm:been-applied (Value=0)	has od applied	B2221-1
E2221-3	Orphan designation procedure number:	rdm:odp-number	od procedure number	B2221-2
E2221-4	Pending	rdm:pending	Authorisation Status CTL	B2221-2, B2221-3
E2221-5	Orphan Designation Granted	rdm:granted	Authorisation Status CTL	B2221-2, B2221-3, B2221-4
E2221-6	Date:	rdm:od-authorisation/rdm:oda-date	od status date	B2221-4
E2221-7	Based on the criterion of "significant benefit":			B2221-4
E2221-8	Yes	rdm:selected (Value=1)	is based significant benefit	B2221-4, B2221-5
E2221-9	No	rdm:selected (Value=0)	is based significant benefit	B2221-4, B2221-5
E2221-10	Number in the Community Register of Orphan Medicinal Products:	rdm:od-authorisation/rdm:oda-eu-register-number	od community reg number	B2221-4
E2221-11	Attach copy of the Designation Decision (Annex 5.18)	rdm:attached		B2221-4
E2221-12	Orphan Designation Refused	rdm:refused	Authorisation Status CTL	B2221-2, B2221-3, B2221-6
E2221-13	Date:	rdm:od-authorisation/rdm:oda-date	od status date	B2221-6
E2221-14	Commission decision reference number:	rdm:od-authorisation/rdm:oda-decision-reference-number	Od decision ref number	B2221-6
E2221-15	Orphan Designation Withdrawn	rdm:withdrawn	Authorisation Status CTL	B2221-2, B2221-3, B2221-7
E2221-16	Date:	rdm:od-authorisation/rdm:oda-date	Od status date	B2221-7

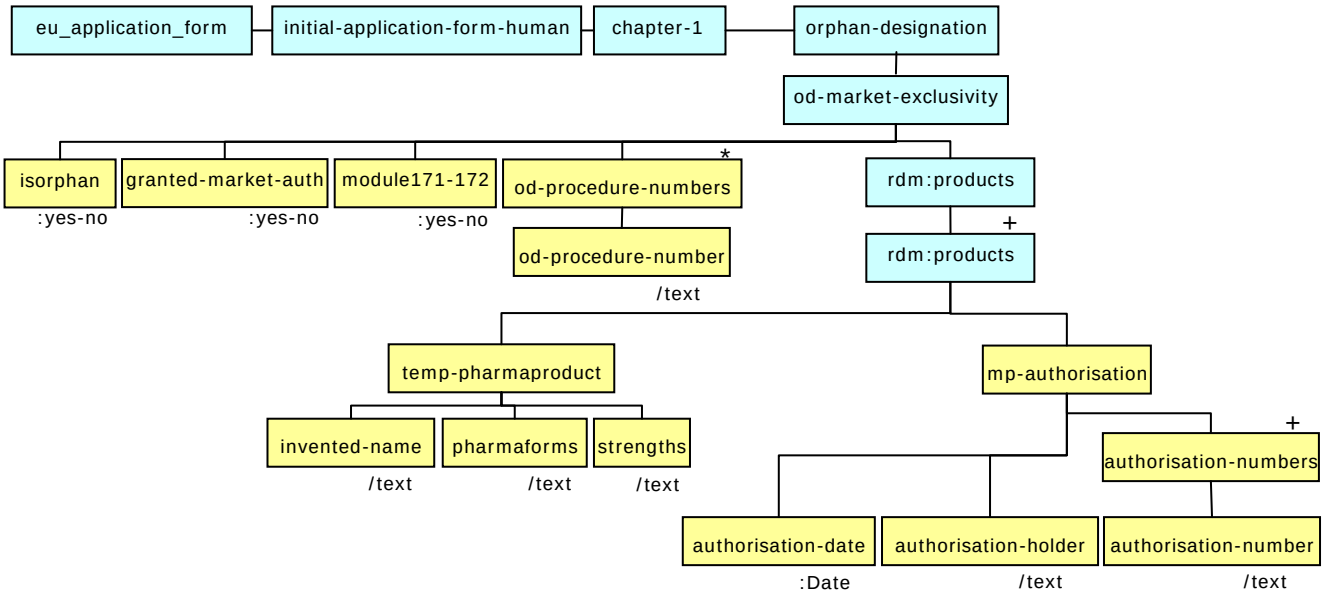
Element Tree Diagram



2.2.2.2. INFORMATION RELATING TO ORPHAN MARKET EXCLUSIVITY

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-1/maa:orphan-designation/maa:od-market-exclusivity/		Application > Orphan Designation >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2222-1	Yes	rdm:isorphan (Value=1)	has mp designated orphan	B2222-1, B2222-2
E2222-2	No	rdm:isorphan (Value=0)	has mp designated orphan	B2222-1
E2222-3	Please specify the EU Orphan Designation Number:	rdm:od-procedure-numbers/rdm:od-procedure-number	OD Number	B2222-2
E2222-4	Has any of the designated orphan medicinal product(s) been granted a marketing authorisation in the EU?			B2222-2
E2222-5	Yes	rdm:granted-market-auth (Value=1)	has od mp gratned ma	B2222-2, B2222-3, B2222-4
E2222-6	No	rdm:granted-market-auth (Value=0)	has od mp gratned ma	B2222-2, B2222-3
E2222-7	Please specify:			
E2222-8	Product (invented) name	rdm:products/rdm:product/rdm:temp-pharmaproduct/rdm:invented-name	Reference Medicinal Product > Medicinal Product > Pharmaceutical Product > Ingredient >Substance	B2222-4
E2222-9	Pharmaceutical form(s)	rdm:products/rdm:product/rdm:temp-pharmaproduct/rdm:pharmaforms	Reference Medicinal Product > Medicinal Product > Pharmaceutical Dose Form CTL	B2222-4
E2222-10	Strength(s)	rdm:products/rdm:product/rdm:temp-pharmaproduct/rdm:strengths	Reference Medicinal Product > Medicinal Product > Pharmaceutical Product > Ingredient	B2222-4
E2222-11	Marketing authorisation holder	rdm:products/rdm:product/rdm:mp-authorisation/rdm:authorisation-holder	Role > Party > Organisation > Name	B2222-4
E2222-12	Marketing authorisation number	rdm:products/rdm:product/rdm:mp-authorisation/rdm:authorisation-numbers/rdm:authorisation-number	MP Authorisation > authorization number	B2222-4
E2222-13	Date of authorisation	rdm:products/rdm:product/rdm:mp-authorisation/rdm:authorisation-date	MP Authorisation > authorization date	B2222-4
E2222-14	Is the medicinal product, subject of this application, considered as "similar" to any of the authorised orphan medicinal product(s)? *(as defined in Article 3 of commission regulation (EC) no 847/2000)*			B2222-4
E2222-15	Yes(modules 1.7.1 and 1.7.2 to be completed)	rdm:module171-172 (Value=1)	is mp similar to authorised	B2222-4, B2222-5
E2222-16	No(module 1.7.1 to be completed)	rdm:module171-172 (Value=0)	is mp similar to authorised	B2222-4, B2222-5

Element Tree Diagram

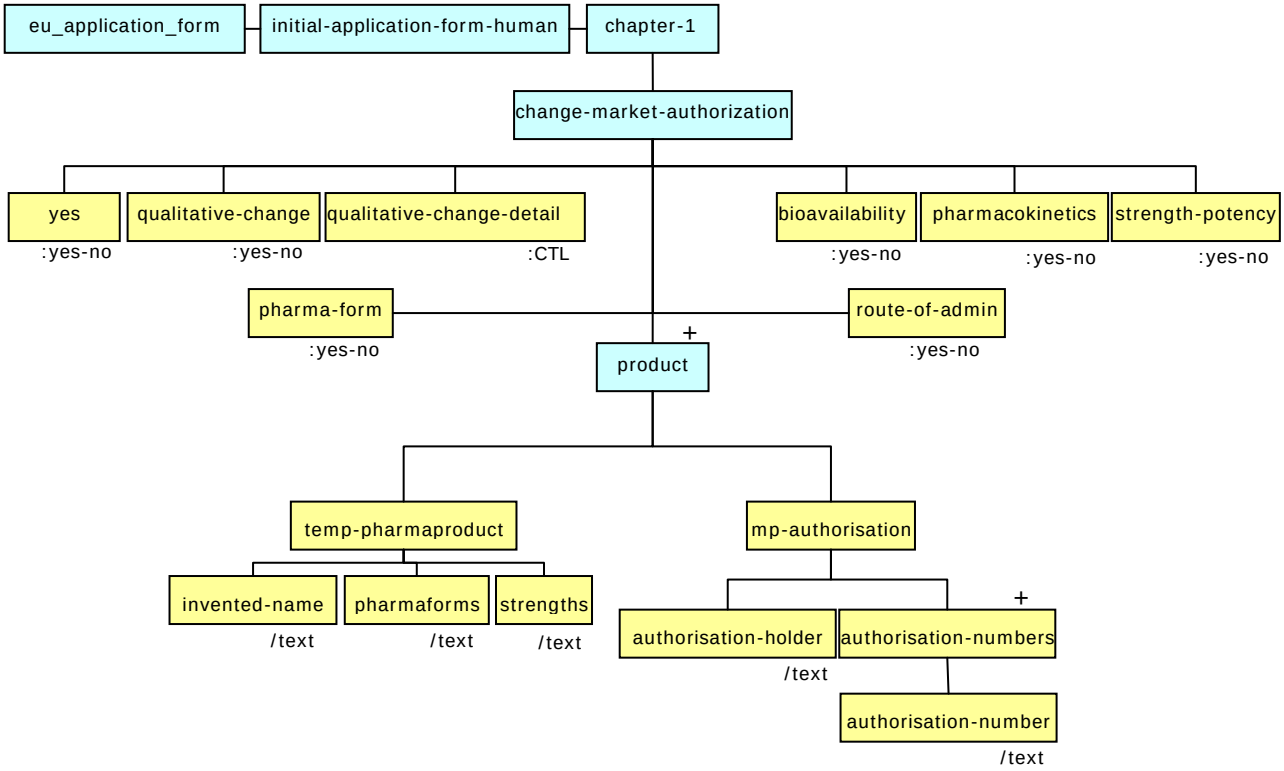


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2222-1	E2222-1, E2222-2	Mandatory.	Mutually exclusive.	
B2222-2	E2222-1, E2222-3 to E2222-6	Mandatory for E2222-1, optional for the rest.	If E2222-1 is selected, the rest is mandatory.	
B2222-3	E2222-5, E2222-6	Optional.	Mutually Exclusive.	
B2222-4	E2222-5, E2222-8 - E2222-16	Optional.	If E2222-5 is selected, the rest is mandatory.	
B2222-5	E2222-15, E2222-16	Optional.	Mutually exclusive.	

2.2.3. IS THIS AN APPLICATION FOR A CHANGE TO YOUR EXISTING MARKETING AUTHORISATION LEADING TO AN EXTENSION AS REFERRED TO IN ANNEX II OF REGULATIONS (EC) NO 1084/2003 OR 1085/2003, OR ANY NATIONAL LEGISLATION, WHERE APPLICABLE?

	Common DES 3.0 Context		**Common RDM Entry point**	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-1/maa:change-market-authorization/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E223-1	Yes *(complete sections below and also complete 1.4 + 1.6)*	maa:yes (Value=1)	change in existing ma	B223-1, B223-2
E223-2	No *(complete section 1.4 + 1.6)*	maa:yes (Value=0)	change in existing ma	B223-1
E223-3	Please specify:			
E223-4	Qualitative change in declared active substance NOT DEFINED AS A NEW ACTIVE SUBSTANCE	maa:qualitative-change	Difference CTL	B223-2, B223-3
E223-5	Replacement by a different salt/ester, complex/derivative (same therapeutic moiety)	maa:qualitative-change-detail (Value=1)	Difference CTL	B223-3, B223-4
E223-6	Replacement by a different isomer, mixture of isomers, of a mixture by an isolated isomer	maa:qualitative-change-detail (Value=2)	Difference CTL	B223-3, B223-4
E223-7	Replacement of a biological substance or product of biotechnology	maa:qualitative-change-detail (Value=3)	Difference CTL	B223-3, B223-4
E223-8	New ligand or coupling mechanism for a radiopharmaceutical	maa:qualitative-change-detail (Value=4)	Difference CTL	B223-3, B223-4
E223-9	Change to the extraction solvent or the radio of herbal drug to herbal drug preparation	maa:qualitative-change-detail (Value=5)	Difference CTL	B223-3, B223-4
E223-10	Change of bioavailability	maa:bioavailability	Difference CTL	B223-2
E223-11	Change of pharmacokinetics	maa:pharmacokinetics	Difference CTL	B223-2
E223-12	Change or addition of a new strength/potency	maa:strength-potency	Difference CTL	B223-2
E223-13	Change or addition of a new pharmaceutical form	maa:pharma-form	Difference CTL	B223-2
E223-14	Change or addition of a new route of administration	maa:route-of-admin	Difference CTL	B223-2
E223-15	*Note: - the applicant of the present application must be the same as the marketing authorisation holder of the existing marketing authorisation - this section should be completed without prejudice to the provisions of Articles 8(3), 10.1, 10a, 10b, 10c, and Directive 2001/83/EC*			B223-2
E223-16	For existing marketing authorisation in the Community/Member State where the application is made:			B223-2
E223-17	Product (invented) name	maa:product/rdm:temp-pharmaproduct/rdm:invented-name	Reference Medicinal Product > Medicinal Product>Pharmaceutical Product>Ingredient>Substance	B223-2
E223-18	Pharmaceutical form(s)	maa:product/rdm:temp-pharmaproduct/rdm:pharmaforms	Reference Medicinal Product > Medicinal Product > Pharmaceutical Dose Form CTL	B223-2
E223-19	Strength(s)	maa:product/rdm:temp-pharmaproduct/rdm:strengths	Reference Medicinal Product > Medicinal Product > Pharmaceutical Product > Ingredient	B223-2
E223-20	Marketing authorisation holder	maa:product/rdm:mp-authorisation/rdm:authorisation-holder	Role > Party > Organisation > Name	B223-2
E223-21	Marketing authorisation number	maa:product/rdm:mp-authorisation/rdm:authorisation-numbers/rdm:authorisation-number	MP Authorisation > authorization number	B223-2

Element Tree Diagram

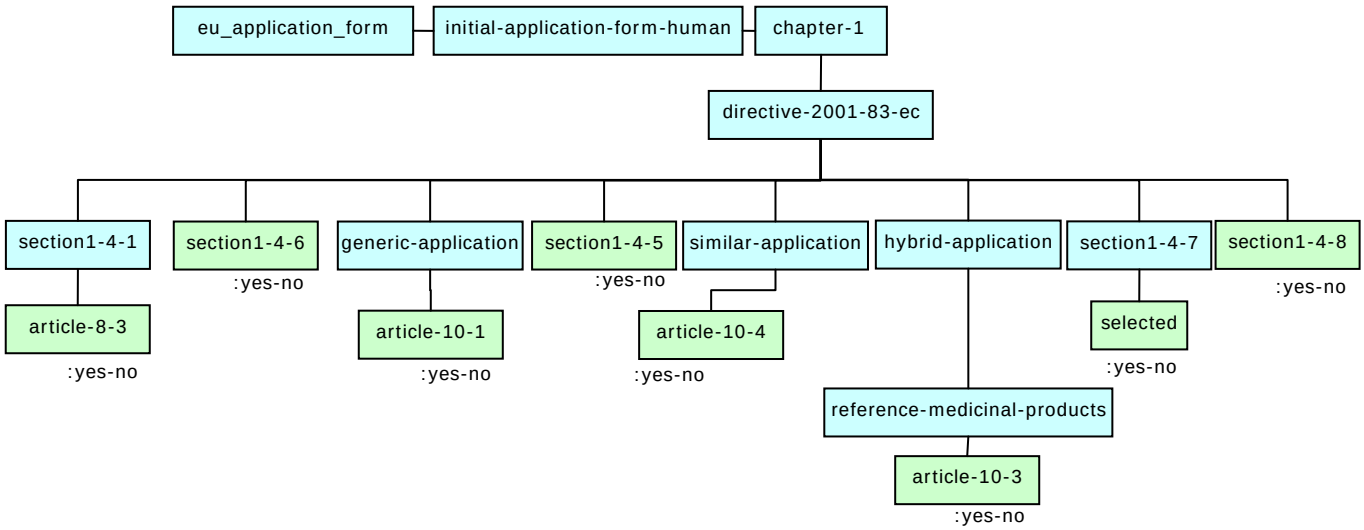


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B223-1	E223-1, E223-2	Mandatory.	Mutually Exclusive.	
B223-2	E223-1, E223-4, E223-10 to E223-21	E223-1 is Mandatory, rest are optional.	If E223-1 is selected, the rest are mandatory.	
B223-3	E223-4, E223-5 to E223-9	Optional.	If E223-4 is selected , the rest is mandatory.	
B223-4	E223-5 to E223-9	Optional.	Mutually Exclusive.	

2.2.1. THIS APPLICATION IS SUBMITTED IN ACCORDANCE WITH THE FOLLOWING ARTICLE IN DIRECTIVE 2001/83/EC

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-1/maa:directive-2001-83-ec/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E224-1	Note: Section to be completed for any application, including applications referred to in section 1.3 For further details, refer to Notice of Applicants, Volume 2A, Chapter 1			
E224-2	Article 8(3) application, (i.e dossier with administrative, quality, pre-clinical and clinical data*)	maa:section1-4-1/maa:article-8-3	Application Category CTL	B224-1, B2241-1
E224-3	Article 10(1) generic application	maa:generic-application/ maa:article-10-1	Application Category CTL	B224-1, B224-2, B2242-1
E224-4	Article 10(3) hybrid application	maa:hybrid-application/ maa:reference-medicinal-products/maa:article10-3	Application Category CTL	B224-1, B224-2, B2243-1
E224-5	Article 10(4) similar biological application	maa:similar-application/maa:article-10-4	Application Category CTL	B224-1, B2244-1,
E224-6	Article 10a well-established use application	maa:section1-4-5	Application Category CTL	B224-1
E224-7	Article 10b fixed combination application	maa:section1-4-6	Application Category CTL	B224-1
E224-8	Article 10c informed consent application	maa:section1-4-7/maa:selected	Application Category CTL	B224-1, B2245-1
E224-9	Article 16a Traditional use registration for herbal medicinal product	maa:section1-4-8	Application Category CTL	B224-1

Element Tree Diagram

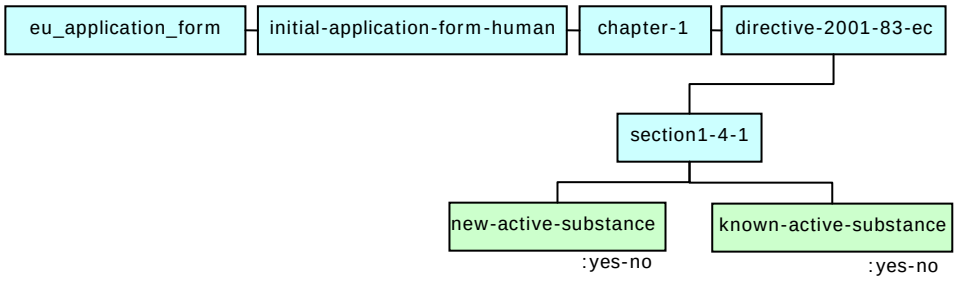


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B224-1	E224-2 to E224-9	Mandatory.	Considering that E224-3 and E224-4 is a single element, E224-2 to E224-9 are mutually exclusive.	
B224-2	E224-3, E224-4	Mandatory.	They are not mutually exclusive.	

2.2.1.1. Article 8(3) application, (i.e. dossier with administrative, quality, pre-clinical and clinical data)*

	Common DES 3.0 Context		**Common RDM Entry point**	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-1/maa:directive-2001-83-ec/ maa:section1-4-1/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2241-1	New active substance	maa:new-active-substance	Application Category CTL	B2241-1, B2241-2
E2241-2	Known active substance	maa:known-active-substance	Application Category CTL	B2241-1, B2241-2

Element Tree Diagram

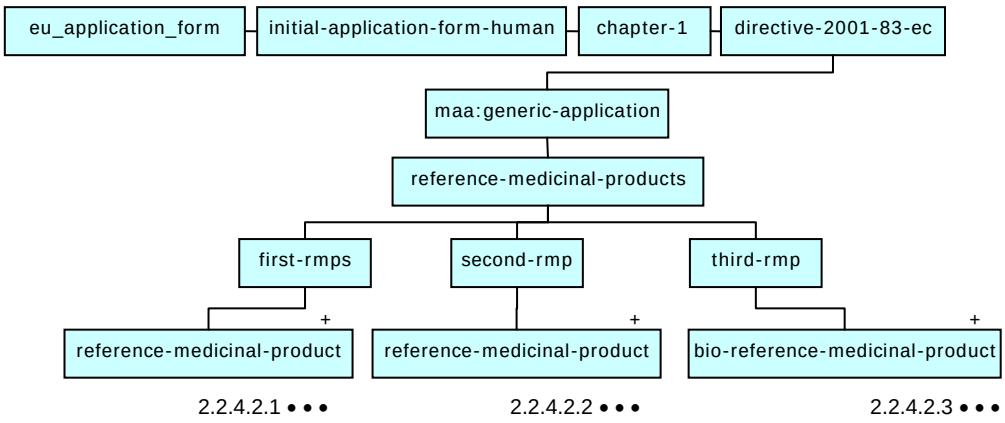


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2241-1	E224-2, E2241-1, E2241-2	E224-2 is mandatory. Rest is optional.	When E224-2 is selected, then the rest is mandatory.	
B2241-2	E2241-1, E2241-2	Optional.	Mutually exclusive.	

2.2.1.2. Article 10(1) generic application

	Common DES 3.0 Context		**Common RDM Entry point**	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-1/maa:directive-2001-83-ec/maa:generic-application/maa:reference-medicinal-products/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2242-1	*Note: . application for a generic medicinal product as defined in Article 10(2)(b) referring to a so-called reference medicinal product with a marketing authorisation granted in a Member State or in the Community.* *. complete administrative and quality data, appropriate pre-clinical and clinical data when applicable.* *. refer to Notice to Applicants, Volume 2A, Chapter 1.*			
E2242-2	Reference medicinal product:			
E2242-3	*Note: The chosen reference medicinal product must be a medicinal product authorised in the Community on the basis of a complete dossier in accordance with the provisions of the Article 8 of Directive 2001/83/EC.*			
E2242-4	Medicinal product which is or has been authorised in accordance with Community provisions in force for not less than 6/10 years in the EEA:	maa:first-rmps/maa:reference-medicinal-product/	Reference Medicinal Product> RMP Usage CTL	B2242-1, See Section 2.2.4.2.1
E2242-5	Medicinal product authorised in the Community/Member State where the application is made or European reference medicinal product:	maa:second-rmp/maa:reference-medicinal-product/	Reference Medicinal Product> RMP Usage CTL	B2242-1, See Section 2.2.4.2.2
E2242-6	Medicinal product which is or has been authorised in accordance with Community provisions in force and to which bioequivalence has been demonstrated by appropriate bioavailability studies:	maa:third-rmp /maa:bio-reference-medicinal-product/	Reference Medicinal Product> RMP Usage CTL	See Section 2.2.4.2.3

Element Tree Diagram

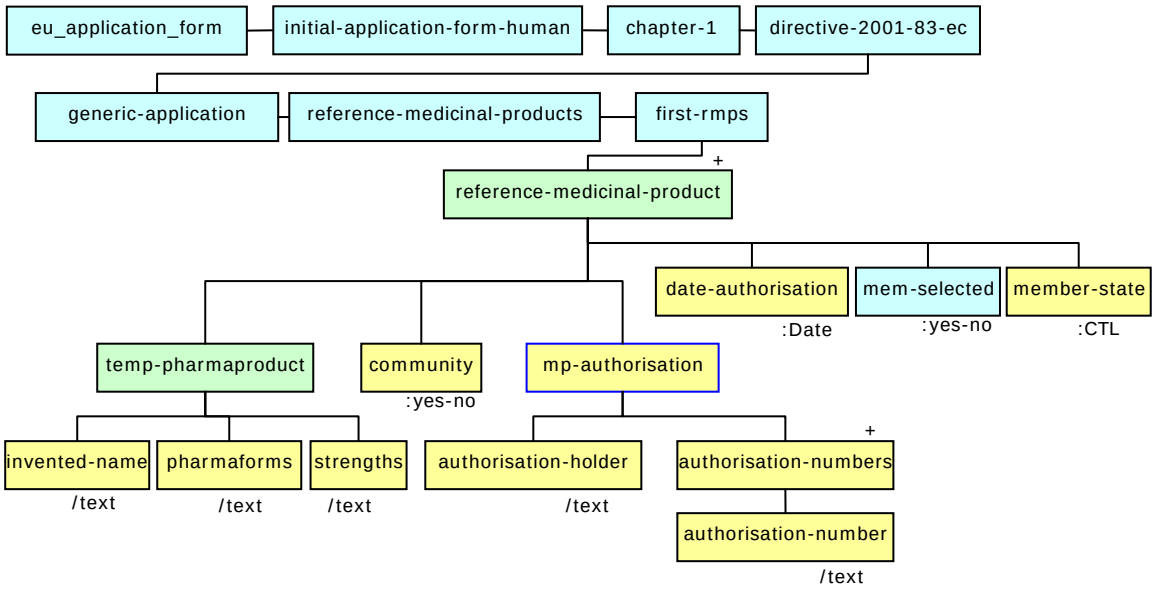


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2242-1	E224-3, E2242-4, E2242-5	E224-3 is mandatory. rest are optional.	When E224-3 is selected, then the rest are mandatory	

2.2.1.2.1. Medicinal product which is or has been authorised in accordance with Community provisions in force for not less than 6/10 years in the EEA

	Common DES 3.0 Context		**Common RDM Entry point**	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-1/maa:directive-2001-83-ec/maa:generic-application/maa:reference-medicinal-products/maa:first-rmps/maa:reference-medicinal-product/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E22421-1	Product (Invented) name	rdm:temp-pharmaproduct/ rdm:invented-name	Reference Medicinal Product > Medicinal Product > Medicinal Product Name	
E22421-2	Pharmaceutical form(s)	rdm:temp-pharmaproduct/ rdm:pharmaforms	Reference Medicinal Product > Medicinal Product > Pharmaceutical Product > Pharmaceutical Dose Form CTL	
E22421-3	Strength(s)	rdm:temp-pharmaproduct/ rdm:strengths	Ingredient	
E22421-4	Marketing authorisation holder	rdm:mp-authorisation/ rdm:authorisation-holder	Role > Party> Organisation> Name	
E22421-5	Marketing authorisation number	rdm:mp-authorisation/ rdm:authorisation-numbers/ rdm:authorisation-number	MP Authorisation > authorisation number	
E22421-6	Date of authorisation	rdm:date-authorisation	MP Authorisation > authorisation date	
E22421-7	Marketing authorisation granted by			
E22421-8	Community	rdm:community	MP Authorisation > Country CTL	
E22421-9	Member State(EEA)	rdm:mem-selected		
E22421-10	Member State(EEA)	rdm:member-state	MP Authorisation > Country CTL	
E22421-11	Note: This section defines the reference medicinal product chosen for the purposes of establishing the expiry of the data protection period.			

