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Information Technology

Electronic Application Form Data Exchange Standard 3.0

Supplementary Specification Annex 1 “Initial Human Application Form” v.1.23.0.0

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

An agency of the European Union

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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 XML schema file that provides a 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. This schema file can be found on the esubmissions website under the eAF page at the following link:

http://esubmission.ema.europa.eu/eaf/index.html

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. This again can be found on the esubmissions website under the eAF page.

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.

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.

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.

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)

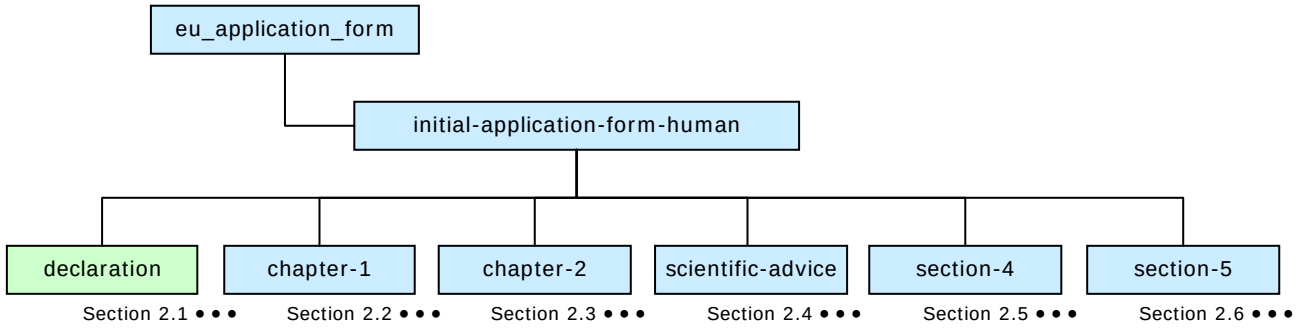
The diagrams of this version reflect the DES 3.0 standard described in the DES 3.0 Supplementary Specifications document. The ETD shows which are the concepts involved in the mapping of all the application form fields in the Element Mapping Table and the hierarchical constrains between them.

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

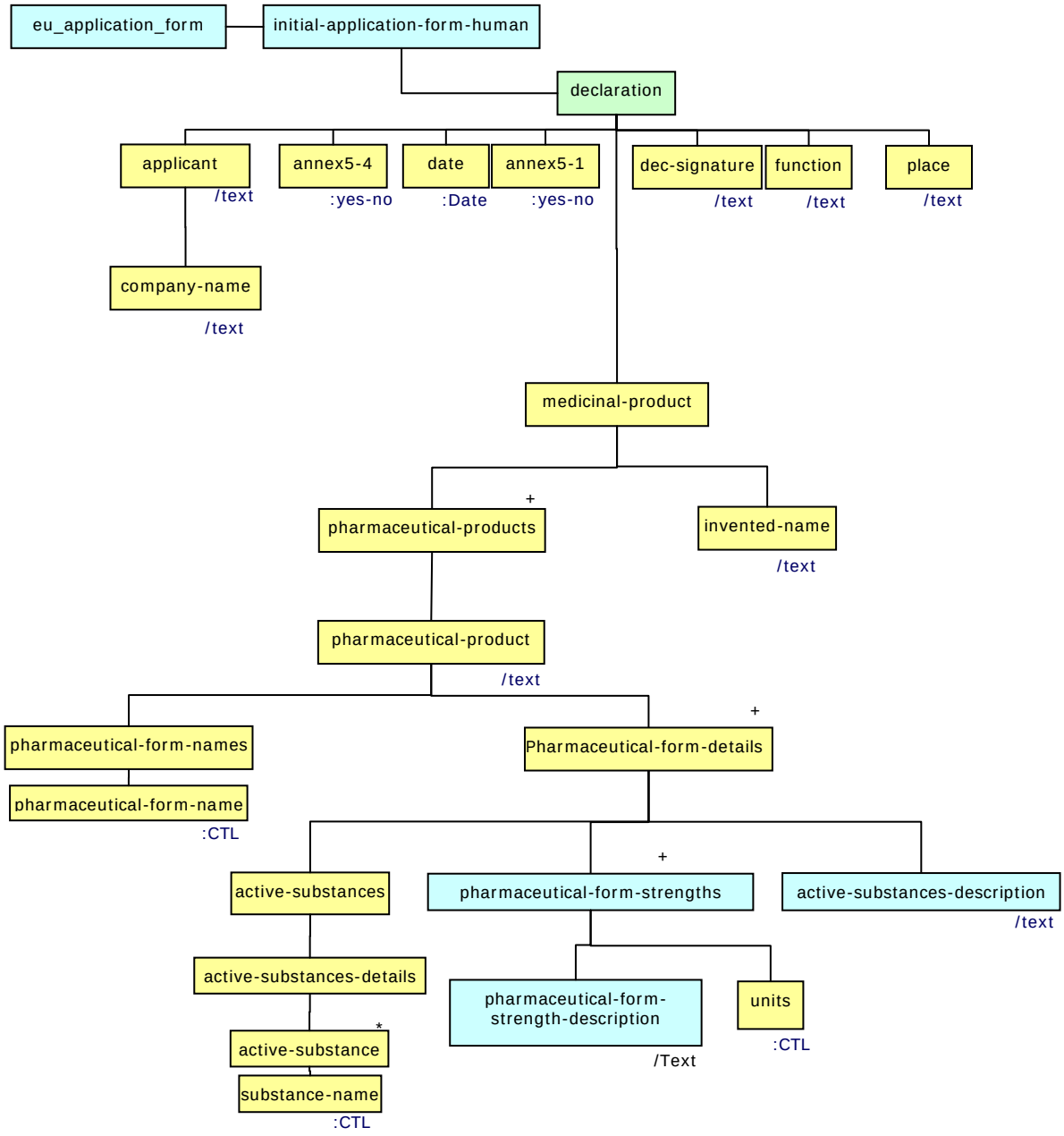
Element Tree Diagram



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-products/ 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-products/rdm:pharmaceutical-product/rdm:pharmaceutical-form-details/rdm pharmaceutical-form-strengths/rdm:pharmaceutical-form-strength-description		
E21-3a	Units	rdm:medicinal-product/rdm:pharmaceutical-products/rdm:pharmaceutical-product/rdm:pharmaceutical-form-details/rdm pharmaceutical-form-strengths/rdm:units		
E21-4	Active Substance(s)	rdm:medicinal-product/rdm:pharmaceutical-products/rdm:pharmaceutical-product/rdm:pharmaceutical-form-details/rdm:active-substances-description		
E21-5	Active Substance	rdm:medicinal-product/rdm:pharmaceutical-products/rdm:pharmaceutical-product/rdm:pharmaceutical-form-details/rdm:active-substances/rdm: active-substances-details/rdm:active-substance/rdm:substance-name	Ingredient > Substance CTL, Ingredient > IngredientRole CTL	
E21-6	Applicant details	maa:applicant/rdm:company-name	Role > Party > Person > company-name	
E21-7	Address	maa:applicant/rdm:contact-details		
E21-14	Signature(s)	maa:dec-signature	Not mapped	
E21-15	Title	maa:signature/rdm:personal-title	Role > Party > Person > Personal title	
E21-16	First name	maa:signature/rdm:given-name	Role > Party > Person > given name	
E21-17	Surname	maa:signature/rdm: family-name	Role > Party > Person > family name	
E21-18	Function	maa:function	Manufacturer MP> functions performed	
E21-19	Address	maa:place	signature place	
E21-20	Date	maa:date	signature date	
E21-21	*Note: please attach letter of authorisation for communication/signing on behalf of the applicant in annex 5.4*	maa:annex5-4		
E21-22	*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		

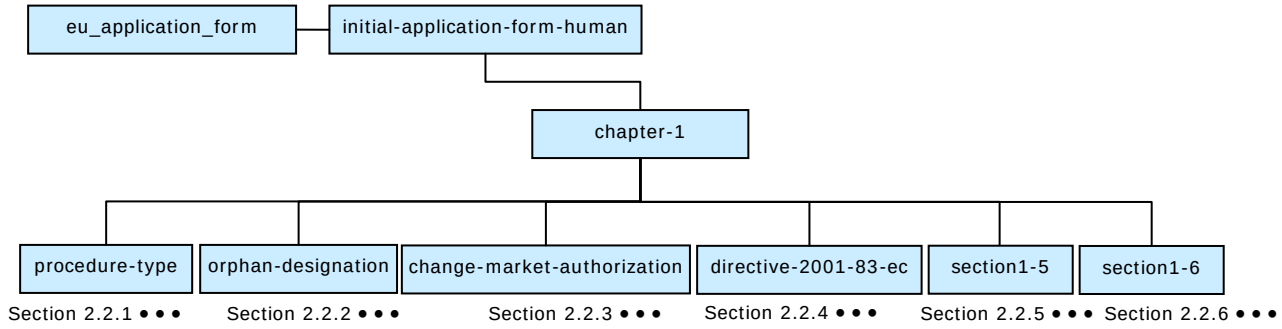
Element Tree Diagram



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 APPLICATION FOR A CHANGE TO EXISTING MARKETING AUTHORISATION LEADING TO AN EXTENSION AS REFERRED TO IN ANNEX I OF REGULATIONS (EC) NO 1234/2008 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 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

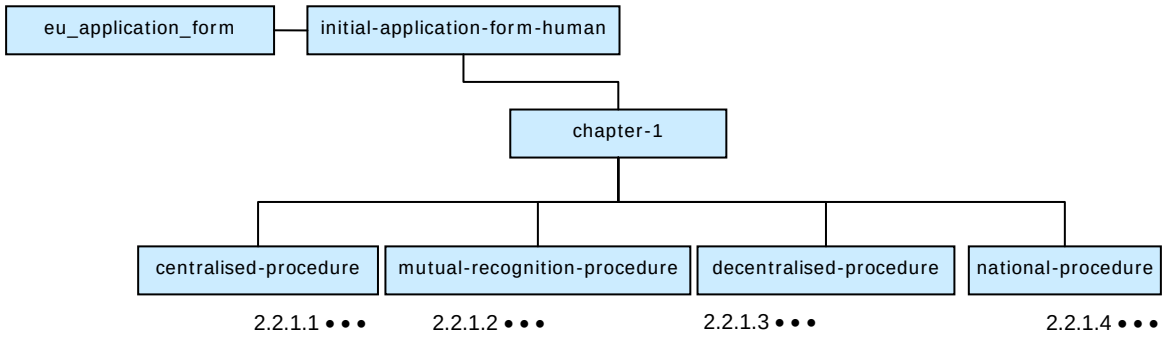
Element Tree Diagram



2.2. 1THIS 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 (1a) (Advanced Therapy Medicinal Product)	rdm:mandatory/rdm:advanced-therapy-medicinal-product/	Basis for Eligibility CTL	
E2211-5	Gene therapy medicinal product	rdm:mandatory/rdm:advanced-therapy-medicinal-product/rdm:atmp-type (Value = 1)	Basis for Eligibility CTL	
E2211-6	Somatic cell therapy medicinal product	rdm:mandatory/rdm:advanced-therapy-medicinal-product/rdm:atmp-type (Value = 2)	Basis for Eligibility CTL	
E2211-7	Tissue engineered product	rdm:mandatory/rdm:advanced-therapy-medicinal-product/rdm:atmp-type (Value = 3)	Basis for Eligibility CTL	
E2211-8	Combined Advanced Therapy Medicinal Product	rdm:mandatory/rdm:advanced-therapy-medicinal-product/product-is-also (Value = 1)	Basis for Eligibility CTL	
E2211-9	Annex (3) (New active substance for mandatory indications)	rdm:mandatory/rdm:annex (Value=2)	Basis for Eligibility CTL	B2211-2
E2211-10	Annex (4) (Orphan designated medicinal product)	rdm:mandatory/rdm:annex (Value=3)	Basis for Eligibility CTL	B2211-2
E2211-11	« Optional scope » (Article 3(2))	rdm:selected_scope (Value=2)	Basis for Eligibility CTL	B2211-1
E2211-12	Annex 3(2)(a) (New active substance)	rdm:optional-scope/rdm:annex (Value=1)	Basis for Eligibility CTL	B2211-3
E2211-13	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
E2211-14	« Generic of a Centrally Authorised Medicinal Product » (Article 3(3))	rdm:selected_scope (Value=3)	Basis for Eligibility CTL	B2211-1
E2211-15	« Marketing Authorisation including paediatric indication » (Article 28 of Regulation (EC) No 1901/2006)	rdm:selected_scope (Value=4)	Basis for Eligibility CTL	B2211-1
E2211-16	« Article 29 application » (Article 29 of Regulation (EC) No 1901/2006)	rdm:selected_scope (Value=5)	Basis for Eligibility CTL	B2211-1
E2211-17	« Paediatric Use Marketing Authorisation (PUMA) » (Article 31 of Regulation (EC) No 1901/2006)	rdm:selected_scope (Value=6)	Basis for Eligibility CTL	B2211-1
E2211-18	Date of acceptance/confirmation by CHMP:	rdm:article31/ rdm:date-of-acceptance	chmp acceptance date	
E2211-19	CHMP Rapporteur	rdm:non-atmp/ rdm:chmp-rapporteur_selected	Role > Party> Party Type CTL (Value="Person")	B2211-4
E2211-59	EMA Product Number	rdm:article31/ rdm:ema-product-number		B2211-14
E2211-20	Title	rdm:non-atmp/rdm:chmp-rapporteur/ rdm:personal-title	Role > Party > Person > Personal Title	B2211-4
E2211-21	First name	rdm:non-atmp/rdm:chmp-rapporteur/ rdm:given-name	Role > Party > Person > Given Name	B2211-4
E2211-22	Surname	rdm:non-atmp/rdm:chmp-rapporteur/ rdm:family-name	Role > Party > Person > Family Name	B2211-4
E2211-23	CHMP Co-Rapporteur:	rdm:non-atmp/ rdm:chmp-co-rapporteur_selected	Role > Party> Party Type CTL (Value="Person")	B2211-5
E2211-24	Title	rdm:non-atmp/rdm:chmp-co-rapporteur/ rdm:personal-title	Role > Party > Person > Personal Title	B2211-5
E2211-25	First name	rdm:non-atmp/rdm:chmp-co-rapporteur/ rdm:given-name	Role > Party > Person > Given Name	B2211-5
E2211-26	Surname	rdm:non-atmp/rdm:chmp-co-rapporteur/ rdm:family-name	Role > Party > Person > Family Name	B2211-5
E2211-27	PRAC Rapporteur	rdm:non-atmp/ rdm:prac-rapporteur_selected	Role > Party> Party Type CTL (Value="Person")	B2211-6
E2211-28	Title	rdm:non-atmp/rdm:prac-rapporteur/rdm:personal-title	Role > Party > Person > Personal Title	B2211-6

E2211-29	First name	rdm:non-atmp/rdm:prac-rapporteur/rdm:given-name	Role > Party > Person > Given Name	B2211-6
E2211-30	Surname	rdm:non-atmp/rdm:prac-rapporteur/rdm:family-name	Role > Party > Person > Family Name	B2211-6
E2211-31	PRAC Co-Rapporteur:	rdm:non-atmp/rdm:prac-co-rapporteur_selected	Role > Party> Party Type CTL (Value="Person")	B2211-7
E2211-32	Title	rdm:non-atmp/rdm:prac-co-rapporteur/rdm:personal-title	Role > Party > Person > Personal Title	B2211-7
E2211-33	First name	rdm:non-atmp/rdm:prac-co-rapporteur/rdm:given-name	Role > Party > Person > Given Name	B2211-7
E2211-34	Surname	rdm:non-atmp/rdm:prac-co-rapporteur/rdm:family-name	Role > Party > Person > Family Name	B2211-7
E2211-35	CAT Rapporteur	rdm:atmp/ rdm:cat-rapporteur_selected	Role > Party> Party Type CTL (Value="Person")	B2211-8
E2211-36	Title	rdm:atmp/rdm:cat-rapporteur/ rdm:personal-title	Role > Party > Person > Personal Title	B2211-8
E2211-37	First name	rdm:atmp/rdm:cat-rapporteur/ rdm:given-name	Role > Party > Person > Given Name	B2211-8
E2211-38	Surname	rdm:atmp/rdm:cat-rapporteur/ rdm:family-name	Role > Party > Person > Family Name	B2211-8
E2211-39	CAT Co-Rapporteur:	rdm:atmp/rdm:cat-co-rapporteur_selected	Role > Party> Party Type CTL (Value="Person")	B2211-9
E2211-40	Title	rdm:atmp/rdm:cat-co-rapporteur/rdm:personal-title	Role > Party > Person > Personal Title	B2211-9
E2211-41	First name	rdm:atmp/rdm:cat-co-rapporteur/rdm:given-name	Role > Party > Person > Given Name	B2211-9
E2211-42	Surname	rdm:atmp/rdm:cat-co-rapporteur/rdm:family-name	Role > Party > Person > Family Name	B2211-9
E2211-43	CHMP Coordinator	rdm:atmp / rdm:chmp-coordinator_selected	Role > Party> Party Type CTL (Value="Person")	B2211-10
E2211-44	Title	rdm:atmp /rdm: chmp-coordinator/ rdm:personal-title	Role > Party > Person > Personal Title	B2211-10
E2211-45	First name	rdm:atmp /rdm: chmp-coordinator/rdm:given-name	Role > Party > Person > Given Name	B2211-10
E2211-46	Surname	rdm:atmp /rdm: chmp-coordinator/rdm:family-name	Role > Party > Person > Family Name	B2211-10
E2211-47	CHMP Co-Coordinator	rdm:atmp /rdm:chmp-co-coordinator _selected	Role > Party> Party Type CTL (Value="Person")	B2211-11
E2211-48	Title	rdm:atmp/rdm:chmp-co-coordinator/rdm:personal-title	Role > Party > Person > Personal Title	B2211-11
E2211-49	First name	rdm:atmp/rdm:chmp-co-coordinator/rdm:given-name	Role > Party > Person > Given Name	B2211-11
E2211-50	Surname	rdm:atmp/chmp-co-coordinator/ rdm:family-name	Role > Party > Person > Family Name	B2211-11
E2211-51	PRAC Rapporteur	rdm:atmp/rdm:prac-rapporteur_selected	Role > Party> Party Type CTL (Value="Person")	B2211-12
E2211-52	Title	rdm:atmp/rdm:prac-rapporteur/ rdm:personal-title	Role > Party > Person > Personal Title	B2211-12
E2211-53	First name	rdm:atmp/rdm:prac-rapporteur/ rdm:given-name	Role > Party > Person > Given Name	B2211-12
E2211-54	Surname	rdm:atmp/rdm:prac-rapporteur/ rdm:family-name	Role > Party > Person > Family Name	B2211-12
E2211-55	PRAC Co-Rapporteur	rdm:atmp/ rdm:prac-co-rapporteur_selected	Role > Party> Party Type CTL (Value="Person")	B2211-13
E2211-56	Title	rdm:atmp/rdm:prac-co-rapporteur/ rdm:personal-title	Role > Party > Person > Personal Title	B2211-13
E2211-57	First name	rdm:atmp/rdm:prac-co-rapporteur/ rdm:given-name	Role > Party > Person > Given Name	B2211-13
E2211-58	Surname	rdm:atmp/rdm:prac-co-rapporteur/ rdm:family-name	Role > Party > Person > Family Name	B2211-13

Element Tree Diagram

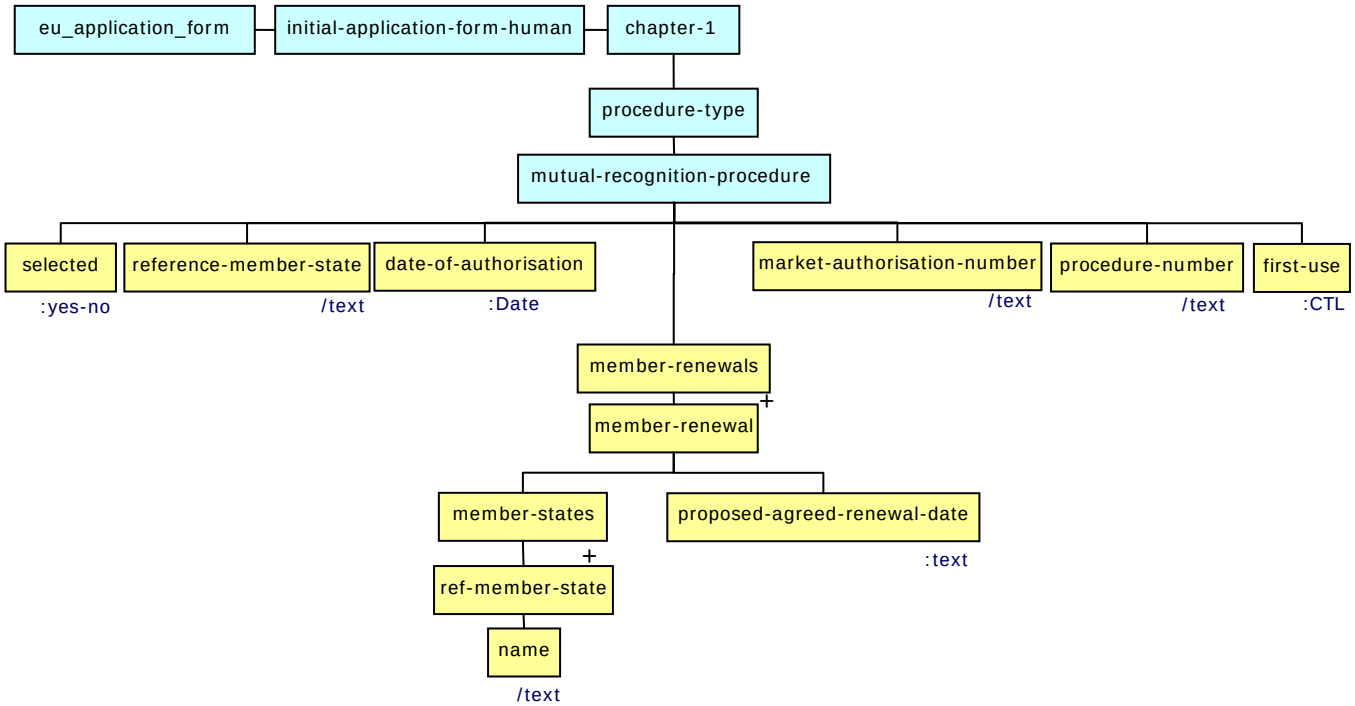
Business Rules

Rule ID	Element id(s)	Default BR	Rule	Effect(s)
B2211-1	E2211-2, E2211-11, E2211-14 to E2211-17	Mandatory.	Fields are mutually exclusive.	Can only have one of them active at a time.
B2211-2	E2211-3 to E2211-10	Mandatory if E2211-2 is selected.	Fields are mutually exclusive.	Can only have one of them active at a time.
B2211-3	E2211-12, E2211-13	Mandatory if E2211-11 is selected.	Fields are mutually exclusive.	Can only have one of them active at a time.
B2211-4	E2211-19, E2211-20 to E2211-22	E2211-19 is mandatory.	If E2211-19, then E2211-20 to E2211-22 are mandatory.	
B2211-5	E2211-23, E2211-24 to E2211-26	E2211-23 is mandatory, rest are optional.	If E2211-23, then E2211-24 to E2211-26 are mandatory.	
B2211-6	E2211-27, E2211-28 to E2211-30	E2211-27 is mandatory.	If E2211-27, then E2211-28 to E2211-30 are mandatory.	
B2211-7	E2211-31, E2211-32 to E2211-34	All are optional.	If E2211-31, then E2211-32 to E2211-34 are mandatory.	
B2211-8	E2211-35, E2211-36 to E2211-38	E2211-35 is mandatory.	If E2211-35, then E2211-36 to E2211-38 are mandatory.	
B2211-9	E2211-39, E2211-40 to E2211-42	E2211-39 is mandatory, rest are optional.	If E2211-39, then E2211-40 to E2211-42 are mandatory.	
B2211-10	E2211-43, E2211-44 to E2211-46	E2211-43 is mandatory.	If E2211-43, then E2211-44 to E2211-46 are mandatory.	
B2211-11	E2211-47, E2211-48 to E2211-50	E2211-47 is mandatory, rest are optional.	If E2211-47, then E2211-48 to E2211-50 are mandatory.	
B2211-12	E2211-51, E2211-52 to E2211-54	E2211-51 is mandatory.	If E2211-51, then E2211-52 to E2211-54 are mandatory.	
B2211-13	E2211-55, E2211-56 to E2211-58	All are optional.	If E2211-55, then E2211-56 to E2211-58 are mandatory.	
B2211-14	E2211-59	Optional		