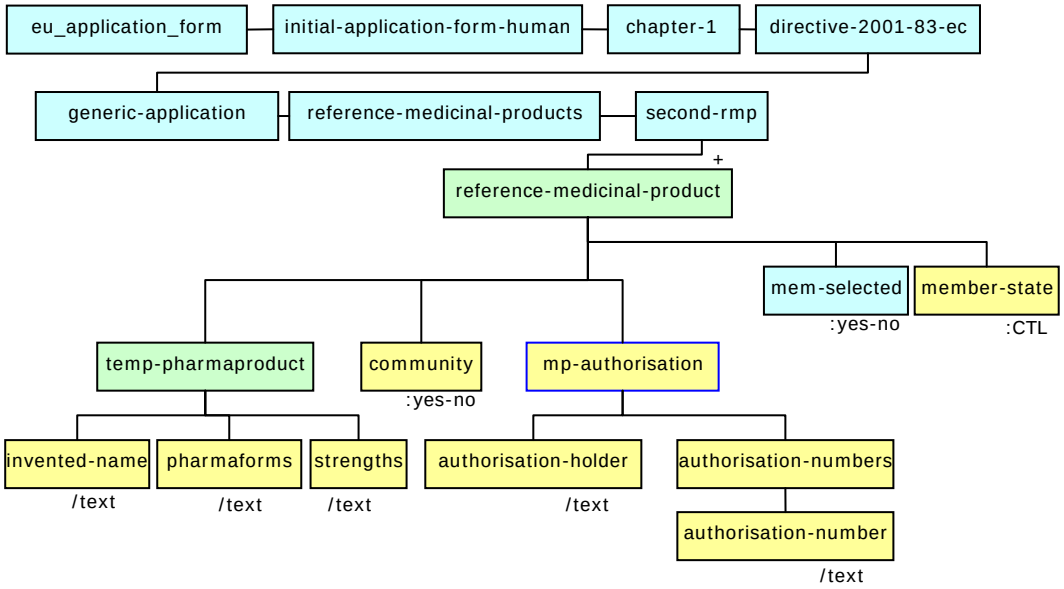
Element Tree Diagram



2.2.1.2.2. Medicinal product authorised in the Community/Member State where the application is made or European reference medicinal product:

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-1/maa:directive-2001-83-ec/maa:generic-application/maa:reference-medicinal-products/maa:second-rmp/maa:reference-medicinal-product/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E22422-1	Product (Invented) name	rdm:temp-pharmaproduct/ rdm:invented-name	Reference Medicinal Product > Medicinal Product > Medicinal Product Name	
E22422-2	Pharmaceutical form(s)	rdm:temp-pharmaproduct /rdm:pharmaforms	Reference Medicinal Product > Medicinal Product > Pharmaceutical Product > Pharmaceutical Dose Form CTL	
E22422-3	Strength(s)	rdm:temp-pharmaproduct/ rdm:strengths	Ingredient	
E22422-4	Marketing authorisation holder	rdm:mp-authorisation/ rdm:authorisation-holder	Role > Party> Organisation> Name	
E22422-5	Marketing authorisation number	rdm:mp-authorisation/ rdm:authorisation-numbers/ rdm:authorisation-number	MP Authorisation > authorisation number	
E22422-6	Marketing authorisation granted by			
E22422-7	Community	rdm:community	MP Authorisation > Country CTL	
E22422-8	Member State(EEA)	rdm:mem-selected		
E22422-9	Member State(EEA)	rdm:member-state	MP Authorisation > Country CTL	

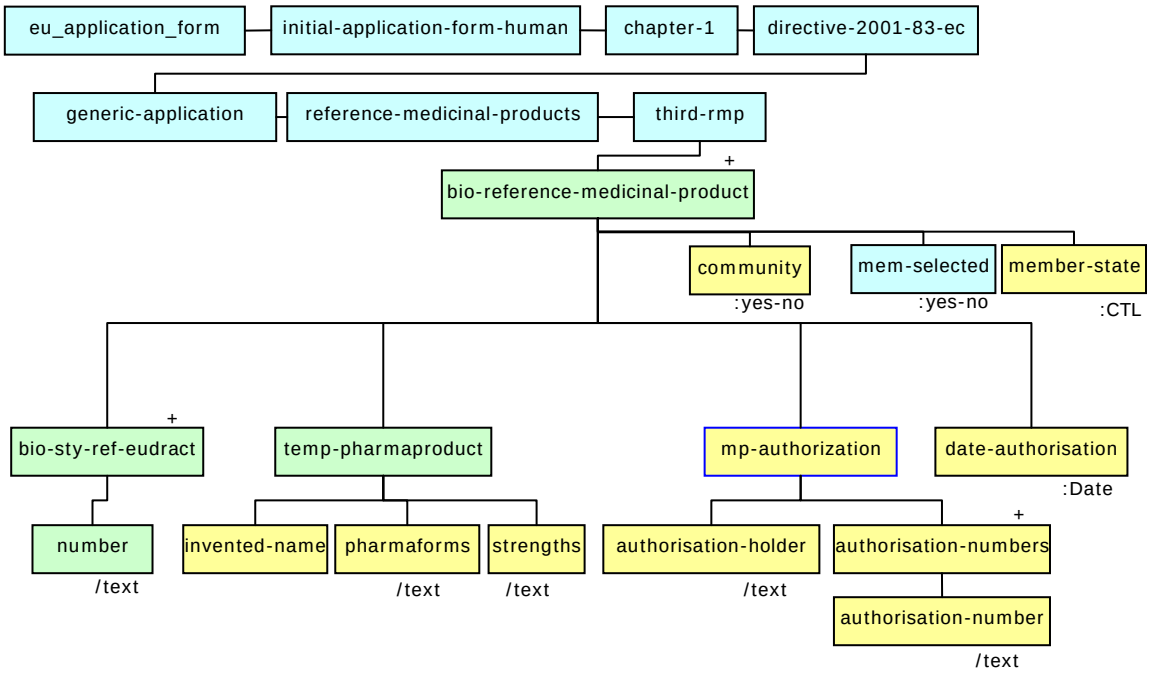
Element Tree Diagram



2.2.1.2.3. Medicinal product which is or has been authorised in accordance with Community provisions in force and to which bioequivalence has been demonstrated by appropriate bioavailability studies:

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-1/maa:directive-2001-83-ec/maa:generic-application/maa:reference-medicinal-products/maa:third-rmp/maa:bio-reference-medicinal-product/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E22423-1	*Note: Should be in accordance with the notion of global marketing authorisation, if different from the medicinal product identified above..*			
E22423-2	Product (Invented) name	rdm:temp-pharmaproduct/ rdm:invented-name	Reference Medicinal Product > Medicinal Product > Medicinal Product Name	
E22423-3	Pharmaceutical form(s)	rdm:temp-pharmaproduct/ rdm:pharmaforms	Reference Medicinal Product > Medicinal Product > Pharmaceutical Product > Pharmaceutical Dose Form CTL	
E22423-4	Strength(s)	rdm:temp-pharmaproduct/ rdm:strengths	Ingredient	
E22423-5	Marketing authorisation holder	rdm:mp-authorisation/ rdm:authorisation-holder	Role > Party> Organisation> Name	
E22423-6	Marketing authorisation number	rdm:authorisation-numbers/ rdm:authorisation-number	MP Authorisation > authorisation number	
E22423-7	Date of authorisation	rdm:date-authorization	MP Authorisation > authorisation date	
E22423-8	Member State of source	rdm:member-state-source	Reference Medicinal Product > Country CTL	
E22423-9	Bioavailability study(ies) reference number(s)/EudraCT numbers(s):	rdm:bio-sty-ref-eudract/ rdm:number	Reference Medicinal Product > study ref number	
E22423-10	Marketing authorisation granted by			
E22423-11	Community	rdm:community	MP Authorisation > Country CTL	
E22423-12	Member State(EEA)	rdm:mem-selected		
E22423-13	Member State(EEA)	rdm:member-state	MP Authorisation > Country CTL	

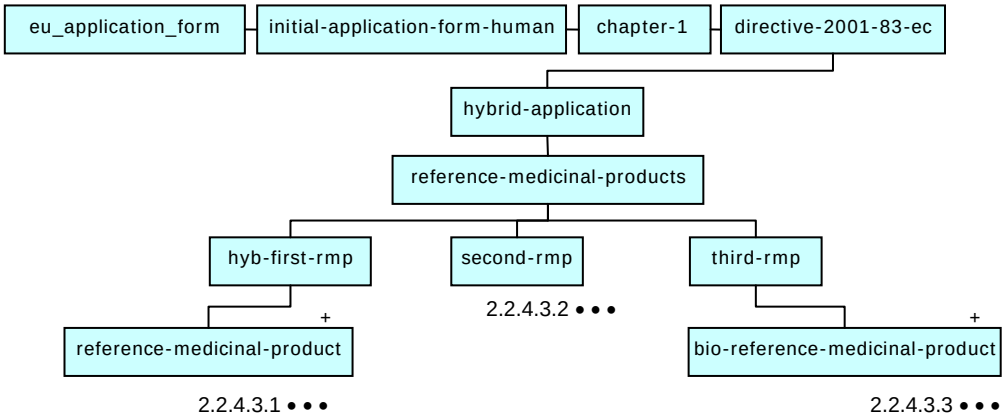
Element Tree Diagram



2.2.1.3. Article 10(3) hybrid application

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-1/maa:directive-2001-83-ec/maa:hybrid-application/maa:reference-medicinal-products/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2243-1	*Note: Application for a medicinal product referring to a so-called reference medicinal product with a Marketing Authorisation in a Member State or in a Community (e.g. different pharmaceutical form, different therapeutic use .....) Complete administrative and quality data, appropriate preclinical and clinical data. Refer to Notice to Applicants, Volume 2A, Chapter 1.*			B2243-1
E2243-2	Reference medicinal product			B2243-1
E2243-3	*Note: The chosen reference medicinal product must be a medicinal product authorised in the Community on the basis of a complete dossier in accordance with the provisions of the Article 8 of Directive 2001/83/EC.*			B2243-1
E2243-4	Medicinal product which is or has been authorised in accordance with Community provisions in force for not less than 6/10 years in the EEA	maa:hyb-first-rmp/reference-medicinal-product/	RMP Usage CTL	B2243-1, See Section 2.2.4.3.1
E2243-5	Medicinal product authorised in the Community/Member State where the application is made or European reference medicinal product	maa:second-rmp/	RMP Usage CTL	B2243-1, See Section 2.2.4.3.2
E2243-6	Medicinal product which is or has been authorised in accordance with Community provisions in force used for the demonstration of bioequivalence (if applicable) and/or in other studies	maa:third-rmp/maa:bio-reference-medicinal-product	RMP Usage CTL	B2243-1, See Section 2.2.4.3.3

Element Tree Diagram

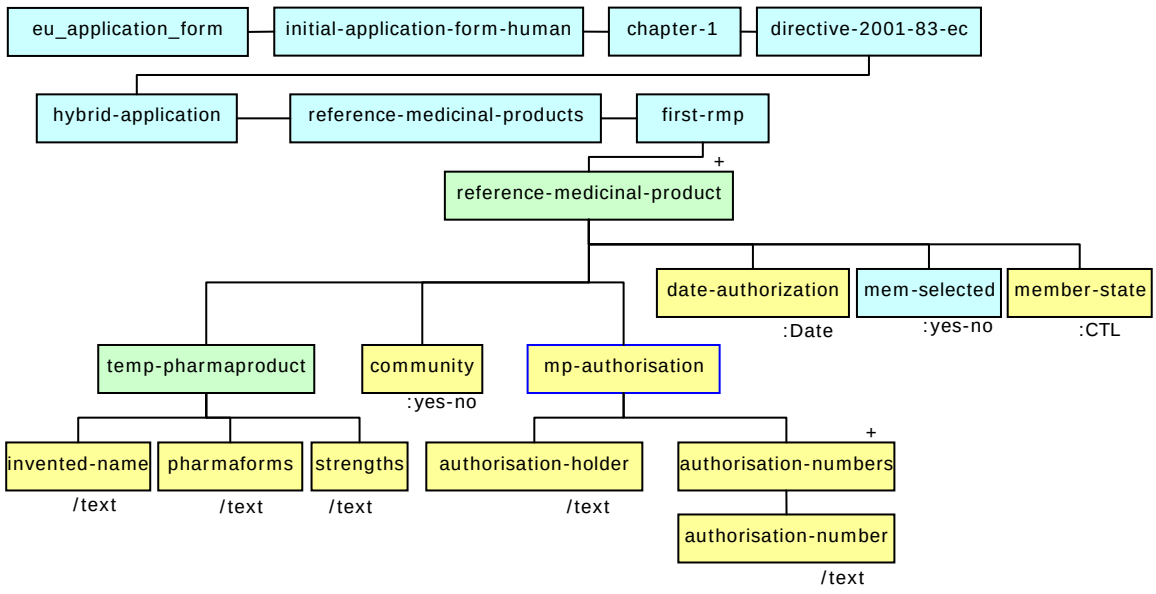


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2243-1	E224-4, E2243-4 to E2243-5	E224-4 is mandatory. rest are optional.	When E224-4 is selected, then the rest are mandatory.	

2.2.1.3.1. Medicinal product which is or has been authorised in accordance with Community provisions in force for not less than 6/10 years in the EEA

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-1/maa:directive-2001-83-ec/maa:hybrid-application/maa:reference-medicinal-products/maa:first-rmp/maa:reference-medicinal-product/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E22431-1	*Note: This section defines the reference medicinal product chosen for the purposes of establishing the expiry of the data protection period.*			
E22431-2	Product (Invented) name	rdm:temp-pharmaproduct/ rdm:invented-name	Reference Medicinal Product > Medicinal Product > Medicinal Product Name	
E22431-3	Pharmaceutical form(s)	rdm:temp-pharmaproduct/ rdm:pharmaforms	Reference Medicinal Product > Medicinal Product > Pharmaceutical Product > Pharmaceutical Dose Form CTL	
E22431-4	Strength(s)	rdm:temp-pharmaproduct/ rdm:strengths	Ingredient	
E22431-5	Marketing authorisation holder	rdm:mp-authorisation/ rdm:authorisation-holder	Role > Party> Organisation> Name	
E22431-6	Marketing authorisation number	rdm:authorisation-numbers/ rdm:authorisation-number	MP Authorisation > authorisation number	
E22431-7	Date of authorisation	rdm:date-authorization	MP Authorisation > authorisation date	
E22431-8	Marketing authorisation granted by			
E22431-9	Community	rdm:community	MP Authorisation > Country CTL	
E22431-10	Member State(EEA)	rdm:mem-selected		
E22431-11	Member State(EEA)	rdm:member-state	MP Authorisation > Country CTL	

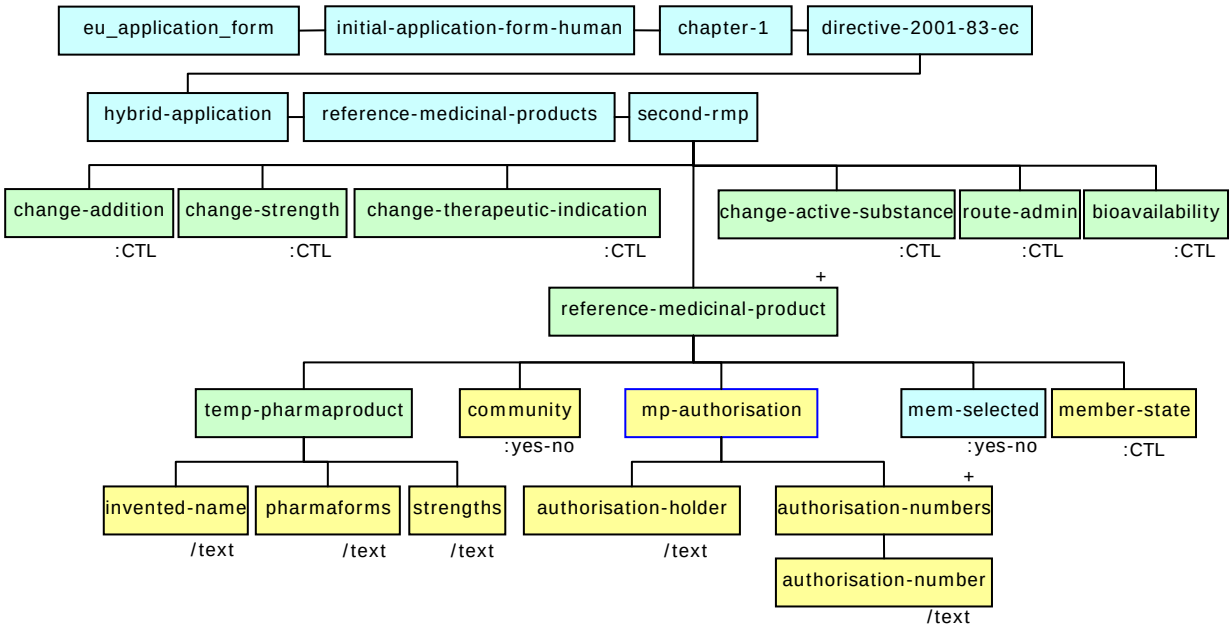
Element Tree Diagram



2.2.1.3.2. Medicinal product authorised in the Community/Member State where the application is made or European reference medicinal product

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-1/maa:directive-2001-83-ec/maa:hybrid-application/maa:reference-medicinal-products/maa:second-rmp/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E22432-1	Product (Invented) name	maa:reference-medicinal-product/ rdm:temp-pharmaproduct/ rdm:invented-name	Reference Medicinal Product > Medicinal Product > Medicinal Product Name	
E22432-2	Pharmaceutical form(s)	maa:reference-medicinal-product/ rdm:temp-pharmaproduct/ rdm:pharmaforms	Reference Medicinal Product > Medicinal Product > Pharmaceutical Product > Pharmaceutical Dose Form CTL	
E22432-3	Strength(s)	maa:reference-medicinal-product/ rdm:temp-pharmaproduct/ rdm:strengths	Ingredient	
E22432-4	Marketing authorisation holder	maa:reference-medicinal-product/rdm:mp-authorisation/ rdm:authorisation-holder	Role > Party> Organisation> Name	
E22432-5	Marketing authorisation number	maa:reference-medicinal-product/ rdm:authorisation-numbers/ rdm:authorisation-number	MP Authorisation > authorisation number	
E22432-6	Marketing authorisation granted by			
E22432-7	Community	maa:reference-medicinal-product/rdm:community	MP Authorisation > Country CTL	
E22432-8	Member State(EEA)	maa:reference-medicinal-product/rdm:mem-selected		
E22432-9	Member State(EEA)	maa:reference-medicinal-product/rdm:member-state	MP Authorisation > Country CTL	
E22432-10	Difference(s) compared to this reference medicinal product:			
E22432-11	changes in the active substance(s)	maa:change-active-substance	Difference CTL	
E22432-12	change in therapeutic indications	maa:change-therapeutic-indication	Difference CTL	
E22432-13	change in pharmaceutical form	maa:change-addition	Difference CTL	
E22432-14	change in strength(quantitative change to the active substance(s))	maa:change-strength	Difference CTL	
E22432-15	change in route of administration	maa:route-admin	Difference CTL	
E22432-16	bioequivalence cannot be demonstrated through bioavailability studies	maa:bioavailability	Difference CTL	

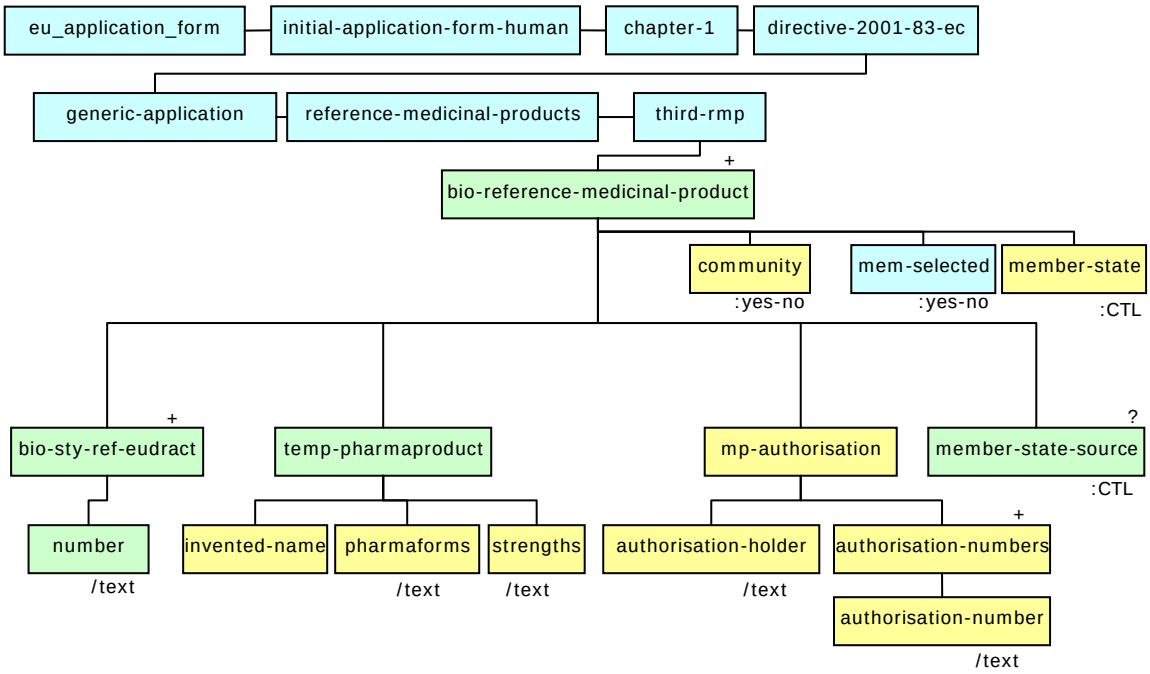
Element Tree Diagram



2.2.1.3.3. Medicinal product which is or has been authorised in accordance with Community provisions in force used for the demonstration of bioequivalence (if applicable) and/or in other studies

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-1/maa:directive-2001-83-ec/maa:hybrid-application/maa:reference-medicinal-products/maa:third-rmp/maa:reference-medicinal-product/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E22433-1	Study reference number/EudraCT number	rdm:bio-sty-ref-eudract/ rdm:number	Reference Medicinal Product > study ref number	
E22433-2	Product (Invented) name	rdm:temp-pharmaproduct/ rdm:invented-name	Reference Medicinal Product > Medicinal Product > Medicinal Product Name	
E22433-3	Pharmaceutical form(s)	rdm:temp-pharmaproduct/ rdm:pharmaforms	Reference Medicinal Product > Medicinal Product > Pharmaceutical Product > Pharmaceutical Dose Form CTL	
E22433-4	Strength(s)	rdm:temp-pharmaproduct/ rdm:strengths	Ingredient	
E22433-5	Marketing authorisation holder	rdm:mp-authorisation/ rdm:authorisation-holder	Role > Party> Organisation> Name	
E22433-6	Marketing authorisation number	rdm:authorisation-numbers/ rdm:authorisation-number	MP Authorisation > authorisation number	
E22433-7	Marketing authorisation granted by			
E22433-8	Community	rdm:community	MP Authorisation > Country CTL	
E22433-9	Member State(EEA)	rdm:mem-selected		
E22433-10	Member State(EEA)	rdm:member-state	MP Authorisation > Country CTL	
E22433-11	Member State of source	rdm:member-state-source	Reference Medicinal Product > Country CTL	

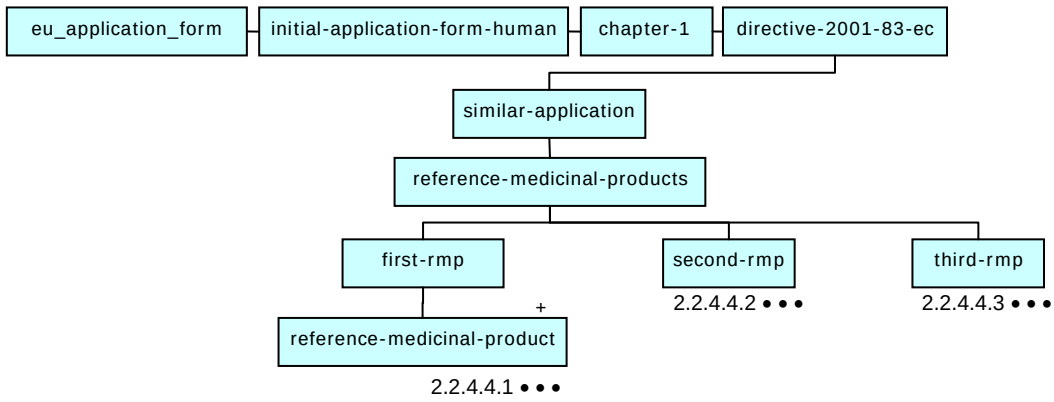
Element Tree Diagram



2.2.1.4. Article 10(4) similar biological application

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter1/maa:directive-2001-83-ec/maa:similar-application/maa:reference-medicinal-products/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2244-1	Note: Application for a product referring to a reference biological product. administrative and quality data, appropriate pre-clinical and clinical data.Refer to Notice of Applicants, Volume 2A, Chapter 1.			B2244-1
E2244-2	Reference medicinal product:			B2244-1
E2244-3	Note: The chosen reference medicinal product must be a medicinal product authorised in the Community on the basis of a complete dossier in accordance with the provisions of Article 8 of Directive 2001/83/EC.			B2244-1
E2244-4	Medicinal product which is or has been authorised in accordance with Community provisions in force for not less than 6/10 years in the EEA	maa:first-rmp/ maa:reference-medicinal-product	RMP Usage CTL	B2244-1, See Section 2.2.4.4.1
E2244-5	Medicinal product authorised in the Community/Member State where the application is made or European reference medicinal product	maa:second-rmp	RMP Usage CTL	B2244-1, See Section 2.2.4.4.2
E2244-6	Medicinal product which is or has been authorised in accordance with Community provisions in force and to which comparability tests and studies have been conducted	maa:third-rmp	RMP Usage CTL	B2244-1, See Section 2.2.4.4.3

Element Tree Diagram

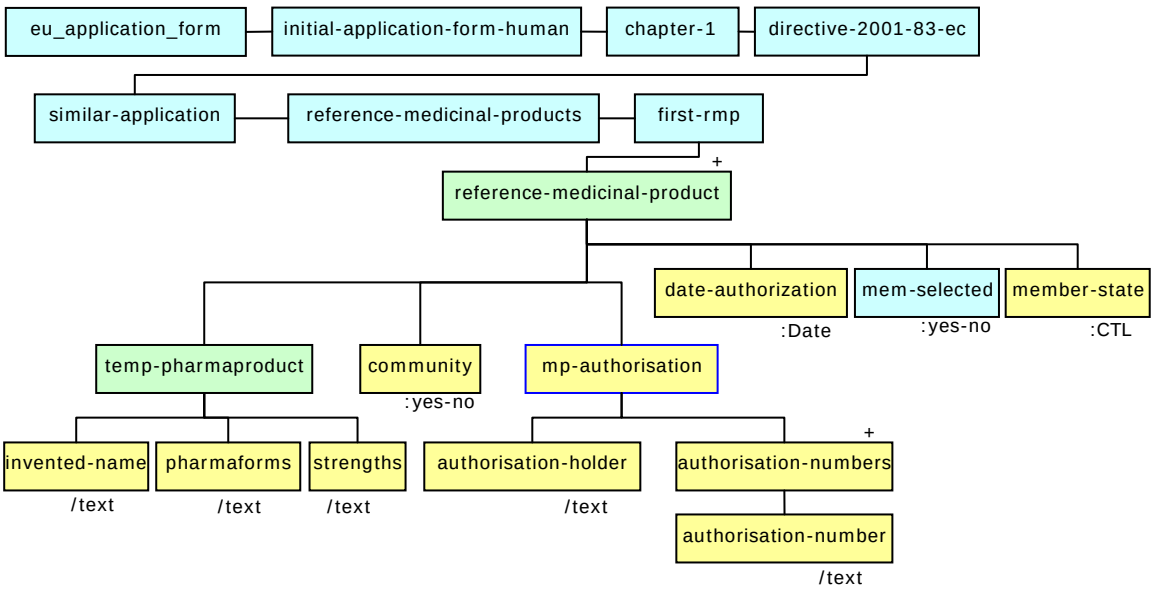


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2244-1	E224-5, E2244-1 to E2243-6	E224-5 is mandatory. Rest is optional.	When E224-5 is selected, then the rest is mandatory.	

2.2.1.4.1. Medicinal product which is or has been authorised in accordance with Community provisions in force for not less than 6/10 years in the EEA

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-1/maa:directive-2001-83-ec/maa:similar-application/maa:reference-medicinal-products/maa:first-rmp/ maa:reference-medicinal-product/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E22441-1	Product (Invented) name	rdm:temp-pharmaproduct/ rdm:invented-name	Reference Medicinal Product > Medicinal Product > Medicinal Product Name	
E22441-2	Pharmaceutical form(s)	rdm:temp-pharmaproduct/ rdm:pharmaforms	Reference Medicinal Product > Medicinal Product > Pharmaceutical Product > Pharmaceutical Dose Form CTL	
E22441-3	Strength(s)	rdm:temp-pharmaproduct/ rdm:strengths	Ingredient	
E22441-4	Marketing authorisation holder	rdm:mp-authorisation/ rdm:authorisation-holder	Role > Party> Organisation> Name	
E22441-5	Marketing authorisation number	rdm:authorisation-numbers/ rdm:authorisation-number	MP Authorisation > authorisation number	
E22441-6	Date of authorisation	rdm:date-authorization	MP Authorisation > authorisation date	
E22441-7	Marketing authorisation granted by			
E22441-8	Community	rdm:community	MP Authorisation > Country CTL	
E22441-9	Member State(EEA)	rdm:mem-selected		
E22441-10	Member State(EEA)	rdm:member-state	MP Authorisation > Country CTL	
E22441-11	Note: This section defines the reference medicinal product chosen for the purposes of establishing the expiry of the data protection period.			