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	
E2212-7	Repeat use (Please also complete section 4.2)	rdm:first-use (Value=2)	Procedure Use CTL	
E2212-8	Wave	rdm:member-renewals/rdm:member-renewal	Procedure Use > waive id	
E2212-9	Concerned Member State (specify)	rdm:member-renewals/ rmd:member-renewal/ rdm:member-states/ rdm:ref-member-state/rdm:name	Procedure Use > Role > Country CTL	
E2212-10	Proposed/Agreed common renewal date	rdm:member-renewals/ rmd:member-renewal/ rdm:proposed-agreed-renewal-date	Procedure Use > Proposed / agreed common renewal date	

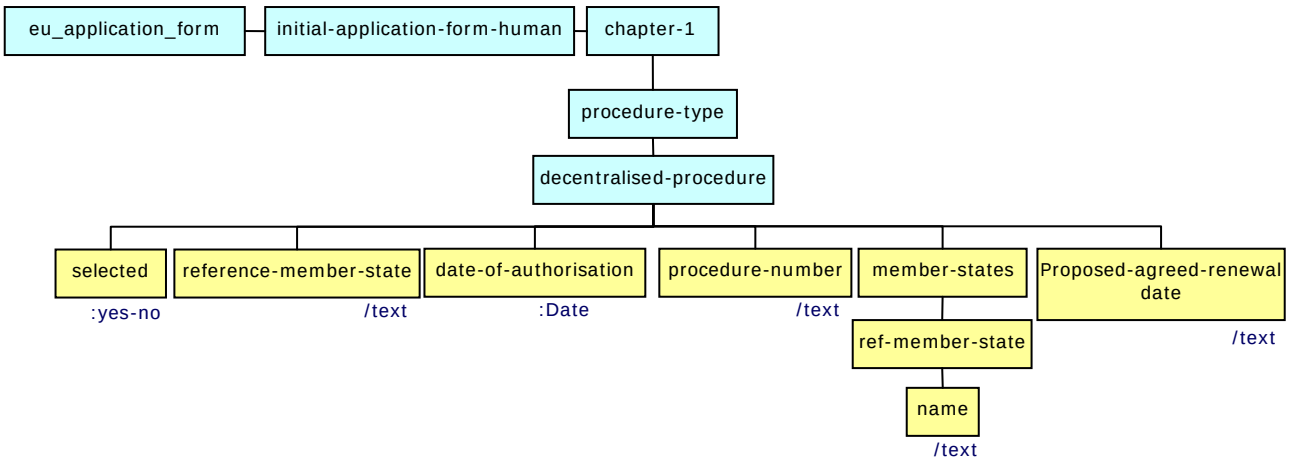
Element Tree Diagram



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	
E213-6	Proposed/Agreed common Reewal Date	rdm:proposed-agreed-renewal-date		

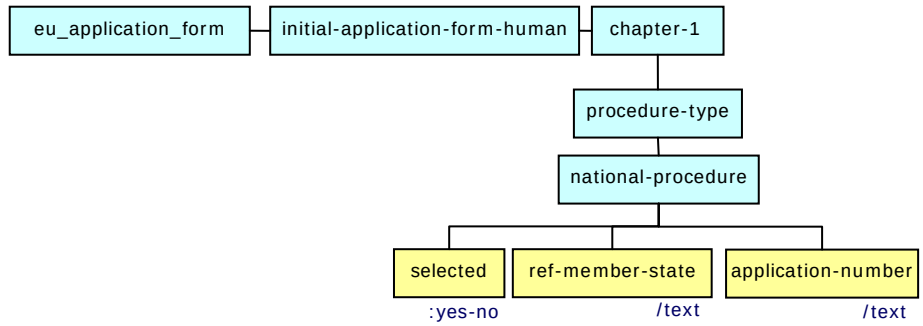
Element Tree Diagram



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	Member State	rdm:ref-member-state	Role > Country CTL	
E2214-3	Application number (if available)	rdm:application-number	previous app number	

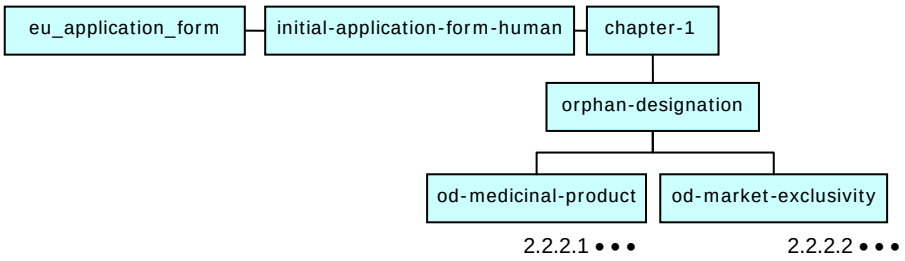
Element Tree Diagram



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

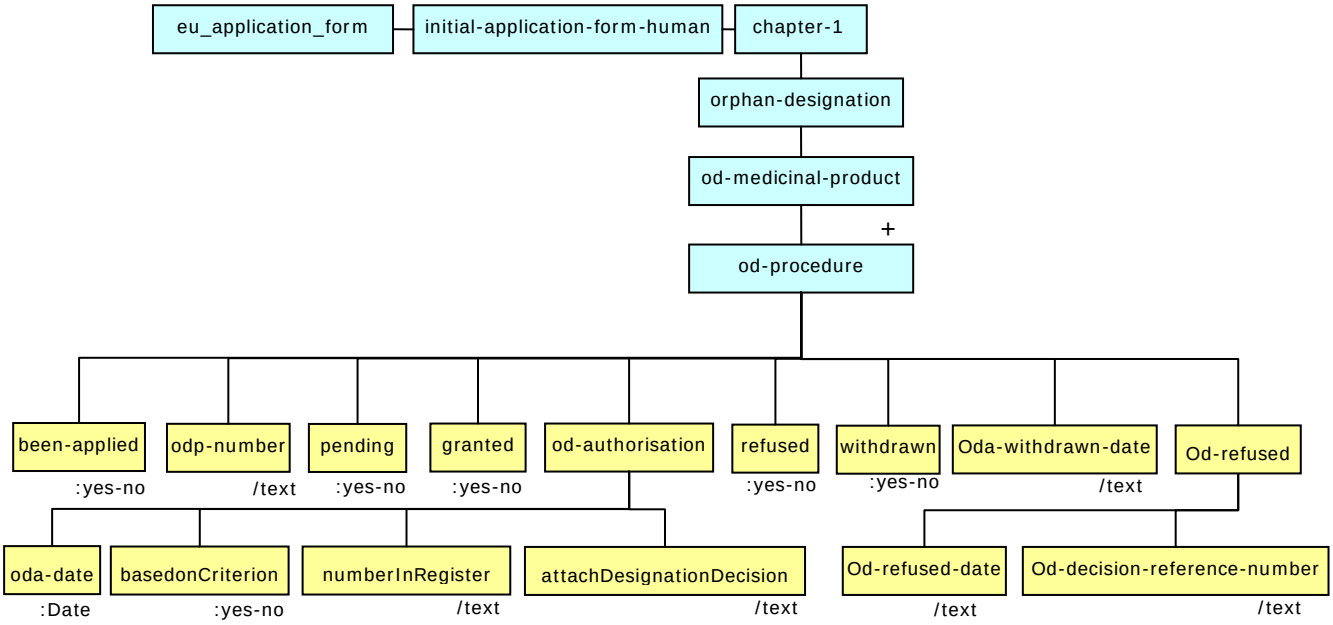
Element Tree Diagram



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/maa:od-procedure		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-numbers/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:od-authorisation/ rdm:basedOnCriterion (Value=1)	is based significant benefit	B2221-4, B2221-5
E2221-9	No	rdm:od-authorisation/ rdm:basedOnCriterion (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:numberInRegister	od community reg number	B2221-4
E2221-11	Attach copy of the Designation Decision (Annex 5.18)	rdm:od-authorisation/ rdm:attachedDesignationDecision		B2221-4
E2221-12	Orphan Designation Refused	rdm:od-refused	Authorisation Status CTL	B2221-2, B2221-3, B2221-6
E2221-13	Date:	rdm:od-refused /rdm:od-refused-date	od status date	B2221-6
E2221-14	Commission decision reference number:	rdm:od-refused /rdm:od-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:oda-withdrawn-date	Od status date	B2221-7

Element Tree Diagram



Business Rules

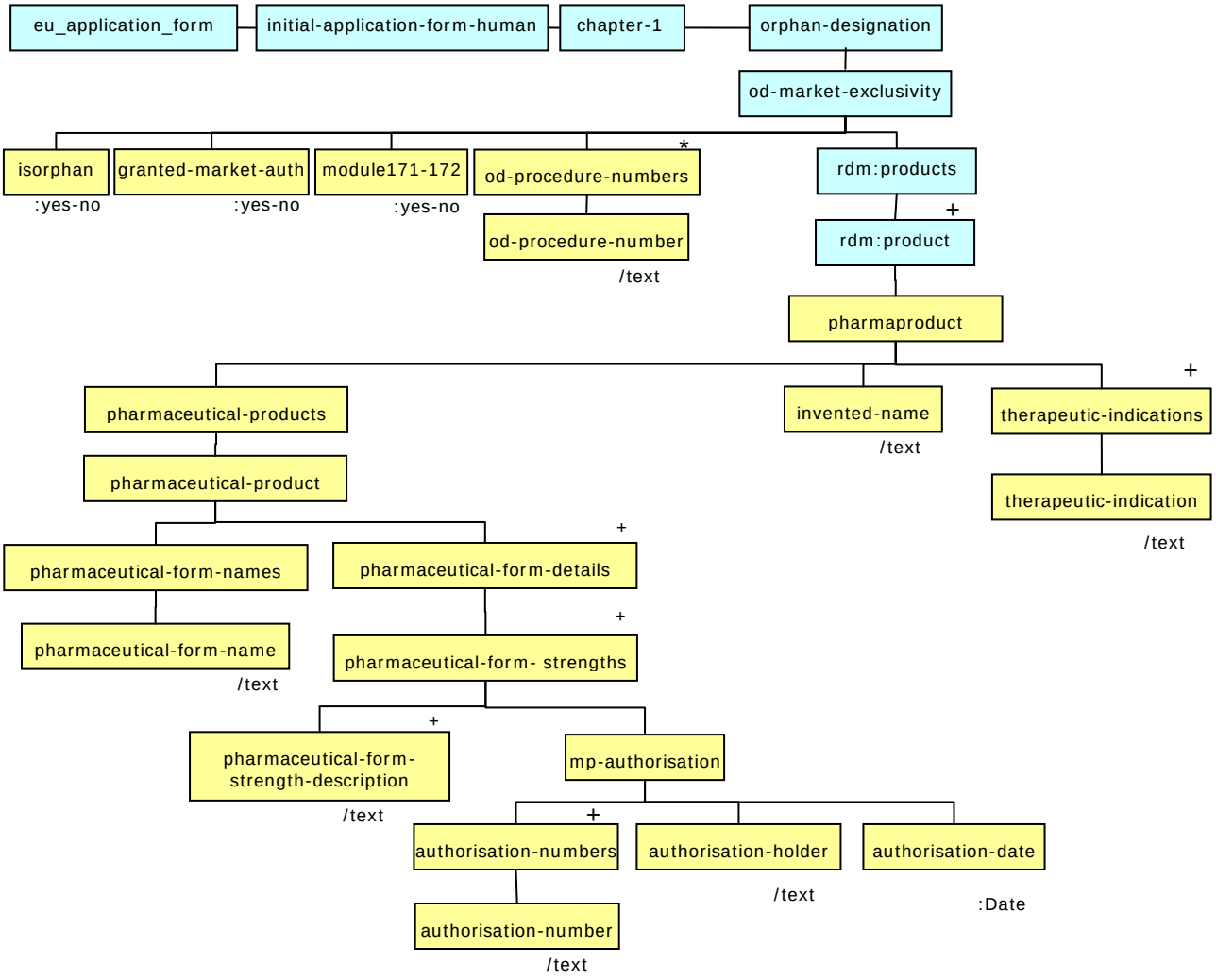
Rule ID	Element id(s)	Default BR	Rule	Effect(s)
B2221-1	E2221-1, E2221-2	Mandatory.	Mutually exclusive.	
B2221-2	E2221-1, E2221-3 to E2221-5, E2221-12,E2221-15	E2221-1 is mandatory, rest are optional.	If E2221-1, then the rest is mandatory, else they are optional.	
B2221-3	E2221-4, E2221-5, E2221-12,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

2.2.2.2 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	Therapeutic indication(s)	rdm:products/rdm:product/ rdm:pharmaproduct/rdm:therapeutic-indications/rdm:therapeutic-indication		B2222-4
E2222-9	Product (invented) name	rdm:products/rdm:product/rdm:pharmaproduct/rdm:invented-name	Reference Medicinal Product > Medicinal Product > Pharmaceutical Product > Ingredient >Substance	B2222-4
E2222-10	Pharmaceutical form(s)	rdm:products/rdm:product/ rdm:pharmaproduct/rdm: pharmaceutical-products/rdm: pharmaceutical-product / rdm: pharmaceutical-form-names/rdm: pharmaceutical-form-name	Reference Medicinal Product > Medicinal Product > Pharmaceutical Dose Form CTL	B2222-4
E2222-11	Strength(s)	rdm:products/rdm:product/rdm: pharmaproduct/ rdm: pharmaceutical-products/rdm: pharmaceutical-product /rdm: pharmaceutical-form-details/rdm: pharmaceutical-form-strengths/rdm: pharmaceutical-form-strength-description	Reference Medicinal Product > Medicinal Product > Pharmaceutical Product > Ingredient	B2222-4
E2222-12	Marketing authorisation holder	rdm:products/rdm:product/rdm: pharmaproduct/ rdm: pharmaceutical-products/rdm: pharmaceutical-product /rdm: pharmaceutical-form-details/rdm: pharmaceutical-form-strengths /rdm:mp-authorisation/ rdm:authorisation-holder	Role > Party > Organisation > Name	B2222-4
E2222-13	Marketing authorisation number	rdm:products/rdm:product/rdm: pharmaproduct/ rdm: pharmaceutical-products/rdm: pharmaceutical-product /rdm: pharmaceutical-form-details/rdm: pharmaceutical-form-strengths /rdm:mp-authorisation/ rdm:authorisation-numbers/rdm:authorisation-number	MP Authorisation > authorization number	B2222-4
E2222-14	Date of authorisation	rdm:products/rdm:product/rdm: pharmaproduct/ rdm: pharmaceutical-products/rdm: pharmaceutical-product /rdm: pharmaceutical-form-details/rdm: pharmaceutical-form-strengths/ rdm:mp-authorisation/ rdm:authorisation-date	MP Authorisation > authorization date	B2222-4
E2222-15	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
E2222-16	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

E2222-17	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



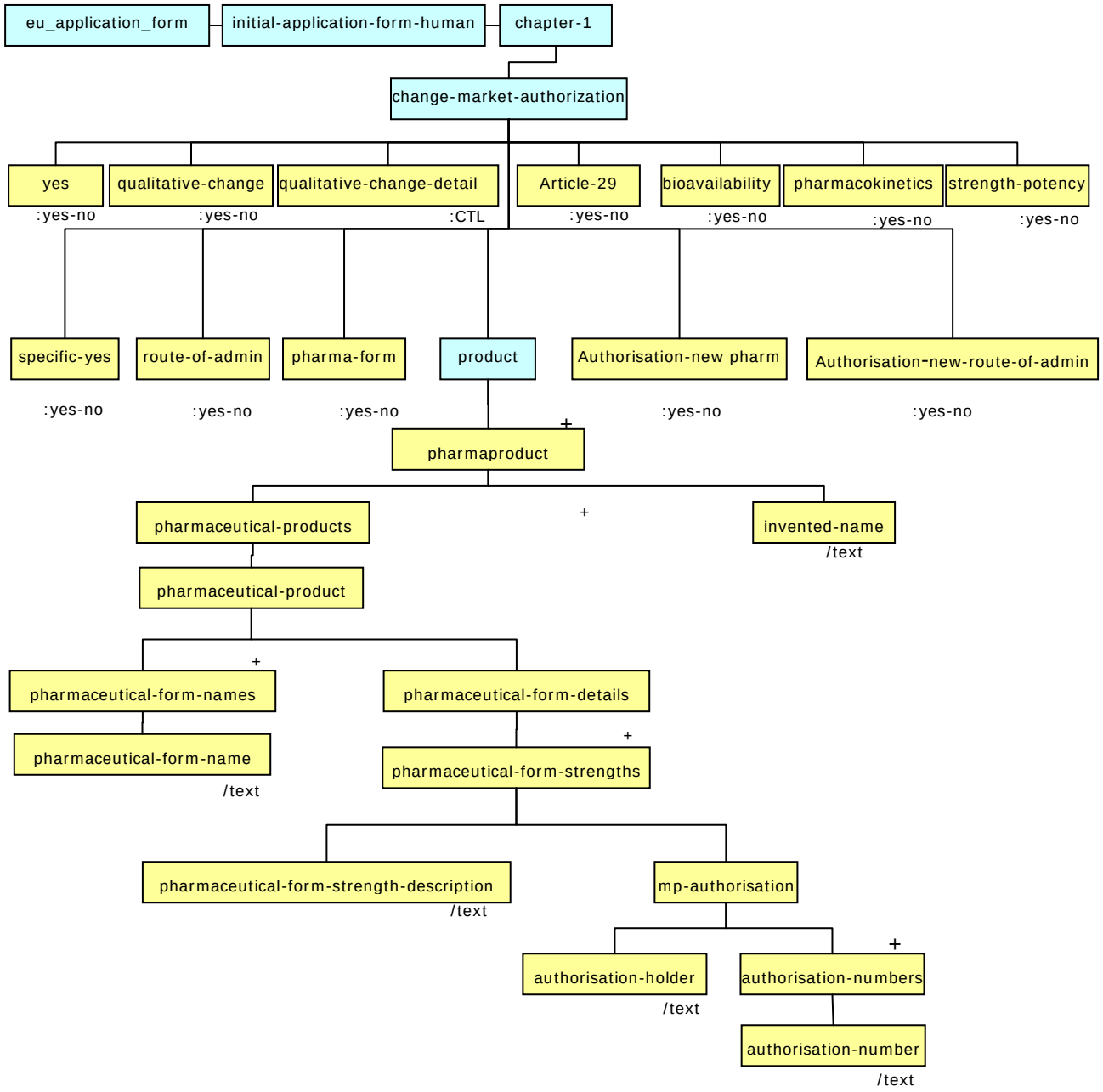
Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2222-1	E2222-1, E2222-2	Mandatory.	Mutually exclusive.	
B2222-2	E2222-1, E2222-3 to E2222-6	Mandatory for E2222-1, optional for the rest.	If E2222-1 is selected, the rest is mandatory.	
B2222-3	E2222-5, E2222-6	Optional.	Mutually Exclusive.	
B2222-4	E2222-5, E2222-8 - E2222-17	Optional.	If E2222-5 is selected, the rest is mandatory.	
B2222-5	E2222-16, E2222-17	Optional.	Mutually exclusive.	

2.2. 3 APPLICATION FOR A CHANGE TO EXISTING MARKETING AUTHORISATION LEADING TO AN EXTENSION AS REFERRED TO IN ANNEX I OF REGULATIONS (EC) NO 1234/2008, 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	« Article 29 application » (Article 29 of Regulation (EC) No 1901/2006)	maa:article-29		B223-2
E223-17	Authorization of a new pharmaceutical form	maa:authorisation-new-pharma-form		
E223-18	Authorization of a new route of administration	Maa:authorisation-new-route-of-admin		
E223-19	Product (invented) name	maa:product/ rdm:pharmaproduct/ rdm:invented-name	Reference Medicinal Product > Medicinal Product>Pharmaceutical Product>Ingredient>Substance	B223-2
E223-20	Pharmaceutical form(s)	maa:product/ rdm:pharmaproduct/rdm:pharmaceutical-products/ rdm:pharmaceutical-product / rdm:pharmaceutical-form-names/rdm:pharmaceutical-form-name	Reference Medicinal Product > Medicinal Product > Pharmaceutical Dose Form CTL	B223-2
E223-21	Strength(s)	maa:product/ rdm:pharmaproduct/rdm:pharmaceutical-products/ rdm:pharmaceutical-product/ rdm:pharmaceutical-form-details/rdm:pharmaceutical-form-strengths/rdm:	Reference Medicinal Product > Medicinal Product > Pharmaceutical Product > Ingredient	B223-2

		pharmaceutical-form-strength-description		
E223-22	Marketing authorisation holder	maa:product/ rdm:pharmaproduct/rdm:pharmaceutical-products/ rdm:pharmaceutical-product / rdm:pharmaceutical-form-details/rdm:pharmaceutical-form-strengths /rdm:mp-authorisation/rdm:authorisation-holder	Role > Party > Organisation > Name	B223-2
E223-23	Marketing authorisation number	maa:product/ rdm:pharmaproduct/rdm:pharmaceutical-products/ rdm:pharmaceutical-product / rdm:pharmaceutical-form-details/rdm:pharmaceutical-form-strengths/rdm:mp-authorisation/rdm:authorisation-numbers/rdm:authorisation-number	MP Authorisation > authorization number	B223-2

Element Tree Diagram



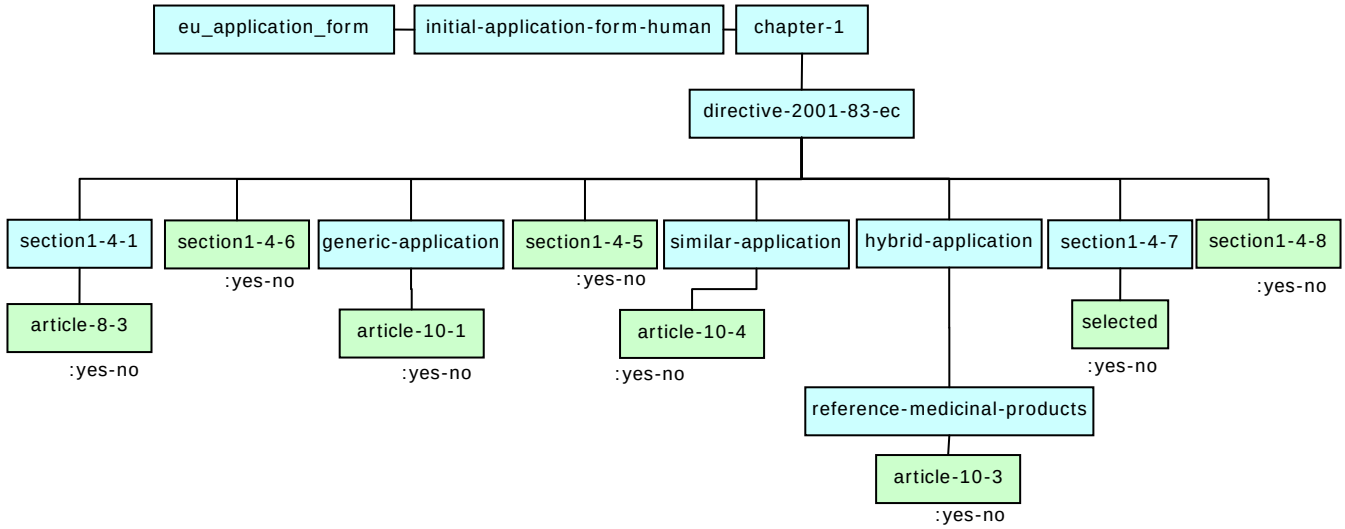
Business Rules

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 E223-23	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. 4 APPLICATION 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



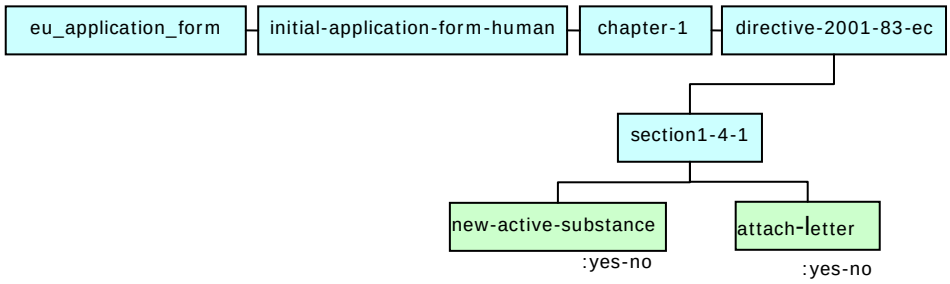
Business Rules

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.	

2.2.4.1 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/maa:attach-letter		
E2241-2	please provide evidence and justification to support the claim of new active substance status in annex 5.23	maa:attach-letter		

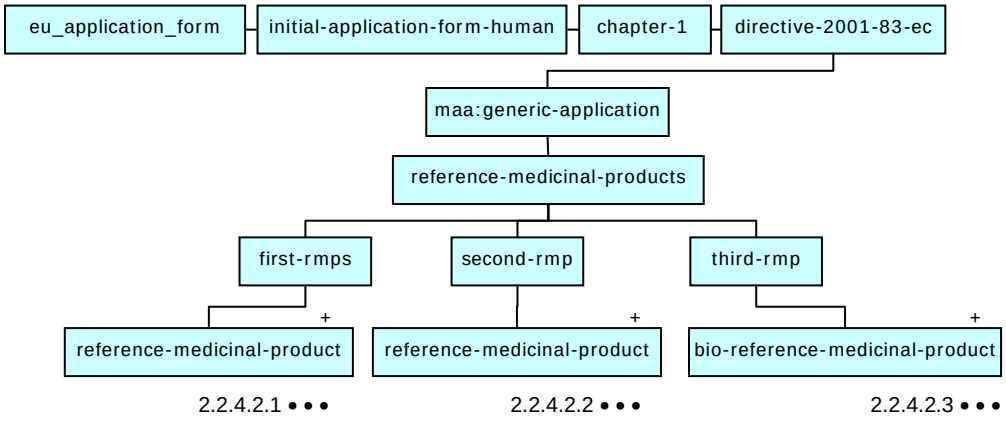
Element Tree Diagram



2.2.4.2 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 Union 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 Union provisions in force for not less than 6/8/10 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 Union/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

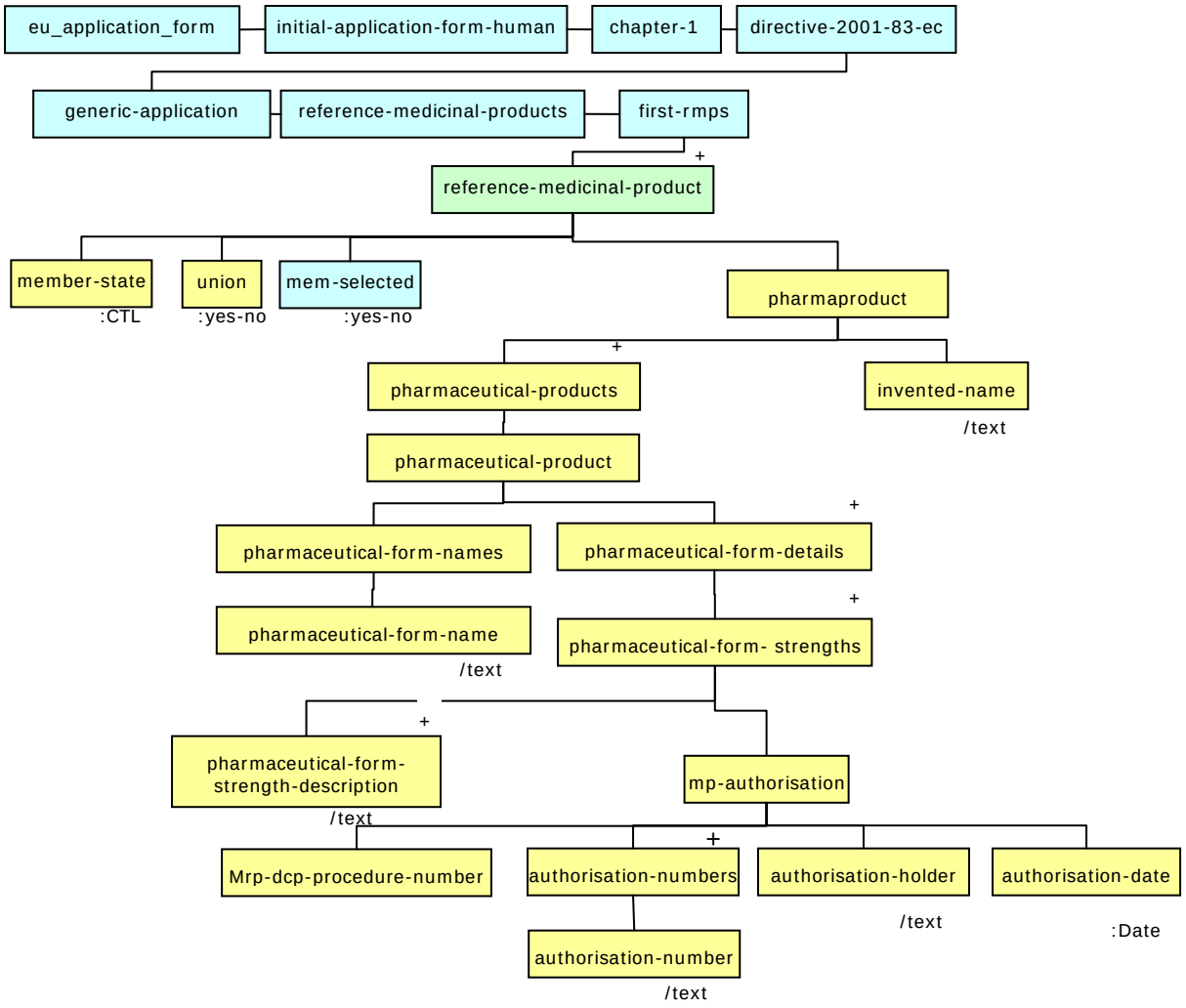


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2242-1	E224-3, E2242-4, E2242-5	E224-3 is mandatory. rest are optional.	When E224-3 is selected, then the rest are mandatory	

2.2.4.2.1 Medicinal product which is or has been authorised in accordance with Union provisions in force for not less than 6/8/10 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:pharmaproduct/rdm:invented-name	Reference Medicinal Product > Medicinal Product > Medicinal Product Name	
E22421-2	Pharmaceutical form(s)	rdm:pharmaproduct/rdm: pharmaceutical-products/rdm: pharmaceutical-product / rdm: pharmaceutical-form-names/rdm: pharmaceutical-form-name	Reference Medicinal Product > Medicinal Product > Pharmaceutical Product > Pharmaceutical Dose Form CTL	
E22421-3	Strength(s)	rdm: pharmaproduct/ rdm: pharmaceutical-products/rdm: pharmaceutical-product /rdm: pharmaceutical-form-details/rdm: pharmaceutical-form-strengths/rdm: pharmaceutical-form-strength-description	Ingredient	
E22421-4	Marketing authorisation holder	rdm: pharmaproduct/ rdm: pharmaceutical-products/rdm: pharmaceutical-product /rdm: pharmaceutical-form-details/rdm: pharmaceutical-form-strengths /rdm:mp-authorisation/ rdm:authorisation-holder	Role > Party> Organisation> Name	
E22421-5	Marketing authorisation number	rdm: pharmaproduct/ rdm: pharmaceutical-products/rdm: pharmaceutical-product /rdm: pharmaceutical-form-details/rdm: pharmaceutical-form-strengths /rdm:mp-authorisation/ rdm:authorisation-numbers/rdm:authorisation-number	MP Authorisation > authorisation number	
E22421-12	Procedure number for MRP/DCP (if applicable)	rdm: pharmaproduct/ rdm: pharmaceutical-products/rdm: pharmaceutical-product /rdm: pharmaceutical-form-details/rdm: pharmaceutical-form-strengths /rdm:mp-authorisation/ rdm:authorisation-numbers/rdm:mrp-dcp-procedure-number		
E22421-6	Date of authorisation	rdm: pharmaproduct/ rdm: pharmaceutical-products/rdm: pharmaceutical-product /rdm: pharmaceutical-form-details/rdm: pharmaceutical-form-strengths/ rdm:mp-authorisation/ rdm:authorisation-date	MP Authorisation > authorisation date	
E22421-7	Marketing authorisation granted by			
E22421-8	Union	rdm:community	MP Authorisation > Country CTL	B22421-1
E22421-9	Member State(EEA)	rdm:mem-selected		B22421-1, B22421-2
E22421-10	Member State(EEA)	rdm:member-state	MP Authorisation > Country CTL	B22421-2
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

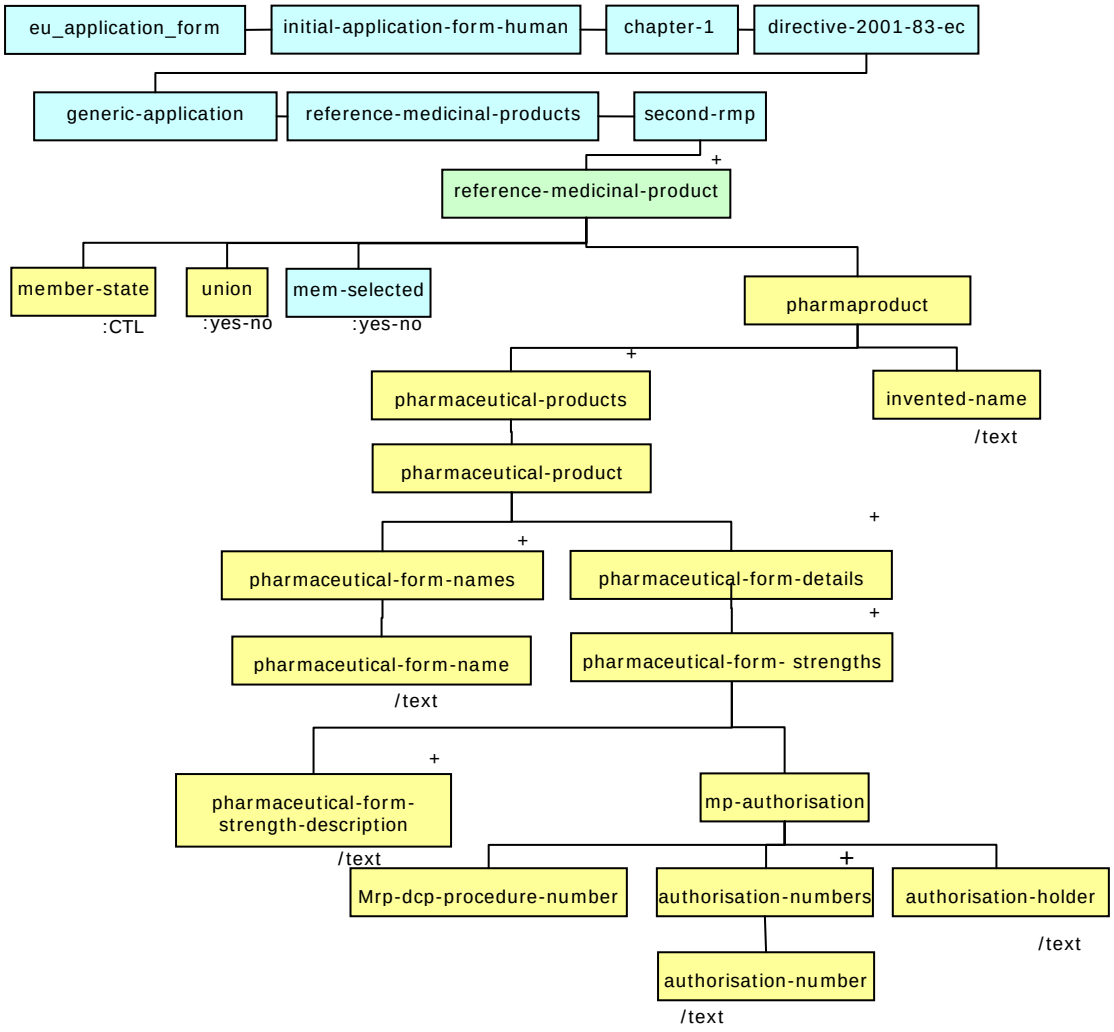


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B22421-1	E22421-8 to 9	Optional	Mutually Exclusive	
B22421-2	E22421-9 to 10	Optional	If E22421-9 is selected, then E22421-10 is required	
B22421-3	E22421-12	Optional		

2.2.4.2.2 Medicinal product authorised in the Union/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:pharmaproduct/rdm:invented-name	Reference Medicinal Product > Medicinal Product > Medicinal Product Name	
E22422-2	Pharmaceutical form(s)	rdm:pharmaproduct/rdm: pharmaceutical-products/rdm: pharmaceutical-product / rdm: pharmaceutical-form-names/rdm: pharmaceutical-form-name	Reference Medicinal Product > Medicinal Product > Pharmaceutical Product > Pharmaceutical Dose Form CTL	
E22422-3	Strength(s)	rdm: pharmaproduct/ rdm: pharmaceutical-products/rdm: pharmaceutical-product /rdm: pharmaceutical-form-details/rdm: pharmaceutical-form-strengths/rdm: pharmaceutical-form-strength-description	Ingredient	
E22422-4	Marketing authorisation holder	rdm: pharmaproduct/ rdm: pharmaceutical-products/rdm: pharmaceutical-product /rdm: pharmaceutical-form-details/rdm: pharmaceutical-form-strengths /rdm:mp-authorisation/ rdm:authorisation-holder	Role > Party> Organisation> Name	
E22422-5	Marketing authorisation number	rdm: pharmaproduct/ rdm: pharmaceutical-products/rdm: pharmaceutical-product /rdm: pharmaceutical-form-details/rdm: pharmaceutical-form-strengths /rdm:mp-authorisation/ rdm:authorisation-numbers/rdm:authorisation-number	MP Authorisation > authorisation number	
E22422-10	Procedure number for MRP/DCP (if applicable)	rdm: pharmaproduct/ rdm: pharmaceutical-products/rdm: pharmaceutical-product /rdm: pharmaceutical-form-details/rdm: pharmaceutical-form-strengths /rdm:mp-authorisation/ rdm:authorisation-numbers /rdm:mrp-dcp-procedure-number		
E22422-6	Marketing authorisation granted by			
E22422-7	Union	rdm:community	MP Authorisation > Country CTL	B22422-2
E22422-8	Member State(EEA)	rdm:mem-selected		B22422-2, B22422-3
E22422-9	Member State(EEA)	rdm:member-state	MP Authorisation > Country CTL	B22422-3

Element Tree Diagram

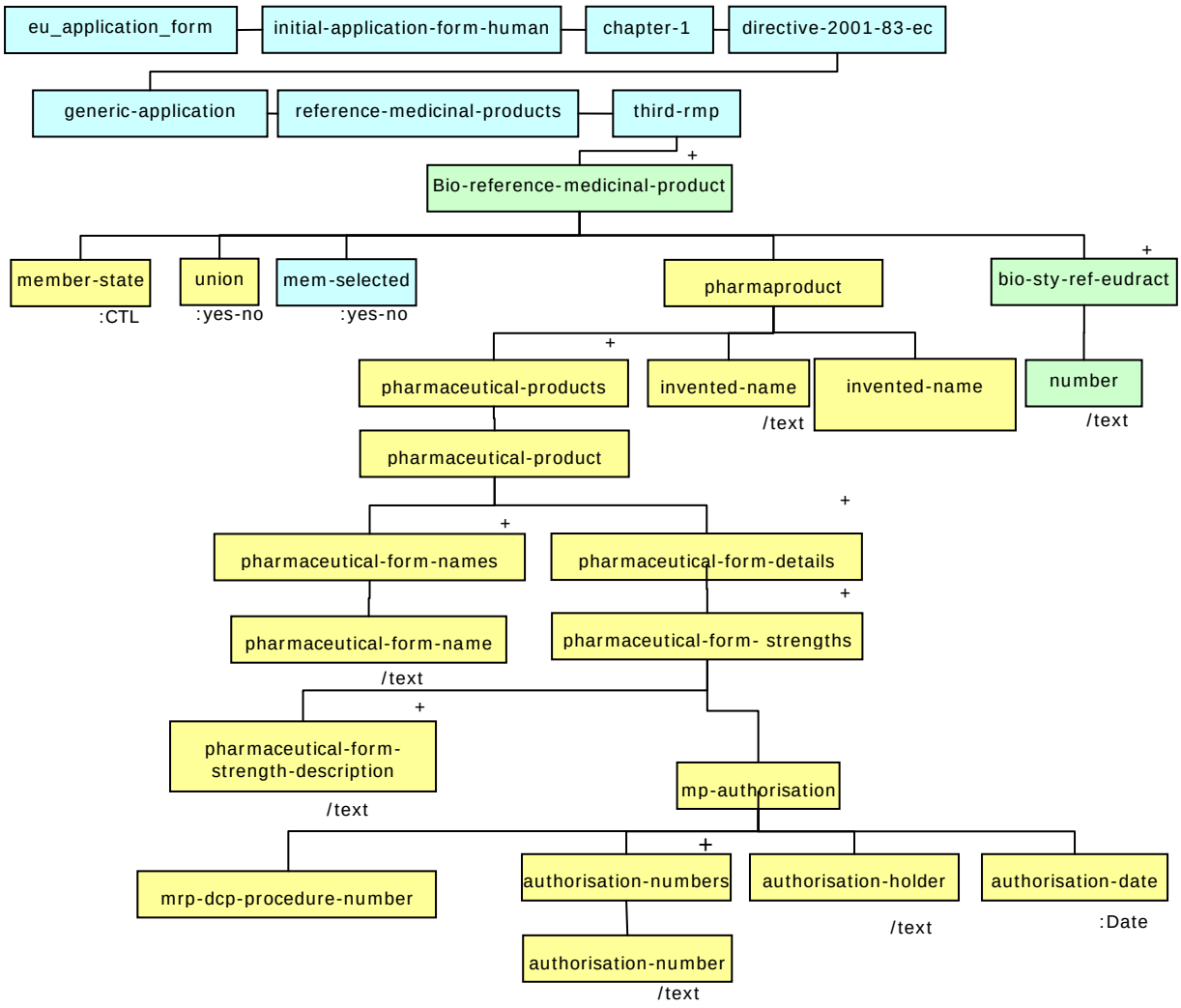


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B22422-1	E22422-10,	E22422-10, is not visible.	When E221-2 or E221-3 is selected, then E22422-10 is visible and mandatory	
B22422-2	E22422-7 to 8	Optional	Mutually Exclusive	
B22422-3	E22422-8 to 9	Optional	If E22422-8 is selected, then E22422-9 is required	
B22422-4	E22422-10	Optional		

2.2.4.2.3 Medicinal product which is or has been authorised in accordance with Union 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:pharmaproduct/rdm:invented-name	Reference Medicinal Product > Medicinal Product > Medicinal Product Name	
E22423-3	Pharmaceutical form(s)	rdm:pharmaproduct/rdm: pharmaceutical-products/rdm: pharmaceutical-product / rdm: pharmaceutical-form-names/rdm: pharmaceutical-form-name	Reference Medicinal Product > Medicinal Product > Pharmaceutical Product > Pharmaceutical Dose Form CTL	
E22423-4	Strength(s)	rdm: pharmaproduct/ rdm: pharmaceutical-products/rdm: pharmaceutical-product /rdm: pharmaceutical-form-details/rdm: pharmaceutical-form-strengths/rdm: pharmaceutical-form-strength-description	Ingredient	
E22423-5	Marketing authorisation holder	rdm: pharmaproduct/ rdm: pharmaceutical-products/rdm: pharmaceutical-product /rdm: pharmaceutical-form-details/rdm: pharmaceutical-form-strengths /rdm:mp-authorisation/ rdm:authorisation-holder	Role > Party> Organisation> Name	
E22423-6	Marketing authorisation number	rdm: pharmaproduct/ rdm: pharmaceutical-products/rdm: pharmaceutical-product /rdm: pharmaceutical-form-details/rdm: pharmaceutical-form-strengths /rdm:mp-authorisation/ rdm:authorisation-numbers/rdm:authorisation-number	MP Authorisation > authorisation number	
E22423-14	Procedure number for MRP/DCP (if applicable)	rdm: pharmaproduct/ rdm: pharmaceutical-products/rdm: pharmaceutical-product /rdm: pharmaceutical-form-details/rdm: pharmaceutical-form-strengths /rdm:mp-authorisation/ rdm:authorisation-numbers rdm:mrp-dcp-procedure-number		
E22423-7	Date of authorisation	rdm: pharmaproduct/ rdm: pharmaceutical-products/rdm: pharmaceutical-product /rdm: pharmaceutical-form-details/rdm: pharmaceutical-form-strengths/ rdm:mp-authorisation/ rdm:authorisation-date	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	Union	rdm:community	MP Authorisation > Country CTL	B22423-1
E22423-12	Member State(EEA)	rdm:mem-selected		B22423-1
E22423-13	Member State(EEA)	rdm:member-state	MP Authorisation > Country CTL	B22423-2

Element Tree Diagram

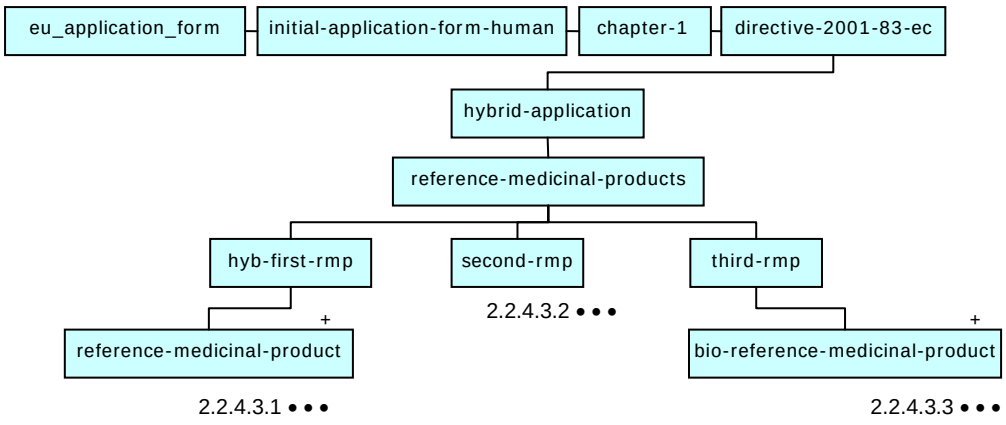


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B22423-1	E22423-11 to 12	Optional	Mutually Exclusive	
B22423-2	E22423-12 to 13	Optional	If E22423-12 is selected, then E22423-13 is required	
B22423-3	E22423-14	Optional		

2.2.4.3 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 the Union (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 Union 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 Union 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 Union/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 Union 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

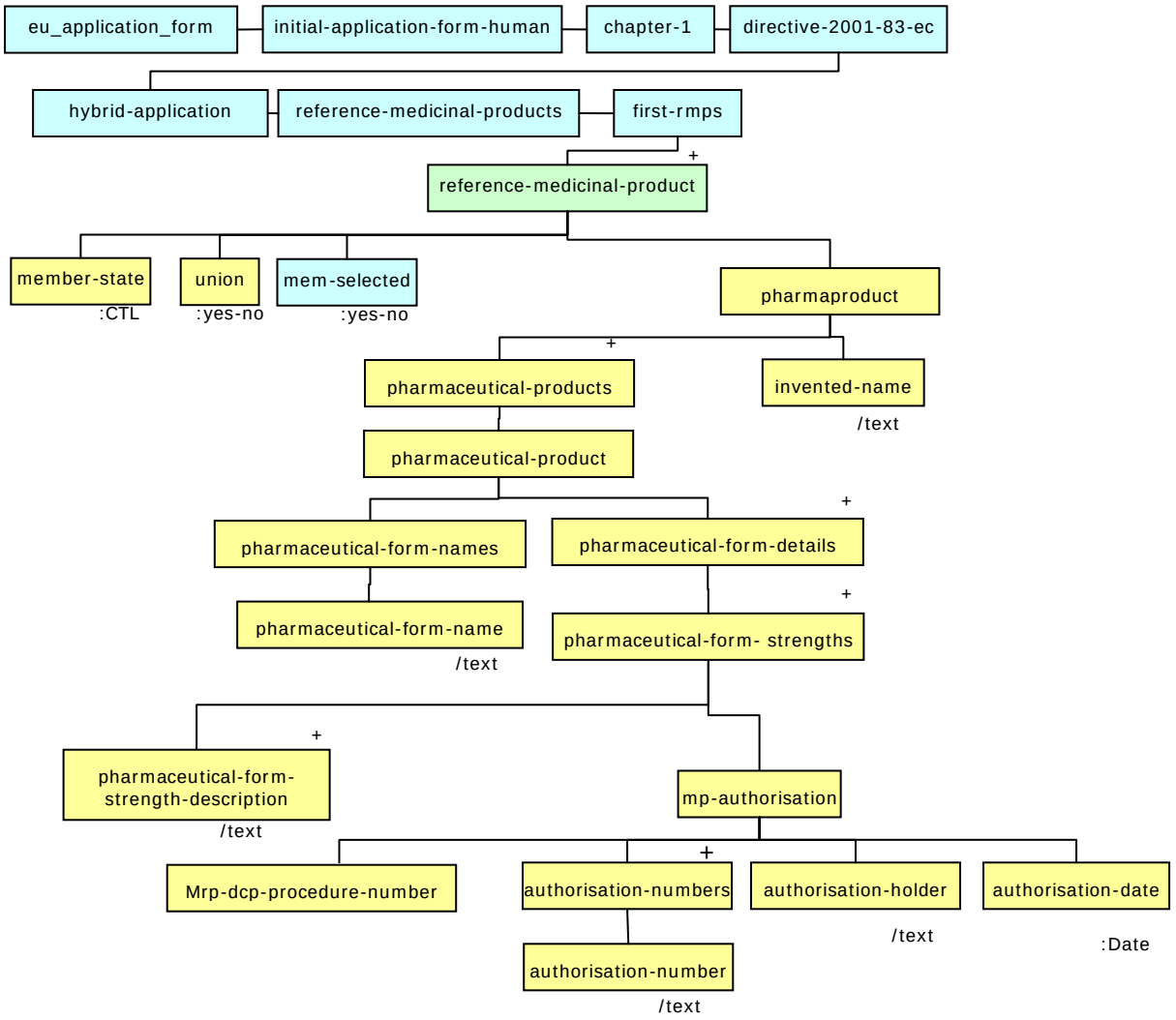


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2243-1	E224-4, E2243-4 to E2243-5	E224-4 is mandatory. rest are optional.	When E224-4 is selected, then the rest are mandatory.	