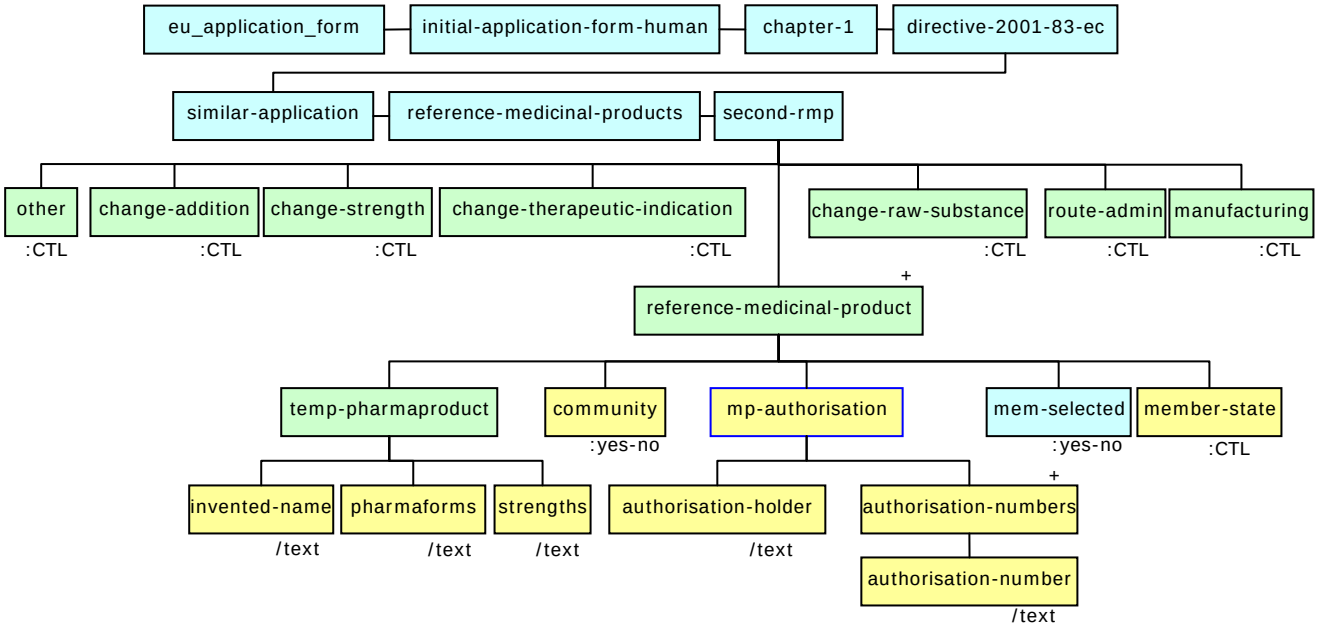
Element Tree Diagram



2.2.1.4.2. Medicinal product authorised in the Community/Member State where the application is made or European reference medicinal product

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-1/maa:directive-2001-83-ec/maa:similar-application/maa:reference-medicinal-products/maa:second-rmp/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E22442-1	Product (Invented) name	maa:reference-medicinal-product/rdm:temp-pharmaproduct/ rdm:invented-name	Reference Medicinal Product > Medicinal Product > Medicinal Product Name	
E22442-2	Pharmaceutical form(s)	maa:reference-medicinal-product/rdm:temp-pharmaproduct/ rdm:pharmaforms	Reference Medicinal Product > Medicinal Product > Pharmaceutical Product > Pharmaceutical Dose Form CTL	
E22442-3	Strength(s)	maa:reference-medicinal-product/rdm:temp-pharmaproduct/ rdm:strengths	Ingredient	
E22442-4	Marketing authorisation holder	maa:reference-medicinal-product/rdm:mp-authorisation/ rdm:authorisation-holder	Role > Party> Organisation> Name	
E22442-5	Marketing authorisation number	maa:reference-medicinal-product/rdm:authorisation-numbers/ rdm:authorisation-number	MP Authorisation > authorisation number	
E22442-6	Marketing authorisation granted by			
E22442-7	Community	maa:reference-medicinal-product/rdm:community	MP Authorisation > Country CTL	
E22442-8	Member State(EEA)	maa:reference-medicinal-product/rdm:mem-selected		
E22442-9	Member State(EEA)	maa:reference-medicinal-product/rdm:member-state	MP Authorisation > Country CTL	
E22442-10	Difference(s) compared to this reference medicinal product:			
E22442-11	change(s) in the raw material(s)	maa:change-raw-substance	Difference CTL	
E22442-12	change(s) in the manufacturing process(es)	maa:manufacturing	Difference CTL	
E22442-13	change in therapeutic indication(s)	maa:change-therapeutic-indication	Difference CTL	
E22442-14	change in pharmaceutical form(s)	maa:change-addition	Difference CTL	
E22442-15	change in strength (quantitative change to the active substance(s))	maa:change-strength	Difference CTL	
E22442-16	change in route of administration(s)	maa:route-admin	Difference CTL	
E22442-17	other	maa:other	Difference CTL	

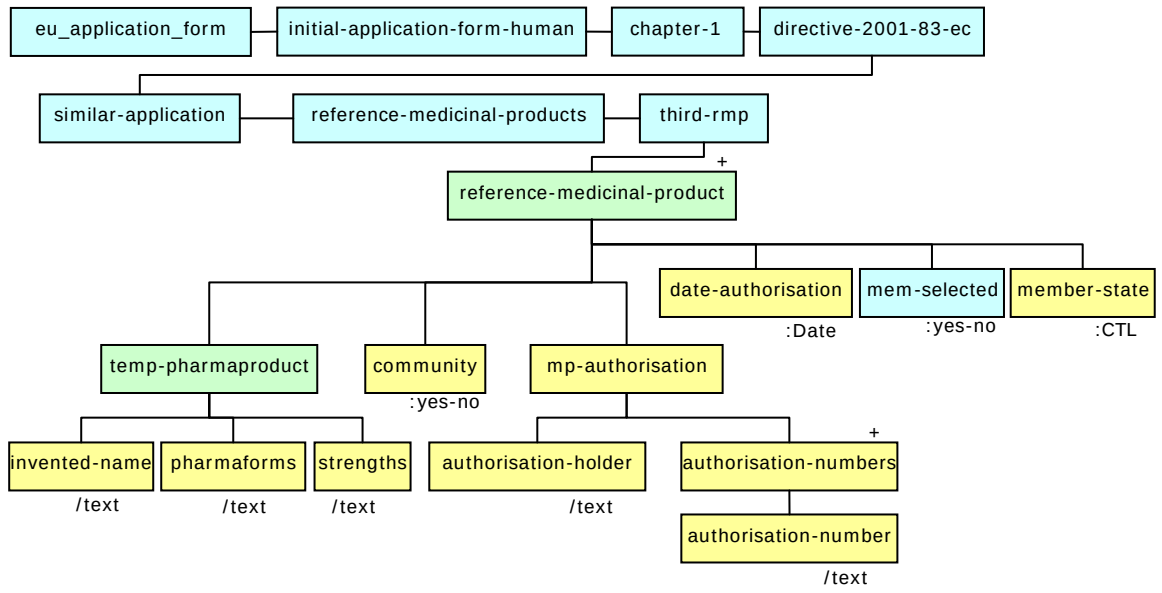
Element Tree Diagram



2.2.1.4.3. Medicinal product which is or has been authorised in accordance with Community provisions in force and to which comparability tests and studies have been conducted

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-1/maa:directive-2001-83-ec/maa:similar-application/maa:reference-medicinal-products/maa:third-rmp/maa:reference-medicinal-product/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E22443-1	Note: This chosen reference medicinal product must be a medicinal product authorised in the Community and should be used though out the comparability programme for quality, safety and efficacy studies..			
E22443-2	Product (Invented) name	rdm:temp-pharmaproduct/ rdm:invented-name	Reference Medicinal Product > Medicinal Product > Medicinal Product Name	
E22443-3	Pharmaceutical form(s)	rdm:temp-pharmaproduct/ rdm:pharmaforms	Reference Medicinal Product > Medicinal Product > Pharmaceutical Product > Pharmaceutical Dose Form CTL	
E22443-4	Strength(s)	rdm:temp-pharmaproduct/ rdm:strengths	Ingredient	
E22443-5	Marketing authorisation holder	rdm:mp-authorisation/ rdm:authorisation-holder	Role > Party> Organisation> Name	
E22443-6	Marketing authorisation number	rdm:authorisation-numbers/ rdm:authorisation-number	MP Authorisation > authorisation number	
E22443-7	Date of authorisation	rdm:date-authorisation	MP Authorisation > authorisation date	
E22443-8	Marketing authorisation granted by			
E22443-9	Community	rdm:community	MP Authorisation > Country CTL	
E22443-10	Member State(EEA)	rdm:mem-selected		
E22443-11	Member State(EEA)	rdm:member-state	MP Authorisation > Country CTL	

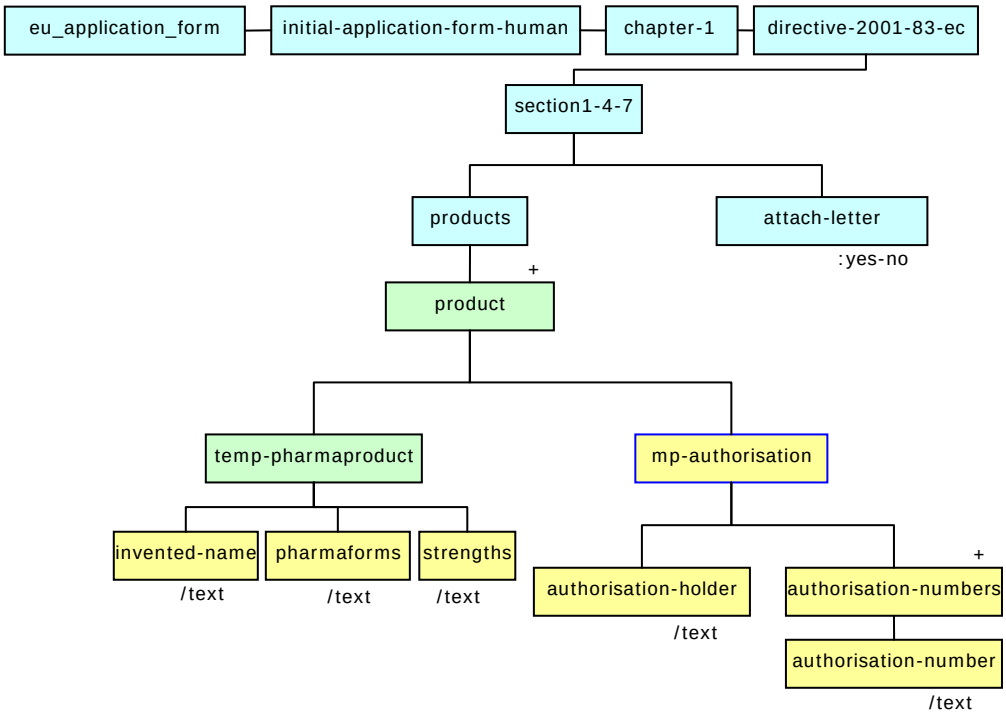
Element Tree Diagram



2.2.1.5. Article 10c informed consent application

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-1/maa:directive-2001-83-ec/maa:section1-4-7/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2245-1	Note: - Application for a medicinal product possessing the same qualitative and quantitative composition in terms of active substances and the same pharmaceutical form of an authorised product where consent has been given by the existing marketing authorisation holder to use their data in support of this application - Complete administrative data should be provided with consent to pharmaceutical, preclinical and clinical data - The authorised product and the informed consent application can have the same or different MAH			B2245-1
E2245-2	Authorised product in the Community/Member State where the application is made:			B2245-1
E2245-3	Product (Invented) name	maa:products/maa:product/rdm:temp-pharmaproduct/ rdm:invented-name	Reference Medicinal Product > Medicinal Product > Medicinal Product Name	B2245-1
E2245-4	Pharmaceutical form(s)	maa:products/maa:product/rdm:temp-pharmaproduct/ rdm:pharmaforms	Reference Medicinal Product > Medicinal Product > Pharmaceutical Product > Pharmaceutical Dose Form CTL	B2245-1
E2245-5	Strength(s)	maa:products/maa:product/rdm:temp-pharmaproduct/ rdm:strengths	Ingredient	B2245-1
E2245-6	Marketing authorisation holder	maa:products/maa:product/rdm:mp-authorisation/ rdm:authorisation-holder	Role > Party> Organisation> Name	B2245-1
E2245-7	Marketing authorisation number	maa:products/maa:product/ rdm:mp-authorisation/ rdm:authorisation-numbers/ rdm:authorisation-number	MP Authorisation > authorisation number	B2245-1
E2245-8	Attach letter of consent from marketing authorisation holder of the authorised product (Annex 5.2)	maa:attach-letter		B2245-1

Element Tree Diagram

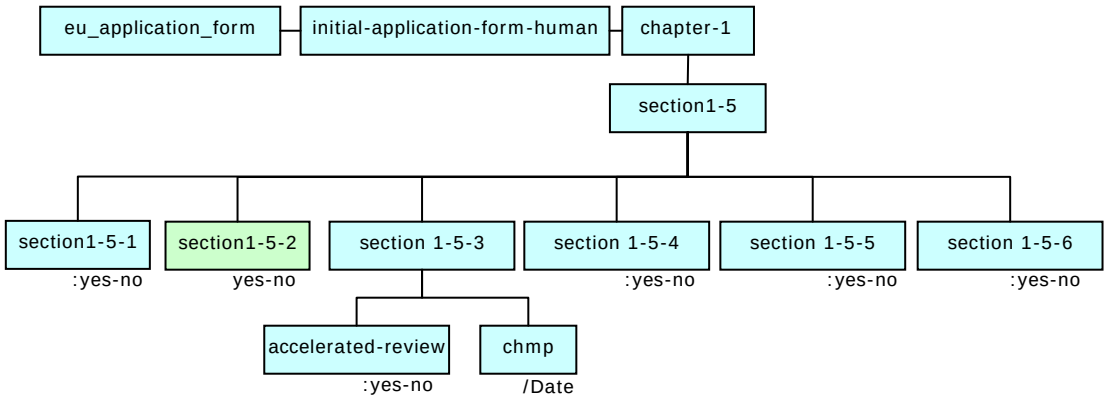


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2245-1	E224-8, E2245-1 to E2245-8	E224-5 is mandatory. Rest are optional.	When E224-5 is selected, then the rest are mandatory.	

2.2.2. CONSIDERATION OF THIS APPLICATION IS ALSO REQUESTED UNDER THE FOLLOWING ARTICLE IN DIRECTIVE 2001/83/EC OR REGULATION (EC) No 726/2004

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-1/maa:section1-5/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E225-1	Conditional Approval			
E225-2	Note: centralised procedure only according to Article 14(7) of Regulation (EC) No 726/2004	maa:section1-5-1	Consideration CTL	B225-1
E225-3	Exceptional Circumstances	maa:section1-5-2	Consideration CTL	B225-1
E225-4	Note: According to Article 22 of Directive 2001/83/EC and Article 14(8) of Regulation (EC) No 726/2004			
E225-5	Accelerated Review	maa:section1-5 3/ maa:accelerated-review	Consideration CTL	B225-2
E225-6	Note: Centralised procedure only according to Article 14(9) of Regulation (EC) No 726/2004			
E225-7	Date of acceptance by CHMP	maa:section1-5-3/maa:chmp	MP Procedure > chmp acceptane date	B225-2
E225-8	Article 10(1) of Directive 2001/83/EC / Article 14(11) of Regulation (EC) No 726/2004	maa:section1-5-4	Consideration CTL	B225-1
E225-9	(one year of market exclusivity for a new indication)		Consideration CTL	
E225-10	Article 10(5) of Directive 2001/83/EC (one year of data exclusivity for a new indication)	maa:section1-5-5	Consideration CTL	B225-1
E225-11	Article 74(a) of Directive 2001/83/EC (one year of data exclusivity for a change in classification)	maa:section1-5-6	Consideration CTL	B225-1

Element Tree Diagram

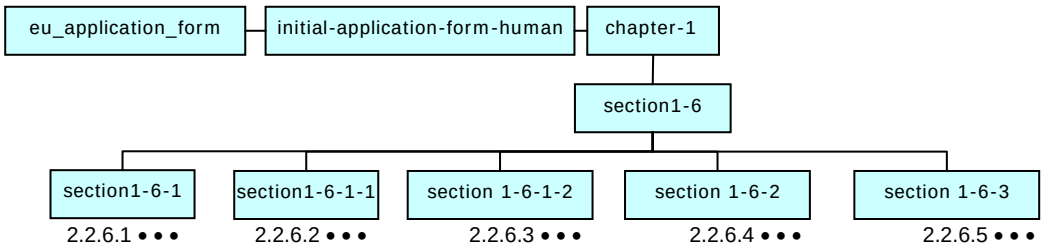


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B225-1	E225-2, E225-3, E225-8, E225-10, E225-21	Mandatory.	Mutually exclusive.	
B225-2	E225-5, E225-7	E225-5 is mandatory, E225-7 is optional.	If E225-5 is selected, then E225-7 is mandatory.	

2.2.3. REQUIREMENTS ACCORDING TO REGULATION (EC) No 1901/2006 ('PAEDIATRIC REGULATION')

	Common DES 3.0 Context		**Common RDM Entry point**	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-1/maa:section1-6/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E226-1	*(Note: The notion of 'global marketing authorisation' as stated in Article 6(1) 2nd subparagraph of Directive 2001/83/EC, as amended, should be taken into account for products belonging to the same[5] marketing authorisation holder)*			
E226-2	Does the same[5] applicant hold other marketing authorisation(s) for a medicinal product(s) containing the same active substance(s) in the EEA?	maa:section1-6-1		See Section 2.2.6.1
E226-3	ARTICLE 7 OF PAEDIATRIC REGULATION APPLIES TO THIS APPLICATION, SINCE:	maa:section1-6-1-1		See Section 2.2.6.2
E226-4	ARTICLE 8 OF PAEDIATRIC REGULATION APPLIES TO THIS APPLICATION, SINCE:	maa:section1-6-1-2	Paed Regulation App CTL	See Section 2.2.6.3
E226-5	ARTICLE 30 (PUMA) OF THE PAEDIATRIC REGULATION APPLIES TO THIS APPLICATION:	maa:section1-6-2		See Section 2.2.6.4
E226-6	HAS THIS APPLICATION BEEN SUBJECT TO PIP COMPLIANCE VERIFICATION?	maa:section1-6-3		See Section 2.2.6.5

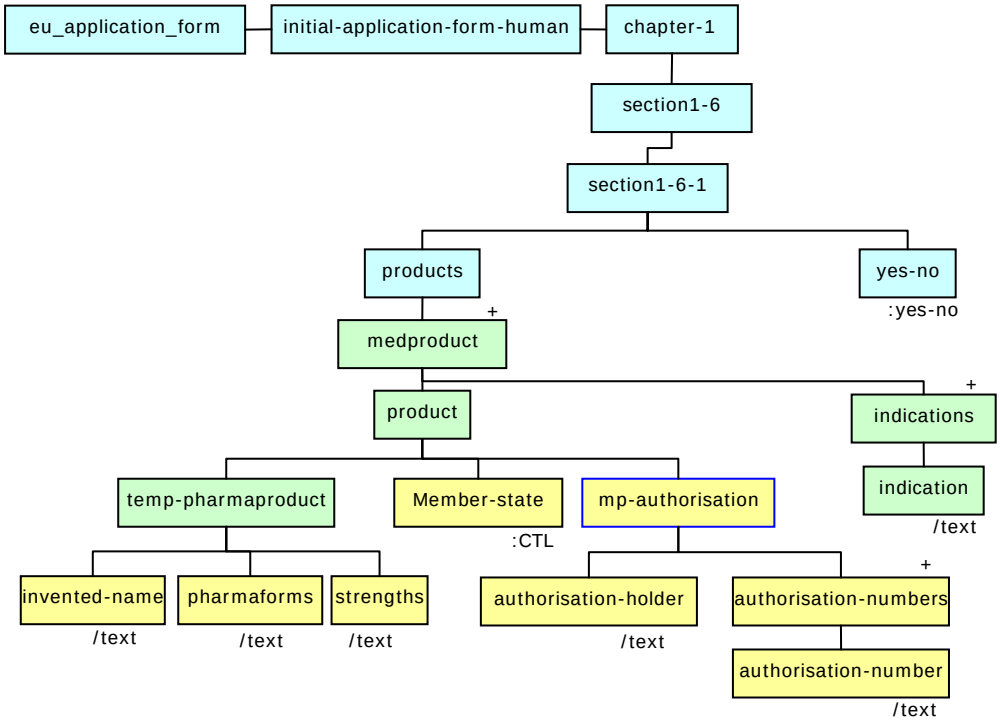
Element Tree Diagram



2.2.3.1. Does the same applicant hold other marketing authorisation(s) for a medicinal product(s) containing the same active substance(s) in the EEA?

	Common DES 3.0 Context		**Common RDM Entry point**	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-1/maa:section1-6/maa:section1-6-1/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2261-1	Yes (Complete section 1.6.1.2)	maa:yes-no (Value = 1)	Paediatric Designation > has same active substance	B2261-1, B2261-2, B2263-1
E2261-2	No (Complete section 1.6.1.1)	maa:yes-no (Value = 0)	Paediatric Designation > has same active substance	B2261-1, B2262-1
E2261-3	Product (invented) name	maa:products/maa:medproduct:/ maa:product/rdm:temp-pharmaproduct/ rdm:invented-name	Reference Medicinal Product > Medicinal Product > Pharmaceutical Product > Ingredient >Substance	B2261-2
E2261-4	Pharmaceutical form(s)	maa:products/maa:medproduct:/ maa:product/rdm:temp-pharmaproduct/ rdm:pharmaforms	Reference Medicinal Product > Medicinal Product > medicinal product name	B2261-2
E2261-5	Strength(s)	maa:products/maa:medproduct/ maa:product/rdm:temp-pharmaproduct/ rdm:strengths	Reference Medicinal Product > Medicinal Product > Pharmaceutical Product > Ingredient	B2261-2
E2261-6	Marketing authorisation holder	maa:products/maa:medproduct:/ maa:product/rdm:mp-authorisation/rdm:authorisation-holder	Role > Party > Organisation > Name	B2261-2
E2261-7	Member State/Community where product is authorised:	maa:products/maa:medproduct/ maa:member-state	MP Authorisation > Country CTL	B2261-2
E2261-8	Marketing authorisation number	maa:products/maa:medproduct/ maa:product/rdm:mp-authorisation/ rdm:authorisation-numbers/rdm:authorisation-number	MP Authorisation > authorisation number	B2261-2
E2261-9	Indication	maa:products/maa:medproduct/ maa:indications/maa:indication	Reference Medicinal Product > paed indication	B2261-2
E2261-10	[5] "Same" applicant/marketing authorisation holder: as per the Commission Communication (98/C 299/03) (i.e. belonging to the same mother company or group of companies or which are "licensees")			B2261-2

Element Tree Diagram

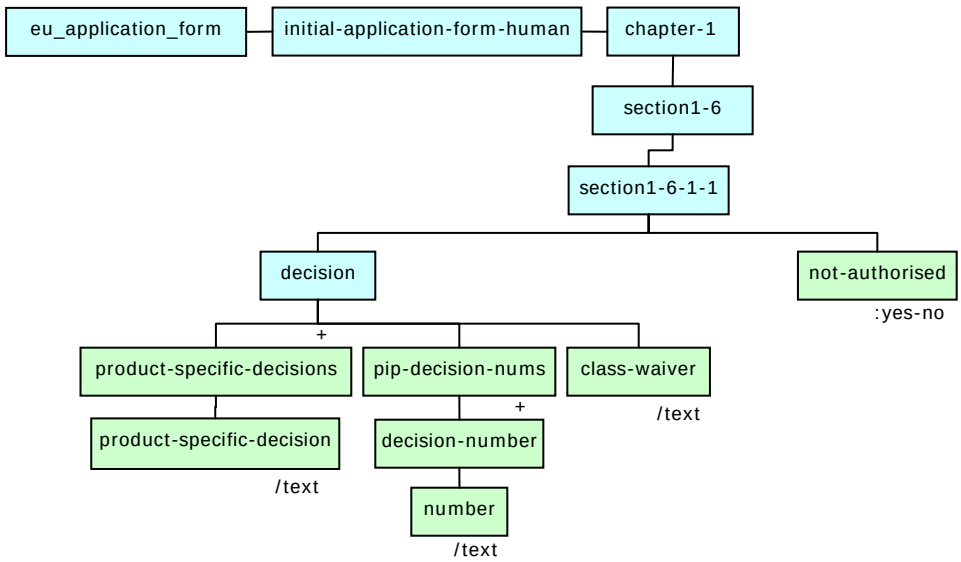


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2261-1	E2261-1, E2261-2	Mandatory.	Mutually exclusive.	
B2261-2	E2261-1, E2261-3 to E2261-10		If E2261-1 is selected, then the other fields are mandatory.	

2.2.3.2. ARTICLE 7 OF PAEDIATRIC REGULATION APPLIES TO THIS APPLICATION, SINCE:

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-1/maa:section1-6/maa:section1-6-1-1/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2262-1	*(Note: Does not apply to well-established use, generic, hybrid and bio-similar applications and traditional herbal medicinal products)*			
E2262-2	The medicinal product is not authorised in the Community on 26 July 2008	maa:not-authorised	Paediatric Designation > not authorised on	B2262-1
E2262-3	THIS APPLICATION INCLUDES:			B2262-1
E2262-4	PIP Decision Number	maa:decision/rdm:pip-decision-nums/rmd:decision-number/rdm:number	Paediatric Designation > art 7 pip decision number	B2262-1
E2262-5	Product-Specific Waiver Decision Number	maa:decision/rdm:product-specific-decisions/rdm:product-specific-decision	Paediatric Designation > art 7 product waiver number	B2262-1
E2262-6	Class Waiver Decision Number	maa:decision/rdm:class-waiver	Paediatric Designation > art 7 pip class waiver number	B2262-1
E2262-7	*(Note: a copy of the PIP/Waiver decision is to be included in Module 1.10)*			B2262-1

Element Tree Diagram

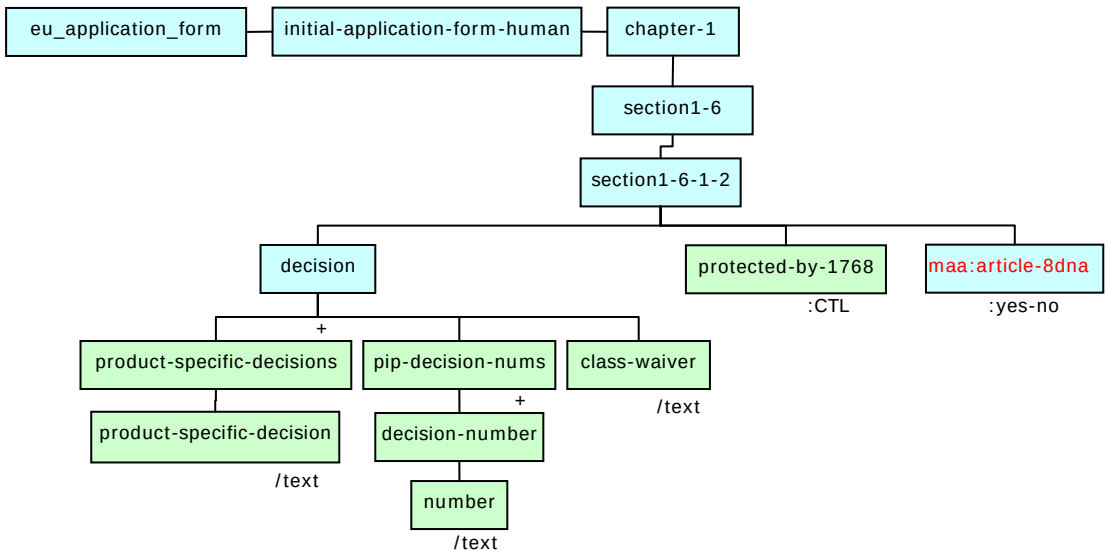


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2262-1	E2261-2, E2262-2 to E2262-7	E2262-2 to E2262-7 are optional.	If E2261-2 is selected, then the other fields are mandatory.	

2.2.3.3. ARTICLE 8 OF PAEDIATRIC REGULATION APPLIES TO THIS APPLICATION, SINCE:

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-1/maa:section1-6/maa:section1-6-1-2/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2262-1	*(Note: Does not apply to well-established use, generic, hybrid and bio-similar applications and traditional herbal medicinal products)*			
E2263-2	The application relates to a new indication, new pharmaceutical form or new route of administration of an authorised medicinal product, which			
E2263-3	is protected by a supplementary protection certificate under Regulation (EEC) No 1768/92	maa:protected-by-1768 (Value=1)	Paed Regulation App CTL	B2263-1, B2263-2, B2263-3
E2263-4	is protected by a patent which qualifies for the granting of the supplementary protection certificate	maa:protected-by-1768 (Value=2)	Paed Regulation App CTL	B2263-1, B2263-2, B2263-3
E2263-5	THIS APPLICATION INCLUDES:			B2263-1, B2263-3
E2263-6	PIP Decision Number	maa:decision/rdm:pip-decision-nums/rmd:decision-number/rdm:number	Paediatric Designation > art 8 pip decision number	B2263-1
E2263-7	Product-Specific Waiver Decision Number	maa:decision/rdm:product-specific-decisions/rdm:product-specific-decision	Paediatric Designation > art 8 product waiver number	B2263-1, B2263-3
	(Note: a copy of the PIP/Waiver decision is to be included in Module 1.10)			B2263-1, B2263-3
E2263-8	Class Waiver Decision Number	maa:decision/rdm:class-waiver	Paediatric Designation > art 8 class waiver number	B2263-1, B2263-3
E2263-9	THIS APPLICATION DOES NOT FALL WITHIN THE SCOPE OF ARTICLE 8 OF THE PAEDIATRIC REGULATION	maa:article-8dna		B2263-3, B2263-3

Element Tree Diagram

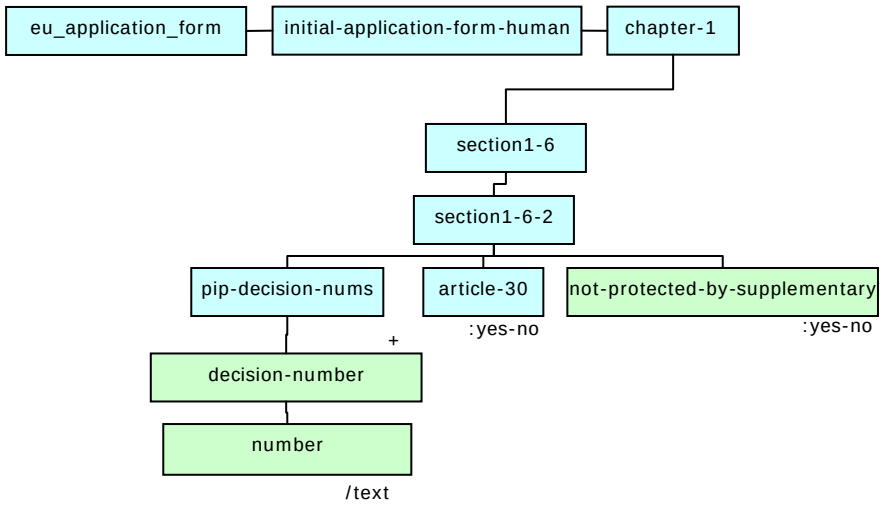


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2263-1	E2261-1, E2263-2 to E2263-8	E2263-2 to E2262-8 are optional.	If E2261-1 is selected, then the other fields are mandatory.	
B2263-2	E2263-3, E2263-4	Optional.	Mutually Exclusive.	
B2263-3	E2263-9, E2263-2 to E2263-8	E2263-2 to E2262-8 are optional.	If E2263-9 is selected, then the other fields are not displayed.	

2.2.3.4. ARTICLE 30 (PUMA) OF THE PAEDIATRIC REGULATION APPLIES TO THIS APPLICATION:

	Common DES 3.0 Context		**Common RDM Entry point**	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-1/maa:section1-6/maa:section1-6-2/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2264-1	ARTICLE 30 (PUMA) OF THE PAEDIATRIC REGULATION APPLIES TO THIS APPLICATION:	maa:article-30		B2264-1
E2264-2	*(Note: Also applies to Extension applications of PUMA)*			
E2264-3	The application relates to a medicinal product, which is not protected by either a supplementary protection certificate under Regulation (EEC) No 1768/92, or by a patent which qualifies for the granting of the supplementary protection certificate	maa:not-protected-by-supplementary	Paediatric Designation > relates to non protected product	B2264-1
E2264-4	PIP Decision Number:	maa:pip-decision-nums/maa:decision-number/maa:number	Paediatric Designation > art 30 pip decision number	B2264-1
E2264-5	*(Note: a copy of the PIP/Waiver decision is to be included in Module 1.10)*			B2264-1

Element Tree Diagram

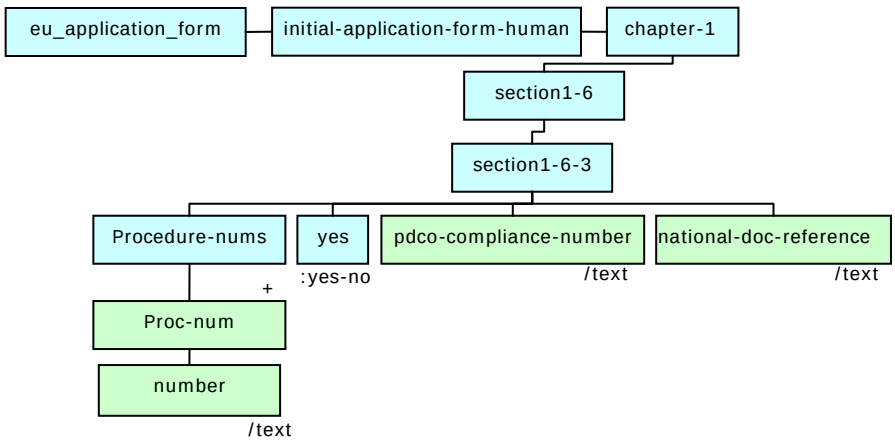


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2264-1	E2264-1 , E2264-3 to E2264-5	E2264-1 is mandatory, rest are optional.	If E2264-1 is selected, the other fields become visible and mandatory.	

2.2.3.5. HAS THIS APPLICATION BEEN SUBJECT TO PIP COMPLIANCE VERIFICATION?

	Common DES 3.0 Context		**Common RDM Entry point**	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-1/maa:section1-6/maa:section1-6-3/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2265-1	Yes	maa:yes (Value=1)	Paediatric Designation > subject to pip compliance	
E2265-2	No	maa:yes (Value=0)	Paediatric Designation > subject to pip compliance	
E2265-3	If, yes, please specify			B2265-1
E2265-4	PDCO compliance Opinion Number	maa:pdco-compliance-number	Paediatric Designation > pdco opinion number	B2265-1
E2265-5	National competent authority/EMEA document reference	maa:national-doc-reference	Paediatric Designation > nca emea doc reference	B2265-1
E2265-6	*(Note: if available a copy of the PDCO opinion + report, document issued by the national competent authority/EMEA, or applicant's compliance report is to be included in Module 1.10)*			B2265-1
E2265-7	Please identify any parallel, ongoing or previous variation(s) or extension(s) containing paediatric data relevant for the full PIP compliance verification, if applicable			B2265-1
E2265-8	Procedure-number	maa:procedure-nums/maa:proc-num/maa:number	Paediatric Procedure > paed procedure number	B2265-1

Element Tree Diagram



Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2265-1	E2265-1, E2265- to E2265-8	E2265-1 is mandatory, rest are optional.	If E2265-1 is selected, the other fields are visble and mandatory.	

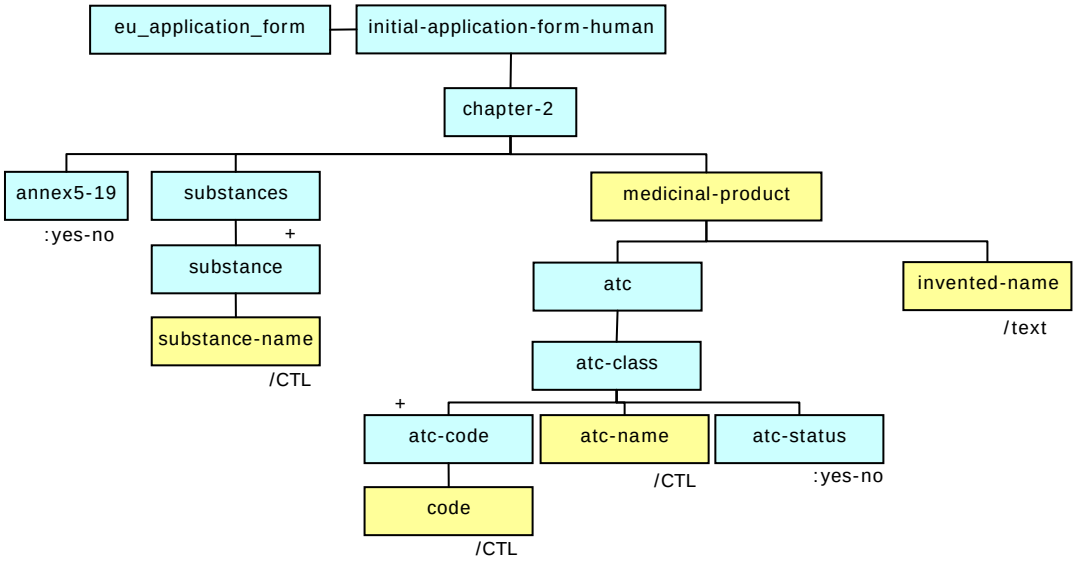
2.3. MARKETING AUTHORISATION APPLICATION PARTICULARS

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-2/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E23-1	NAME(S) and ATC CODE			See Section 2.3.1
E23-2	STRENGTH, PHARMACEUTICAL FORM, ROUTE OF ADMINISTRATION, CONTAINER AND PACK SIZES			See Section 2.3.2
E23-3	LEGAL STATUS			See Section 2.3.3
E23-4	MARKETING AUTHORISATION HOLDER/ CONTACT PERSONS/ COMPANY			See Section 2.3.4
E23-5	Manufacturers *Note: ALL manufacturing and control sites mentioned throughout the whole dossier MUST be consistent regarding their names, detailed addresses and activities.*			See Section 2.3.5
E23-6	Qualitative and Quantitative composition			See Section 2.3.6

2.3.1. NAME(S) and ATC CODE

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-2/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E231-1	Proposed (invented) name of the medicinal product in the Community/Member State/ Iceland/ Liechtenstein/Norway:	rdm:medicinal-product/rdm:invented-name	Medicinal Product Group > invented name	
E231-2	If different (invented) names in different Member States are proposed in a mutual recognition or decentralised procedure, these should be listed in Annex 5.19	maa:annex5-19		
E231-3	Name of the active substance(s)			
E231-4	*Note: Only one name should be given in the following order of priority: INN*, Ph.Eur., National Pharmacopeia, common name, scientific name;* The active substance should be declared by its recommended INN, accompanied by its salt or hydrate form if relevant (for further details, consult the Guideline on the SPC)*			
E231-5	Active substance	maa:active-substances/ maa:active-substance/ maa:substance-name	Medicinal Product > Pharmaceutical Product > Ingredient > Substance CTL > term id Medicinal Product > Pharmaceutical Product > Ingredient > Ingredient Role CTL > term id	
E231-6	Pharmacotherapeutic group (Please use current ATC code)			
E231-7	ATC code	rdm:medicinal-product/ rdm:atc/rdm:atc-class:rdm:atc-code/rdm:code	Medicinal Product > ATC Code CTL	
E231-8	Group	rdm:medicinal-product/ rdm:atc/maa:atc-class/maa:atc-name	Medicinal Product > ATC Code CTL	
E231-9	If no ATC code has been assigned, please indicate if an application for ATC code has been made	rdm:medicinal-product/ rdm:atc/maa:atc-class/maa:atc-status		

Element Tree Diagram

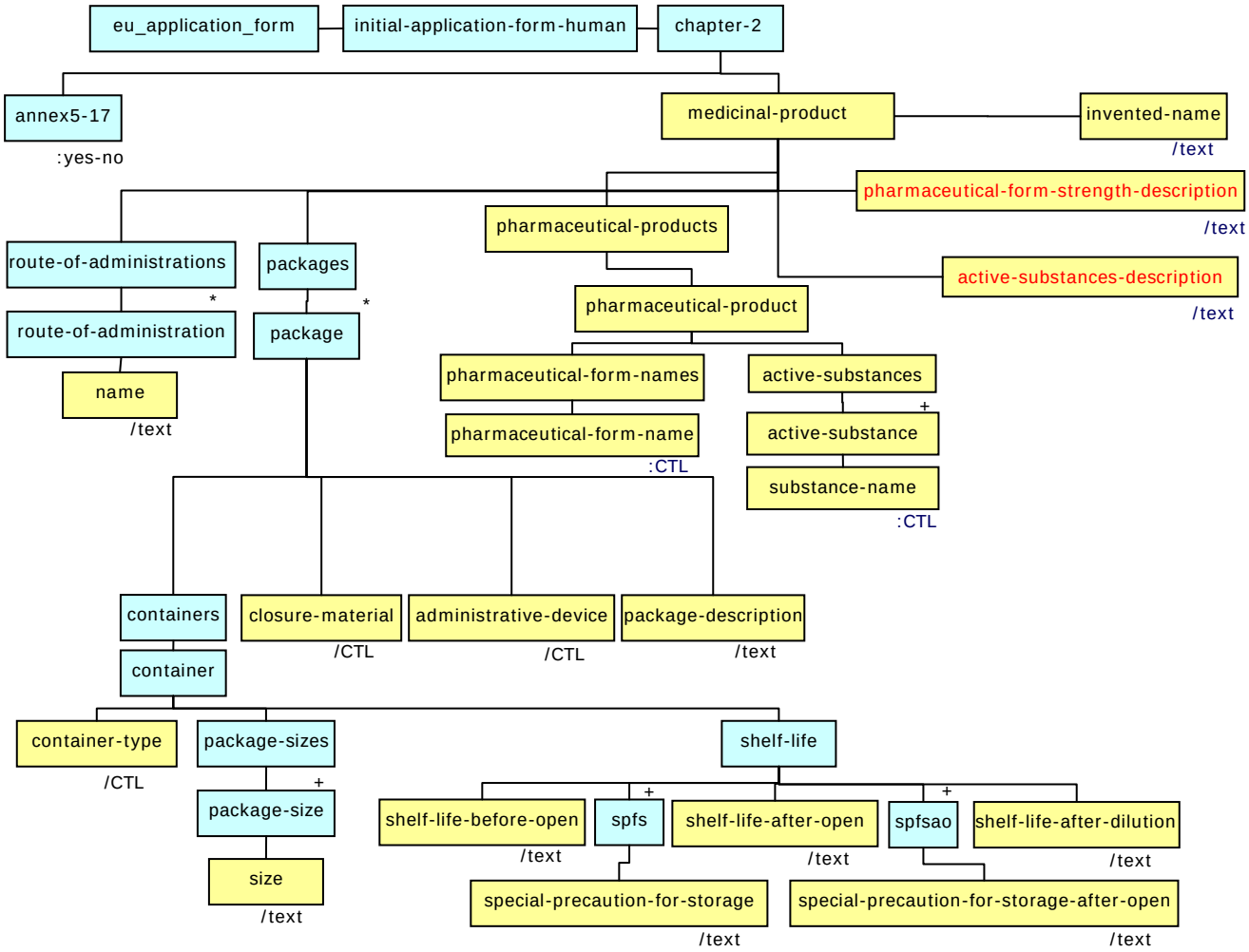


2.3.2. STRENGTH, PHARMACEUTICAL FORM, ROUTE OF ADMINISTRATION, CONTAINER AND PACK SIZES

	Common DES 3.0 Context		**Common RDM Entry point**	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-2/		Application > Medicinal Product >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E232-1	Strength and pharmaceutical form (use current list of standard terms - European Pharmacopoeia)			
E232-2	Pharmaceutical form(s)	rdm:medicinal-product/ rdm:pharmaceutical-product/ rdm:pharmaceutical-form-names/ rdm:pharmaceutical-form-name	Pharmaceutical Product > Pharmaceuticla Dose Form CTL	
E232-3	Strength(s)	rdm:medicinal-product/rdm:pharmaceutical-product/rdm:pharmaceutical-form-strength-description		
E232-4	Active Substance(s)	rdm:medicinal-product/rdm:pharmaceutical-product/rdm:active-substances-description		
E232-5	Active Substance	rdm:medicinal-product/rdm:pharmaceutical-product/rdm:active-substances/rdm:active-substance/rdm:substance-name	Ingredient > Substance CTL, Ingredient > IngredientRole CTL	
E232-6	Route(s) of administration (use current list of standard terms - European Pharmacopoeia)			
E232-7	Route of Administration	rdm:medicinal-product/maa:route-of-administrations/rdm:route-of-administration/rdm:name	Pharmaceutical Product > Route of Administration CTL	
E232-8	Container, closure and administration device(s), including description of material from which it is constructed. (use current list of standard terms - European Pharmacopoeia)	rdm:medicinal-product/maa:packages/rdm:package/rdm:package-description	Package > Package Description	

E232-9	For each type of pack give:			
E232-10	Container	rdm:medicinal-product/maa:packages/rdm:package/rdm:containers/rdm:container/rdm:container-type	Package > Outer Container > Container CTL	
E232-11	Closure	rdm:medicinal-product/maa:packages/rdm:package/rdm:containers/rdm:container/rdm: closure-material	Package > Immediate Container > Container CTL	
E232-12	Administration Device	rdm:medicinal-product/maa:packages/rdm:package/rdm:containers/rdm:container/rdm:administrative-device	Package > Outer Container > Administration Device > Administration Device CTL	
E232-13	Package size	rdm:medicinal-product/maa:packages/rdm:package/rdm:containers/rdm:container/rdm:package-sizes/rdm:package-size/rdm:size	Package > package Size	
E232-14	*Note: For mutual recognition and decentralised procedures, all package sizes authorised in the Reference Member State should be listed*			
E232-15	Proposed shelf life (before first opening container)	rdm:medicinal-product/maa:packages/rdm:package/rdm:containers/rdm:container/rdm:shelf-life/rdm:shelf-life-before-open	Shelf Life > Shelf Life Type CTL	
E232-16	Proposed shelf life (after first opening container)	rdm:medicinal-product/maa:packages/rdm:package/rdm:containers/rdm:container/rdm:shelf-life/rdm:shelf-life-after-open	Shelf Life > Shelf Life Type CTL	B232-1
E232-17	Proposed shelf life (after reconstitution or dilution)	rdm:medicinal-product/maa:packages/rdm:package/rdm:containers/rdm:container/rdm:shelf-life/rdm:shelf-life-after-dilution	Shelf Life > Shelf Life Type CTL	B232-1
E232-18	Proposed storage conditions	rdm:medicinal-product/maa:packages/rdm:package/rdm:containers/rdm:container/rdm:shelf-life/rdm:spfs/rdm:special-precaution-for-storage	Precaution for Storage > Special Precaution for Storage CTL	B232-1
E232-19	Proposed storage conditions after first opening	rdm:medicinal-product/maa:packages/rdm:package/rdm:containers/rdm:container/rdm:shelf-life/rdm:spfsao/rdm:special-precaution-for-storage-after-open	Precaution for Storage > Special Precaution for Storage CTL	B232-1
E232-20	Attach a list of Mock-ups or Samples/specimens sent with the application, as appropriate (see Notice to Applicants, volume 2A, chapter 7) (Annex 5.17)	maa:annex5-17		B232-1

Element Tree Diagram

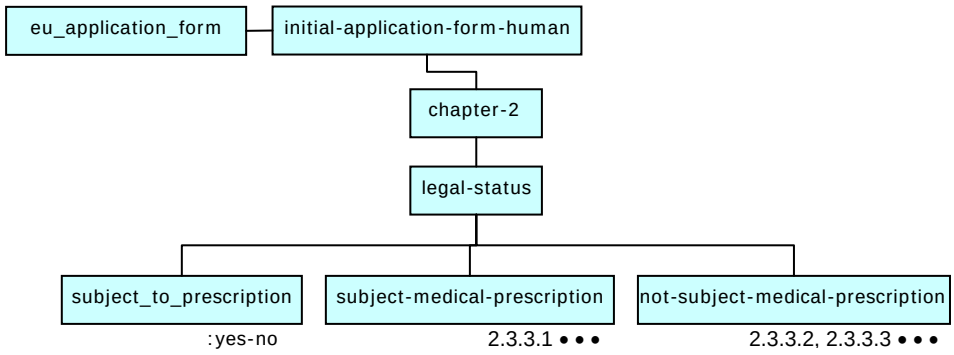


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B232-1	E232-16, E232-17, E232-18, E232-19, E232-20	Optional.	These fields are optional.	

2.3.3. LEGAL STATUS

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-2/maa:legal-status/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E233-1	Proposed dispensing/classification			
E233-2	(Classification under Article 1(19) of Directive 2001/83/EC)			
E233-3	Subject to medical prescription *(Complete 2.3.2)*	maa:subject_to_prescription (Value=1)		B233-1, B233-3
E233-4	Not subject to medical prescription *(Complete 2.3.3 & 2.3.4)*	maa:subject_to_prescription (Value=2)		B233-1, B233-4
E233-5	For products subject to medicinal prescription	maa:subject-medical-prescription		B233-2, B233-3
E233-6	Supply for products not subject to medical prescription	maa:not-subject-medical-prescription		B233-2, B233-4
E233-7	Promotion for products not subject to medical prescription	maa:not-subject-medical-prescription		B233-2, B233-4

Element Tree Diagram



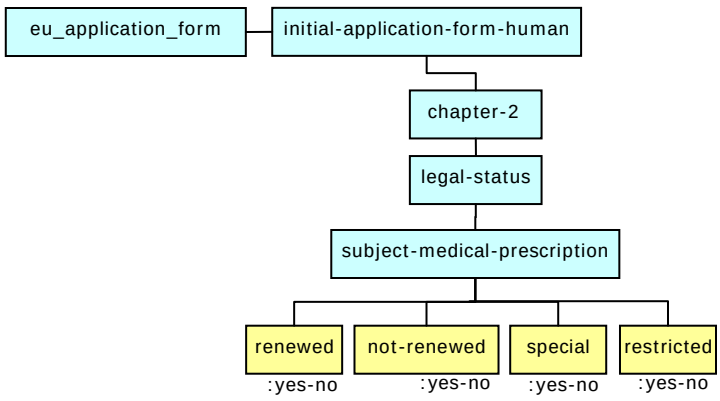
Business Rules

Rule ID	Element id(s)	Default BR	Rule	Effect(s)
B233-1	E233-3, E233-4	Mandatory.	Mutually Exclusive.	
B233-2	E233-5 to E233-7	Optional.	Fields are optional by default.	
B233-3	E233-3, E233-5	E233-3 is mandatory, E233-5 is optional.	If E233-3 is selected, then E233-5 is visible and mandatory.	
B233-4	E233-4, E233-6, E233-7	E233-4 is mandatory, rest are optional.	If E233-4 is selected, then E233-6 and E233-7 are visible and mandatory.	

2.3.3.1. For products subject to medicinal prescription

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-2/maa:legal-status/maa:subject-medical-prescription/		Application > Medicinal Product > Package Legal Status >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2331-1	Product on prescription which may be renewed (if applicable)	maa:renewed	Supply CTL	
E2331-2	Product on prescription which may not be renewed (if applicable)	maa:not-renewed	Supply CTL	
E2331-3	Product on special prescription*	maa:special	Supply CTL	
E2331-4	Product on restricted prescription*	maa:restricted	Supply CTL	
E2331-5	*(Not all the listed options are available in each member state. Applicants are invited to indicate which categories they are requesting, however, the Member States reserve the right to apply only those categories provided for in their national legislation)* *Note: *For further information, please refer to Article 71 of Directive 2001/83/EC*			

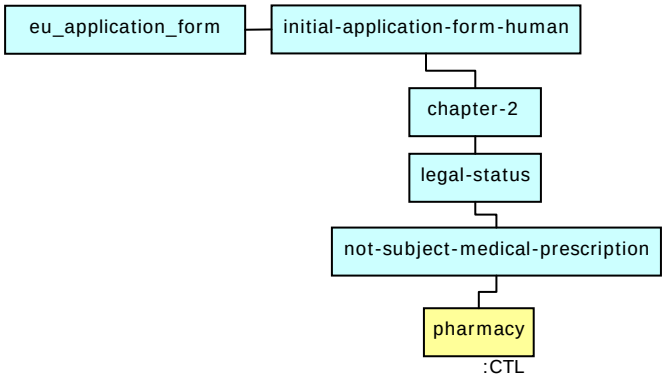
Element Tree Diagram



2.3.3.2. Supply for products not subject to medical prescription

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-2/maa:legal-status/maa:not-subject-medical-prescription /		Application > Medicinal Product > Package Legal Status >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2332-1	Supply through pharmacy only	maa:pharmacy (Value=1)	Legal Status for the Supply CTL	B2332-1
E2332-2	Supply through non-pharmacy outlets and pharmacies (if applicable)	maa:pharmacy (Value=2)	Legal Status for the Supply CTL	B2332-1

Element Tree Diagram

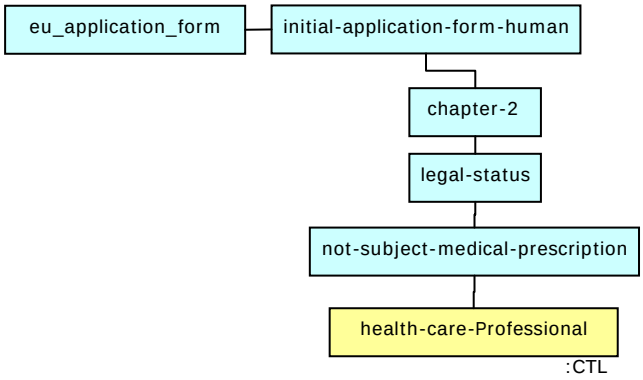


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2332-1	E2332-1, E2332-2	Optional.	Mutually Exclusive.	

2.3.3.3. Promotion for products not subject to medical prescription

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-2/maa:legal-status/maa:not-subject-medical-prescription /		Application > Medicinal Product > Package Legal Status >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2333-1	Promotion to health care professionals only	maa:health-care-Professional (Value=1)	Legal Status for the Supply CTL	B2333-1
E2333-2	Promotion to general public and health care professionals	maa:health-care-Professional (Value=2)	Legal Status for the Supply CTL	B2333-1

Element Tree Diagram

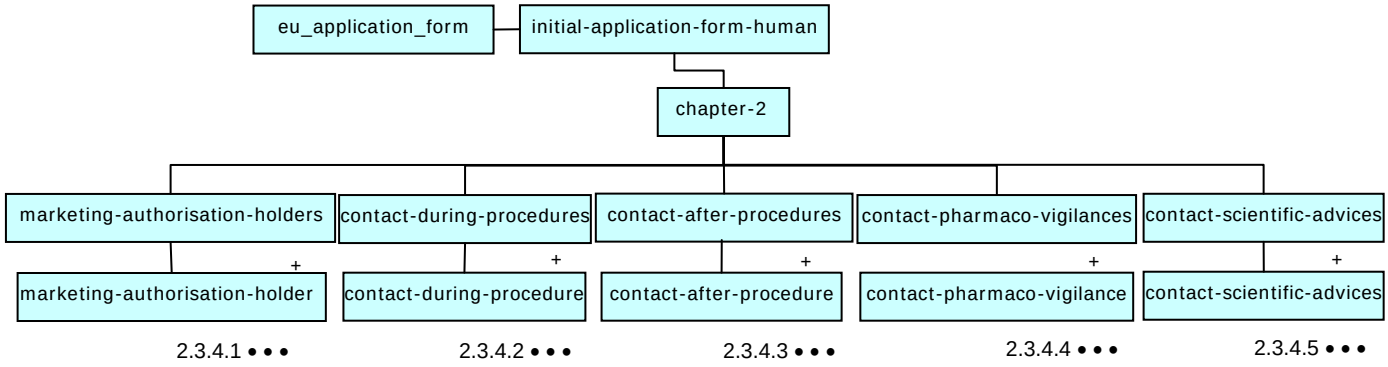


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2333-1	E2333-1, E2333-2	Optional.	Mutually Exclusive.	