2.2.4.3.1 Medicinal product which is or has been authorised in accordance with Union provisions in force for not less than 6/8/10 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:pharmaproduct/rdm:invented-name	Reference Medicinal Product > Medicinal Product > Medicinal Product Name	
E22431-3	Pharmaceutical form(s)	rdm:pharmaproduct/rdm: pharmaceutical-products/rdm: pharmaceutical-product / rdm: pharmaceutical-form-names/rdm: pharmaceutical-form-name	Reference Medicinal Product > Medicinal Product > Pharmaceutical Product > Pharmaceutical Dose Form CTL	
E22431-4	Strength(s)	rdm: pharmaproduct/ rdm: pharmaceutical-products/rdm: pharmaceutical-product /rdm: pharmaceutical-form-details/rdm: pharmaceutical-form-strengths/rdm: pharmaceutical-form-strength-description	Ingredient	
E22431-5	Marketing authorisation holder	rdm: pharmaproduct/ rdm: pharmaceutical-products/rdm: pharmaceutical-product /rdm: pharmaceutical-form-details/rdm: pharmaceutical-form-strengths /rdm:mp-authorisation/ rdm:authorisation-holder	Role > Party> Organisation> Name	
E22431-12	Procedure number for MRP/DCP (if applicable)	rdm: pharmaproduct/ rdm: pharmaceutical-products/rdm: pharmaceutical-product /rdm: pharmaceutical-form-details/rdm: pharmaceutical-form-strengths /rdm:mp-authorisation/ /rdm:mrp-dcp-procedure-number		
E22431-6	Marketing authorisation number	rdm: pharmaproduct/ rdm: pharmaceutical-products/rdm: pharmaceutical-product /rdm: pharmaceutical-form-details/rdm: pharmaceutical-form-strengths /rdm:mp-authorisation/ rdm:authorisation-numbers/rdm:authorisation-number	MP Authorisation > authorisation number	
E22431-7	Date of authorisation	rdm: pharmaproduct/ rdm: pharmaceutical-products/rdm: pharmaceutical-product /rdm: pharmaceutical-form-details/rdm: pharmaceutical-form-strengths/ rdm:mp-authorisation/ rdm:authorisation-date	MP Authorisation > authorisation date	
E22431-8	Marketing authorisation granted by			
E22431-9	Union	rdm:community	MP Authorisation > Country CTL	B22431-1
E22431-10	Member State(EEA)	rdm:mem-selected		B22431-1, B22431-2
E22431-11	Member State(EEA)	rdm:member-state	MP Authorisation > Country CTL	B22431-2

Element Tree Diagram



Business Rules

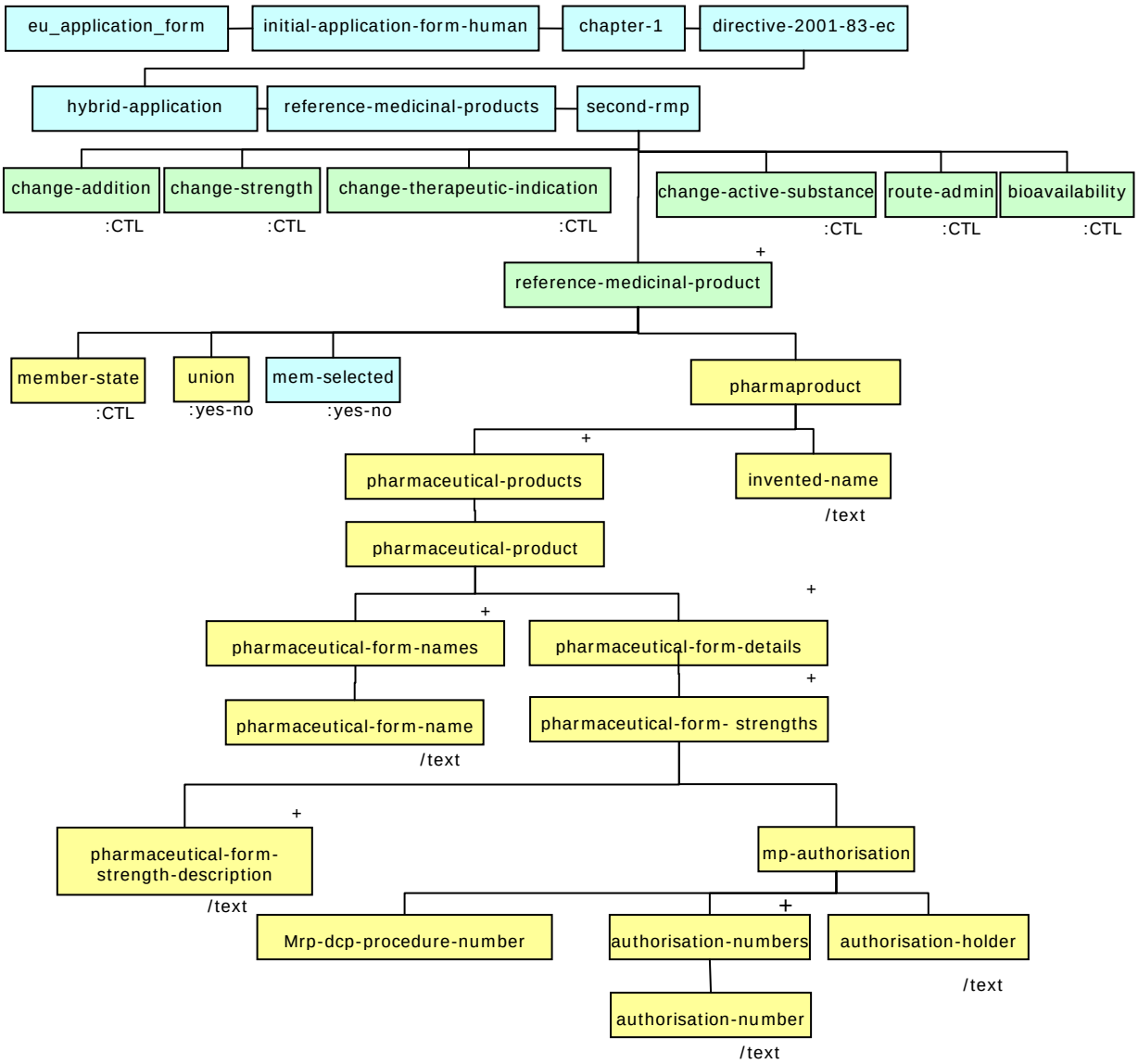
Rule ID	Element id(s)	Default BR	Rule	Effect(s)
B22431-1	E22431-9 to 10	Optional	Mutually Exclusive	
B22431-2	E22431-10 to 11	Optional	If E22431-10 is selected, then E22431-11 is required	
B22431-3	E22431-12	Optional		

2.2.4.3.2 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:pharmaproduct/rdm:invented-name	Reference Medicinal Product > Medicinal Product > Medicinal Product Name	
E22432-2	Pharmaceutical form(s)	maa:reference-medicinal-product/rdm:pharmaproduct/rdm:pharmaceutical-products/rdm:pharmaceutical-product / rdm:pharmaceutical-form-names/rdm:pharmaceutical-form-name	Reference Medicinal Product > Medicinal Product > Pharmaceutical Product > Pharmaceutical Dose Form CTL	
E22432-3	Strength(s)	maa:reference-medicinal-product/rdm:pharmaproduct/ rdm:pharmaceutical-products/rdm:pharmaceutical-product /rdm:pharmaceutical-form-details/rdm:pharmaceutical-form-strengths/rdm:pharmaceutical-form-strength-description	Ingredient	
E22432-4	Marketing authorisation holder	maa:reference-medicinal-product/rdm:pharmaproduct/ rdm:pharmaceutical-products/rdm:pharmaceutical-product /rdm:pharmaceutical-form-details/rdm:pharmaceutical-form-strengths /rdm:mp-authorisation/ rdm:authorisation-holder	Role > Party> Organisation> Name	
E22432-5	Marketing authorisation number	maa:reference-medicinal-product/rdm:pharmaproduct/ rdm:pharmaceutical-products/rdm:pharmaceutical-product /rdm:pharmaceutical-form-details/rdm:pharmaceutical-form-strengths /rdm:mp-authorisation/ rdm:authorisation-numbers/rdm:authorisation-number	MP Authorisation > authorisation number	
E22423-18	Procedure number for MRP/DCP (if applicable)	maa:reference-medicinal-product/rdm:pharmaproduct/ rdm:pharmaceutical-products/rdm:pharmaceutical-product /rdm:pharmaceutical-form-details/rdm:pharmaceutical-form-strengths /rdm:mp-authorisation/ rdm:mrp-dcp-procedure-number		
E22432-6	Marketing authorisation granted by			
E22432-7	Union	maa:reference-medicinal-product/rdm:community	MP Authorisation > Country CTL	B22423-1
E22432-8	Member State(EEA)	maa:reference-medicinal-product/rdm:mem-selected		B22423-1. B22423-2
E22432-9	Member State(EEA)	maa:reference-medicinal-product/rdm:member-state	MP Authorisation > Country CTL	B22423-2
E22432-10	Difference(s) compared to this reference medicinal product:			
E22432-11	changes in the active substance(s)	maa:change-active-substance	Difference CTL	B22423-3
E22432-12	change in therapeutic indications	maa:change-therapeutic-indication	Difference CTL	B22423-3
E22432-13	change in pharmaceutical form	maa:change-addition	Difference CTL	B22423-3
E22432-14	change in strength(quantitative change to the active substance(s))	maa:change-strength	Difference CTL	B22423-3
E22432-15	change in route of administration	maa:route-admin	Difference CTL	B22423-3
E22432-16	bioequivalence cannot be demonstrated through bioavailability	maa:bioavailability	Difference CTL	B22423-3

	studies			
E22423-17	Member States	maa:reference-medicinal-product rdm:member-states/rdm:ref-member-state/rdm:name	Procedure Use > Role > Country CTL	B224223-4

Element Tree Diagram

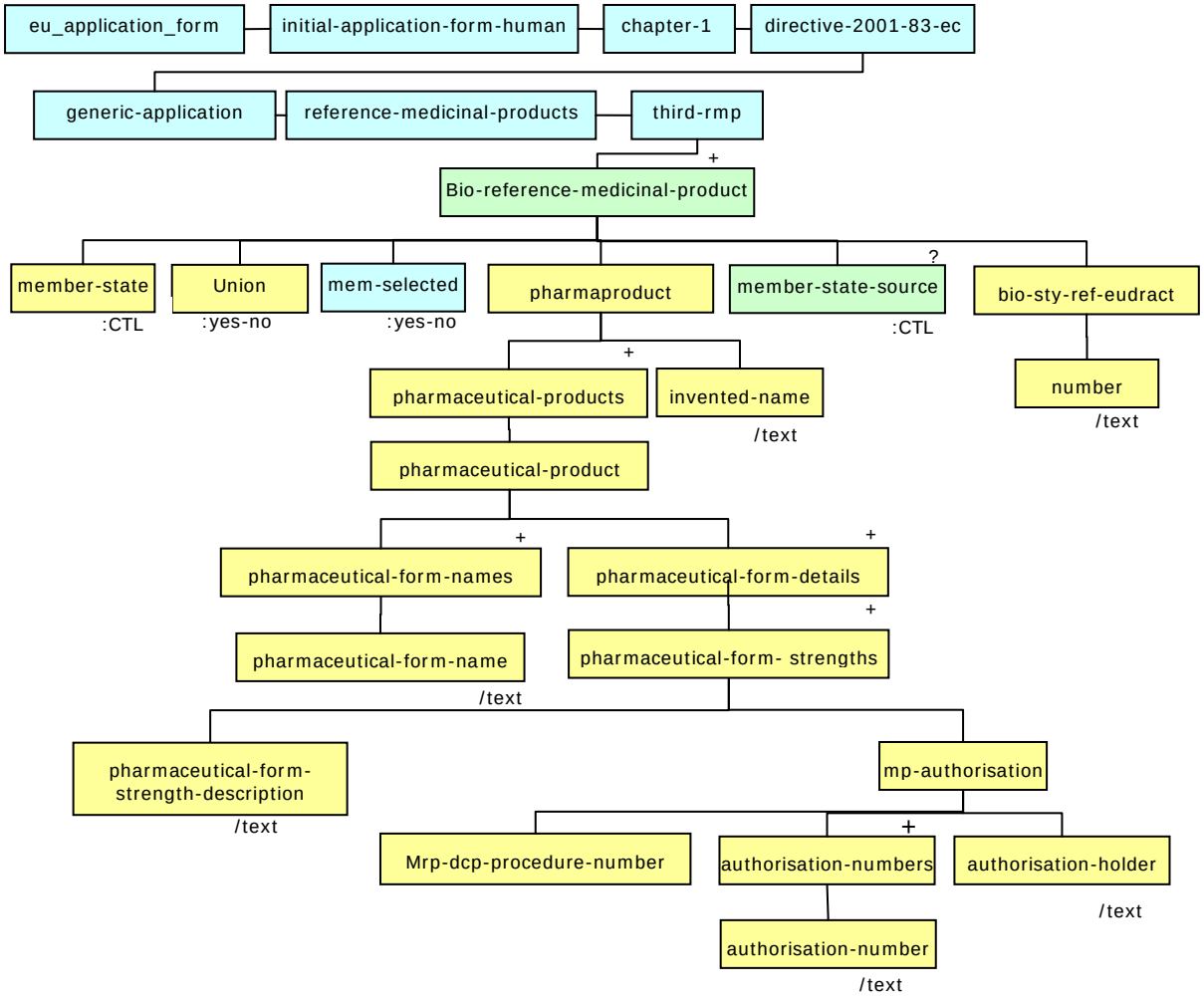


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B22423-1	E22423-7 to 8	Optional	Mutually Exclusive	
B22423-2	E22423-8 to 9	Optional	If E22423-8 is selected, then E22423-9 is required	
B22423-3	E22433-11 to 16	Mandatory	Mutually Exclusive	
B22423-4	E22423-17,	E22423-17, is not visible.	When E221-2 or E221-3 is selected, then E22422-10 is visible and mandatory	
B22423-5	E22423-18	Optional		

2.2.4.3.3 Medicinal product which is or has been authorised in accordance with Union 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:pharmaproduct/rdm:invented-name	Reference Medicinal Product > Medicinal Product > Medicinal Product Name	
E22433-3	Pharmaceutical form(s)	rdm:pharmaproduct/rdm: pharmaceutical-products/rdm: pharmaceutical-product / rdm: pharmaceutical-form-names/rdm: pharmaceutical-form-name	Reference Medicinal Product > Medicinal Product > Pharmaceutical Product > Pharmaceutical Dose Form CTL	
E22433-4	Strength(s)	rdm: pharmaproduct/ rdm: pharmaceutical-products/rdm: pharmaceutical-product /rdm: pharmaceutical-form-details/rdm: pharmaceutical-form-strengths/rdm: pharmaceutical-form-strength-description	Ingredient	
E22433-5	Marketing authorisation holder	rdm: pharmaproduct/ rdm: pharmaceutical-products/rdm: pharmaceutical-product /rdm: pharmaceutical-form-details/rdm: pharmaceutical-form-strengths /rdm:mp-authorisation/ rdm:authorisation-holder	Role > Party> Organisation> Name	
E22433-6	Marketing authorisation number	rdm: pharmaproduct/ rdm: pharmaceutical-products/rdm: pharmaceutical-product /rdm: pharmaceutical-form-details/rdm: pharmaceutical-form-strengths /rdm:mp-authorisation/ rdm:authorisation-numbers/rdm:authorisation-number	MP Authorisation > authorisation number	
E22433-12	Procedure number for MRP/DCP (if applicable)	rdm: pharmaproduct/ rdm: pharmaceutical-products/rdm: pharmaceutical-product /rdm: pharmaceutical-form-details/rdm: pharmaceutical-form-strengths /rdm:mp-authorisation/ rdm:mrp-dcp-procedure-number		
E22433-7	Marketing authorisation granted by			
E22433-8	Union	rdm:community	MP Authorisation > Country CTL	B22433-1
E22433-9	Member State(EEA)	rdm:mem-selected		B22433-1, B22433-2
E22433-10	Member State(EEA)	rdm:member-state	MP Authorisation > Country CTL	B22433-2
E22433-11	Member State of source	rdm:member-state-source	Reference Medicinal Product > Country CTL	

Element Tree Diagram

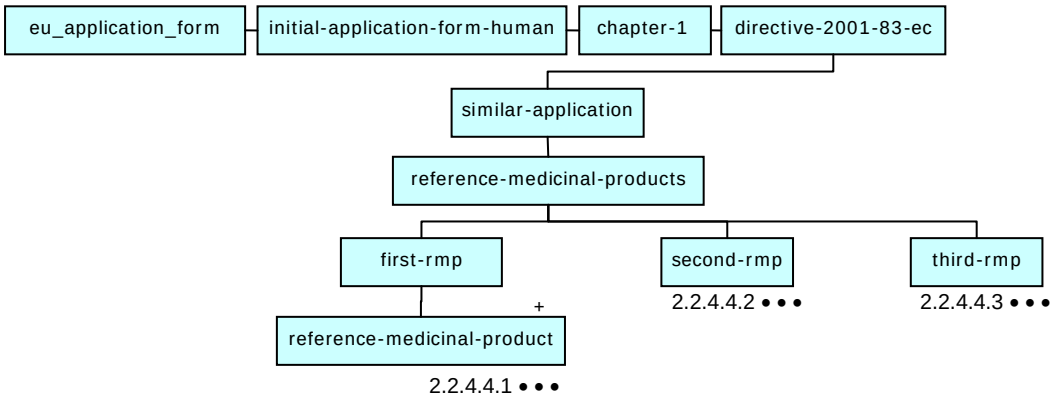


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B22433-1	E22433-8 to 9	Optional	Mutually Exclusive	
B22433-2	E22433-9 to 10	Optional	If E22433-9 is selected, then E22433-10 is required	
B22433-3	E22433-12	Optional		

2.2.4.4 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 Union 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 Union/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 Union 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



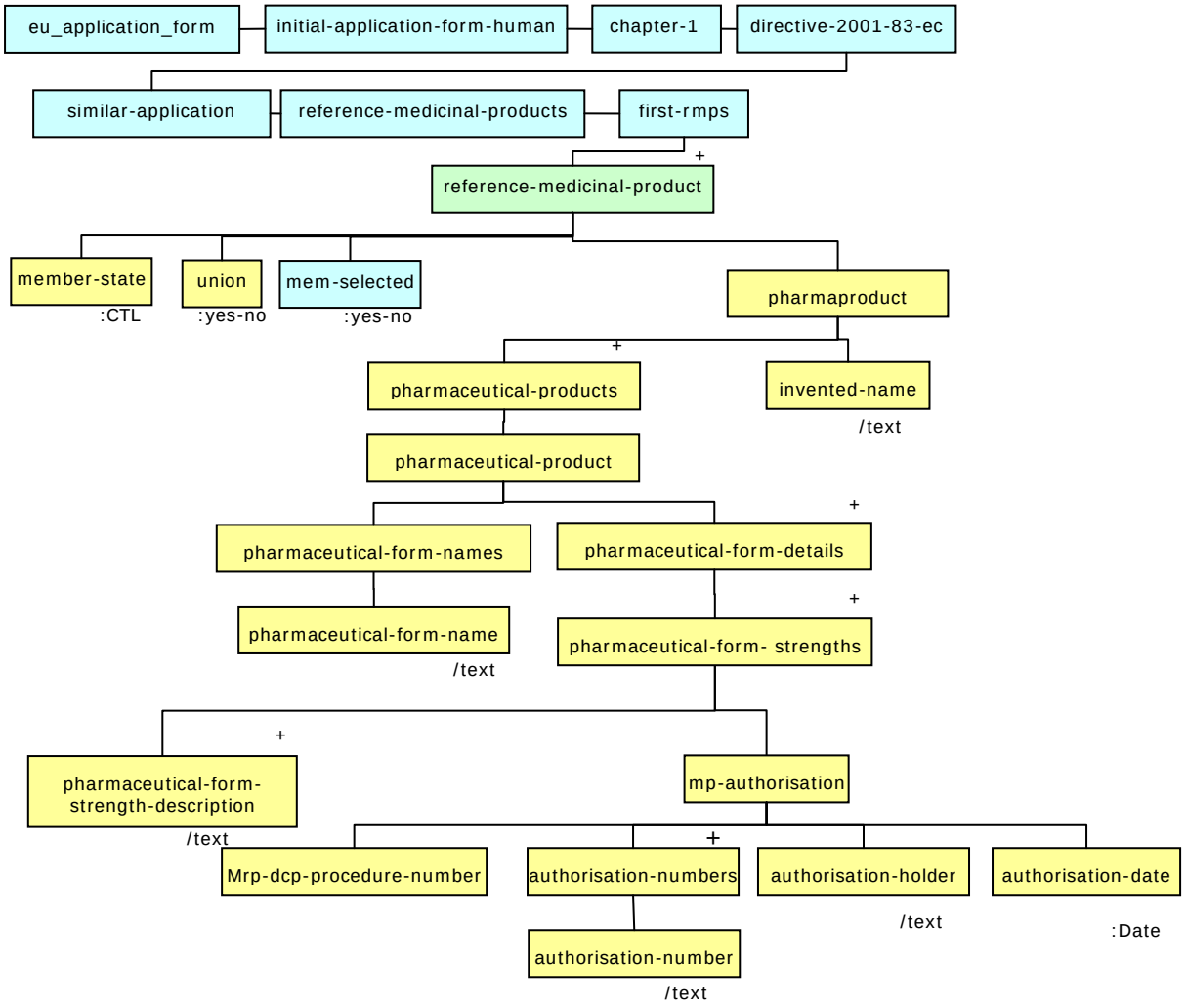
Business Rules

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.	