2.3.4. MARKETING AUTHORISATION HOLDER/ CONTACT PERSONS/ COMPANY

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-2/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E234-1	Proposed marketing authorisation holder/person legally responsible for placing the product on the market in the Community/each MS	maa:marketing-authorisation-holders/maa:marketing-authorisation-holder		See Section 2.3.4.1
E234-2	Person/company authorised for communication on behalf of the applicant during the procedure in the Community/each MS	maa:contact-during-procedures/maa:contact-during-procedure/		See Section 2.3.4.2
E234-3	Person/company authorised for communication between the marketing authorisation holder and the competent authorities after authorisation if different from 2.4.2 in Community/each MS	maa:contact-after-procedures/maa:contact-after-procedure/		See Section 2.3.4.3
E234-4	Qualified person in the EEA for Pharmacovigilance	maa:contact-pharmaco-vigilances/maa:contact-pharmaco-vigilance/		See Section 2.3.4.4
E234-5	[6] For the purposes of this application form, a Qualified Person Responsible for Pharmacovigilance "resides" in the place where he/she makes his/her home, where he/she lives, can be traced, located, identified for all legal and contractual obligations, whether or not it is owned by him/her or he/she is permanently dwelling there.			
E234-6	Scientific service of the MAH in the EEA as referred to in Article 98 of Directive 2001/83/EC (for DCP, MRP and national applications, the contact person in the country where the application is made)	maa:contact-scientific-advices/maa:contact-scientific-advice/		See Section 2.3.4.5

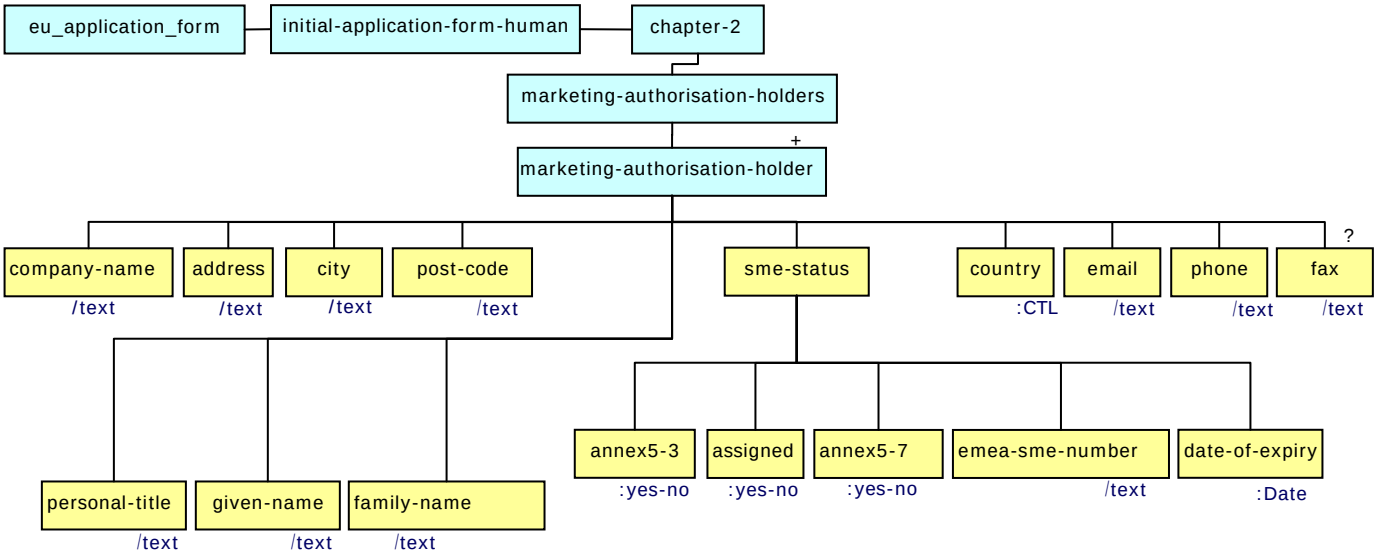
Element Tree Diagram



2.3.4.1. Proposed marketing authorisation holder/person legally responsible for placing the product on the market in the Community/each MS

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-2/maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2341-1	Company name	rdm:company-name	MAH for Placing Product> Role>Party>Organisation>Name	
E2341-2	Address	rdm:address	MAH for Placing Product>Role>Party>Contact Details > Address	
E2341-3	City	rdm:city	MAH for Placing Product>Role>Party>Contact Details > city	
E2341-4	Postcode	rdm:post-code	MAH for Placing Product>Role>Party>Contact Details > Address> post code	
E2341-5	Country	rdm:country	MAH for Placing Product>Role>Party>Contact Details > Address > Country CTL	
E2341-6	Telephone	rdm:phone	MAH for Placing Product>Role>Party>Contact Details > Electronic Contact > electronic contact	
E2341-7	Telefax	rdm:fax	MAH for Placing Product>Role>Party>Contact Details > Electronic Contact > electronic contact	
E2341-8	E-mail	rdm:email	MAH for Placing Product>Role>Party>Contact Details > Electronic Contact > electronic contact	
E2341-9	Contact person at this address (for centralised procedure only):			
E2341-10	Title	rdm:personal-title	MAH for Placing Product>Role>Party>Person> Personal Title	
E2341-11	First name	rdm:given-name	MAH for Placing Product>Role>Party>Person> given name	
E2341-12	Surname	rdm:family-name	MAH for Placing Product>Role>Party>Person> family name	
E2341-13	Attach proof of establishment of the applicant in the EEA (Annex 5.3)	rdm:sme-status/rdm:annex5-3		
E2341-14	Has SME status been assigned by the EMEA?			
E2341-15	Yes	rdm:sme-status/rdm:assigned	MAH for Placing Product> has sme assigned to emea	B2341-1, B2341-2
E2341-16	No	rdm:sme-status/rdm:assigned	MAH for Placing Product> has sme assigned to emea	B2341-1
E2341-17	EMEA-SME Number	rdm:sme-status/rdm:emea-sme-number	Party Identification>identification number	B2341-2
E2341-18	Date of expiry	rdm:sme-status/ rdm:date-of-expiry	Party Identification>expiry date	B2341-2
E2341-19	Attach copy of the "Qualification of SME Status" (Annex 5.7)	rdm:sme-status/rdm:annex5-7		B2341-2

Element Tree Diagram

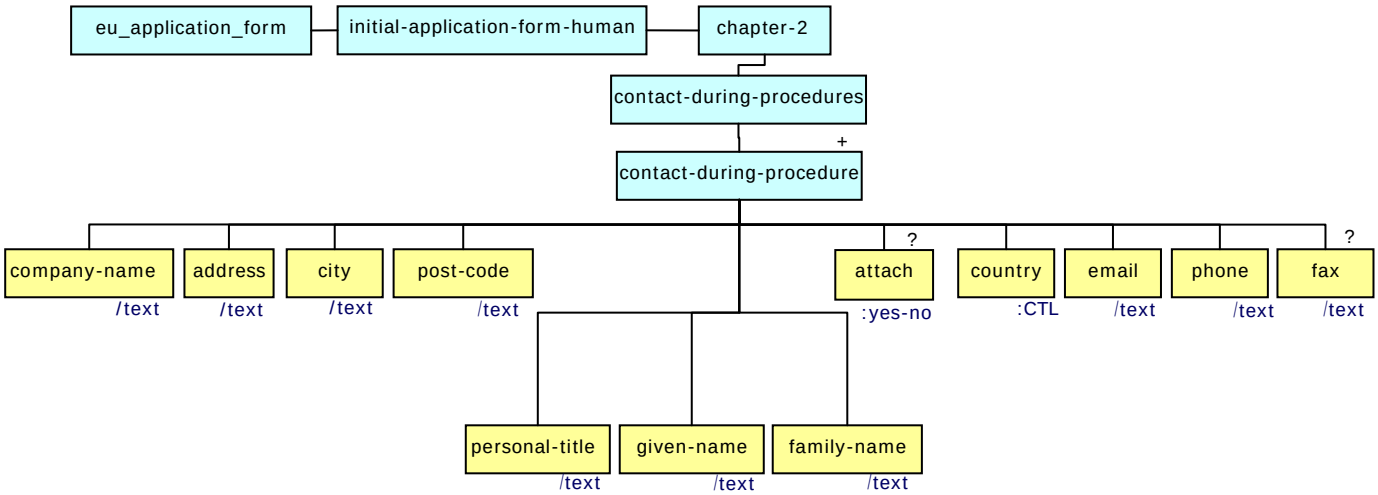


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2341-1	E2341-15, E2341-16	Mandatory.	Mutually Exclusive.	
B2341-2	E2341-15, E2341-17 to E2341-19	Mandatory.	If E2341-15 is selected, then the rest are mandatory, else they are hidden.	

2.3.4.2. Person/company authorised for communication on behalf of the applicant during the procedure in the Community/each MS

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-2/maa:contact-during-procedures/maa:contact-during-procedure/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2342-1	Title	rdm:personal-title	Role>Party>Person> Personal Title	
E2342-2	First name	rdm:given-name	Role>Party>Person> given name	
E2342-3	Surname	rdm:family-name	Role>Party>Person> family name	
E2342-4	Company name	rdm:company-name	Role>Party>Organisation>Name	
E2342-5	Address	rdm:address	Role>Party>Contact Details > Address	
E2342-6	City	rdm:city	Role>Party>Contact Details > city	
E2342-7	Postcode	rdm:post-code	Role>Party>Contact Details > Address> post code	
E2342-8	Country	rdm:country	Role>Party>Contact Details > Address > Country CTL	
E2342-9	Telephone	rdm:phone	Role>Party>Contact Details > Electronic Contact > electronic contact	
E2342-10	Telefax	rdm:fax	Role>Party>Contact Details > Electronic Contact > electronic contact	
E2342-11	E-mail	rdm:email	Role>Party>Contact Details> Electronic Contact > electronic contact	
E2342-12	If different to 2.4.1 above, Attach letter of authorisation (Annex 5.4)	rdm:attach		

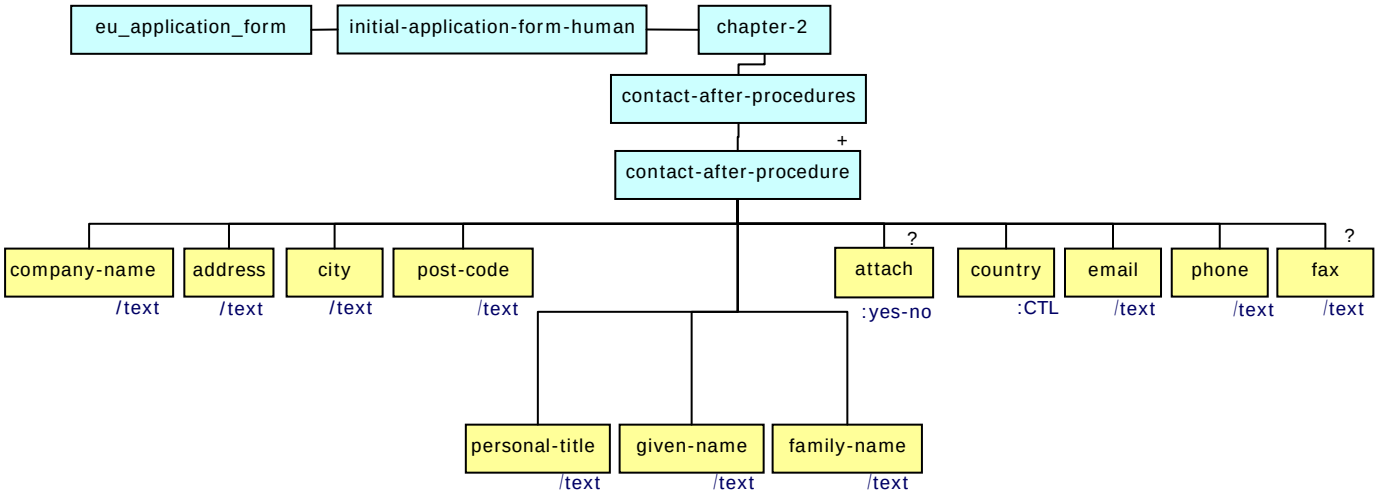
Element Tree Diagram



2.3.4.3. Person/company authorised for communication between the marketing authorisation holder and the competent authorities after authorisation if different from 2.4.2 in Community/each MS

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-2/ maa:contact-after-procedures/maa:contact-after-procedure/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2343-1	Title	rdm:personal-title	Role>Party>Person> Personal Title	B2343-1
E2343-2	First name	rdm:given-name	Role>Party>Person> given name	B2343-1
E2343-3	Surname	rdm:family-name	Role>Party>Person> family name	B2343-1
E2343-4	Company name	rdm:company-name	Role>Party>Organisation>Name	B2343-1
E2343-5	Address	rdm:address	Role>Party>Contact Details > Address	B2343-1
E2343-6	City	rdm:city	Role>Party>Contact Details > city	B2343-1
E2343-7	Postcode	rdm:post-code	Role>Party>Contact Details > Address> post code	B2343-1
E2343-8	Country	rdm:country	Role>Party>Contact Details > Address > Country CTL	B2343-1
E2343-9	Telephone	rdm:phone	Role>Party>Contact Details > Electronic Contact > electronic contact	B2343-1
E2343-10	Telefax	rdm:fax	Role>Party>Contact Details > Electronic Contact > electronic contact	B2343-1
E2343-11	E-mail	rdm:email	Role>Party>Contact Details> Electronic Contact > electronic contact	B2343-1
E2343-12	If different to 2.4.1 above, Attach letter of authorisation (Annex 5.4)	rdm:attach		B2343-1

Element Tree Diagram

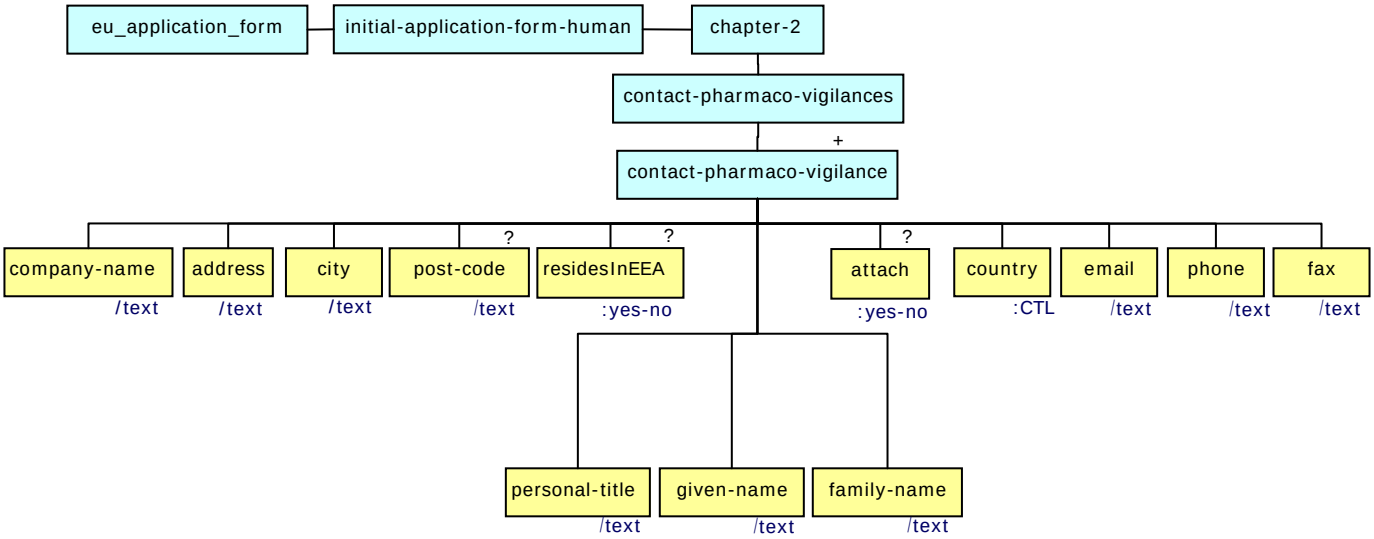


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2343-1	E2343-1 to E2343-12	Optional.	Elements should be optional.	

2.3.4.4. Qualified person in the EEA for Pharmacovigilance

	Common DES 3.0 Context		**Common RDM Entry point**	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-2/maa:contact-pharmaco-vigilances/maa:contact-pharmaco-vigilance/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2344-1	Title	rdm:personal-title	Role>Party>Person> Personal Title	
E2344-2	First name	rdm:given-name	Role>Party>Person> given name	
E2344-3	Surname	rdm:family-name	Role>Party>Person> family name	
E2344-4	Company name	rdm:company-name	Role>Party>Organisation>Name	
E2344-5	Address	rdm:address	Role>Party>Contact Details > Address	
E2344-6	City	rdm:city	Role>Party>Contact Details > city	
E2344-7	Postcode	rdm:post-code	Role>Party>Contact Details > Address> post code	
E2344-8	Country	rdm:country	Role>Party>Contact Details > Address > Country CTL	
E2344-9	Telephone	rdm:phone	Role>Party>Contact Details > Electronic Contact > electronic contact	
E2344-10	Telefax	rdm:fax	Role>Party>Contact Details > Electronic Contact > electronic contact	
E2344-11	E-mail	rdm:email	Role>Party>Contact Details> Electronic Contact > electronic contact	
E2344-12	Attach C.V. of qualified person (Annex 5.5)	rdm:attach		
E2344-13	The above-mentioned qualified person resides[6] in the EEA	rdm:residesInEEA		

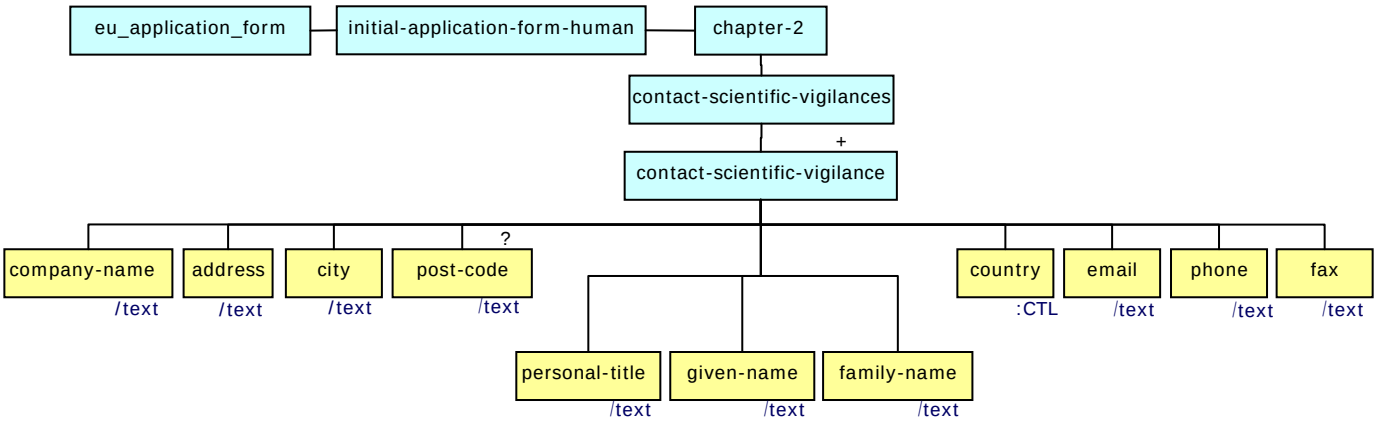
Element Tree Diagram



2.3.4.5. Scientific service of the MAH in the EEA as referred to in Article 98 of Directive 2001/83/EC (for DCP, MRP and national applications, the contact person in the country where the application is made)

	Common DES 3.0 Context		**Common RDM Entry point**	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-2/maa:contact-scientific-advices/maa:contact-scientific-advice/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2345-1	Title	rdm:personal-title	Role>Party>Person> Personal Title	
E2345-2	First name	rdm:given-name	Role>Party>Person> given name	
E2345-3	Surname	rdm:family-name	Role>Party>Person> family name	
E2345-4	Company name	rdm:company-name	Role>Party>Organisation>Name	
E2345-5	Address	rdm:address	Role>Party>Contact Details > Address	
E2345-6	City	rdm:city	Role>Party>Contact Details > city	
E2345-7	Postcode	rdm:post-code	Role>Party>Contact Details > Address> post code	
E2345-8	Country	rdm:country	Role>Party>Contact Details > Address > Country CTL	
E2345-9	Telephone	rdm:phone	Role>Party>Contact Details > Electronic Contact > electronic contact	
E2345-10	Telefax	rdm:fax	Role>Party>Contact Details > Electronic Contact > electronic contact	
E2345-11	E-mail	rdm:email	Role>Party>Contact Details> Electronic Contact > electronic contact	

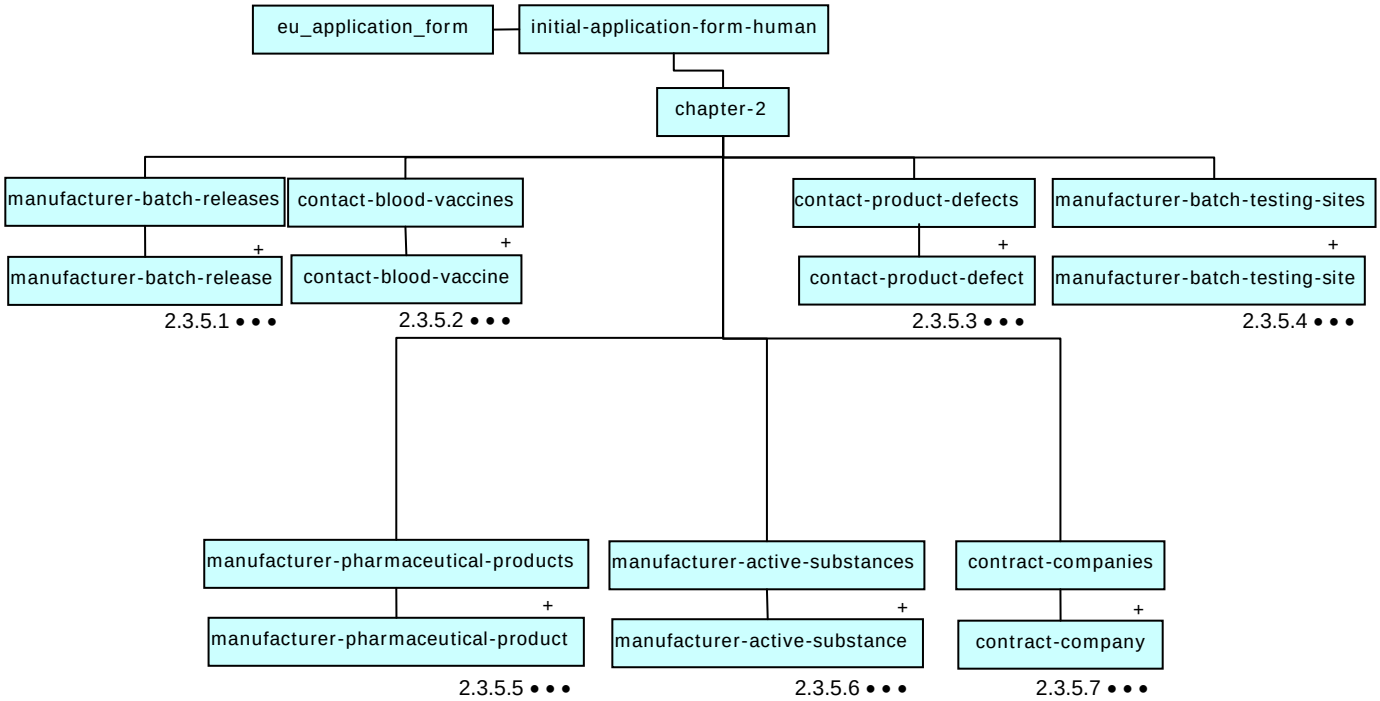
Element Tree Diagram



2.3.5. Manufacturers

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-2/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E235-1	Authorised manufacturer(s) (or importer(s)) responsible for batch release in the EEA in accordance with Article 40 and Article 51 of Directive 2001/83/EC (as shown in the package leaflet and where applicable in the labelling of Annex II of the Commission Decision):	maa:manufacturer-batch-releases/maa:manufacturer-batch-release/		See Section 2.3.5.1
E235-2	Official batch release for Blood products and Vaccines Details of the Official Medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official batch release (in accordance with Articles 111(1), 113, 114(1)-(2) and 115 of Directive 2001/83/EC as amended)	maa:contact-blood-vaccines/maa:contact-blood-vaccine/		See Section 2.3.5.2
E235-3	Contact person in the EEA for product defects and recalls	maa:contact-product-defects/maa:contact-product-defect		See Section 2.3.5.3
E235-4	Batch control Testing arrangements Site(s) in the EEA or in countries where an MRA or other Community arrangements apply, where batch control testing takes place as required by Article 51 of Directive 2001/83/EC:	maa:manufacturer-batch-testing-sites/maa:manufacturer-batch-testing-site/		See Section 2.3.5.4
E235-5	Manufacturer(s) of the medicinal product and site(s) of manufacture: *(Note: including manufacturing sites of any diluent/solvent presented in a separate container but forming part of the medicinal product, quality control/ in-process testing sites, and importer(s))*	maa:manufacturer-pharmaceutical-products/maa:manufacturer-pharmaceutical-product/		See Section 2.3.5.5
E235-6	Manufacturer(s) of the active substance(s) and site(s) of manufacture *Note: All manufacturing sites involved the manufacturing process of each source of active substance, including quality control/ in-process testing sites, should be listed. Broker or supplier details alone are not acceptable. For biotech products include all sites of storage of master and working cell bank and preparation of working cell banks.*	maa:manufacturer-active-substances/maa:manufacturer-active-substance		See Section 2.3.5.6
E235-7	Contract companies used for clinical trial(s) on bioavailability or bioequivalence or used for the validation of blood product manufacturing processes. For each contract company, state where analytical tests are performed and where clinical data are collected and give:	maa:contract-companies/maa:contract-company		See Section 2.3.5.7

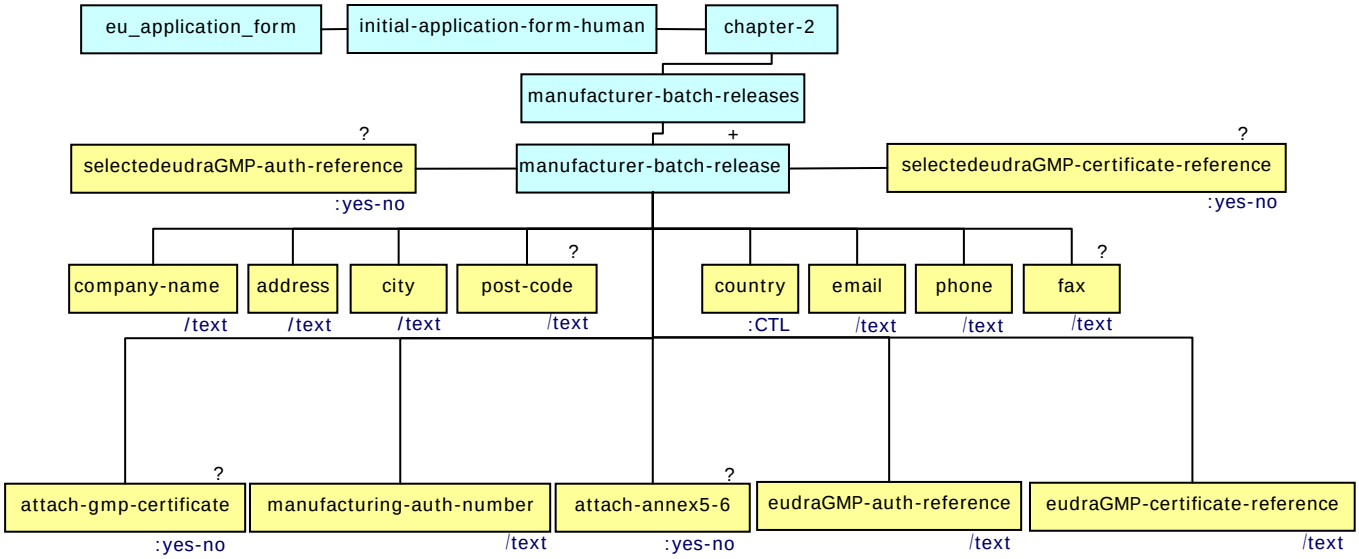
Element Tree Diagram



2.3.5.1. Authorised manufacturer(s) (or importer(s)) responsible for batch release in the EEA in accordance with Article 40 and Article 51 of Directive 2001/83/EC (as shown in the package leaflet and where applicable in the labelling of Annex II of the Commission Decision):

	Common DES 3.0 Context		**Common RDM Entry point**	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-2/maa:manufacturer-batch-releases/maa:manufacturer-batch-release/		Application > Manufacturer Batch Release	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2351-1	Company name	rdm:company-name	Role>Party>Organisation>Name	
E2351-2	Address	rdm:address	Role>Party>Contact Details > Address	
E2351-3	City	rdm:city	Role>Party>Contact Details > city	
E2351-4	Postcode	rdm:post-code	Role>Party>Contact Details > Address> post code	
E2351-5	Country	rdm:country	Role>Party>Contact Details > Address > Country CTL	
E2351-6	Telephone	rdm:phone	Role>Party>Contact Details > Electronic Contact > electronic contact	
E2351-7	Telefax	rdm:fax	Role>Party>Contact Details > Electronic Contact > electronic contact	
E2351-8	E-mail	rdm:email	Role>Party>Contact Details> Electronic Contact > electronic contact	
E2351-9	Manufacturing Authorisation number	rdm:manufacturing-auth-number	Manufacturing auth number	
E2351-10	Attach copy of manufacturing authorisation(s) (Annex 5.6)	rdm:attach-annex5-6		B2351-1
E2351-11	Enter EudraGMP manufacturing authorisation reference	rdm:selectedeudraGMP-auth-reference		B2351-1, B2351-3
E2351-12	Enter EudraGMP manufacturing authorisation reference	rdm:eudraGMP-auth-reference	Eudragmp auth ref	B2351-3
E2351-13	Attach latest GMP certificate (Annex 5.9)	rdm:attach-gmp-certificate		B2351-2
E2351-14	Enter EudraGMP certificate reference number	rdm:selectedeudraGMP-certificate-reference		B2351-2, B2351-4
E2351-15	Enter EudraGMP certificate reference number	rdm:eudraGMP-certificate-reference	Eudragmp certificate ref no	B2351-4

Element Tree Diagram

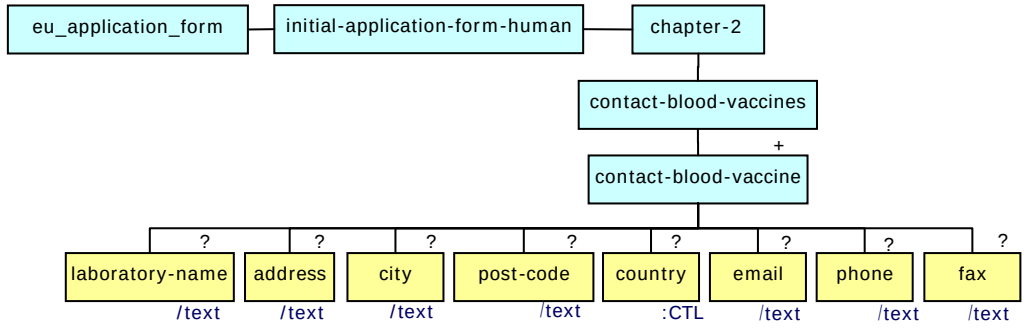


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2351-1	E2351-10, E2343-11	Mandatory.	Mutually Exclusive.	
B2351-2	E2351-13, E2351-14	Mandatory.	Mutually Exclusive.	
B2351-3	E2351-11, E2351-12	Mandatory, Optional.	If E2351-11 is selected, E2351-12 is mandatory.	
B2351-4	E2351-14, E2351-15	Mandatory, Optional.	If E2351-14 is selected, E2351-15 is mandatory.	

2.3.5.2. Official batch release for Blood products and Vaccines Details of the Official Medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official batch release (in accordance with Articles 111(1), 113, 114(1)-(2) and 115 of Directive 2001/83/EC as amended)

	Common DES 3.0 Context		**Common RDM Entry point**	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-2/maa:contact-blood-vaccines/maa:contact-blood-vaccine/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2352-1	Laboratory name	rdm:laboratory-name	Role>Party>Organisation>Name	
E2352-2	Address	rdm:address	Role>Party>Contact Details > Address	
E2352-3	City	rdm:city	Role>Party>Contact Details > city	
E2352-4	Postcode	rdm:post-code	Role>Party>Contact Details > Address> post code	
E2352-5	Country	rdm:country	Role>Party>Contact Details > Address > Country CTL	
E2352-6	Telephone	rdm:phone	Role>Party>Contact Details > Electronic Contact > electronic contact	
E2352-7	Telefax	rdm:fax	Role>Party>Contact Details > Electronic Contact > electronic contact	
E2352-8	E-mail	rdm:email	Role>Party>Contact Details> Electronic Contact > electronic contact	

Element Tree Diagram

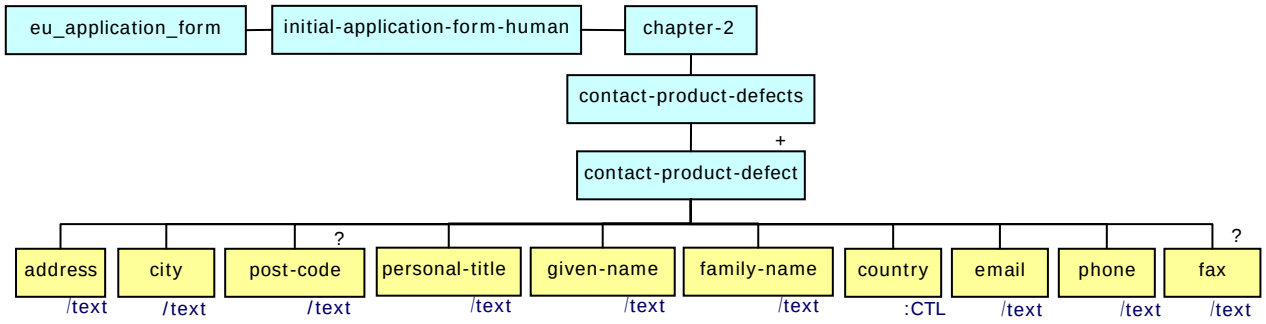


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2352-1	E2352-1 to E2352-8	Optional	Elements should be optional	

2.3.5.3. Contact person in the EEA for product defects and recalls

	Common DES 3.0 Context		**Common RDM Entry point**	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-2/maa:contact-product-defects/maa:contact-product-defect/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2353-1	Title	rdm:personal-title	Role>Party>Person> Personal Title	
E2353-2	First name	rdm:given-name	Role>Party>Person> given name	
E2353-3	Surname	rdm:family-name	Role>Party>Person> family name	
E2353-4	Address	rdm:address	Role>Party>Contact Details > Address	
E2353-5	City	rdm:city	Role>Party>Contact Details > city	
E2353-6	Postcode	rdm:post-code	Role>Party>Contact Details > Address> post code	
E2353-7	Country	rdm:country	Role>Party>Contact Details > Address > Country CTL	
E2353-8	24H Telephone	rdm:phone	Role>Party>Contact Details > Electronic Contact > electronic contact	
E2353-9	Telefax	rdm:fax	Role>Party>Contact Details > Electronic Contact > electronic contact	
E2353-10	E-mail	rdm:email	Role>Party>Contact Details> Electronic Contact > electronic contact	

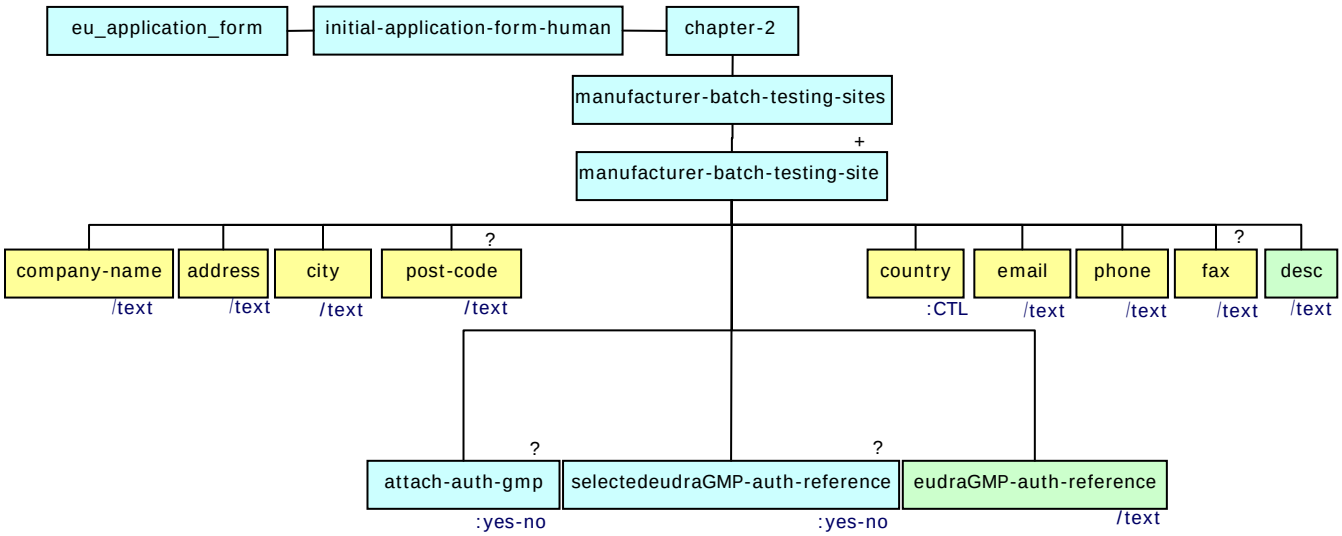
Element Tree Diagram



2.3.5.4. Batch control Testing arrangements Site(s) in the EEA or in countries where an MRA or other Community arrangements apply, where batch control testing takes place as required by Article 51 of Directive 2001/83/EC:

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-2/maa:manufacturer-batch-testing-sites/maa:manufacturer-batch-testing-site/		Application > Batch Control Arrangement >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2354-1	Company name	rdm:company-name	Role>Party>Organisation>Name	
E2354-2	Address	rdm:address	Role>Party>Contact Details > Address	
E2354-3	City	rdm:city	Role>Party>Contact Details > city	
E2354-4	Postcode	rdm:post-code	Role>Party>Contact Details > Address> post code	
E2354-5	Country	rdm:country	Role>Party>Contact Details > Address > Country CTL	
E2354-6	Telephone	rdm:phone	Role>Party>Contact Details > Electronic Contact > electronic contact	
E2354-7	Telefax	rdm:fax	Role>Party>Contact Details > Electronic Contact > electronic contact	
E2354-8	E-mail	rdm:email	Role>Party>Contact Details> Electronic Contact > electronic contact	
E2354-9	Brief description of control tests carried out by the laboratory(ies) concerned	rdm:desc	control test carried	
E2354-10	Attach copy of manufacturing authorisation(s) or other proof of GMP compliance (Annex 5.6)	rdm:attach-auth-gmp		B2354-1
E2354-11	Enter EudraGMP manufacturing authorisation reference	rdm:selectedeudraGMP-auth-reference		B2354-1, B2354-2
E2354-12	Enter EudraGMP manufacturing authorisation reference	rdm:eudraGMP-auth-reference	Batch Control Arrangement > eudragmp auth ref	B2354-2

Element Tree Diagram



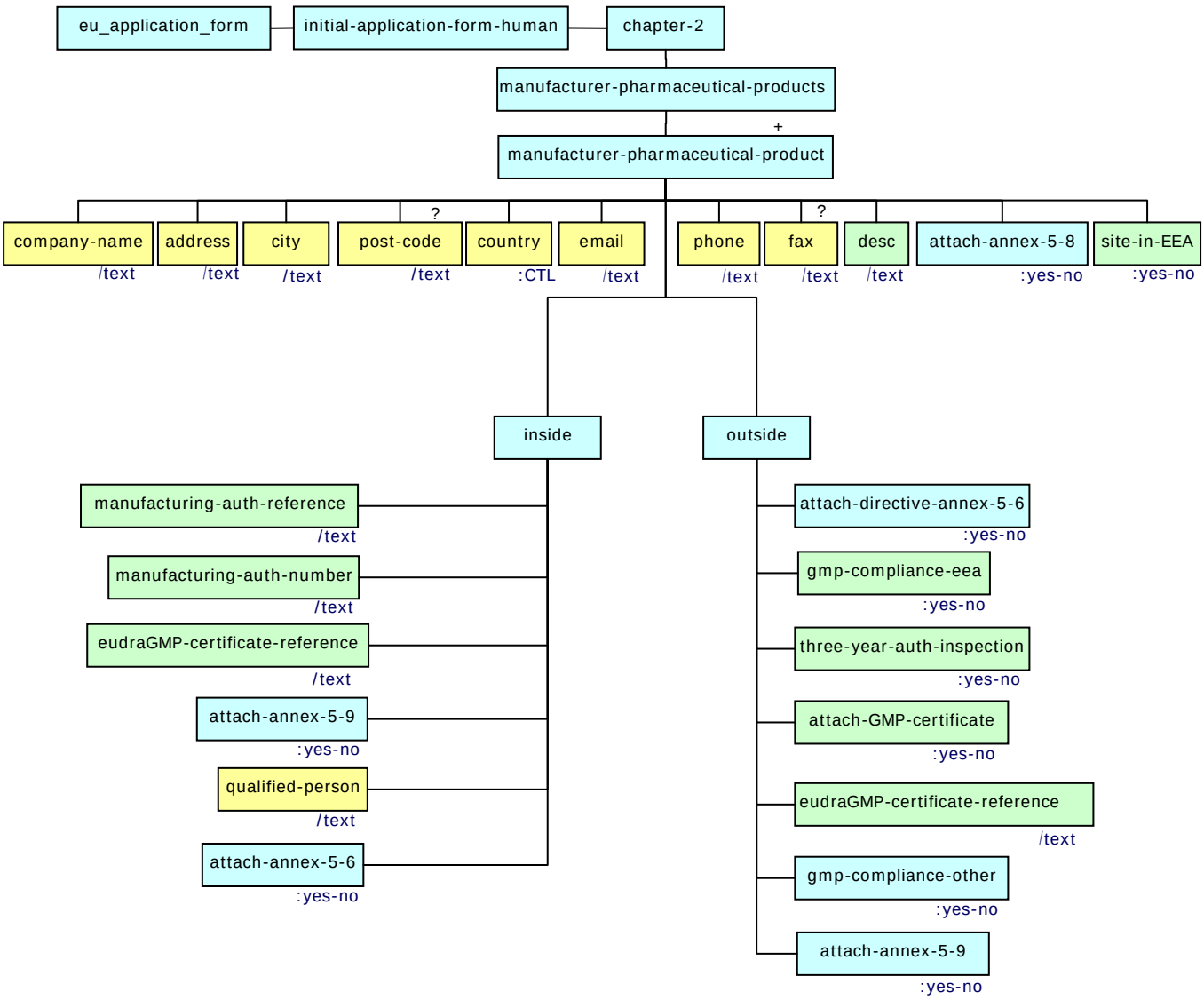
Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2354-1	E2352-10, E2352-11	Mandatory.	Elements are mutually exclusive.	
B2354-2	E2352-11, E2352-12	E2352-11 is Mandatory, E2352-12 is Optional.	If E2352-11 is selected then E2352-12 is mandatory.	

2.3.5.5. Manufacturer(s) of the medicinal product and site(s) of manufacture: (Note: including manufacturing sites of any diluent/solvent presented in a separate container but forming part of the medicinal product, quality control/ in-process testing sites, and importer(s))

	Common DES 3.0 Context		**Common RDM Entry point**	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-2/maa:manufacturer-pharmaceutical-products/maa:manufacturer-pharmaceutical-product/		Application > Manufacturer MP >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2355-1	Company name	rdm:company-name	Role>Party>Organisation>Name	
E2355-2	Address	rdm:address	Role>Party>Contact Details > Address	
E2355-3	City	rdm:city	Role>Party>Contact Details > city	
E2355-4	Postcode	rdm:post-code	Role>Party>Contact Details > Address> post code	
E2355-5	Country	rdm:country	Role>Party>Contact Details > Address > Country CTL	
E2355-6	Telephone	rdm:phone	Role>Party>Contact Details > Electronic Contact > electronic contact	
E2355-7	Telefax	rdm:fax	Role>Party>Contact Details > Electronic Contact > electronic contact	
E2355-8	E-mail	rdm:email	Role>Party>Contact Details> Electronic Contact > electronic contact	
E2355-9	Brief description of functions performed:	rdm:desc	functions performed	
E2355-10	Attach flow chart indicating the sequence and activities of the different sites involved in the manufacturing process, including testing sites (Annex 5.8)	rdm:attach-annex-5-8		
E2355-11	Site is in the EEA:	rdm:site-in-EEA	is site in eea	B2355-2
E2355-12	Site is outside the EEA:	rdm:site-in-EEA	is site in eea	B2355-5
E2355-13	Manufacturing authorisation number	rdm:inside/ rdm:manufacturing-auth-number	manufacturing auth number	B2355-2
E2355-14	Attach copy of manufacturing authorisation(s) (Annex 5.6)	rdm:inside/rdm:attach-annex-5-6		B2355-2
E2355-15	Enter EudraGMP Manufacturing Authorisation reference	rdm:inside/rdm:manufacturing-auth-reference	eudragmp auth ref	B2355-2
E2355-16	Attach latest GMP certificate (Annex 5.9)	rdm:inside/rdm:attach-annex-5-9		B2355-3
E2355-17	Enter EudraGMP certificate reference number	rdm:inside/rdm:eudraGMP-certificate-reference	eudragmp certificate ref no	B2355-3
E2355-18	Name of qualified person	rdm:inside/rdm:qualified-person	Role>Party>Person> given name	B2355-4
E2355-19	Attach document equivalent of manufacturing authorisation in accordance with Article 8(k) of Directive 2001/83/EC (Annex 5.6)	rdm:outside/rdm:attach-directive-annex-5-6		B2355-5
E2355-20	Has the site been inspected for GMP compliance by an EEA authority or by an authority of countries where MRA or other Community arrangements apply within the terms of the agreement?			B2355-5
E2355-21	Yes	rdm:outside/ rdm:gmp-compliance-eea	inspected by eea authority	B2355-5, B2355-6, B2355-7

E2355-22	No	rdm:outside/ rdm:gmp-compliance-eea	inspected by eea authority	B2355-5, B2355-6
E2355-23	A statement less than 3 years old from the competent authority which carried out the inspection	rdm:outside/ rdm:three-year-auth-inspection		B2355-7
E2355-24	Attach latest GMP certificate	rdm:outside/rdm:attach-GMP-certificate		B2355-7, B2355-8
E2355-25	Enter EudraGMP certificate reference number:	rdm:outside/ rdm:eudraGMP-certificate-reference	eudragmp certificate ref no	B2355-7, B2355-8
E2355-26	Has the site been inspected for GMP compliance by any other authority (including those of countries where MRA or other Community arrangements apply but not within their respective territory)?			B2355-5
E2355-27	Yes	rdm:outside/ rdm:gmp-compliance-other	inspected by other authority	B2355-5, B2355-9, B2355-10
E2355-28	No	rdm:outside/rdm:gmp-compliance-other	inspected by other authority	B2355-5, B2355-9
E2355-29	Please provide summary information in Annex 5.9 (and, if available a GMP certificate or a statement from the competent authority which carried out the inspection)	rdm:outside/rdm:attach-annex-5-9		B2355-10

Element Tree Diagram



Business Rules

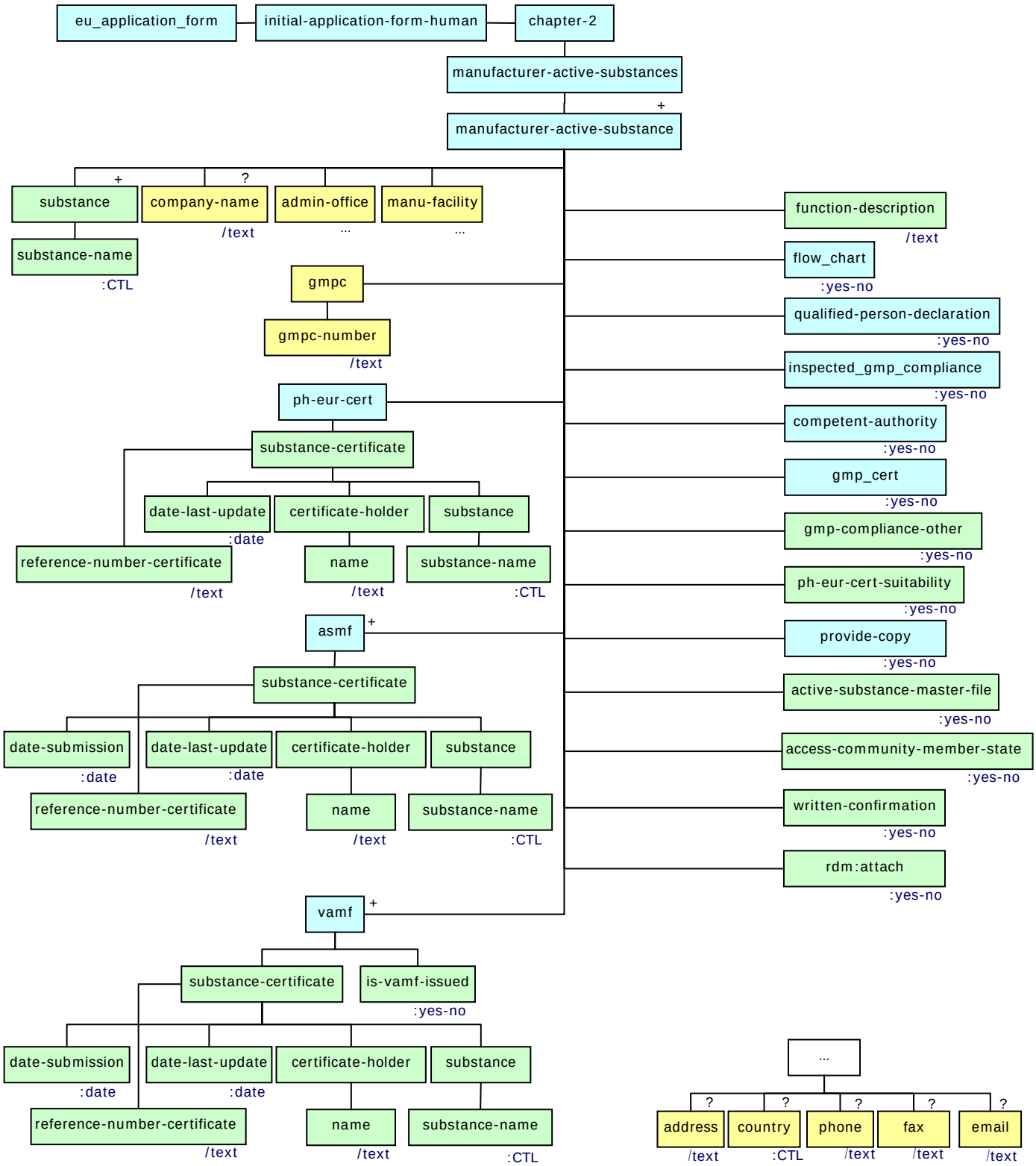
Rule ID	Element id(s)	Default BR	Rule	Effect(s)
B2355-1	E2355-11, E2355-12	Mandatory.	Mutually Exclusive.	
B2355-2	E2355-11, E2355-13 to E2355-15	Mandatory.	If E2355-11 is selected, then the other fields are required.	
B2355-3	E2355-16, E2355-17	Optional.	Mutually Exclusive.	
B2355-4	E2355-18	Optional.		
B2355-5	E2355-12, E2355-19 to E2355-22, E2355-26 to E2355-28	E2355-12 is Mandatory, rest are Optional.	If E2355-12 is selected, then the other fields are mandatory.	
B2355-6	E2355-21, E2355-22	Optional.	Mutually Exclusive.	
B2355-7	E2355-21, E2355-23 to E2355-25	Optional.	If E2355-21 is selected, then the rest are required.	
B2355-8	E2355-23, E2355-24	Optional.	Mutually Exclusive.	
B2355-9	E2355-27, E2355-28	Optional.	Mutually Exclusive.	
B2355-10	E2355-27, E2355-29	Optional.	If E2355-27 is selected, then E2355-29 is required.	

2.3.5.6. Manufacturer(s) of the active substance(s) and site(s) of manufacture Note: All manufacturing sites involved the manufacturing process of each source of active substance, including quality control/ in-process testing sites, should be listed. Broker or supplier details alone are not acceptable. For biotech products include all sites of storage of master and working cell bank and preparation of working cell banks.

	Common DES 3.0 Context		**Common RDM Entry point**	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-2/maa:manufacturer-active-substances/maa:manufacturer-active-substance/		Application > Manufacturer Substance	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2356-1	Active Substance	rdm:substance/rdm:substance-name	Substance CTL	
E2356-2	Company Name	rdm:company-name	Role > Party > Organisation> Name	
E2356-3	Admin Office Address	rdm:admin-office/rdm:address	Role>Party>Contact Details > Address	
E2356-4	Admin Office Country	rdm:admin-office/rdm:country	Role>Party>Contact Details > Address > Country CTL	
E2356-5	Admin Office Telephone	rdm:admin-office/rdm:phone	Role>Party>Contact Details > Electronic Contact > electronic contact	
E2356-6	Admin Office Telefax	rdm:admin-office/rdm:fax	Role>Party>Contact Details > Electronic Contact > electronic contact	
E2356-7	Admin Office E-mail	rdm:admin-office/rdm:email	Role>Party>Contact Details > Electronic Contact > electronic contact	
E2356-8	Manufacturing Facility Address	rdm:manu-facility/ rdm:address	Role>Party>Contact Details > Address	
E2356-9	Manufacturing Facility Country	rdm:manu-facility/ rdm:country	Role>Party>Contact Details > Address > Country CTL	
E2356-10	Manufacturing Facility Telephone	rdm:manu-facility/rdm:phone	Role>Party>Contact Details > Electronic Contact > electronic contact	
E2356-11	Manufacturing Facility Telefax	rdm:manu-facility/rdm:fax	Role>Party>Contact Details > Electronic Contact > electronic contact	
E2356-12	Manufacturing Facility E-mail	rdm:manu-facility/rdm:email	Role>Party>Contact Details > Electronic Contact > electronic contact	
E2356-13	Brief description of manufacturing steps performed by manufacturing site:	rdm:function-description	Manufacturing steps	
E2356-14	Attach flow-chart indicating the sequence and activities of the different sites involved in the manufacturing process, including batch control sites (Annex 5.8)	rdm:flow_chart		
E2356-15	For each active substance, attach a Qualified Person declaration that the active substance is manufactured in compliance with the detailed Guidelines on good manufacturing practice for starting materials (Annex 5.22)	rdm:qualified-person-declaration		
E2356-16	Has the site been inspected for GMP compliance by an EEA authority or by an authority of countries where MRA or other Community arrangements apply within the terms of agreement?			
E2356-17	Yes	rdm:inspected_gmp_compliance (Value=1)	inspected by eea authority	B2356-1, B2356-2
E2356-18	No	rdm:inspected_gmp_compliance (Value=0)	inspected by eea authority	B2356-1
E2356-19	Please provide in Annex 5.9			
E2356-20	A statement from the competent authority which carried out the inspection	rdm:competent-authority		B2356-2, B2356-3
E2356-21	Attach latest GMP certificate	rdm:gmp_cert		B2356-2, B2356-3
E2356-22	EudraGMP certificate reference number	rdm:gmpc/rdm:gmpc-number	Eudragmp certificate ref no	B2356-2
E2356-23	Has the site been inspected for GMP compliance by any other authority (including those of countries where MRA or other Community arrangements apply but not within their respective territory)?			
E2356-24	Yes	rdm:gmp-compliance-other (Value=1)	inspected by other authority	B2356-4, B2356-5
E2356-25	No	rdm:gmp-compliance-other (Value=0)	inspected by other authority	B2356-4

E2356-26	If yes, please provide summary information in Annex 5.9 (and, if available a GMP certificate or a statement from the competent authority which carried out the inspection)	rdm:summary-information		B2356-5
E2356-27	Has a Ph.Eur. Certificate of suitability been issued for the active substance(s):			
E2356-28	Yes	rdm:ph-eur-cert-suitability (Value=1)	Ph Eur Certificate > has certificate issued	B2356-6, B2356-7
E2356-30	No	rdm:ph-eur-cert-suitability (Value=0)	Ph Eur Certificate > has certificate issued	B2356-6
E2356-31	Provide copy in Annex 5.10	rdm:provide-copy		
E2356-32	Active Substance	rdm:ph-eur-cert/rdm:substance-certificate/ rdm:substance/rdm:substance-name	Ph Eur Certificate > Substance CTL	B2356-7
E2356-33	Name of the manufacturer	rdm:ph-eur-cert/rdm:substance-certificate/rdm:certificate-holder/rdm:name	Role > Party > Organisation> Name	B2356-7
E2356-34	Reference number	rdm:ph-eur-cert/rdm:substance-certificate/rdm:reference-number-certificate	PH Eur Certificate > reference number	B2356-7
E2356-35	Date of last update	rdm:ph-eur-cert/ rdm:substance-certificate/ rdm:date-last-update	PH Eur Certificate > last update date	B2356-7
E2356-36	Is a Active Substance Master File (European Drug Master File) to be used for the active substance(s) reference/original?			
E2356-38	Yes	rdm:active-substance-master-file (Value=1)	European Drug Master File > used for active substance	B2356-8, B2356-9
E2356-39	No	rdm:active-substance-master-file (Value=0)	European Drug Master File > used for active substance	B2356-8
E2356-40	Active Substance	rdm:asmf/rdm:substance-certificate/ rdm:substance/rdm:substance-name	European Drug Master File > Substance CTL	B2356-9
E2356-41	Name of the manufacturer	rdm:asmf/rdm:substance-certificate/rdm:certificate-holder/rdm:name	Role > Party > Organisation> Name	B2356-9
E2356-42	Reference number for EMEA/competent authority	rdm:asmf/rdm:substance-certificate/rdm:reference-number-certificate	European Drug Master File > Reference number	B2356-9
E2356-43	Date of submission	rdm:asmf/rdm:substance-certificate/rdm:date-submission	European Drug Master File > Submission date	B2356-9
E2356-44	Date of last update	rdm:asmf/rdm:substance-certificate/rdm:date-last-update	European Drug Master File > Last update date	B2356-9
E2356-45	Attach letter of access for Community/Member State authorities where the application is made (see "European ASMF procedure for active ingredients") (Annex 5.10)	rdm:access-community-member-state		B2356-9
E2356-46	Attach copy of written confirmation from the manufacturer of the active substance to inform the applicant in case of modification of the manufacturing process or specifications according to Annex 1 of Directive 2001/82/EC (Annex 5.11)	rdm:written-confirmation		B2356-9
E2356-47	Is an EMEA certificate for a Vaccine Antigen Master File (VAMF) issued or submitted in accordance with Directive 2001/83/EC Annex I, Part III, being used for this MAA?			
E2356-48	Yes	rdm:vamf/rdm:is-vamf-issued (Value=1)	Vaccine Antigen Master File>is certificate issued	B2356-10
E2356-49	No	rdm:vamf/rdm:is-vamf-issued (Value=0)	Vaccine Antigen Master File>is certificate issued	B2356-10
E2356-50	Active Substance	rdm:vamf/rdm:substance-certificate/rdm:substance	Vaccine Antigen Master File>Substance CTL	
E2356-51	Name of the VAMF Certificate Holder/VAMF Applicant	rdm:vamf/rdm:substance-certificate/rdm:certificate-holder/rdm:name	Role > Party > Organisation> Name	
E2356-52	Reference number of Application/ Certificate	rdm:vamf/rdm:substance-certificate/rdm:reference-number-certificate	Vaccine Antigen Master File>reference Number	
E2356-53	Date of submission (if pending)	rdm:vamf/rdm:substance-certificate/rdm:date-submission	Vaccine Antigen Master File > submission date	
E2356-54	Date of approval or last update (if approved)	rdm:vamf/rdm:substance-certificate/rdm:date-last-update	Vaccine Antigen Master File > last update date	
E2356-55	Provide copy in (Annex 5.20)	rdm:attach		

Element Tree Diagram

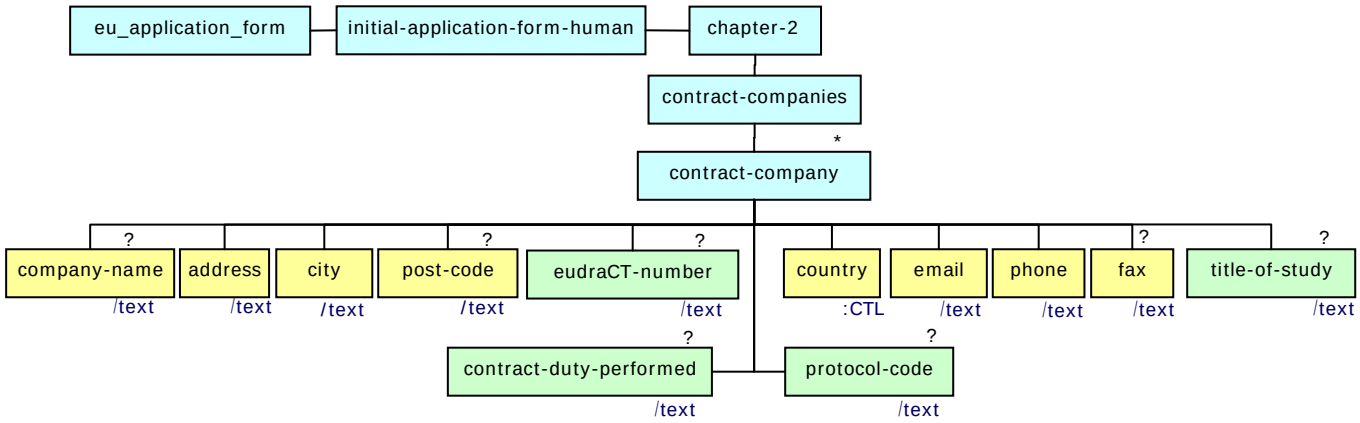


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2356-1	E2356-17, E2356-18	Mandatory.	Mutually Exclusive.	
B2356-2	E2356-17, E2356-20 to E2356-22	E2356-20 to E2356-22 are optional, E2356-17is mandatory.	If E2356-17 is selected, then E2356-20 to E2356-22 are required.	
B2356-3	E2356-20, E2356-21	Optional.	Mutually Exclusive.	
B2356-4	E2356-24, E2356-25	Mandatory.	Mutually Exclusive.	
B2356-5	E2356-24, E2356-26	Mandatory.	If E2356-24 is selected, then E2356-26 is required.	
B2356-6	E2356-28, E2356-29	Mandatory.	Mutually Exclusive.	
B2356-7	E2356-28, E2356-32 to E2356-35	E2356-28 is Mandatory, Rest are optional.	If E2356-28 is selected, the rest are required.	
B2356-8	E2356-38, E2356-39	Mandatory.	Mutually Exclusive.	
B2356-9	E2356-38, E2356-40 to E2356-46	E2356-38 is Mandatory, Rest are optional.	If E2356-38 is selected, the rest are required.	
B2356-10	E2356-48, E2356-49	Mandatory.	Mutually Exclusive.	
B2356-11	E2356-48, E2356-50 to E2356-55	E2356-48 is Mandatory, Rest are optional.	If E2356-48 is selected, the rest are required.	