2.2.4.4.1 Medicinal product which is or has been authorised in accordance with Community provisions in force for not less than 6/8/10 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:pharmaproduct/rdm:invented-name	Reference Medicinal Product > Medicinal Product > Medicinal Product Name	
E22441-2	Pharmaceutical form(s)	rdm:pharmaproduct/rdm: pharmaceutical-products/rdm: pharmaceutical-product / rdm: pharmaceutical-form-names/rdm: pharmaceutical-form-name	Reference Medicinal Product > Medicinal Product > Pharmaceutical Product > Pharmaceutical Dose Form CTL	
E22441-3	Strength(s)	rdm:pharmaproduct/ rdm: pharmaceutical-products/rdm: pharmaceutical-product /rdm: pharmaceutical-form-details/rdm: pharmaceutical-form-strengths/rdm: pharmaceutical-form-strength-description	Ingredient	
E22441-4	Marketing authorisation holder	rdm:pharmaproduct/ rdm: pharmaceutical-products/rdm: pharmaceutical-product /rdm: pharmaceutical-form-details/rdm: pharmaceutical-form-strengths /rdm:mp-authorisation/ rdm:authorisation-holder	Role > Party> Organisation> Name	
E22441-5	Marketing authorisation number	rdm:pharmaproduct/ rdm: pharmaceutical-products/rdm: pharmaceutical-product /rdm: pharmaceutical-form-details/rdm: pharmaceutical-form-strengths /rdm:mp-authorisation/ rdm:authorisation-numbers/rdm:authorisation-number	MP Authorisation > authorisation number	
E22441-12	Procedure number for MRP/DCP (if applicable)	rdm:pharmaproduct/ rdm: pharmaceutical-products/rdm: pharmaceutical-product /rdm: pharmaceutical-form-details/rdm: pharmaceutical-form-strengths /rdm:mp-authorisation/rdm:mrp-dcp-authorisation-number		
E22441-6	Date of authorisation	rdm:pharmaproduct/ rdm: pharmaceutical-products/rdm: pharmaceutical-product /rdm: pharmaceutical-form-details/rdm: pharmaceutical-form-strengths/ rdm:mp-authorisation/ rdm:authorisation-date	MP Authorisation > authorisation date	
E22441-7	Marketing authorisation granted by			
E22441-8	Union	rdm:community	MP Authorisation > Country CTL	B22441-1
E22441-9	Member State(EEA)	rdm:mem-selected		B22441-1, B22441-2
E22441-10	Member State(EEA)	rdm:member-state	MP Authorisation > Country CTL	B22441-2
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



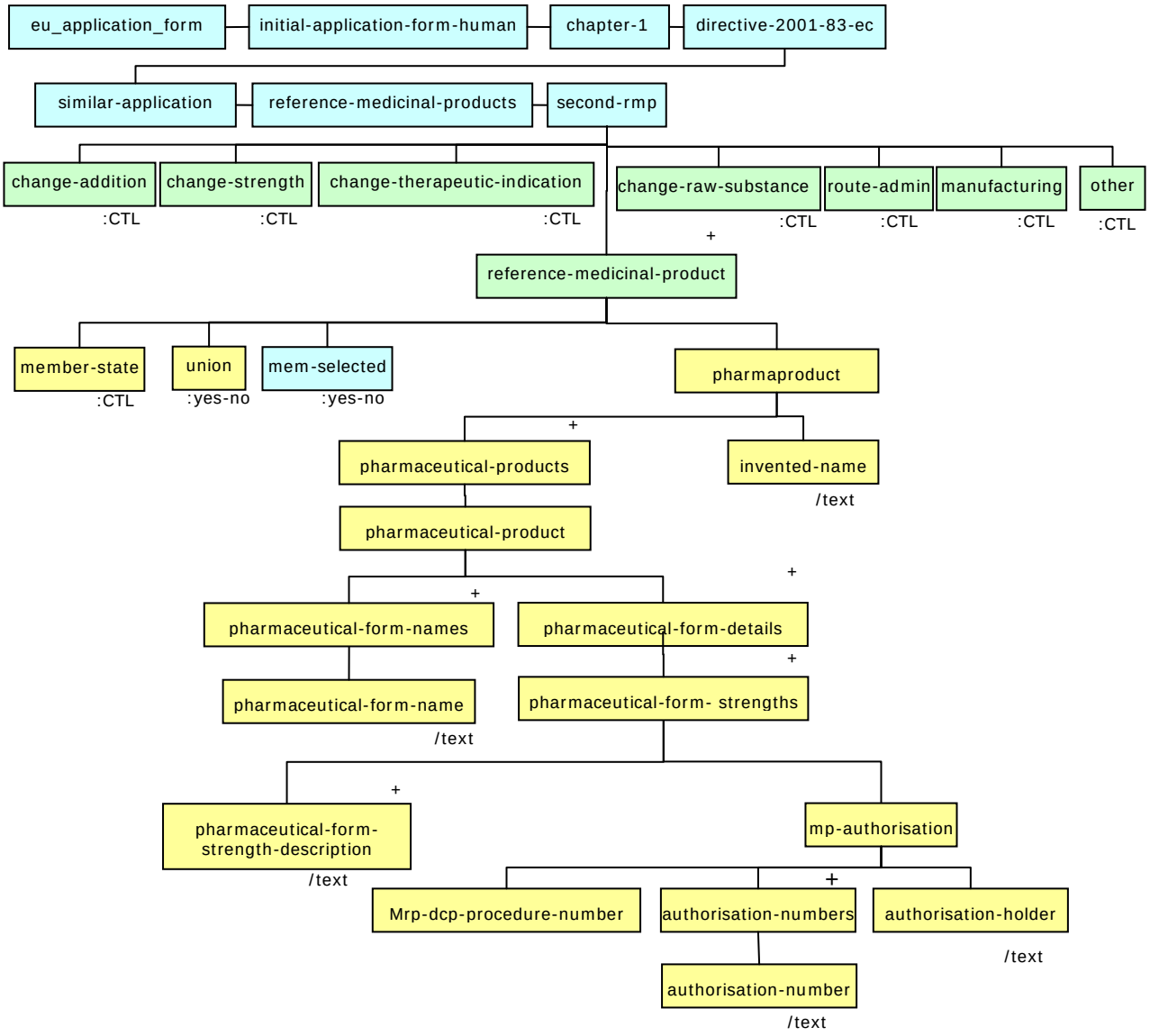
Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B22441-1	E22441-8 to 9	Optional	Mutually Exclusive	
B22441-2	E22441-9 to 10	Optional	If E22441-9, then E22441-10 is required	
B22441-3	E22441-12	Optional		

2.2.4.4.2 Medicinal product authorised in the Union/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:pharmaproduct/rdm:invented-name	Reference Medicinal Product > Medicinal Product > Medicinal Product Name	
E22442-2	Pharmaceutical form(s)	maa:reference-medicinal-product/rdm:pharmaproduct/rdm: pharmaceutical-products/rdm: pharmaceutical-product / rdm:pharmaceutical-form-names/rdm:pharmaceutical-form-name	Reference Medicinal Product > Medicinal Product > Pharmaceutical Product > Pharmaceutical Dose Form CTL	
E22442-3	Strength(s)	maa:reference-medicinal-product/rdm:pharmaproduct/ rdm:pharmaceutical-products/rdm: pharmaceutical-product /rdm: pharmaceutical-form-details/rdm: pharmaceutical-form-strengths/rdm: pharmaceutical-form-strength-description	Ingredient	
E22442-4	Marketing authorisation holder	maa:reference-medicinal-product/rdm:pharmaproduct/ rdm:pharmaceutical-products/rdm: pharmaceutical-product /rdm: pharmaceutical-form-details/rdm: pharmaceutical-form-strengths /rdm:mp-authorisation/ rdm:authorisation-holder	Role > Party> Organisation> Name	
E22442-5	Marketing authorisation number	maa:reference-medicinal-product/rdm: pharmaproduct/ rdm: pharmaceutical-products/rdm: pharmaceutical-product /rdm: pharmaceutical-form-details/rdm: pharmaceutical-form-strengths /rdm:mp-authorisation/ rdm:authorisation-numbers/rdm:authorisation-number	MP Authorisation > authorisation number	
E22442-18	Procedure number for MRP/DCP (if applicable)	maa:reference-medicinal-product/rdm: pharmaproduct/ rdm: pharmaceutical-products/rdm: pharmaceutical-product /rdm: pharmaceutical-form-details/rdm: pharmaceutical-form-strengths /rdm:mp-authorisation/rdm:mrp-dcp-procedure-number		
E22442-6	Marketing authorisation granted by			
E22442-7	Union	maa:reference-medicinal-product/rdm:community	MP Authorisation > Country CTL	B22442-1
E22442-8	Member State(EEA)	maa:reference-medicinal-product/rdm:mem-selected		B22442-1, B22442-2
E22442-9	Member State(EEA)	maa:reference-medicinal-product/rdm:member-state	MP Authorisation > Country CTL	B22442-2
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	B22442-3
E22442-12	change(s) in the manufacturing process(es)	maa:manufacturing	Difference CTL	B22442-3
E22442-13	change in therapeutic indication(s)	maa:change-therapeutic-indication	Difference CTL	B22442-3
E22442-14	change in pharmaceutical form(s)	maa:change-addition	Difference CTL	B22442-3
E22442-15	change in strength (quantitative	maa:change-strength	Difference CTL	B22442-3

	change to the active substance(s))			
E22442-16	change in route of administration(s)	maa:route-admin	Difference CTL	B22442-3
E22442-17	other	maa:other	Difference CTL	B22442-3

Element Tree Diagram

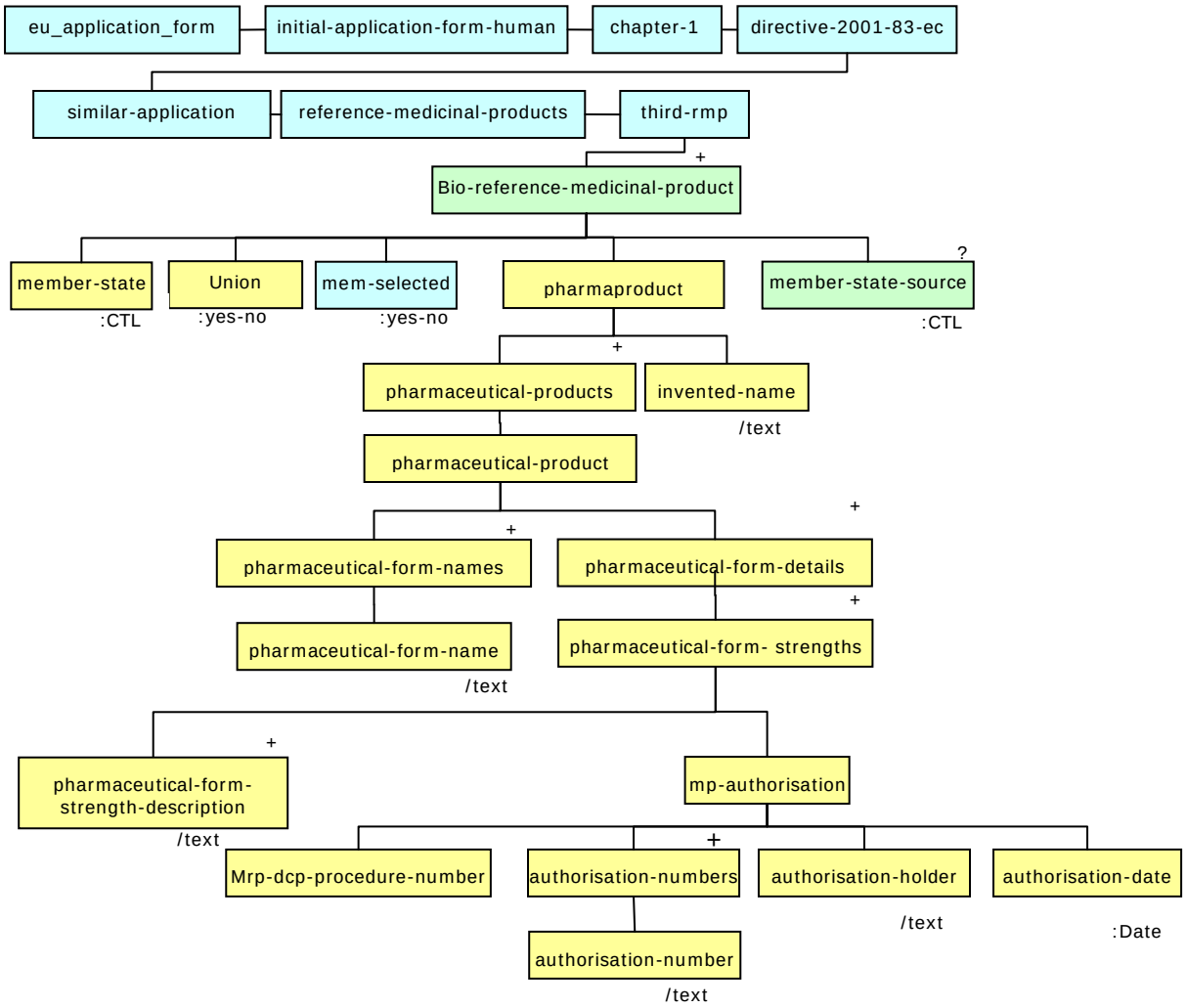


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B22442-1	E22442-7 to 8	Optional	Mutually Exclusive	
B22442-2	E22442-8 to 9	Optional	If E22442-8, then E22442-9 is required	
B22442-3	E22442-11 to 17	Mandatory	Mutually Exclusive	
B22442-4	E22442-18	Optional		

2.2.4.4.3 Medicinal product which is or has been authorised in accordance with Union 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 thoughout the comparability programme for quality, safety and efficacy studies.			
E22443-2	Product (Invented) name	rdm:pharmaproduct/rdm:invented-name	Reference Medicinal Product > Medicinal Product > Medicinal Product Name	
E22443-3	Pharmaceutical form(s)	rdm:pharmaproduct/rdm:pharmaceutical-products/rdm:pharmaceutical-product / rdm:pharmaceutical-form-names/rdm:pharmaceutical-form-name	Reference Medicinal Product > Medicinal Product > Pharmaceutical Product > Pharmaceutical Dose Form CTL	
E22443-4	Strength(s)	rdm: pharmaproduct/ rdm:pharmaceutical-products/rdm:pharmaceutical-product /rdm:pharmaceutical-form-details/rdm: pharmaceutical-form-strengths/rdm:pharmaceutical-form-strength-description	Ingredient	
E22443-5	Marketing authorisation holder	rdm: pharmaproduct/ rdm:pharmaceutical-products/rdm:pharmaceutical-product /rdm:pharmaceutical-form-details/rdm: pharmaceutical-form-strengths /rdm:mp-authorisation/ rdm:authorisation-holder	Role > Party> Organisation> Name	
E22443-6	Marketing authorisation number	rdm: pharmaproduct/ rdm:pharmaceutical-products/rdm:pharmaceutical-product /rdm:pharmaceutical-form-details/rdm: pharmaceutical-form-strengths /rdm:mp-authorisation/ rdm:authorisation-numbers/rdm:authorisation-number	MP Authorisation > authorisation number	
E22443-12	Procedure number for MRP/DCP (if applicable)	rdm: pharmaproduct/ rdm:pharmaceutical-products/rdm:pharmaceutical-product /rdm:pharmaceutical-form-details/rdm: pharmaceutical-form-strengths /rdm:mp-authorisation/rdm:mrp-dcp-procedure-number		
E22443-7	Date of authorisation	rdm: pharmaproduct/ rdm:pharmaceutical-products/rdm:pharmaceutical-product /rdm:pharmaceutical-form-details/rdm: pharmaceutical-form-strengths/ rdm:mp-authorisation/ rdm:authorisation-date	MP Authorisation > authorisation date	
E22443-8	Marketing authorisation granted by			
E22443-9	Union	rdm:community	MP Authorisation > Country CTL	B22443-1
E22443-10	Member State(EEA)	rdm:mem-selected		B22443-1, B22443-2
E22443-11	Member State(EEA)	rdm:member-state	MP Authorisation > Country CTL	B22443-2

Element Tree Diagram



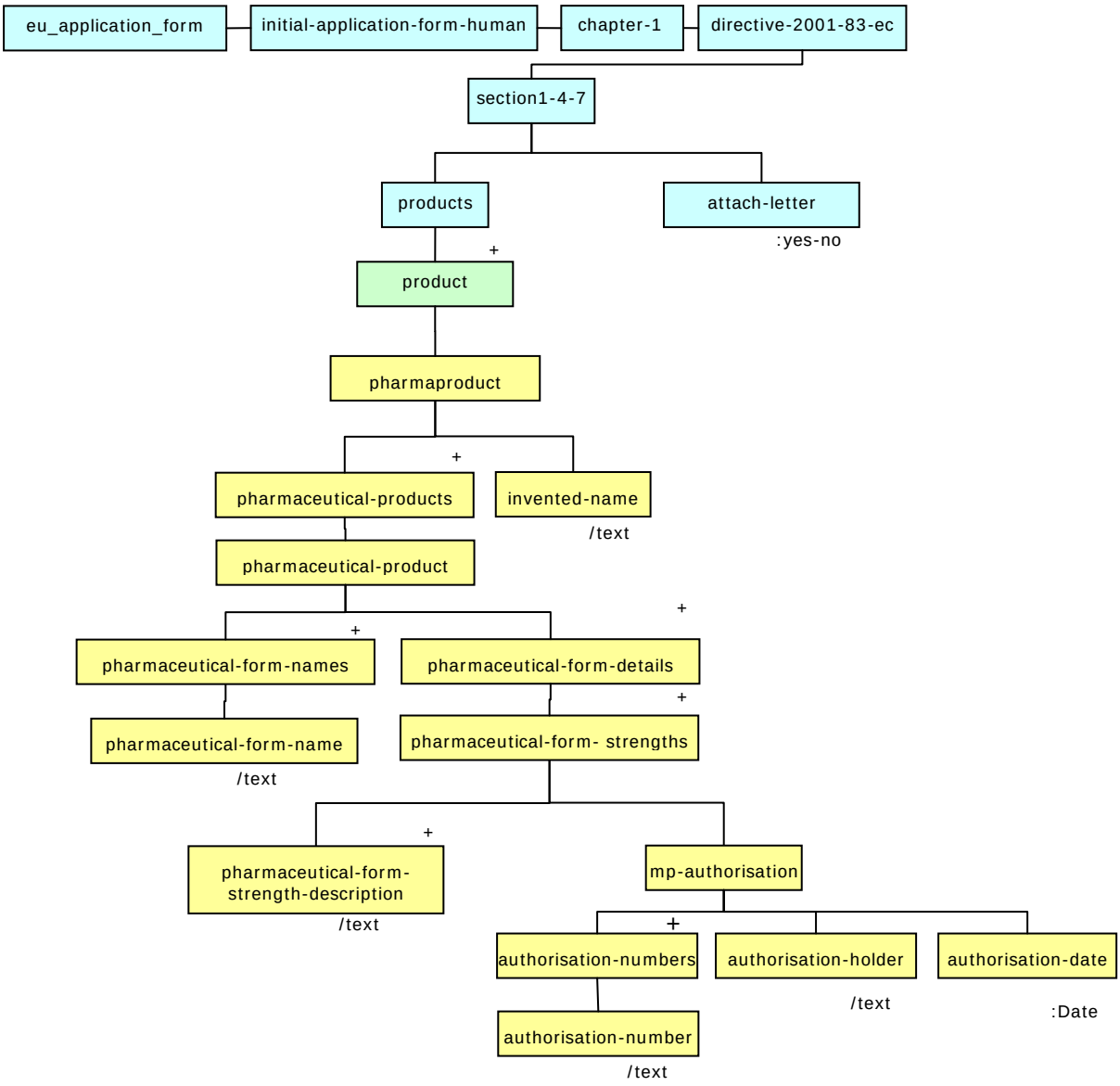
Business Rules

Rule ID	Element id(s)	Default BR	Rule	Effect(s)
B22443-1	E22443-9 to 10	Optional	Mutually Exclusive	
B22443-2	E22443-10 to 11	Optional	If E22443-10, then E22443-11 is required	
B22443-3	E22443-12	Optional		

2.2.4.5 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 Union/Member State where the application is made:			B2245-1
E2245-3	Product (Invented) name	rdm:products/rdm:product/rdm:pharmaproduct/rdm:invented-name	Reference Medicinal Product > Medicinal Product > Medicinal Product Name	B2245-1
E2245-4	Pharmaceutical form(s)	rdm:products/rdm:product/ rdm:pharmaproduct/rdm: pharmaceutical-products/rdm: pharmaceutical-product / rdm: pharmaceutical-form-names/rdm:pharmaceutical-form-name	Reference Medicinal Product > Medicinal Product > Pharmaceutical Product > Pharmaceutical Dose Form CTL	B2245-1
E2245-5	Strength(s)	rdm:products/rdm:product/rdm: pharmaproduct/ rdm: pharmaceutical-products/rdm: pharmaceutical-product /rdm: pharmaceutical-form-details/rdm: pharmaceutical-form-strengths/rdm: pharmaceutical-form-strength-description	Ingredient	B2245-1
E2245-6	Marketing authorisation holder	rdm:products/rdm:product/rdm: pharmaproduct/ rdm: pharmaceutical-products/rdm: pharmaceutical-product /rdm: pharmaceutical-form-details/rdm: pharmaceutical-form-strengths /rdm:mp-authorisation/ rdm:authorisation-holder	Role > Party> Organisation> Name	B2245-1
E2245-7	Marketing authorisation number	rdm:products/rdm:product/rdm: pharmaproduct/ rdm: pharmaceutical-products/rdm: pharmaceutical-product /rdm: pharmaceutical-form-details/rdm: pharmaceutical-form-strengths /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

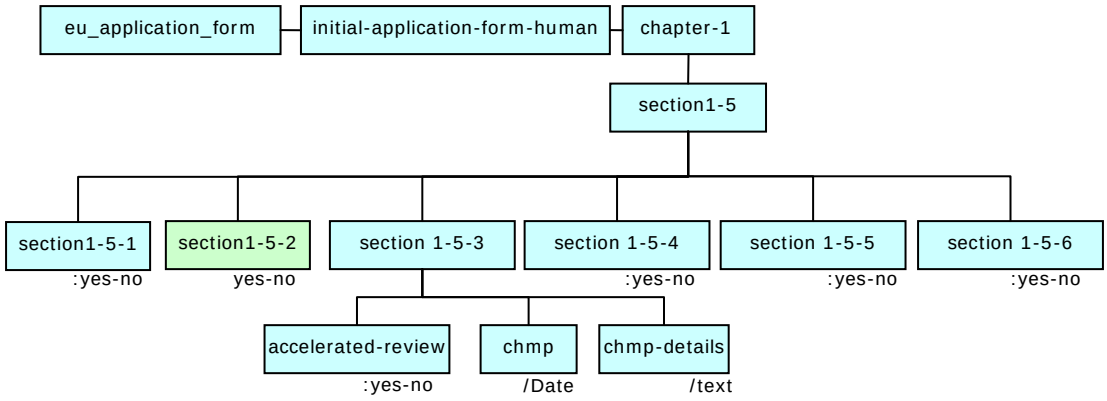


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2245-1	E224-8, E2245-1 to E2245-8	E224-5 is mandatory. Rest are optional.	When E224-5 is selected, then the rest are mandatory.	

2.2. 5CONSIDERATION 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
E225-7a	Free text field	maa:section1-5-3/maa:chmp-details	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

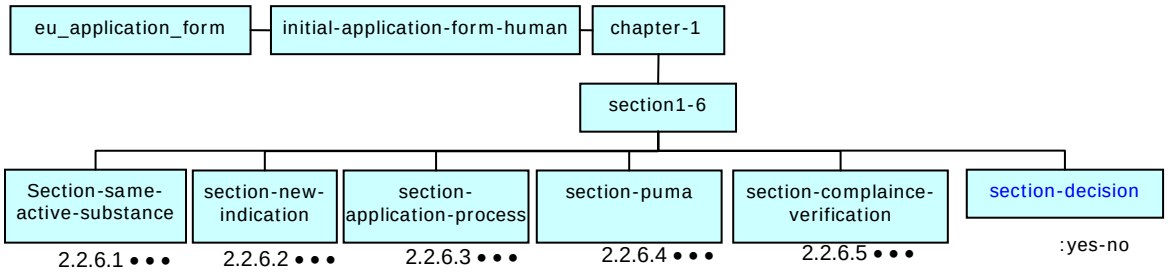


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B225-1	E225-1, E225-2, E225-8, E225-10 and E225-11	optional.		E225-1, E225-2, E225-8, E225-10 and E225-11
B225-1	E225-5 to E225-7	optional.	When E224-5 is selected, then When E224-7 is mandatory.	E225-5 to E225-7

2.2. 6 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	Sections 1.6.1, 1.6.2 and 1.6.3 not applicable for well-established use, generic, hybrid and bio-similar applications and traditional herbal medicinal products	maa:section-decision		
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:section-same-active-substance		See Section 2.2.6.1
E226-3	ARTICLE 7 OF PAEDIATRIC REGULATION APPLIES TO THIS APPLICATION, SINCE:	maa:section-new-indication		See Section 2.2.6.2
E226-4	ARTICLE 8 OF PAEDIATRIC REGULATION APPLIES TO THIS APPLICATION, SINCE:	maa:section-application-process	Paed Regulation App CTL	See Section 2.2.6.3
E226-5	ARTICLE 30 (PUMA) OF THE PAEDIATRIC REGULATION APPLIES TO THIS APPLICATION:	maa:section-puma		See Section 2.2.6.4
E226-6	HAS THIS APPLICATION BEEN SUBJECT TO PIP COMPLIANCE VERIFICATION?	maa:section-complaince-verification		See Section 2.2.6.5

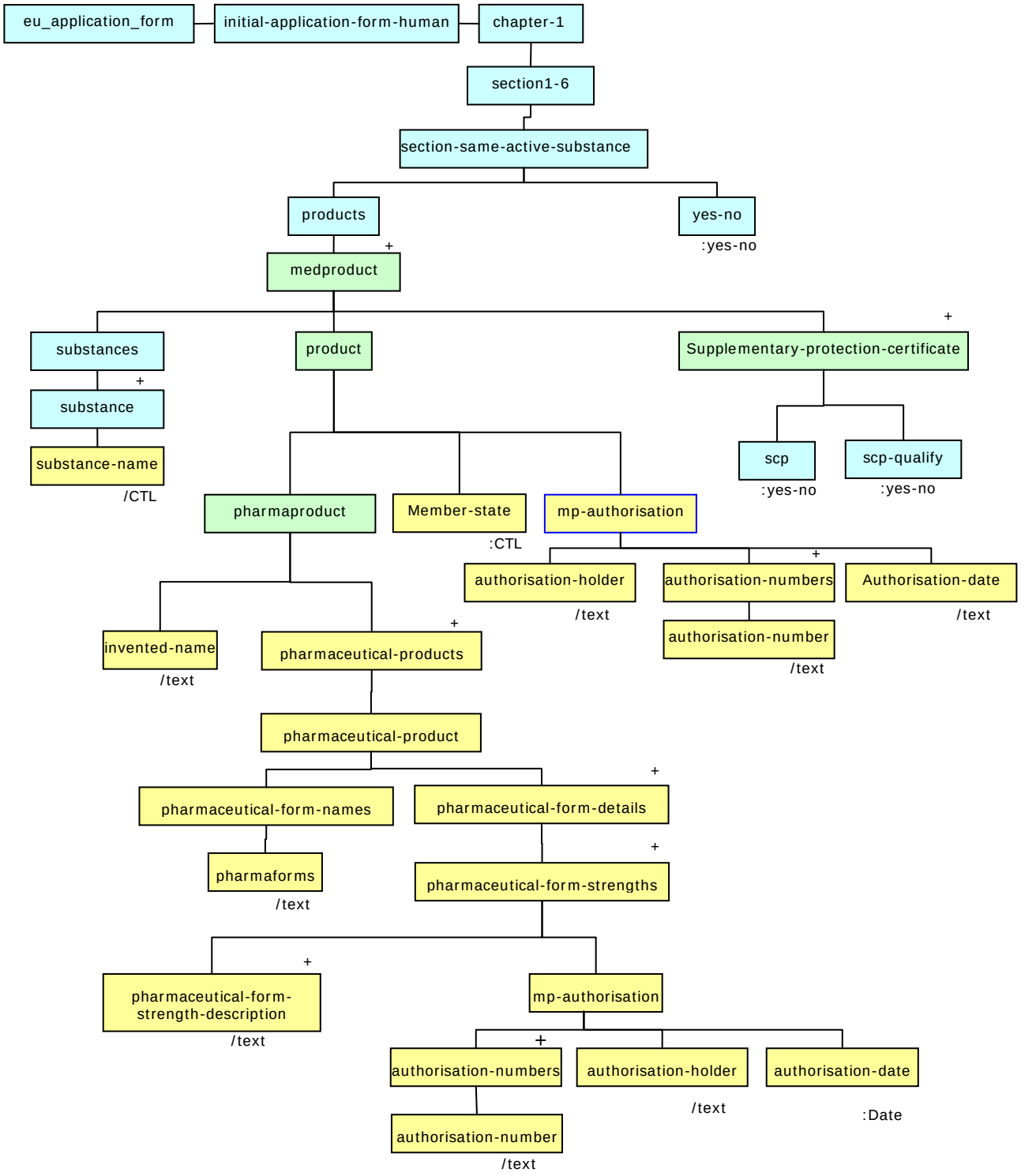
Element Tree Diagram



2.2.6.1 Does the same[3] 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:section-same-active-substance/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2261-1	Yes	maa:yes-no (Value = 1)	Paediatric Designation > has same active substance	B2261-1, B2261-2, B2263-1
E2261-2	No (Complete section 1.6.3)	maa:yes-no (Value = 0)	Paediatric Designation > has same active substance	B2261-1, B2262-1
E2261-3	Active substance	maa:products/maa:medproduct:/ maa:active-substances/ maa:active-substance/ maa:substance-name	Medicinal Product > Pharmaceutical Product > Ingredient > Substance CTL > term id	B2261-2
E2261-4	Product (invented) name	maa:products/maa:medproduct:/ maa:product/rdm:pharmaproduct/ rdm:invented-name	Reference Medicinal Product > Medicinal Product > Pharmaceutical Product > Ingredient >Substance	B2261-2
E2261-5	Pharmaceutical form(s)	maa:products/maa:medproduct:/ maa:product/ rdm:pharmaproduct/rdm: pharmaceutical-products/rdm: pharmaceutical-product / rdm:pharmaceutical-form-names/rdm: pharmaceutical-form-name	Reference Medicinal Product > Medicinal Product > medicinal product name	B2261-2
E2261-6	Strength(s)	maa:products/maa:medproduct/ maa:product/ rdm:pharmaproduct/rdm: pharmaceutical-products/rdm: pharmaceutical-product /rdm: pharmaceutical-form-details/rdm: pharmaceutical-form-strengths/rdm: pharmaceutical-form-strength-description	Reference Medicinal Product > Medicinal Product > Pharmaceutical Product > Ingredient	B2261-2
E2261-7	Marketing authorisation holder	maa:products/maa:medproduct:/ maa:product/rdm:pharmaproduct/rdm: pharmaceutical-products/rdm: pharmaceutical-product /rdm: pharmaceutical-form-details/rdm: pharmaceutical-form-strengths /rdm:mp-authorisation/ rdm:authorisation-holder	Role > Party > Organisation > Name	B2261-2
E2261-8	Member State/European Union where product is authorised:	maa:products/maa:medproduct/ maa:member-state	MP Authorisation > Country CTL	B2261-2
E2261-9	Marketing authorisation number	maa:products/maa:medproduct/ maa:product/rdm:pharmaproduct/rdm: pharmaceutical-products/rdm: pharmaceutical-product /rdm: pharmaceutical-form-details/rdm: pharmaceutical-form-strengths /rdm:mp-authorisation/ rdm:authorisation-numbers/rdm:authorisation-number	MP Authorisation > authorisation number	B2261-2
E2261-10	Date(s) of marketing authorisation(s)	maa:products/maa:medproduct/ maa:product/rdm:mp-authorisation/ rdm:authorisation-date	MP Authorisation > authorisation date	
E2261-11	scp	maa:products/maa:medproduct/ maa:supplementary-production-certificate/maa:scp	Reference Medicinal Product > paed indication	B2261-2
E2261-12	Scp-qualify	maa:products/maa:medproduct/ maa:supplementary-production-certificate/maa:scp-qualify	Reference Medicinal Product > paed indication	B2261-2
E2261-13	[3] "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

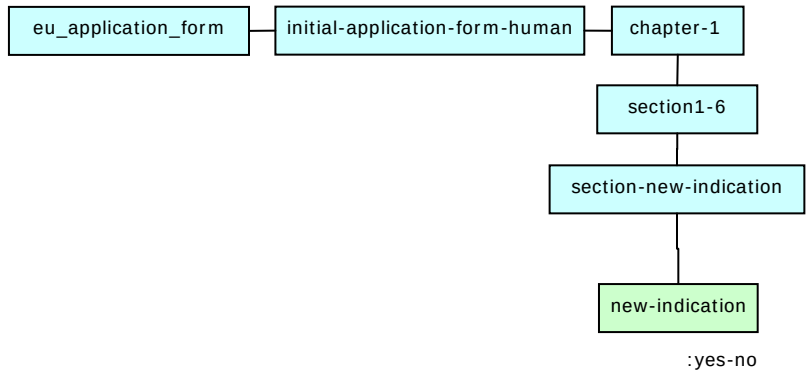


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2261-1	E2261-1, E2261-2	Mandatory.	Mutually exclusive.	
B2261-2	E2261-1, E2261-3 to E2261-13		If E2261-1 is selected, then the other fields are mandatory.	

2.2.6.2 DOES THIS APPLICATION RELATE TO A NEW INDICATION, NEW PHARMACEUTICAL FORM OR NEW ROUTE OF ADMINISTRATION?

	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:section-new-indication/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2262-1	Yes/ (Complete section-application-process)	maa:new-indication (Value = 1)	Paediatric Designation > has same active substance	B2262-1,
E2262-2	No	maa:new-indication (Value = 0)	Paediatric Designation > has same active substance	B2262-1,

Element Tree Diagram



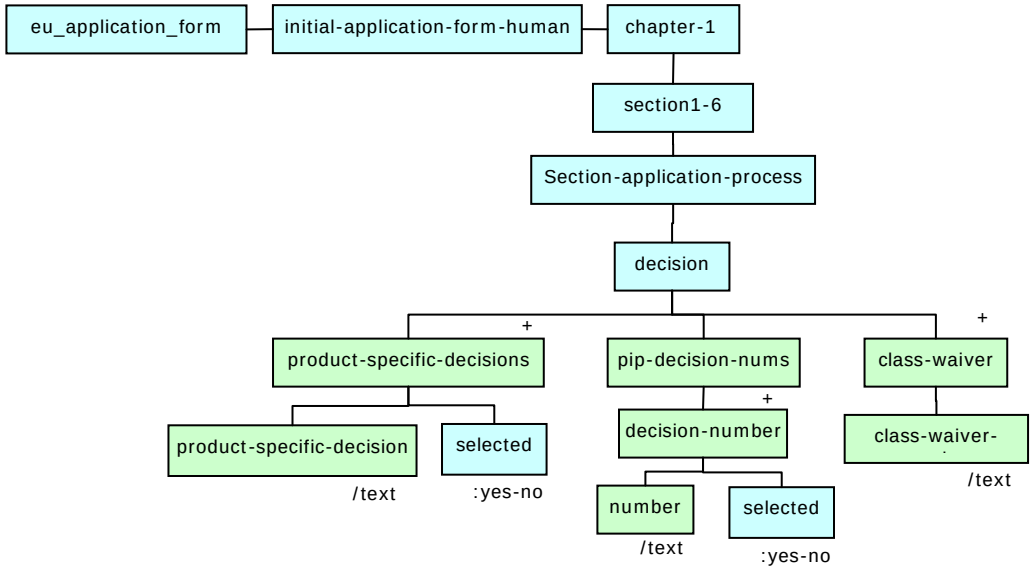
Business Rules

Rule ID	Element id(s)	Default BR	Rule	Effect(s)
B2262-1	E2261-1, E2262-2	E2262-1 is optional.	If E2262-1 is yes, then section-application-process needs to be visible and mandatory.	2.2.3.3

2.2.6.3 This Application Includes

	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:section-application-process/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2263-1	THIS APPLICATION INCLUDES:			B2263-1
E2263-2	PIP Decision Number(s)	maa:decision/rdm:pip-decision-nums/rmd:decision-number/rdm:number	Paediatric Designation > art 8 pip decision number	B2263-1
E2263-3	cbCheckBox	maa:decision/rdm:pip-decision-nums/rmd:decision-number/rdm:selected		B2263-1
E2263-4	Product-Specific Waiver Decision Number(s)	maa:decision/rdm:product-specific-decisions/rdm:product-specific-decision	Paediatric Designation > art 8 product waiver number	B2263-1
E2263-5	cbCheckBox	maa:decision/rdm:product-specific-decisions/rdm:selected		B2263-1
E2263-6	Class Waiver Decision Number(s)	maa:decision/rdm:class-waiver/rdm:class-waiver-number	Paediatric Designation > art 8 class waiver number	B2263-1
	(Note: a copy of the PIP/Product-Specific Waiver decision, including the Paediatric Committee (PDCO) opinion and the Summary Report, is to be included in Module 1.10)			B2263-1

Element Tree Diagram

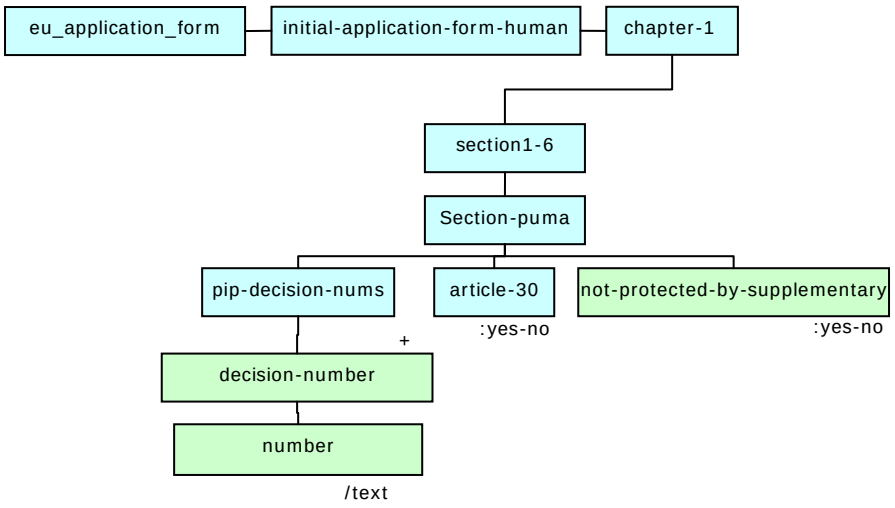


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2263-1	E2261-1, E2263-1 to E2263-6	E2263-1 to E2263-6 are hidden	If E2261-1 is selected, then E2263-1 to E2263-6 fields are visible.	

2.2.6.4 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:section-puma/		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 469/2009, 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

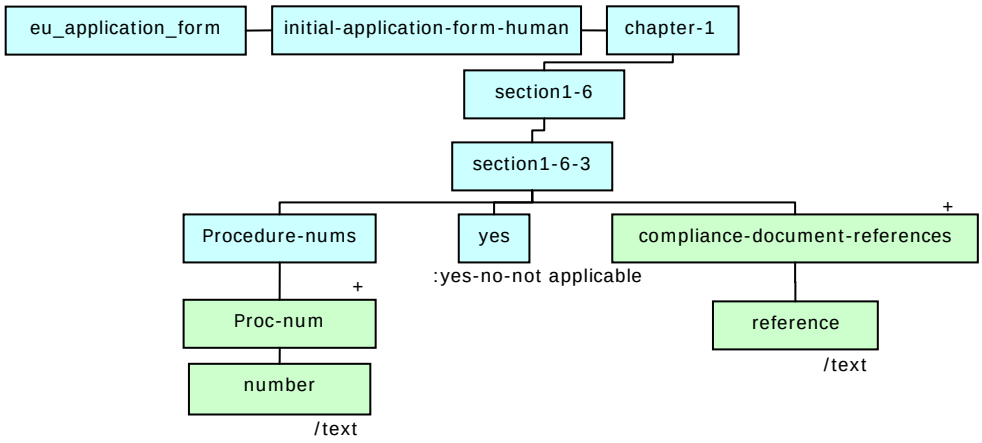


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2264-1	E2264-1 , E2264-3 to E2264-5	E2264-1 is mandatory, rest are optional.	If E2264-1 is selected, the other fields become visible and mandatory.	

2.2.6.5 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:section-complaince-verification/		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	
E2265-2a	Not applicable	maa:yes (Value=2)	Paediatric Designation > subject to pip compliance	
E2265-3	If, yes, please specify			B2265-1
E2265-4	Compliance document reference(s)	maa:compliance-document-references/maa:reference	Paediatric Designation > pdco opinion number	B2265-1
E2265-5	*(Note: if available a copy of the PDCO complaince report with, where applicable, the PSCO opinion or the document issued by the national competent authority is to be included in Module 1.10)*			B2265-1
E2265-6	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
E2265-7	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, E2265-4 to E2265-7	E2265-1 is mandatory, rest are optional.	If E2265-1 is selected, the other fields are visble and mandatory.	

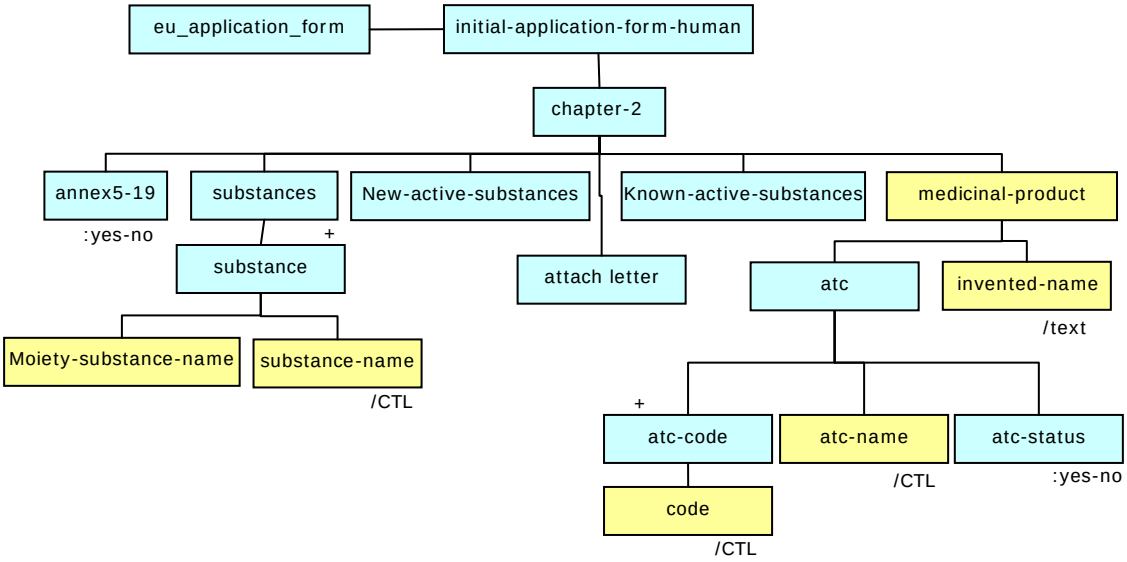
2.3. MARKETING AUTHORISATION APPLICATION PARTICULARS

	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	Full name of the Active substance(s), if applicable including salt or hydrate*.			
E231-4	*Note: *active substance should be indicated here as full substance. If the substance is included in the product as a salt or hydrate, the corresponding base/active moiety should be indicated in the additional field; Name should be based on thefollowing order of priority: INN*, Ph.Eur., National Pharmacopeia, common name, scientific name;**			
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	
E231-10	Base/active moiety of the active substance(s)	maa:active-substances/ maa:active-substance/ maa:moiety-substance-name		
E231-11	Substance type (e.g. chemical substance, recombinant biological substance)	maa:substanceType		
E231-12	*For applications submitted in accordance with Art. 8(3) or Art. 10a of Directive 2001/83/EC:*			
E231-13	Claim for new active substance(s)	maa:new-active-substance		
E231-14	known active substance(s)	maa:known-active-substance		
E231-15	Attach letter	maa:attach-letter		
E231-6	Pharmacotherapeutic group (Please use current ATC code)			
E231-7	ATC code	rdm:medicinal-product/ rdm:atc/rdm:atc-code/rdm:code	Medicinal Product > ATC Code CTL	
E231-8	Group	rdm:medicinal-product/ rdm:atc/rdm: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/rdm:atc-status		