2.3.5.7. Contract companies used for clinical trial(s) on bioavailability or bioequivalence or used for the validation of blood product manufacturing processes. For each contract company, state where analytical tests are performed and where clinical data are collected and give:

	Common DES 3.0 Context		**Common RDM Entry point**	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-2/maa:contract-companies/maa:contract-company/		Application > Cotract Company CT >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2357-1	Title of Study	rdm:title-of-study	Study title	
E2357-2	Protocol Code	rdm:protocol-code	Protocol code	
E2357-3	EudraCT number	rdm:eudraCT-number	Eudract number	
E2357-4	Company Name	rdm:company-name	Role > Party > Organisation> Name	
E2357-5	Address	rdm:address	Role>Party>Contact Details > Address	
E2357-6	City	rdm:city	Role>Party>Contact Details > Address > City	
E2357-7	PostCode	rdm:post-code	Role>Party>Contact Details > Address > post code	
E2357-8	Country	rdm:country	Role>Party>Contact Details > Address > Country CTL	
E2357-9	Telephone	rdm:phone	Role>Party>Contact Details > Electronic Contact > electronic contact	
E2357-10	Telefax	rdm:fax	Role>Party>Contact Details > Electronic Contact > electronic contact	
E2357-11	E-mail	rdm:email	Role>Party>Contact Details > Electronic Contact > electronic contact	
E2357-12	Duty performed according to contract	rdm:contract-duty-performed	Duty performed	

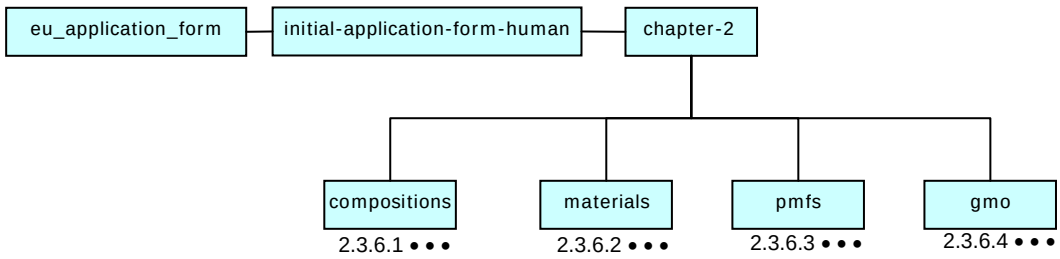
Element Tree Diagram



2.3.6. Qualitative and Quantitative composition

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-2/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E236-1	Qualitative and Quantitttative composition in terms of the active substance(s) and the excipient(s)	maa:compositions/		See Section 2.3.6.1
E236-2	List of materials of animal and/or human origin contained or used in the manufacturing process of the medicinal product?	maa:materials/		See Section 2.3.6.2
E236-3	Is an EMA certificate for a Plasma Master File (PMF) issued or submitted in accordance with Directive 2001/83/EC Annex I, Part III, being used for this MAA?	maa:pmfs/		See Section 2.3.6.3
E236-4	Does the medicinal product contain or consist of Genetically Modified Organisms (GMOs) within the meaning of Directive 2001/18/EC?	maa:gmo/		See Section 2.3.6.4

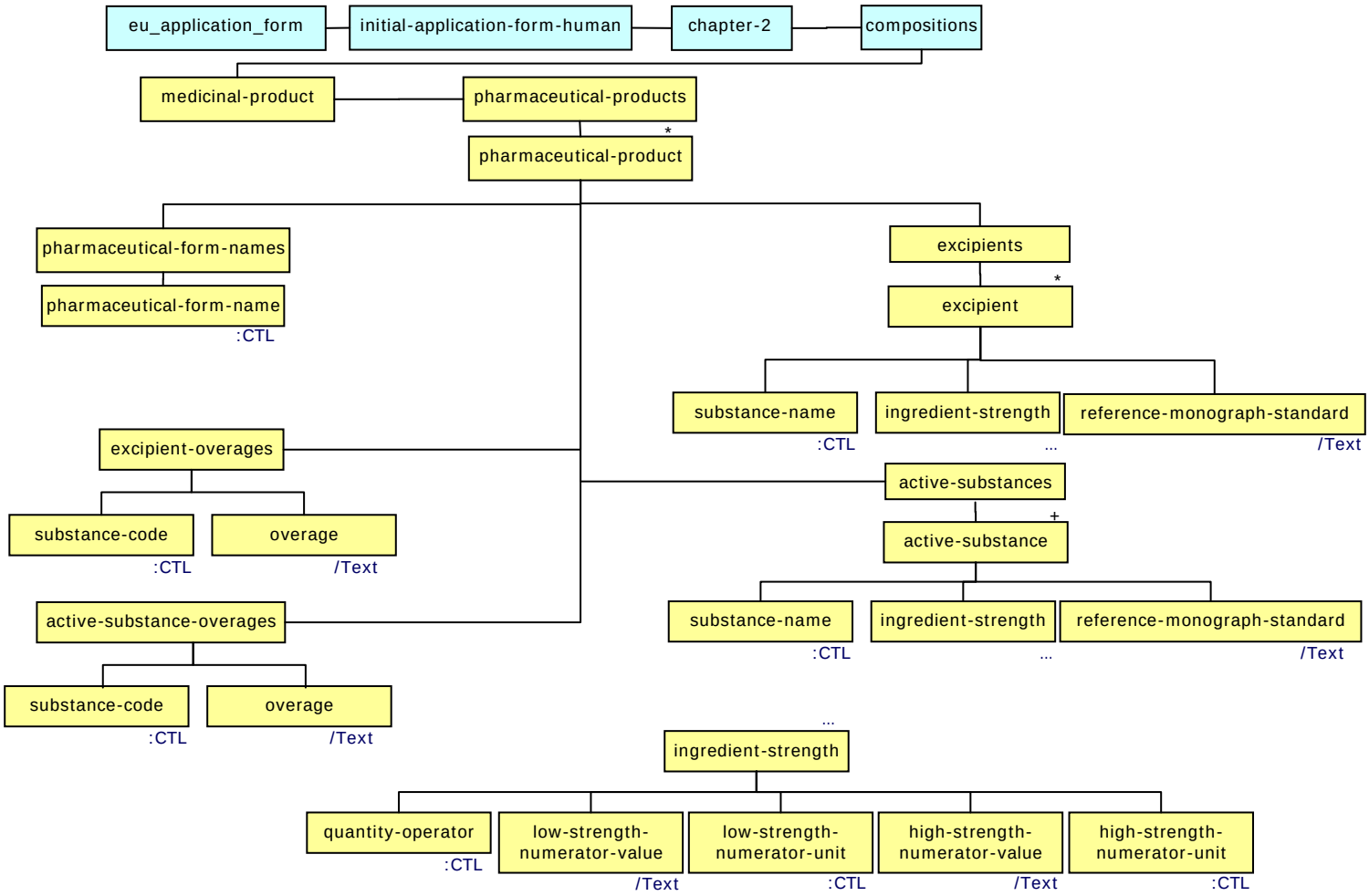
Element Tree Diagram



2.3.6.1. Qualitative and Quantitative composition in terms of the active substance(s) and the excipient(s)

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-2/maa:compositions/maa:composition/rdm:medicinal-product/rdm:pharmaceutical-products/rdm:pharmaceutical-product/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2361-1	A note should be given as to which quantity the composition refers (e.g. 1 capsule)			
E2361-2	Pharmaceutical Form	rdm:pharmaceutical-form-names/rdm:pharmaceutical-form-name/	Pharmaceutical Dose Form CTL > term id	
E2361-3	Strength	rdm:pharmaceutical-form-strength-description		
E2361-4	Name of active substance	rdm:active-substances/rdm:active-substance/rdm:substance-name	Ingredient > Substance CTL	
E2361-5	Quantity / Unit	rdm:active-substances/rdm:active-substance/rdm:ingredient-strength	Ingredient > Unit CTL	
E2361-6	Reference / Monograph Standard	rdm:active-substances/rdm:active-substance/rdm:reference-monograph-standard	??	
E2361-7	Name of Excipient	rdm:excipients /rdm:excipient /rdm:substance-name	Ingredient > Substance CTL	
E2361-8	Quantity / Unit	rdm:excipients /rdm:excipient /rdm:ingredient-strength	Ingredient > Unit CTL	
E2361-9	Reference / Monograph Standard	rdm:excipients /rdm:excipient /rdm:reference-monograph-standard	??	
E2361-10	Active Substance	rdm:active-substance-overages/rdm:substance-code	Ingredient > Substance CTL	
E2361-11	Overage	rdm:active-substance-overages/rdm:overage	Ingredient > Overage	
E2361-12	Excipient	rdm:excipient-overages/rdm:excipient-code	Ingredient > Substance CTL	
E2361-13	Overage	rdm:excipient-overages /rdm:overage	Ingredient > Overage	

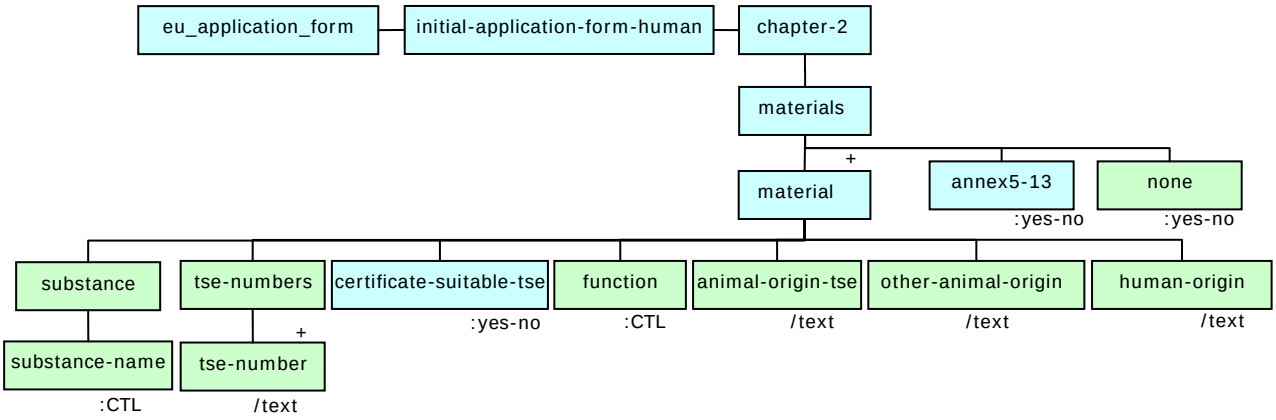
Element Tree Diagram



2.3.6.2. List of materials of animal and/or human origin contained or used in the manufacturing process of the medicinal product?

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-2/maa:materials/		Application > Manufacturing Material	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2362-1	NONE	maa:none	is material used	B2362-1
E2362-2	Material name	maa:material/maa:substance/rdm:substance-name	material name	B2362-1
E2362-3	Function*			B2362-1
E2362-4	AS	maa:material/function (Value=1)	Material Function CTL	B2362-1, B2362-2
E2362-5	EX	maa:material/function (Value=2)	Material Function CTL	B2362-1, B2362-2
E2362-6	R	maa:material/function (Value=3)	Material Function CTL	B2362-1, B2362-2
E2362-7	Animal Origin susceptible to TSE**	maa:material/animal-origin-tse	Material Origin CTL	B2362-1, B2362-3
E2362-8	Other Animal Origin	maa:material/other-animal-origin	Material Origin CTL	B2362-1, B2362-3
E2362-9	Human Origin	maa:material/human-origin	Material Origin CTL	B2362-1, B2362-3
E2362-10	Certificate of suitability for TSE	maa:material/certificate-suitable-tse		B2362-1, B2362-4
E2362-11	TSE number	maa:material/tse-numbers/tse-number	certificate number	B2362-1, B2362-4
E2362-12	If a Ph. Eur. Certificate of suitability for TSE is available according to the Resolution AP/CSP(99)4 of the Council of Europe attach it in Annex 5.12	maa:annex5-13		

Element Tree Diagram

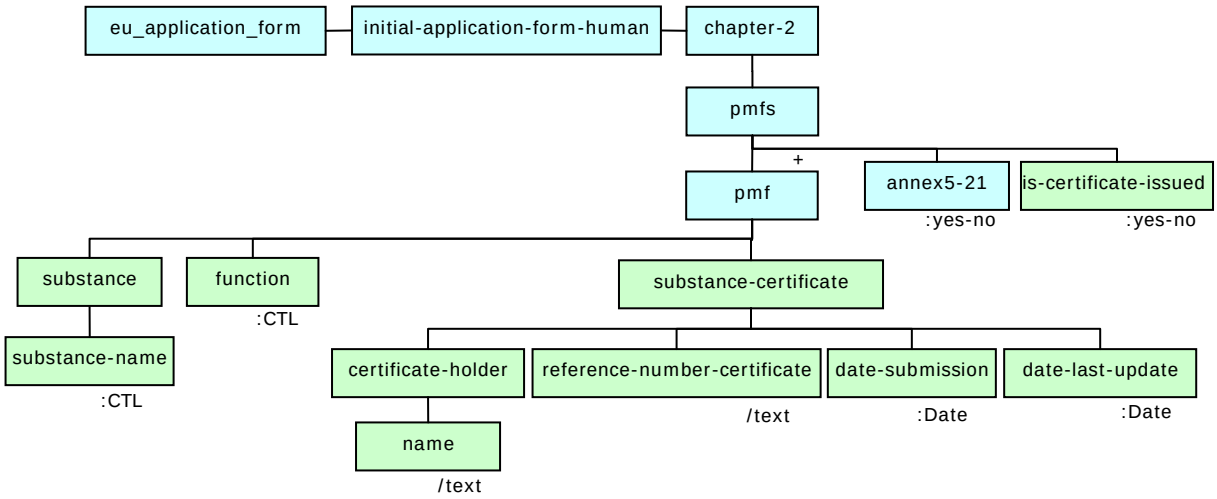


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2362-1	E2362-1, E2362-2 to E2362-11	Mandatory.	If E2362-1 is selected then the rest are optional.	
B2362-2	E2362-4 to E2362-6	Optional.	Mutually Exclusive.	
B2362-3	E2362-7 to E2362-9	Optional.	Mutually Exclusive.	
B2362-4	E2362-10, E2362-11	Optional.	If E2362-10 is selected, E2362-11 is required.	

2.3.6.3. Is an EMA certificate for a Plasma Master File (PMF) issued or submitted in accordance with Directive 2001/83/EC Annex I, Part III, being used for this MAA?

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-2/maa:pmfs/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2363-1	Yes	maa:is-certificate-issued (Value=1)	App PMF Certificate > is certificate issued	B2363-1, B2363-2
E2363-2	No	maa:is-certificate-issued (Value=0)	App PMF Certificate > is certificate issued	B2363-1
E2363-3	Provide copy in Annex 5.21	maa:annex5-21		B2363-2
E2363-4	If yes, Enter Substance(s) referring to PMF:			B2363-2
E2363-5	Active Substance	maa:pmf/maa:substance/rdm:substance-name	App PMF Certificate > Substance CTL	B2363-2
E2363-6	Function*			B2363-2
E2363-7	AS	maa:pmf/maa:function	App PMF Certificate > Material Function CTL	B2363-2, B2363-3
E2363-8	EX	maa:pmf/maa:function	App PMF Certificate > Material Function CTL	B2363-2, B2363-3
E2363-9	R	maa:pmf/maa:function	App PMF Certificate > Material Function CTL	B2363-2, B2363-3
E2363-10	Name of the PMF certificate holder/PMF applicant:	maa:pmf/maa:substance-certificate/rdm:certificate-holder/rdm:name	Role > Party > Organisation> Name	B2363-2
E2363-11	Reference number of application/certificate	maa:pmf/maa:substance-certificate/rdm:reference-number-certificate	App PMF certificate > certificate ref number	B2363-2
E2363-12	Date of submission (if pending)	maa:pmf/maa:substance-certificate/rdm:date-submission	App PMF certificate > submission date	B2363-2
E2363-13	Date of approval or last update (if approved)	maa:pmf/maa:substance-certificate/rdm:date-last-update	App PMF certificate > approval or last update date	B2363-2

Element Tree Diagram

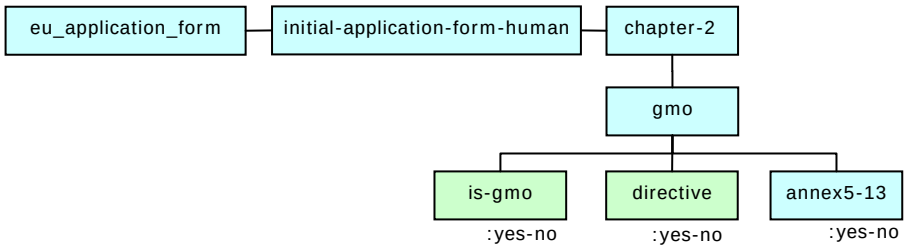


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2363-1	E2363-1, E2363-2	Mandatory.	Mutually Exclusive.	
B2363-2	E2363-1, E2363-3 to E2363-13	E2363-1 is Mandatory, rest are optional.	If E2363-1 is selected, then the rest are required.	
B2363-3	E2363-7 to E2363-9	Optional.	Mutually Exclusive.	

2.3.6.4. Does the medicinal product contain or consist of Genetically Modified Organisms (GMOs) within the meaning of Directive 2001/18/EC?

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-2/maa:gmo/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2364-1	Yes	maa:is-gmo (Value=1)	App GMO > mp consist of gmo	B2364-1
E2364-2	No	maa:is-gmo (Value=0)	App GMO > mp consist of gmo	B2364-1
E2364-3	If yes, does the product comply with Directive 2001/18/EC?			
E2364-4	Yes	maa:directive	App GMO > comply with directive	
E2364-5	No	maa:directive	App GMO > comply with directive	
E2364-6	Attach a copy of any written consent(s) of the competent authorities to the deliberate release into the environment of the GMOs for research and development purposes where provided for by Part B of the above-mentioned Directive (Annex 5.13)	maa:annex5-13		

Element Tree Diagram



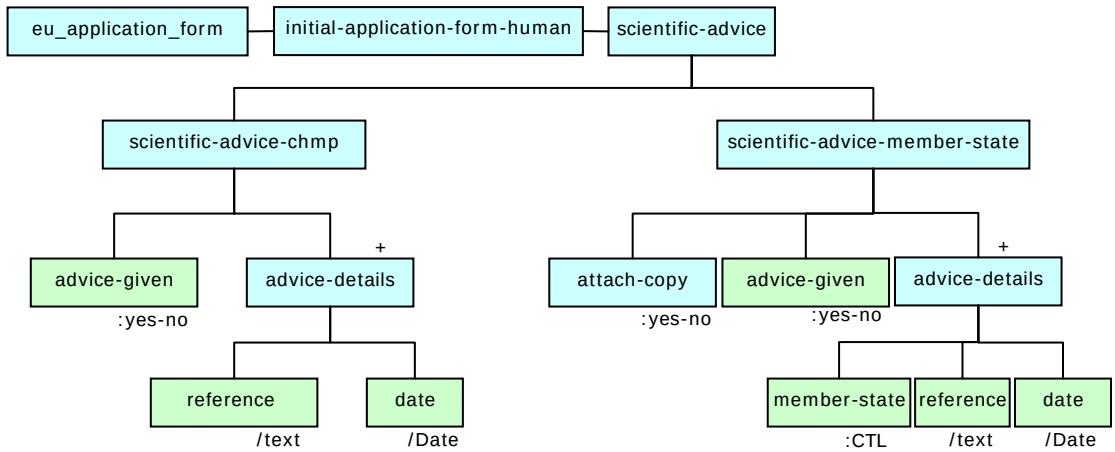
Business Rules

Rule ID	Element id(s)	Default BR	Rule	Effect(s)
B2364-1	E2364-1, E2364-2	Mandatory.	Mutually Exclusive.	
B2364-2	E2364-1, E2364-3 to E2364-6	E2364-1 is Mandatory, rest are optional.	If E2364-1 is selected, then the rest are required.	
B2364-3	E2364-4 , E2364-5	Optional.	Mutually Exclusive.	

2.4. SCIENTIFIC ADVICE

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-human/ maa:scientific-advice/		Application > App Scientific Advice >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E24-1	Was there formal scientific advice(s) given by the CHMP for this medicinal product?			
E24-2	Yes	rdm:scientific-advice-chmp/rdm:advice-given	was scientific advice given	B24-1, B24-2
E24-3	No	rdm:scientific-advice-chmp/rdm:advice-given	was scientific advice given	B24-1
E24-4	Reference(s) of the scientific advice(s)	rdm:scientific-advice-chmp/ rdm:advice-details/rdm:reference	scientific advice ref	B24-2
E24-5	Date	rdm:scientific-advice-chmp/ rdm:advice-details/rdm:date	scientific advice date	B24-2
E24-6	Was there scientific advice(s) given by Member State(s) for this medicinal product?			
E24-7	Yes	rdm:scientific-advice-member-state/rdm:advice-given	scientific Advice Source CTL	B24-3,B24-4
E24-8	No	rdm:scientific-advice-member-state/rdm:advice-given	scientific Advice Source CTL	B24-3
E24-9	Member State	rdm:scientific-advice-member-state/rdm:advice-details/ rdm:member-state	Country CTL	B24-4
E24-10	Date	rdm:scientific-advice-member-state/rdm:advice-details/rdm:date	scientific advice date	B24-4
E24-11	Reference(s) of the scientific advice(s)	rdm:scientific-advice-member-state/rdm:advice-details/ rdm:reference	scientific advice ref	B24-4
E24-12	Attach copy of scientific advice(s) (Annex 5.14)	rdm:scientific-advice-member-state/rdm:attach-copy		

Element Tree Diagram

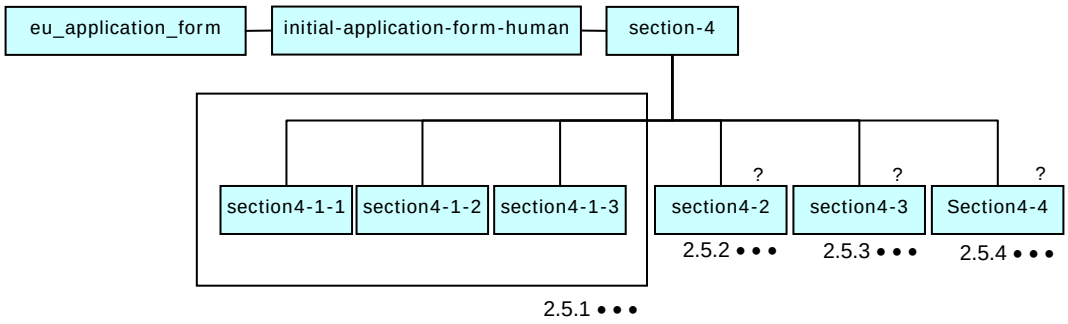


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B24-1	E24-1, E24-2	Mandatory	Mutually Exclusive	
B24-2	E24-1, E24-4, E24-5	Mandatory	If E24-1 is selected, then the others are required	
B24-3	E24-7, E24-8	Mandatory	Mutually Exclusive	
B24-4	E24-7, E24-9 to E24-11	E24-7 is Mandatory, rest are optional	If E24-7 is selected, then the other fields are required.	