Element Tree Diagram

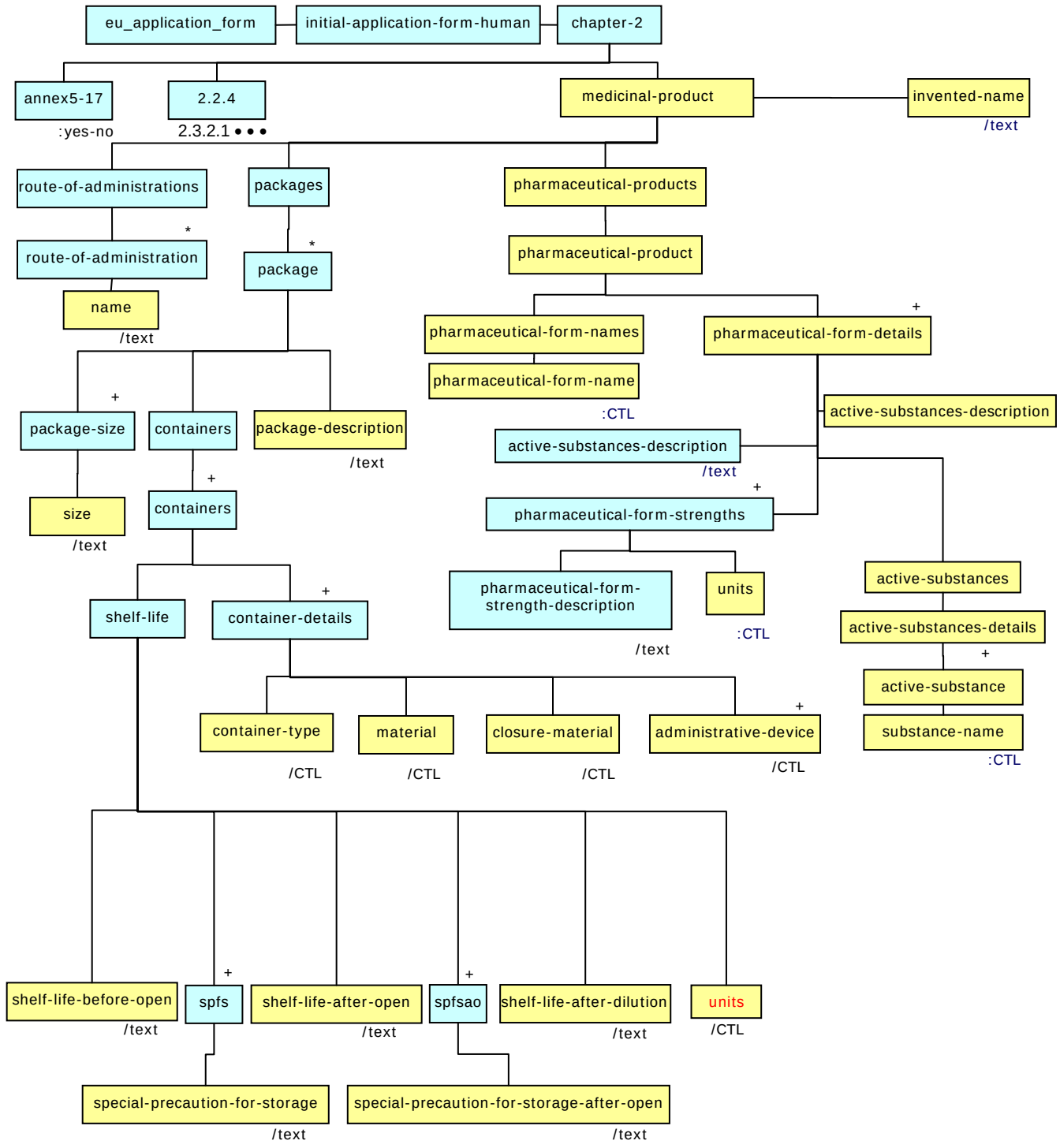


2.3. 2STRENGTH, PHARMACEUTICAL FORM, ROUTE OF ADMINISTRATION, CONTAINER AND PACK SIZES

	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-products/ 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-products/ rdm:pharmaceutical-product/rdm:pharmaceutical-form-details/rdm:pharmaceutical-form-strengths/ rdm:pharmaceutical-form-strength-description		
E232-3a	Units	rdm:medicinal-product/ rdm:pharmaceutical-products/ rdm:pharmaceutical-product/rdm:pharmaceutical-form-details/rdm:pharmaceutical-form-strengths/rdm:units		
E232-4	Active Substance(s)	rdm:medicinal-product/ rdm:pharmaceutical-products/ rdm:pharmaceutical-product/rdm:pharmaceutical-form-details/rdm:active-substances-description		
E232-5	Active Substance	rdm:medicinal-product/ rdm:pharmaceutical-products/ rdm:pharmaceutical-product/rdm:pharmaceutical-form-details/rdm:active-substances/rdm: active-substances-details/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	Package size	rdm:medicinal-product/ maa:packages/rdm:package /rdm:package-size/rdm:size	Package > package Size	
E232-11	*Note: For mutual recognition and decentralised procedures, all package sizes authorised in the Reference Member State should be listed*			
E232-12	Description	rdm:medicinal-product/ maa:packages/rdm:package/rdm: package-description		
E232-13	Container	rdm:medicinal-product/maa:packages/rdm:package/rdm:containers/rdm:container/ rdm:container-details/ rdm:container-type	Package > Outer Container > Container CTL	
E232-14	Material	rdm:medicinal-product/maa:packages/rdm:package/rdm:containers/rdm:container/	Package > Immediate Container > Container CTL	

		rdm:container-details/rdm:material		
E232-15	Closure	rdm:medicinal-product/maa:packages/rdm:package/rdm:containers/rdm:container/rdm:container-details/rdm:closure-material	Package > Immediate Container > Container CTL	B232-1
E232-16	Administration Device	rdm:medicinal-product/maa:packages/rdm:package/rdm:containers/rdm:container/rdm:container-details/rdm:administrative-device	Package > Outer Container > Administration Device > Administration Device CTL	B232-1
E232-17	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	
E232-18	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
E232-19	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
E232-20	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
E232-21	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
E232-22	Attach a list of Mock-ups or Samples/specimens sent with the application, as appropriate (see Annex 5.17)	maa:annex5-17		B232-1
E232-23	units	rdm:medicinal-product/ maa:packages/rdm:package/rdm:containers/rdm:container/rdm:shelf-life/rdm:shelf-life-before-open-units		
E232-24	units	rdm:medicinal-product/maa:packages/rdm:package/rdm:containers/rdm:container/rdm:shelf-life/rdm:shelf-life-after-open-units		
E232-25	units	rdm:medicinal-product/maa:packages/rdm:package/rdm:containers/rdm:container/rdm:shelf-life/rdm:shelf-life-after-dilution-units		

Element Tree Diagram



Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B232-1	E232-11, E232-12, E232-17, E232-18, E232-20- E232-24	Optional.	These fields are optional.	

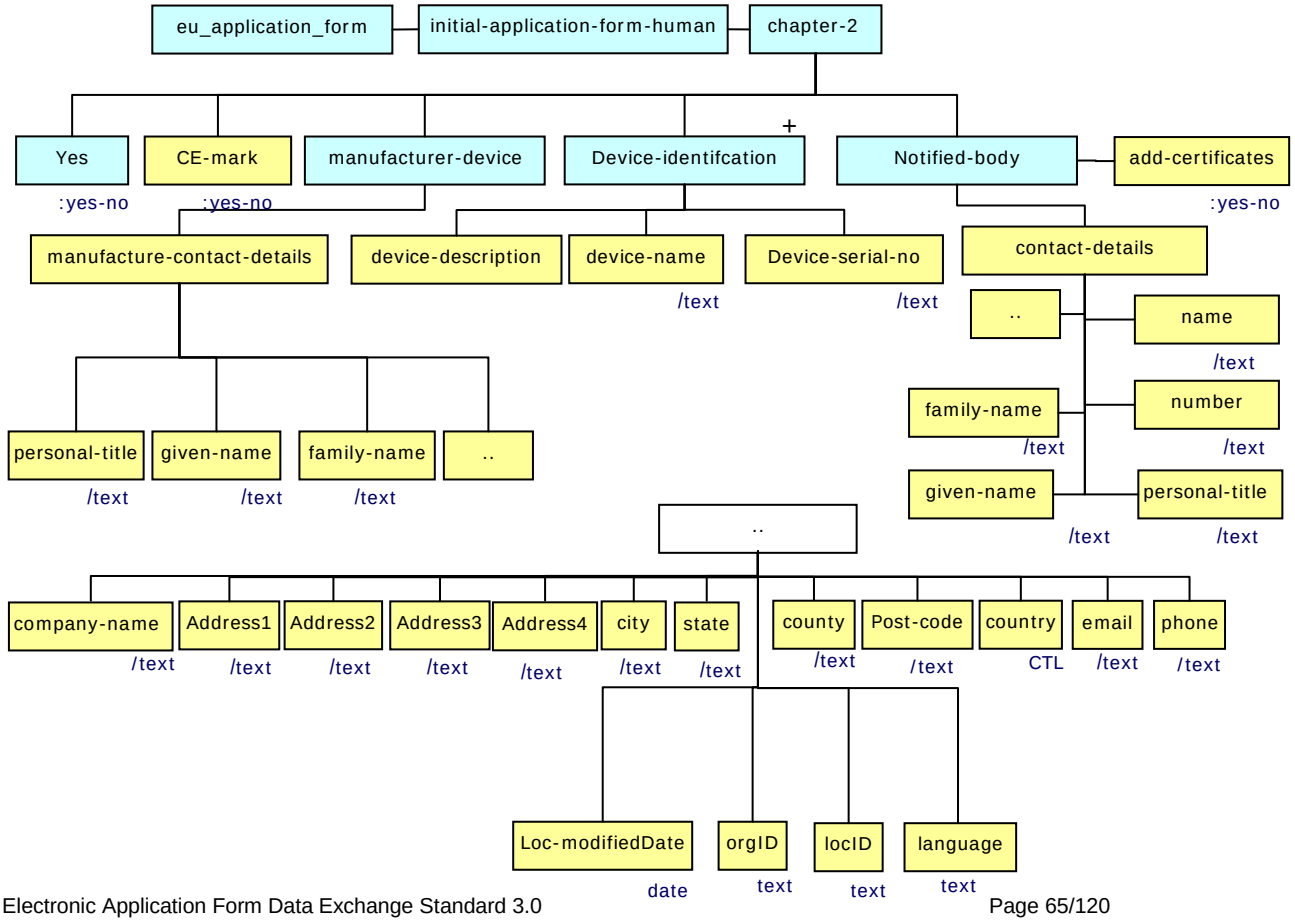
2.3.2 1 THE MEDICINAL PRODUCT INCORPORATES, AS AN INTEGRAL PART, ONE OR MORE MEDICAL DEVICES WITHIN THE MEANING OF Article 1(2)(a) of Directive 93/42/EEC OR ONE OR MORE ACTIVE IMPLANTABLE MEDICAL DEVICES WITHIN THE MEANING OF ARTICLE 1(2)(C) OF DIRECTIVE 90/385/EEC

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-2/Manufacturer-device		Application > Medicinal Product >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2321-0	Yes	maa:manu-device-checkbox		
E2321-1	Manufacturer of the device (for manufactures outside the EEA, please add the authorized representative):			
E2321-2	Name of the contact person			
E2321-3	Title	maa:Manufacture-contact-details/ rdm:personal-title	Role > Party > Person > Personal title	B2321-1
E2321-4	First name	maa:Manufacture-contact-details/ rdm:given-name	Role > Party > Person > given name	B2321-1
E2321-5	Surname	maa:Manufacture-contact-details/ rdm:family-name	Role > Party > Person > family name	B2321-1
E2321-6	Address	maa:Manufacture-contact-details/ rdm:address1	Role>Party>Contact Details > Address	B2321-1
		maa:Manufacture-contact-details/ rdm:address2		
		maa:Manufacture-contact-details/ rdm:address3		
		maa:Manufacture-contact-details/ rdm:address4		
E2321-6a	City	maa:Manufacture-contact-details/ rdm:city		
E2321-6b	State	maa:Manufacture-contact-details/ rdm:state		
E2321-6c	county	maa:Manufacture-contact-details/ rdm:county		
E2321-7	Postcode	maa:Manufacture-contact-details/ rdm:post-code	Role>Party>Contact Details > Address> post code	B2321-1
E2321-8	Country	maa:Manufacture-contact-details/ rdm:country	Role>Party>Contact Details > Address > Country CTL	B2321-1
E2321-8a	orgID	maa:Manufacture-contact-details/ rdm:orgID		
E2321-8b	locID	maa:Manufacture-contact-details/ rdm:locID		
E2321-8c	Loc-modifiedDate	maa:Manufacture-contact-details/ rdm:loc-modifiedDate		
E2321-8d	langugae	maa:Manufacture-contact-details/ rdm:language		
E2321-9	Telephone	maa:Manufacture-contact-details/ rdm:phone	Role>Party>Contact Details > Electronic Contact > electronic contact	B2321-1
E2321-11	E-mail	maa:Manufacture-contact-details/ rdm:email	Role>Party>Contact Details> Electronic Contact > electronic contact	B2321-1
	Medical Device	Maa:manu-device-yes-no		
	Does this application include one or more medical devices within the meaning of Article 1(2)(a) of Directive			Yes or No

	93/42/EEC or one or more active implantable medical devices within the meaning of Article 1(2)(c) of Directive 90/385/EEC intended to administer a medicinal product			
	If yes, does the medical device and the medicinal product form a single integral product, which is intended exclusively for use in the given combination and which is not reusable?			Yes or No
	Note: If no, CE marking of the device is mandatory. If yes, CE marking of the device is optional. Further details must be provided in sections 2.2.4.3 and 2.2.4.4.			
E2321-12	Device(s) identification:			
E2321-13	Name of the device(s)	maa:device-identifcation/device-name/		B2321-1
E2321-38	Brief description of the device	maa:device-identifcation/device-description		
E2321-14	Serial numbers or other indications necessary to delimit precisely the device(s) incorporated	maa:device-identifcation/device-serial-no		B2321-1
E2321-15	CE mark:			
E2321-16	Does the device(s) have a CE mark?			
E2321-17	Yes	maa:/CE-mark (value = 1)		B2321-1
E2321-18	No	maa:/CE-mark (value = 0)		B2321-1
E2321-19	If yes, please add the manufacturers declaration of conformity in module 3.2 R of the EU-CTD			
E2321-20	Notified Body			
E2321-21	Is the device(s) covered by certificates issued by a Notified Body?			
E2321-22	Yes	maa:Notified-body/maa:add-certificates		B2321-1
E2321-23	No	maa:Notified-body/maa:add-certificates		B2321-1
E2321-24	If yes, please add the certificate(s) in module 3.2 R of the EU-CTD.			
E2321-25	Please indicate for each notified Body involved:(For combined ATMPs, identify a Notified Body in any case)			
E2321-26	Name of the Notified Body	maa:Notified-body/rdm:contact-details /rdm:name/		B2321-1
E2321-27	Name of the Notified Number	maa:Notified-body/rdm:contact-details/rdm:number/		B2321-1
E2321-28	Name of the contact person:			
E2321-29	Title	maa:Notified-body/rdm:contact-details/ rdm:personal-title	Role > Party > Person > Personal title	B2321-1
E2321-30	First Name	maa:Notified-body/rdm:contact-details/ rdm:given-name	Role > Party > Person > given name	B2321-1
E2321-31	Surname	maa:Notified-body/rdm:contact-details/ rdm:family-name	Role > Party > Person > family name	B2321-1
E2321-32	Address	maa:Notified-body/rdm:contact-details/ rdm:address1 maa:Notified-body/rdm:contact-details/ rdm:address2 maa:Notified-body/rdm:contact-details/ rdm:address3 maa:Notified-body/rdm:contact-	Role>Party>Contact Details > Address	B2321-1

		details/ rdm:address4		
E2321-32a	City	maa:Notified-body/rdm:contact-details/ rdm:city		
E2321-32b	State	maa:Notified-body/rdm:contact-details/ rdm:state		
E2321-32c	county	maa:Notified-body/rdm:contact-details/ rdm:county		
E2321-33	Postcode	maa:Notified-body/rdm:contact-details/ rdm:post-code	Role>Party>Contact Details > Address> post code	B2321-1
E2321-34	Country	maa:Notified-body/rdm:contact-details/ rdm:country	Role>Party>Contact Details > Address > Country CTL	B2321-1
E2321-35	Telephone	maa:Notified-body/rdm:contact-details/ rdm:phone	Role>Party>Contact Details > Electronic Contact > electronic contact	B2321-1
E2321-35a	orgID	maa:Notified-body/rdm:contact-details/ rdm: orgID		
E2321-35b	locID	maa:Notified-body/rdm:contact-details/ rdm: locID		
E2321-35c	loc-modifiedDate	maa:Notified-body/rdm:contact-details/ rdm: loc-modifiedDate		
E2321-35d	language	maa:Notified-body/rdm:contact-details/ rdm: language		
E2321-37	E-mail	maa:Notified-body/rdm:contact-details/ rdm:email	Role>Party>Contact Details> Electronic Contact > electronic contact	B2321-1

Element Tree Diagram

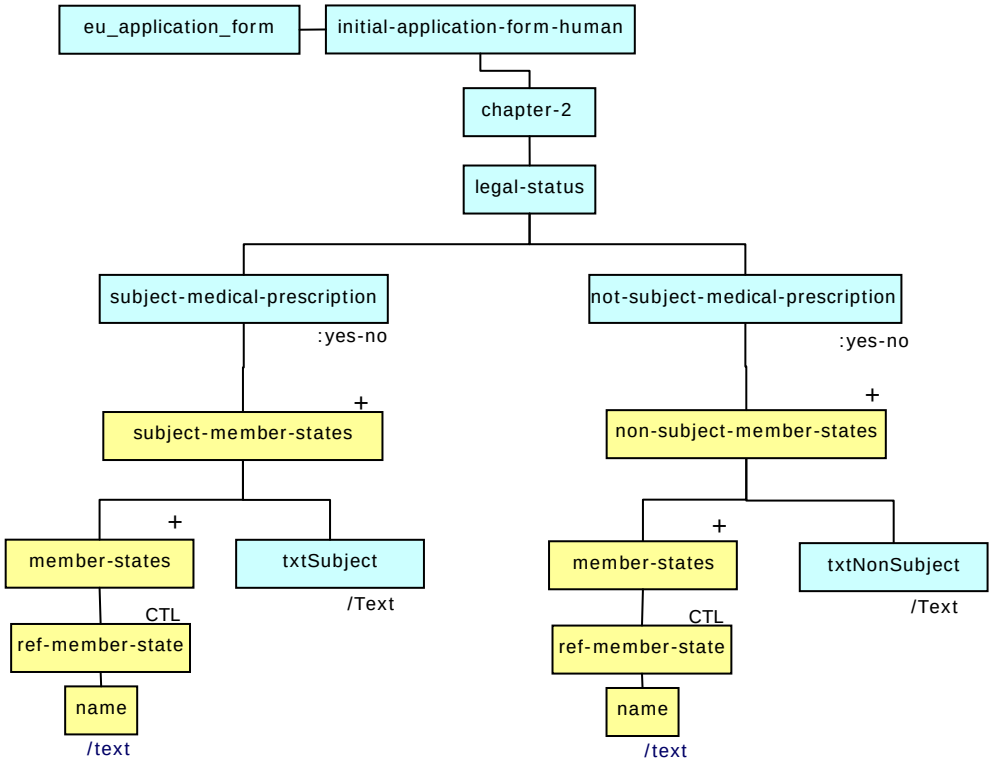


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2321-1	E2321-3 to E2321-11, E2321-13, E2321-14, E2321-17, E2321-18, E2321-22, E2321-23, E2321-26, E2321-37,	Optional.	These fields are optional.	

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		B233-1
E233-4	txtPackageSize	maa:subject_to_prescription_details/maa:subject-package-size		B233-1
E233-5	Member-states	maa:subject_to_prescription_details/maa:subject-member-states/ rdm:ref-member-state/rdm:name	Procedure Use > Role > Country CTL	B233-1
E233-6	Not subject to medical prescription *(Complete 2.3.3 & 2.3.4)*	maa:subject_to_prescription		B233-2
E233-7	txtPackageSize	maa:non-subject_to_prescription_details /maa:non-subject-package-size		B233-2
E233-8	Member-states	maa:non-subject_to_prescription_details / maa:non-subject-member-states/ rdm:ref-member-state/rdm:name	Procedure Use > Role > Country CTL	B233-2

Element Tree Diagram



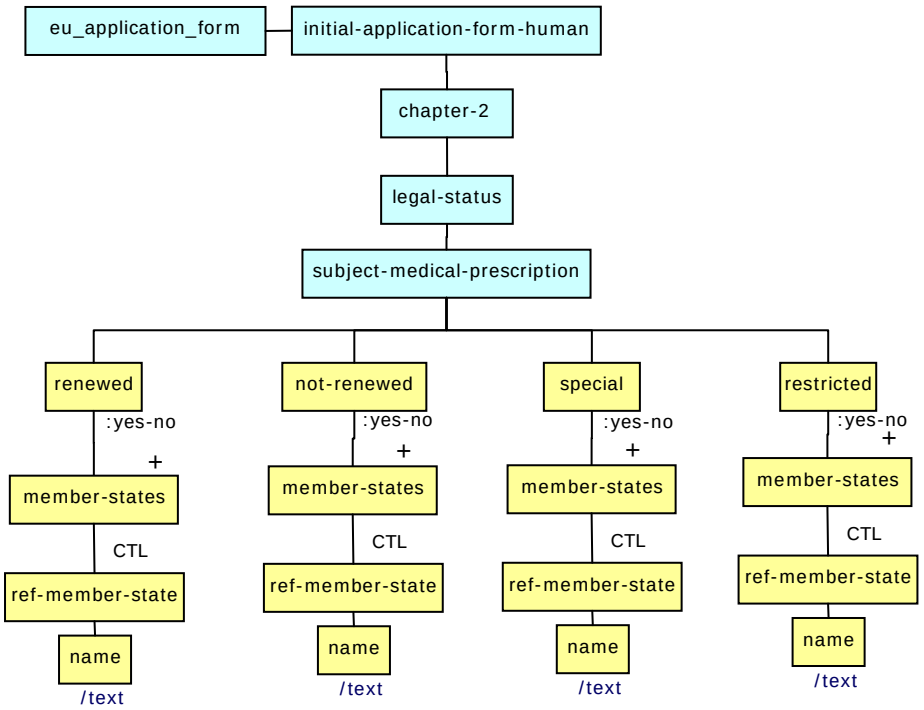
Business Rules

Rule ID	Element id(s)	Default BR	Rule	Effect(s)
B233-1	E233-5	optional	If E233-3 is selected, E233-5 and E233-6 are visible and E233-5 is mandatory	
B233-2	E233-8	optional	If E233-6 is selected, E233-7 and E233-8 are visible and E233-8 is 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*			
E2331-6	Member-states	maa:renewed-member-states/ rdm:ref-member-state/rdm:name	Procedure Use > Role > Country CTL	B2331-1
E2331-7	Member-states	maa:not-renewed-member-states/rdm:ref-member-state/rdm:name	Procedure Use > Role > Country CTL	B2331-2
E2331-8	Member-states	maa:special-member-states/rdm:ref-member-state/rdm:name	Procedure Use > Role > Country CTL	B2331-3
E2331-9	Member-states	maa:restricted-member-states/rdm:ref-member-state/rdm:name	Procedure Use > Role > Country CTL	B2331-4

Element Tree Diagram



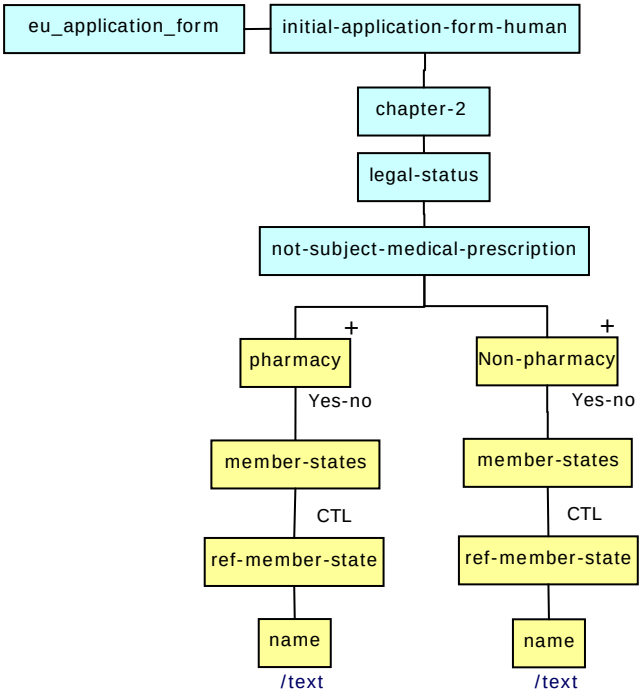
Business Rules

Rule ID	Element id(s)	Default BR	Rule	Effect(s)
B2331-1	E2331-6	Optional.	If E2331-1 is selected then E2331-6 is mandatory	
B2331-2	E2331-7	Optional.	If E2331-2 is selected then E2331-7 is mandatory	
B2331-3	E2331-8	Optional.	If E2331-3 is selected then E2331-8 is mandatory	
B2331-4	E2331-9	Optional.	If E2331-4 is selected then E2331-9 is mandatory	

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	Legal Status for the Supply CTL	B2332-1
E2332-2	Member-states	maa:pharmacy-member-states/rdm:ref-member-state/rdm:name	Procedure Use > Role > Country CTL	B2332-1
E2332-3	Supply through non-pharmacy outlets and pharmacies (if applicable)	maa:non-pharmacy	Legal Status for the Supply CTL	B2332-2
E2332-4	Member-states	maa:non-pharmacy-member-states/rdm:ref-member-state/rdm:name	Procedure Use > Role > Country CTL	B2332-2