2.5. OTHER MARKETING AUTHORISATION APPLICATIONS

	Common DES 3.0 Context		**Common RDM Entry point**	
	maa:eu_application_form/maa:initial-application-form-human/maa:section-4/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E25-1	FOR NATIONAL/MRP/DCP APPLICATIONS, PLEASE COMPLETE THE FOLLOWING IN ACCORDANCE WITH ARTICLE 8(j)-(l) OF DIRECTIVE 2001/83/EC	maa:section4-1-1 and maa:section4-1-2 and maa:section4-1-3		See Section 2.5.1
E25-2	Marketing authorisation applications for the same product in the EEA (same qualitative and quantitative composition in active substance(s) and having the same pharmaceutical form from applicants belonging to the same mother company or group of companies OR which are "licensees").	maa:section4-2		See Section 2.5.2
E25-3	For multiple/duplicate applications of the same medicinal product:	maa:section4-3		See Section 2.5.3
E25-4	Marketing authorisation applications for the same product outside the EEA (i.e from applicants belonging to the same mother company or group of companies OR which are "licensees". Same qualitative and quantitative composition in active substance(s) and having the same pharmaceutical form).	maa:section4-4		See Section 2.5.4

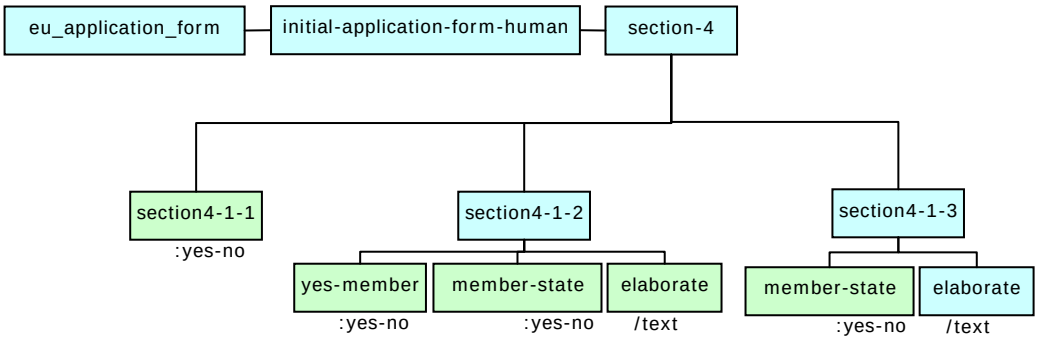
Element Tree Diagram



2.5.1. FOR NATIONAL/MRP/DCP APPLICATIONS, PLEASE COMPLETE THE FOLLOWING IN ACCORDANCE WITH ARTICLE 8(j)-(l) OF DIRECTIVE 2001/83/EC

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-human/ maa:section-4/		Application > Other MA Application	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E251-1	Is there another Member State(s) where an application for the same* product is pending**?			
E251-2	Yes	maa:section4-1-1 (Value=1)	app pending in other ms	B251-1, B252-1
E251-3	No	maa:section4-1-1 (Value=0)	app pending in other ms	B251-1
E251-4	Is there another Member state(s) where an authorisation is granted for the same* product?			
E251-5	Yes	maa:section4-1-2/ maa:yes-member (Value=1)	is auth granted in other ms	B251-2, B251-3, B252-1
E251-6	No	maa:section4-1-2/ maa:yes-member (Value=0)	is auth granted in other ms	B251-2
E251-7	Are there any differences which have therapeutic implications between this application and the applications/authorisations for the same product in other Member States (for national applications, Article 17 or 18 of Directive 2001/83/EC shall apply).			B251-3
E251-8	Yes	maa:section4-1-2/ maa:member-state (Value=1)	are there differences	B251-3, B251-4, B251-5
E251-9	No	maa:section4-1-2/ maa:member-state (Value=0)	are there differences	B251-3, B251-4
E251-10	Please elaborate	maa:section4-1-2/ maa:elaborate	differences description	B251-3, B251-5
E251-11	Is there another Member State(s) where an authorisation was refused/suspended/revoked by competent authorities for the same* product?			
E251-12	Yes	maa:section4-1-3/ maa:yes-member (Value=1)	was auth refused	B251-6, B251-7, B252-1
E251-13	No	maa:section4-1-3/ maa:yes-member (Value=0)	was auth refused	B251-6
E251-14	Please elaborate	maa:section4-1-3/ maa:elaborate		B251-7
E251-15	*Note: * "same product" means same qualitative and quantitative composition in active substance(s) and having the same pharmaceutical form from applicants belonging to the same mother company or group of companies OR which are "licensees".* ** This is covering applications submitted at an earlier time or in parallel to this application if not already listed under 1.1.2 or 1.1.3*			

Element Tree Diagram



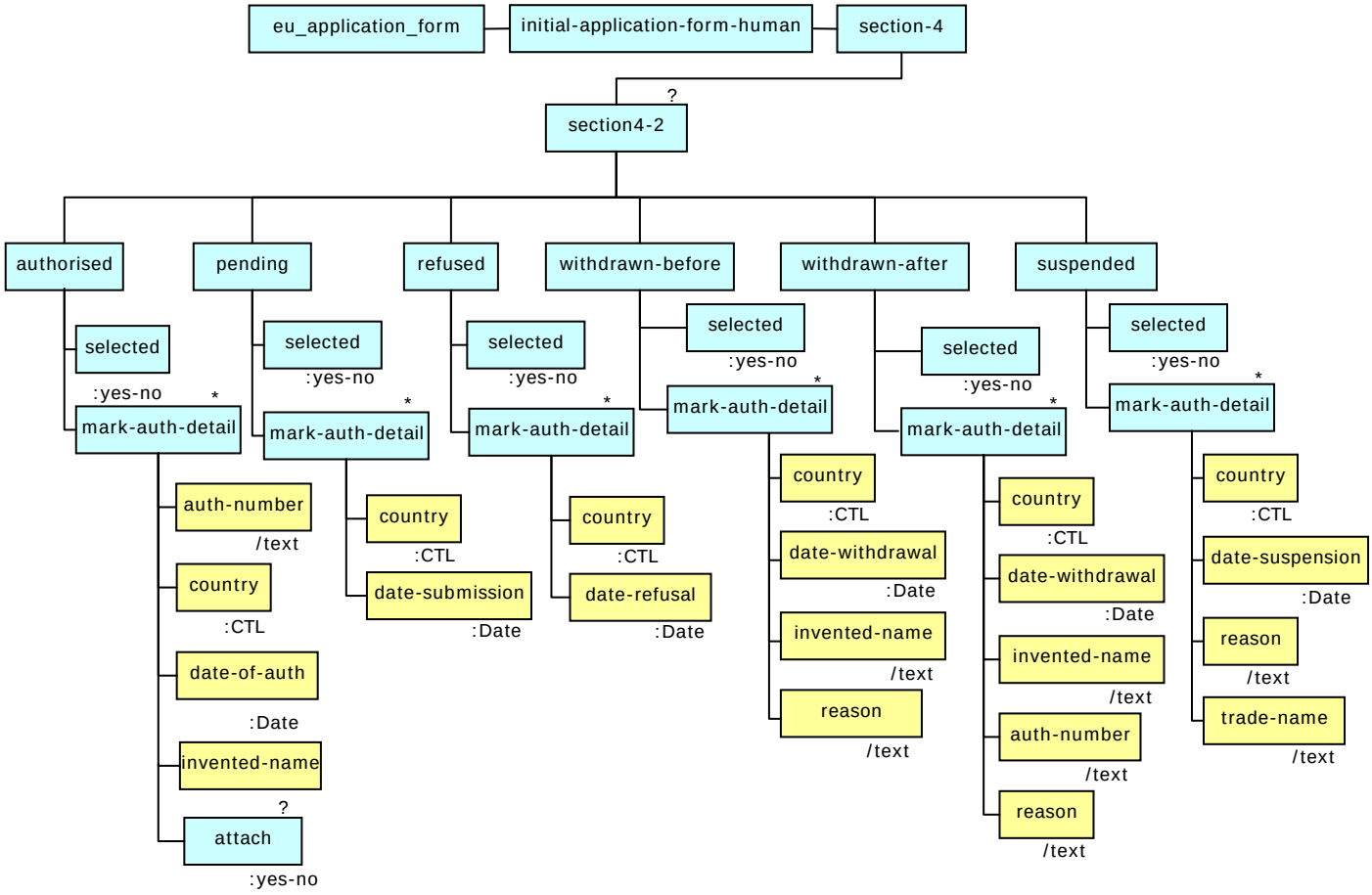
Business Rules

Rule ID	Element id(s)	Default BR	Rule	Effect(s)
B251-1	E251-2, E251-3	Mandatory.	Mutually Exclusive.	
B251-2	E251-5, E251-6	Mandatory.	Mutually Exclusive.	
B251-3	E251-5, E251-7 to E251-10	E251-5 is mandatory, rest are optional.	If E251-5 is selected, then the other fields are required.	
B251-4	E251-8, E251-9	Mandatory.	Mutually Exclusive.	
B251-5	E251-8, E251-10	Optional.	If E251-8 is selected, then E251-10 is required.	
B251-6	E251-12, E251-13	Mandatory.	Mutually Exclusive.	
B251-7	E251-12, E251-14	E251-12 is mandatory, E251-14 is optional.	If E251-12 is selected, then E251-14 is required.	

2.5.2. Marketing authorisation applications for the same product in the EEA (same qualitative and quantitative composition in active substance(s) and having the same pharmaceutical form from applicants belonging to the same mother company or group of companies OR which are "licensees").

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-human/ maa:section-4/maa:section4-2/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E252-1	Authorised	maa:authorised/rdm:selected	Authorisation Status CTL	B252-2
E252-2	Country	maa:authorised/rdm:mark-auth-detail/rdm:country	MP Authorisation > Country CTL	B252-2
E252-3	Date of authorisation	maa:authorised/rdm:mark-auth-detail/rdm:date-of-auth	MP Authorisation > authorisation date	B252-2
E252-4	Invented name	maa:authorised/rdm:mark-auth-detail/rdm:invented-name	Medicinal Product Group > invented name	B252-2
E252-5	Authorisation number	maa:authorised/rdm:mark-auth-detail/rdm:auth-number	MP Authorisation > authorisation number	B252-2
E252-6	Attach marketing authorisation (Annex 5.15)	maa:authorised/rdm:mark-auth-detail/rdm:attach		B252-2
E252-7	Pending	maa:pending/rdm:selected	Authorisation Status CTL	B252-3
E252-8	Country	maa:pending/rdm:mark-auth-detail/rdm:country	MP Authorisation > Country CTL	B252-3
E252-9	Date of submission	maa:pending/rdm:mark-auth-detail/rdm:date-submission	Application > submission date	B252-3
E252-10	Refused	maa:refused/selected	Authorisation Status CTL	B252-3
E252-11	Country	maa:refused/rdm:mark-auth-detail/rdm:country	MP Authorisation > Country CTL	B252-3
E252-12	Date of refusal	maa:refused/rdm:mark-auth-detail/rdm:date-refusal	MP Authorisation > authorisation date	B252-3
E252-13	Withdrawn (by applicant before authorisation)	maa:withdrawn-before/rdm:selected	Authorisation Status CTL	B252-4
E252-14	Country	maa:withdrawn-before/rdm:mark-auth-detail/rdm:country	MP Authorisation > Country CTL	B252-4
E252-15	Date of withdrawal	maa:withdrawn-before/rdm:mark-auth-detail/rdm:date-withdrawal	MP Authorisation > authorisation date	B252-4
E252-16	Invented name	maa:withdrawn-before/rdm:mark-auth-detail/rdm:invented-name	Medicinal Product Group > invented name	B252-4
E252-17	Reason for withdrawal	maa:withdrawn-before/rdm:mark-auth-detail/rdm:reason	MP Authorisation > authorisation description	B252-4
E252-18	Withdrawn (by applicant after authorisation)	maa:withdrawn-after/rdm:selected	Authorisation Status CTL	B252-5
E252-19	Country	maa:withdrawn-after/ rdm:mark-auth-detail/rdm:country	MP Authorisation > Country CTL	B252-5
E252-20	Date of withdrawal	maa:withdrawn-after/ rdm:mark-auth-detail/rdm:date-withdrawal	MP Authorisation > authorisation date	B252-5
E252-21	Authorisation number	maa:withdrawn-after/ rdm:mark-auth-detail/rdm:auth-number	MP Authorisation > authorisation number	B252-5
E252-22	Invented name	maa:withdrawn-after/ rdm:mark-auth-detail/rdm:invented-name	Medicinal Product Group > invented name	B252-5
E252-23	Reason for withdrawal	maa:withdrawn-after/ rdm:mark-auth-detail/rdm:reason	MP Authorisation > authorisation description	B252-5
E252-24	Suspended/revoked (by competent authority)	maa:suspended/rdm:selected	Authorisation Status CTL	B252-6
E252-25	Country	maa:suspended/rdm:mark-auth-detail/rdm:country	MP Authorisation > Country CTL	B252-6
E252-26	Date of suspension/revocation	maa:suspended/rdm:mark-auth-detail/rdm:date-suspension	MP Authorisation > authorisation date	B252-6
E252-27	Reason for suspension/revocation	maa:suspended/rdm:mark-auth-detail/rdm:reason	MP Authorisation > authorisation description	B252-6
E252-28	Invented name	maa:suspended/rdm:mark-auth-detail/rdm:invented-name	Medicinal Product Group > invented name	B252-6

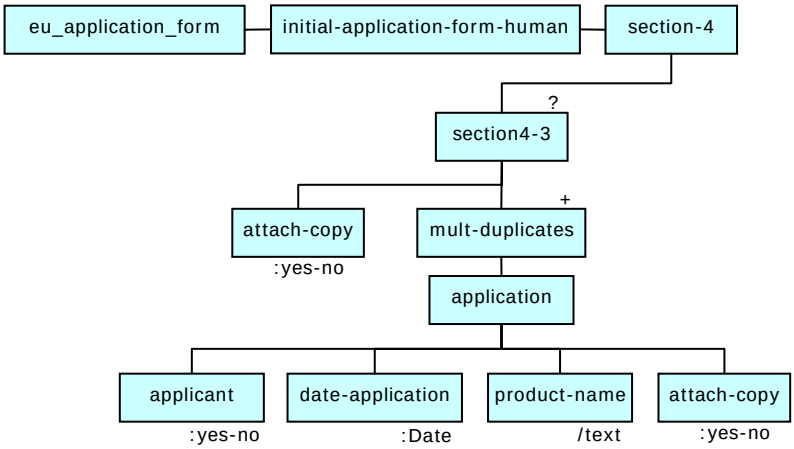
Element Tree Diagram



Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B252-1	E251-1, E251-5, E251-12	Mandatory.	If one of the fields are selected, section 2.5.2 is mandatory.	
B252-2	E252-1 to E252-6	E252-1 mandatory, rest are optional.	If E252-1 is selected, then the rest are mandatory.	
B252-3	E252-7 to E252-12	E252-7 mandatory, rest are optional.	If E252-7 is selected, then the rest are mandatory.	
B252-4	E252-13 to E252-17	E252-13 mandatory, rest are optional.	If E252-13 is selected, then the rest are mandatory.	
B252-5	E252-18 to E252-23	E252-18 mandatory, rest are optional.	If E252-18 is selected, then the rest are mandatory.	
B252-6	E252-24 to E252-28	E252-24 mandatory, rest are optional.	If E252-24 is selected, then the rest are mandatory.	

2.5.3. For multiple/duplicate applications of the same medicinal product:

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-human/maa:section-4/ maa:section4-3/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E253-1	Multiple/duplicate applications for:			
E253-2	Name of other product	maa:mult-duplicates/ maa:application/maa:product-name	Medicinal Product > medicinal product name	
E253-3	Date of application(s)	maa:mult-duplicates/ maa:application/maa:date-application	Application > Submission date	
E253-4	Applicant	maa:mult-duplicates/ maa:application/maa:applicant	Role > Party > Organisation> Name	
E253-5	Attach copy of correspondence with the European Commission, for centralised procedures only (Annex 5.16)	maa:multi-duplicates/maa:application/maa:attach-copy		
E253-6	Attach copy of correspondence with the European Commission, for centralised procedures only (Annex 5.16)	maa:attach-copy		



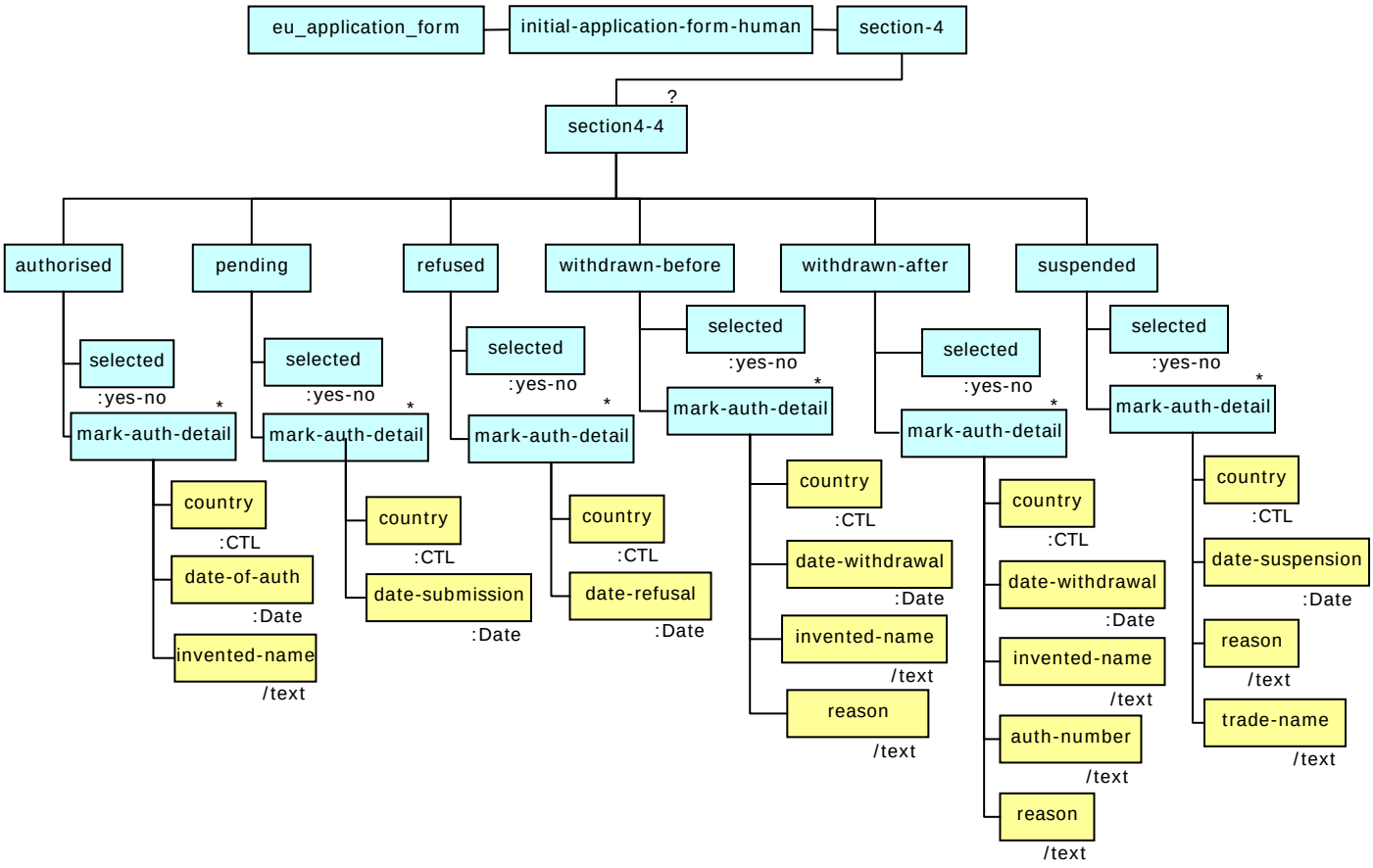
Element Tree Diagram

2.5.4. Marketing authorisation applications for the same product outside the EEA (i.e. from applicants belonging to the same mother company or group of companies OR which are "licensees". Same qualitative and quantitative composition in active substance(s) and

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-human/ maa:section-4/maa:section4-4/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E254-1	Authorised	maa:authorised/rdm:selected	Authorisation Status CTL	B254-1
E254-2	Country	maa:authorised/rdm:mark-auth-detail/rdm:country	MP Authorisation > Country CTL	B254-1
E254-3	Date of authorisation	maa:authorised/rdm:mark-auth-detail/rdm:date-of-auth	MP Authorisation > authorisation date	B254-1
E254-4	Invented name	maa:authorised/rdm:mark-auth-detail/rdm:invented-name	Medicinal Product Group > invented name	B254-1
E254-6	Pending	maa:pending/rdm:selected	Authorisation Status CTL	B254-2
E254-7	Country	maa:pending/rdm:mark-auth-detail/rdm:country	MP Authorisation > Country CTL	B254-2
E254-8	Date of submission	maa:pending/rdm:mark-auth-detail/rdm:date-submission	Application > submission date	B254-2
E254-9	Refused	maa:refused/selected	Authorisation Status CTL	B254-3
E254-10	Country	maa:refused/rdm:mark-auth-detail/rdm:country	MP Authorisation > Country CTL	B254-3
E254-11	Date of refusal	maa:refused/rdm:mark-auth-detail/rdm:date-refusal	MP Authorisation > authorisation date	B254-3
E254-12	Withdrawn (by applicant before authorisation)	maa:withdrawn-before/rdm:selected	Authorisation Status CTL	B254-4
E254-13	Country	maa:withdrawn-before/rdm:mark-auth-detail/rdm:country	MP Authorisation > Country CTL	B254-4
E254-14	Date of withdrawal	maa:withdrawn-before/rdm:mark-auth-detail/rdm:date-withdrawal	MP Authorisation > authorisation date	B254-4
E254-15	Invented name	maa:withdrawn-before/rdm:mark-auth-detail/rdm:invented-name	Medicinal Product Group > invented name	B254-4
E254-16	Reason for withdrawal	maa:withdrawn-before/rdm:mark-auth-detail/rdm:reason	MP Authorisation > authorisation description	B254-4
E254-17	Withdrawn (by applicant after authorisation)	maa:withdrawn-after/rdm:selected	Authorisation Status CTL	B254-5
E254-18	Country	maa:withdrawn-after/ rdm:mark-auth-detail/rdm:country	MP Authorisation > Country CTL	B254-5
E254-19	Date of withdrawal	maa:withdrawn-after/ rdm:mark-auth-detail/rdm:date-withdrawal	MP Authorisation > authorisation date	B254-5
E254-20	Authorisation number	maa:withdrawn-after/ rdm:mark-auth-detail/rdm:auth-number	MP Authorisation > authorisation number	B254-5
E254-21	Invented name	maa:withdrawn-after/ rdm:mark-auth-detail/rdm:invented-name	Medicinal Product Group > invented name	B254-5
E254-22	Reason for withdrawal	maa:withdrawn-after/ rdm:mark-auth-detail/rdm:reason	MP Authorisation > authorisation description	B254-5
E254-23	Suspended/revoked (by competent authority)	maa:suspended/rdm:selected	Authorisation Status CTL	B254-6
E254-24	Country	maa:suspended/rdm:mark-auth-detail/rdm:country	MP Authorisation > Country CTL	B254-6
E254-25	Date of suspension/revocation	maa:suspended/rdm:mark-auth-detail/rdm:date-suspension	MP Authorisation > authorisation date	B254-6
E254-26	Reason for suspension/revocation	maa:suspended/rdm:mark-auth-detail/rdm:reason	MP Authorisation > authorisation description	B254-6
E254-27	Trade name	maa:suspended/rdm:mark-auth-detail/rdm:invented-name	Medicinal Product Group > invented name	B254-6

having the same pharmaceutical form).

Element Tree Diagram

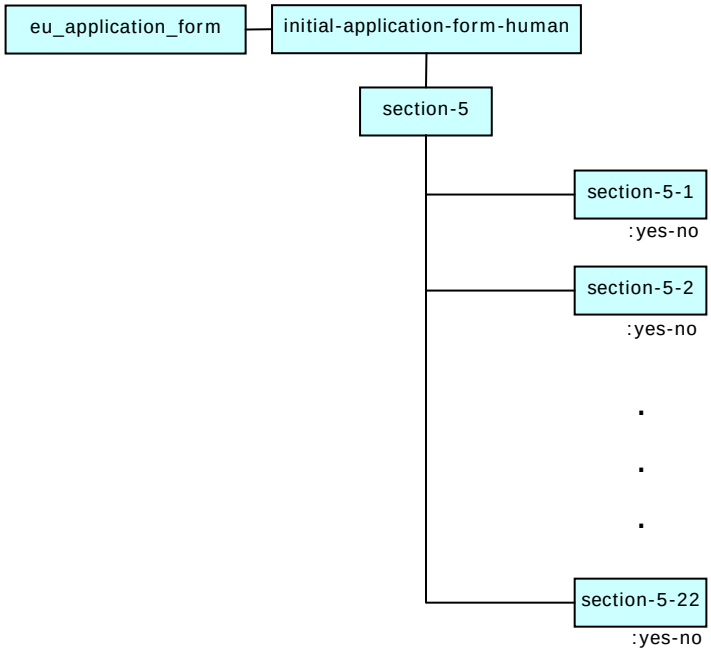


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B254-1	E254-1 to E254-4	E254-1 mandatory, rest are Optional.	If E254-1 is selected, then the rest are mandatory.	
B254-2	E254-6 to E254-8	E254-6 mandatory, rest are Optional.	If E254-7 is selected, then the rest are mandatory.	
B254-3	E254-9 to E254-11	E254-9 mandatory, rest are Optional.	If E254-9 is selected, then the rest are mandatory.	
B254-4	E254-12 to E254-16	E254-12 mandatory, rest are Optional.	If E254-12 is selected, then the rest are mandatory.	
B254-5	E254-17 to E254-22	E254-17 mandatory, rest are Optional.	If E254-17 is selected, then the rest are mandatory.	
B254-6	E254-23 to E254-27	E254-23 mandatory, rest are Optional.	If E254-23 is selected, then the rest are mandatory.	

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-human/ maa:section-5/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E26-1	Proof of payment	maa:section5-1		
E26-2	Informed consent letter of marketing authorisation holder of authorised medicinal product.	maa:section5-2		
E26-3	Proof of establishment of the applicant in the EEA.	maa:section5-3		
E26-4	Letter of authorisation for communication on behalf of the applicant/MAH.	maa:section5-4		
E26-5	Curriculum Vitae of the Qualified person for Pharmacovigilance.	maa:section5-5		
E26-6	Manufacturing Authorisation required under Article 40 of Directive 2001/83/EC (or equivalent, outside of the EEA where MRA or other Community arrangements apply); any proof of authorisation in accordance with Article 8(k) of Directive 2001/83/EC.	maa:section5-6		
E26-7	Copy of the "Qualification of SME Status".	maa:section5-7		
E26-8	Flow-chart indicating all manufacturing and control sites involved in the manufacturing process of the medicinal product and the active substance.	maa:section5-8		
E26-9	GMP certificate(s) or other GMP statement(s); Where applicable a summary of other GMP inspections performed.	maa:section5-9		
E26-10	Letter(s) of access to Active Substance Master File(s) or copy of ph. Eur. Certificate(s) of Suitability.	maa:section5-10		
E26-11	Copy of written confirmation from the manufacturer of the active substance to inform the applicant in case of modification of the manufacturing process or specifications according to Annex I of Directive 2001/83/EC.	maa:section5-11		
E26-12	Ph. Eur. Certificate(s) of suitability for TSE.	maa:section5-12		
E26-13	Written consent(s) of the competent authorities regarding GMO release in the environment.	maa:section5-13		
E26-14	Scientific Advice given by CHMP and/or by member state(s).	maa:section5-14		
E26-15	Copy of Marketing Authorization(s) required under Article 8(j)-(L) of Directive 2001/83/EC in the EEA and the equivalent in third countries on request (a photocopy of the pages which give the marketing authorization number, the date of authorisation and the page which has been signed by the authorizing competent authority will suffice).	maa:section5-15		
E26-16	Correspondence with European Commission regarding multiple applications.	maa:section5-16		
E26-17	List of Mock-ups or Samples/specimens sent with the application, as appropriate (see notice to Applicants, Volume 2A, chapter 7).	maa:section5-17		
E26-18	Copy of the Orphan Designation Decision.	maa:section5-18		
E26-19	List of proposed (invented) names and marketing authorisation holders in the concerned member states.	maa:section5-19		
E26-20	Copy of EMA certificate for a Vaccine Antigen Master File(VAMF).	maa:section5-20		
E26-21	Copy of EMA certificate for a Plasma Master File (PMF).	maa:section5-21		
E26-22	For each active substance, attach a declaration(s) from the Qualified Person of the manufacturing authorisation holder in Section 2.5.1 and from the Qualified Person of the manufacturing authorisation holders (i.e located in EEA) listed in Section 2.5.2 where the active substance is used as a starting material that the active substance is manufactured in compliance with the detailed guidelines on good manufacturing practice for starting materials. Alternatively, such declaration may be signed by one Qualified Person on behalf of all QPs involved (provided this is clearly indicated).	maa:section5-22		

2.6. ANNEXED DOCUMENTS (WHERE APPROPRIATE)

Element Tree Diagram



3. About this Document

3.1. Definitions, Acronyms, and Abbreviations

3.1.1. Acronyms

Name	Definition
cms	concerned member state
DCP	DeCentralised Procedure
DTD	Data Type Definition
ETD	Element Tree Diagem
EU	European Community
MA	Marketing Authorisation
MRP	Mutual Recognition Procedure
NP	National Procedure
RDM	Reference Data Model
rms	Reference member state
TSE	Transmissible Spongiform Encephalopathy
XML	eXtended Markup Language
XSL	XML Stylesheet Language

Referenced documents

Doc ID	Title	Locator
DES 3.0 Document	DES 3.0 Specification	Data Exchange Standards (DES) - v3.0 (Draft)
DES 3.0 XSD	DES 3.0 XSD dictionary file	eaf-dictionary.xsd
DES 3.0 ANNEX 1 XSD	Form XSD for initial human application	maa_human.xsd

Document Approval

Date	Submitted by	Approved by	Approver Role
N/A			

Document history

Version	Who	Date	What
1.2.20	Antonios Yfantis	2012-01-13	First Version
1.4.2	Antonios Yfantis	2012-07-10	Second Version