Element Tree Diagram

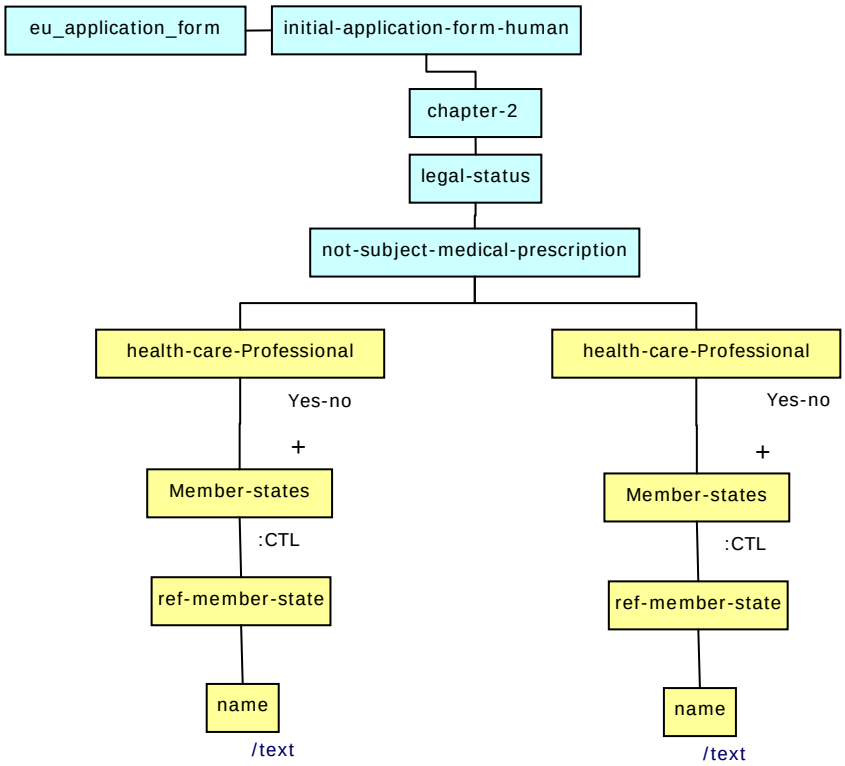


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2332-1	E2332-2	Optional.	If E2332-1 is selected then E2332-2 is visible and mandatory	
B2332-2	E2332-4	Optional.	If E2332-3 is selected then E2332-4 is visible and mandatory	

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	Legal Status for the Supply CTL	B2332-1
E2333-2	Member-states	maa:helath-care-member-states/rdm:ref-member-state/rdm:name	Procedure Use > Role > Country CTL	B2332-1
E2333-3	Promotion to general public and health care professionals	maa:public-health-care-Professional	Legal Status for the Supply CTL	B2332-2
E2333-4	Member-states	maa:public-member-states/rdm:ref-member-state/rdm:name	Procedure Use > Role > Country CTL	B2332-2

Element Tree Diagram

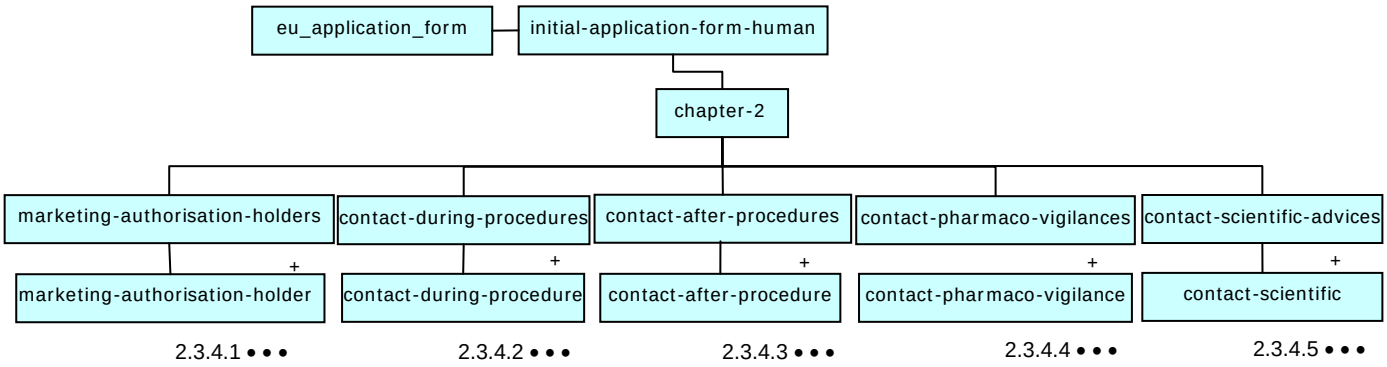


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2333-1	E2333-2	Optional	If E2333-1 is selected then E2333-2 is visible and mandatory	
B2333-2	E2333-4	Optional	If E2333-3 is selected then E2333-4 is visible and mandatory	

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 European Union/each Member State	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 European Union/each Member State	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 European Union/each Member State	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



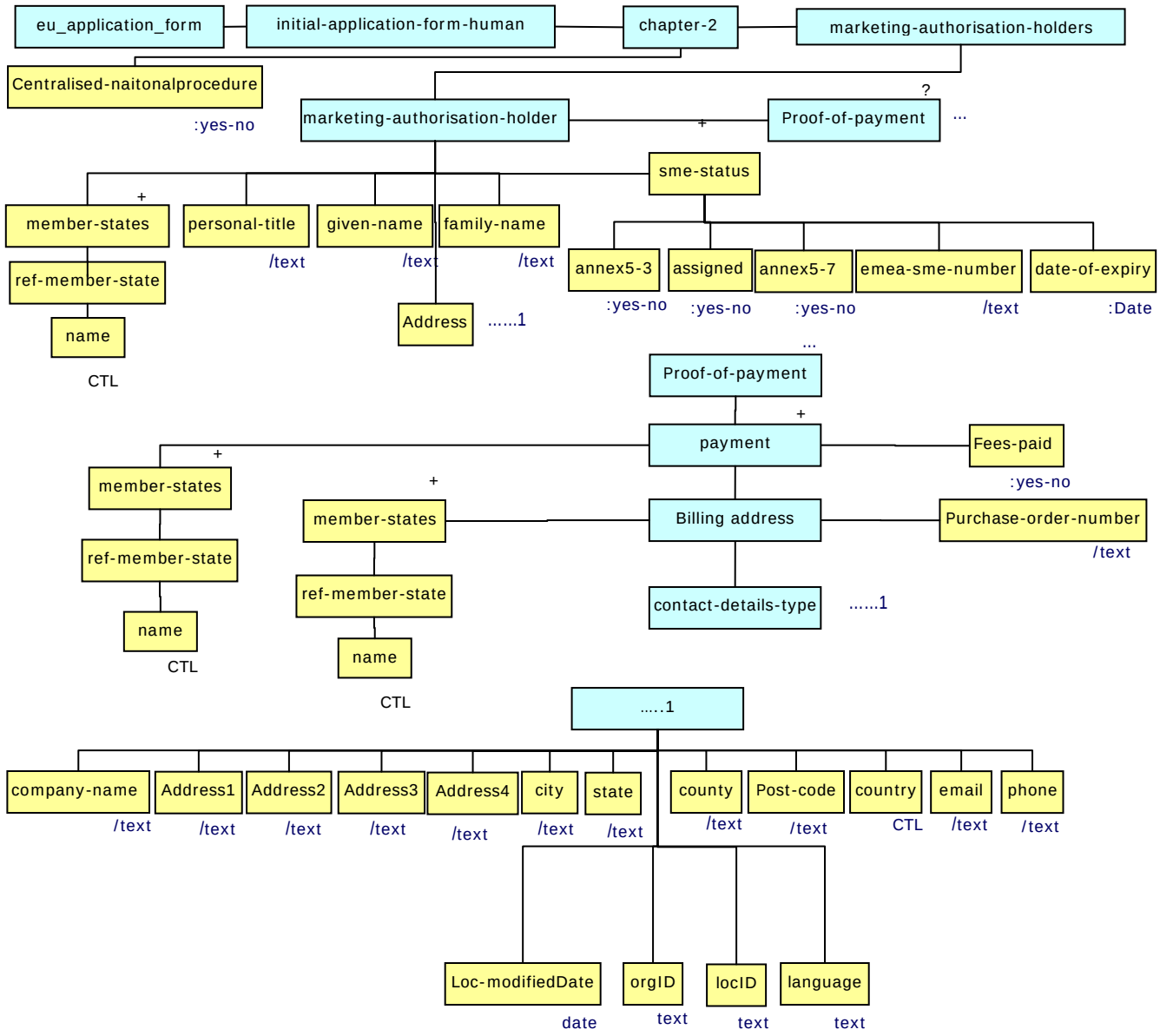
2.3.4.1 Proposed marketing authorisation holder/person legally responsible for placing the product on the market in the European Union/each MS

	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**
E2341-1	National procedure	maa:centralised-nationalprocedure(value=1)	Procedure Type CTL (Value="national")	B2341-3, B2342-1, B2343-2, B2344-1
E2341-2	Centralized procedure	maa:centralised-nationalprocedure(value=2)	Procedure Type CTL (Value="centralised")	B2341-3, B2342-1, B2343-2, B2344-1
E2341-3	Member states	maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:member-states/rdm:ref-member-state/rdm:name	Procedure Use > Role > Country CTL	B2341-3,
E2341-4	Company name	maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:company-name	MAH for Placing Product> Role>Party>Organisation>Name	
E2341-5	Address1	maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:address1	MAH for Placing Product>Role>Party>Contact Details > Address	
		maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:address2		
		maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:address3		
		maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:address4		
E2341-6	city	maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:city	MAH for Placing Product>Role>Party>Contact Details > city	
E2341-6a	state	maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:state		
E2341-6b	county	maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:county		
E2341-7	Postcode	maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:post-code	MAH for Placing Product>Role>Party>Contact Details > Address> post code	
E2341-8	Country	maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:country	MAH for Placing Product>Role>Party>Contact Details > Address > Country CTL	
E2341-8a	orgID	maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:orgID		
E2341-8b	locID	maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:locID		
E2341-8c	Loc-modifiedDate	maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:loc-modifiedDate		
E2341-8d	langugae	maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:language		
E2341-9	Telephone	maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:phone	MAH for Placing Product>Role>Party>Contact Details > Electronic Contact > electronic contact	
E2341-11	E-mail	maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:email	MAH for Placing Product>Role>Party>Contact Details > Electronic Contact > electronic contact	
E2341-12	Contact person at this address			B2341-4
E2341-13	Title	maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:personal-title	MAH for Placing Product>Role>Party>Person> Personal Title	B2341-4
E2341-14	First name	maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:given-name	MAH for Placing Product>Role>Party>Person> given name	B2341-4
E2341-15	Surname	maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:family-name	MAH for Placing Product>Role>Party>Person>family name	B2341-4

E2341-16	Attach proof of establishment of the applicant in the EEA (Annex 5.3)	maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:sme-status/rdm:annex5-3		
E2341-17	Has SME status been assigned by the EMA?			
E2341-18	Yes	maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:sme-status/rdm:assigned	MAH for Placing Product> has sme assigned to emea	B2341-1, B2341-2
E2341-19	No	maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:sme-status/rdm:assigned	MAH for Placing Product> has sme assigned to emea	B2341-1
E2341-20	EMA-SME Number	maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:sme-status/rdm:emea-sme-number	Party Identification>identification number	B2341-2
E2341-21	Date of expiry	maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:sme-status/rdm:date-of-expiry	Party Identification>expiry date	B2341-2
E2341-22	Attach copy of the "Qualification of SME Status" (Annex 5.7)	maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:sme-status/rdm:annex5-7		B2341-2
E2341-23	Proof of payment (when relevant)			
E2341-24	Have all relevant fees been prepaid to competent authorities?			
E2341-25	Yes	maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/maa:Proof-of-payment/maa: payment /maa:fees-paid (1)		B2341-5
E2341-26	No	maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/maa:Proof-of-payment/ maa: payment / maa:fees-paid (0)		B2341-5
E2341-27	For Member States	maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/maa:Proof-of-payment/ maa: payment / member-states/ref-member-state/name		B2341-5
E2341-28	Billing address (when relevant)			B2341-5
E2341-28a	For Member States	maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/maa:Proof-of-payment/ maa: payment /maa: billing-details / member-states/ref-member-state/name		B2341-5
E2341-29	Company Name	maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/maa:Proof-of-payment/ maa: payment /maa: billing-details/rdm:contact-details-type/company-name		B2341-5
E2341-30	VAT Number	maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/maa:Proof-of-payment/ maa: payment / maa:billing-details/maa:VAT-number		B2341-5
E2341-31	Address1	maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/maa:Proof-of-payment/ maa: payment / maa:billing-details/rdm: contact-details-type/rdm:address1	Role>Party>Contact Details > Address	B2341-5
		maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/maa:Proof-of-payment/ maa: payment / maa:billing-details/rdm: contact-details-type/rdm:address2		
		maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/maa:Proof-of-payment/ maa: payment / maa:billing-details/rdm: contact-details-type/rdm:address 3		
		maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/maa:Proof-of-payment/ maa: payment / maa:billing-details/rdm: contact-details-type/rdm:address 4		
E2341-32	city	maa:marketing-authorisation-holders/maa:marketing-authorisation-	MAH for Placing Product>Role>Party>Contact	B2341-5

		holder/rdm:city	Details > city	
E2341-32a	state	maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:state		
E2341-32b	county	maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:county		
E2341-33	Postcode	maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:post-code	MAH for Placing Product>Role>Party>Contact Details > Address> post code	
E2341-34	Country	maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:country	MAH for Placing Product>Role>Party>Contact Details > Address > Country CTL	
E2341-34a	orgID	maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:orgID		
E2341-34b	locID	maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:locID		
E2341-34c	Loc-modifiedDate	maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:loc-modifiedDate		
E2341-34d	langugae	maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:language		
E2341-35	Telephone	maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/maa:Proof-of-payment/ maa: payment / maa:billing-details/rdm: contact-details-type/rdm:phone	Role>Party>Contact Details > Electronic Contact > electronic contact	B2341-5
E2341-37	E-mail	maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/maa:Proof-of-payment/ maa: payment / maa:billing-details/rdm: contact-details-type/rdm:email	Role>Party>Contact Details> Electronic Contact > electronic contact	B2341-5
E2341-38	Purchase Order Number	maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/maa:Proof-of-payment/ maa: payment / maa: billing-details/Purchase-order-number		B2341-5

Element tree diagram

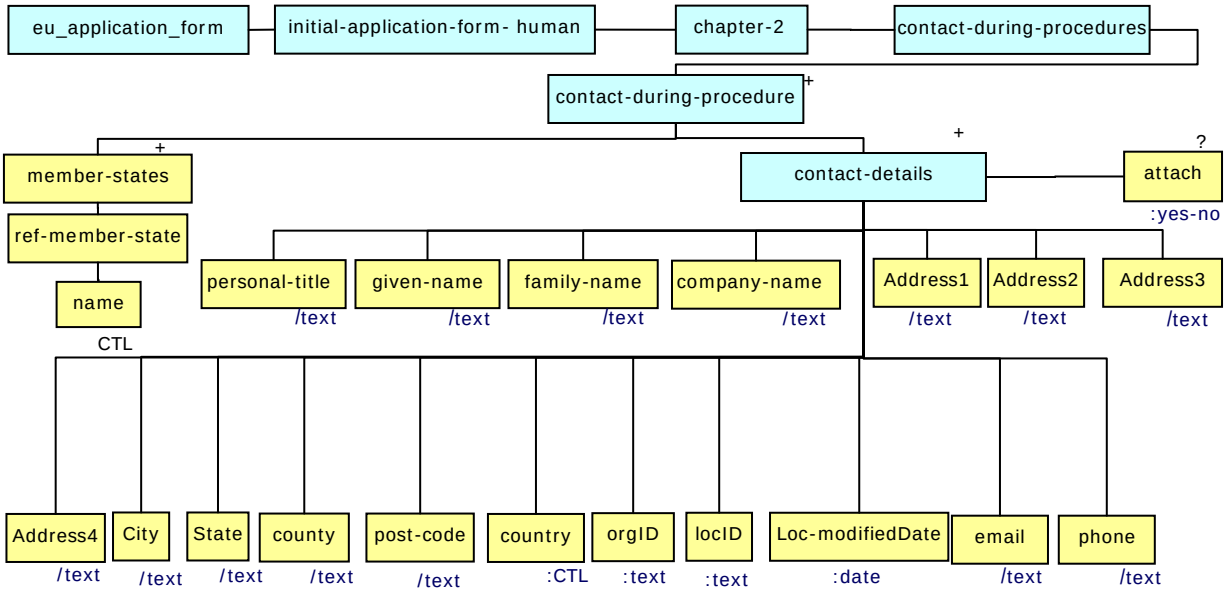


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2341-1	E2341-18, E2341-19	Mandatory.	Mutually Exclusive.	
B2341-2	E2341-18, E2341-20 to E2341-22	Mandatory.	If E2341-18 is selected, then the rest are mandatory, else they are hidden.	
B2341-3	E2341-1, E2341-2, E2341-3	hidden	If E2341-2 is selected then E2341-3 is visible If E2341-1 is selected then E2341-3 is invisible	
B2341-4	E2341-1, E2341-2, E2341-12, E2341-15,	hidden	If E2341-2 is selected then E2341-12 , ... E2341-15 is visible If E2341-1 is selected then E2341-12, E2341-15 is invisible	
B2341-5	E2341-25 to E2341-38	hidden	If E2341-25 is selected, then E2341-27 is visible and E2341-28 to E2341-38 are hidden If E2341-26 is selected, then E2341-28 to E2341-38 are visible and E2341-27 is hidden	

2.3.4.2 Person/company authorised for communication on behalf of the applicant during the procedure in the European Union/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	Member states	rdm:member-states/rdm:ref-member-state/rdm:name	Procedure Use > Role > Country CTL	B2342-1
E2342-2	Title	rdm:contact-details/rdm:personal-title	Role>Party>Person> Personal Title	
E2342-3	First name	rdm:contact-details/rdm:given-name	Role>Party>Person> given name	
E2342-4	Surname	rdm:contact-details/rdm:family-name	Role>Party>Person> family name	
E2342-5	Company name	rdm:contact-details/rdm:company-name	Role>Party>Organisation>Name	
E2342-6	Address1	rdm:contact-details/rdm:address1	Role>Party>Contact Details > Address	
		rdm:contact-details/rdm:address2		
		rdm:contact-details/rdm:address3		
		rdm:contact-details/rdm:address4		
E2342-7	City	rdm:contact-details/rdm:city	Role>Party>Contact Details > city	
E2342-7a	State	rdm:contact-details/rdm:state		
E2342-7b	County	rdm:contact-details/rdm:county		
E2342-8	Postcode	rdm:contact-details/rdm:post-code	Role>Party>Contact Details > postcode	
E2342-9	Country	rdm:contact-details/rdm:country	Role>Party>Contact Details > Address > Country CTL	
E2342-9a	orgID	rdm:contact-details/rdm:orgID		
E2342-9b	locID	rdm:contact-details/rdm:locID		
E2342-9c	Loc-modifiedDate	rdm:contact-details/rdm:loc-modifiedDate		
E2342-9d	langugae	rdm:contact-details /rdm:language		
E2342-10	Telephone	rdm:contact-details/rdm:phone	Role>Party>Contact Details > Electronic Contact > electronic contact	E2342-10
E2342-12	E-mail	rdm:contact-details/rdm:email	Role>Party>Contact Details> Electronic Contact > electronic contact	E2342-12
E2342-13	If different to 2.4.1 above, Attach letter of authorisation (Annex 5.4)	rdm:contact-details/rdm:attach		E2342-13

Element Tree Diagram



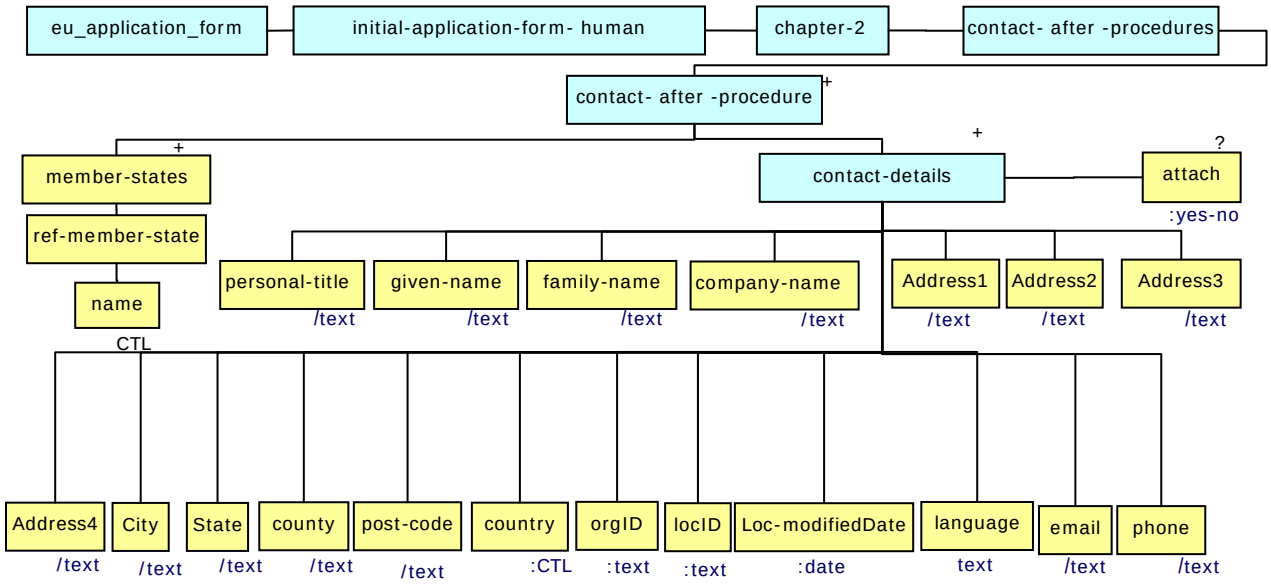
Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2342-1	E2341-1	hidden	If E2341-2 is selected then E2342-1 is visible If E2341-1 is selected then E2342-1 is invisible	

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 the European Union/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	Member states	rdm:member-states/rdm:ref-member-state/rdm:name	Procedure Use > Role > Country CTL	B2343-2
E2343-2	Title	rdm:contact-details/rdm:personal-title	Role>Party>Person> Personal Title	B2343-1
E2343-3	First name	rdm:contact-details/rdm:given-name	Role>Party>Person> given name	B2343-1
E2343-4	Surname	rdm:contact-details/rdm:family-name	Role>Party>Person> family name	B2343-1
E2343-5	Company name	rdm:contact-details/rdm:company-name	Role>Party>Organisation>Name	B2343-1
E2343-6	Address1	rdm:contact-details/rdm:address1	Role>Party>Contact Details > Address	B2343-1
		rdm:contact-details/rdm:address2		
		rdm:contact-details/rdm:address3		
		rdm:contact-details/rdm:address4		
E2343-7	city	rdm:contact-details/rdm:city	Role>Party>Contact Details > city	B2343-1
E2343-7a	state	rdm:contact-details/rdm:state		
E2343-7b	county	rdm:contact-details/rdm:county		

E2343-8	Postcode	rdm:contact-details/rdm:post-code	Role>Party>Contact Details > Address> post code	B2343-1
E2343-9	Country	rdm:contact-details/rdm:country	Role>Party>Contact Details > Address > Country CTL	B2343-1
E2343-9a	orgID	rdm:contact-details/rdm:orgID		
E2343-9b	locID	rdm:contact-details/rdm:locID		
E2343-9c	Loc-modifiedDate	rdm:contact-details/rdm:loc-modifiedDate		
E2343-9d	langugae	rdm:contact-details /rdm:language		
E2343-10	Telephone	rdm:contact-details/rdm:phone	Role>Party>Contact Details > Electronic Contact > electronic contact	B2343-1
E2343-12	E-mail	rdm:contact-details/rdm:email	Role>Party>Contact Details> Electronic Contact > electronic contact	B2343-1
E2343-13	If different to 2.4.1 above, attach aletter of authorisation (Annex 5.4)	rdm:contact-details/rdm:attach		B2343-1

Element Tree Diagram



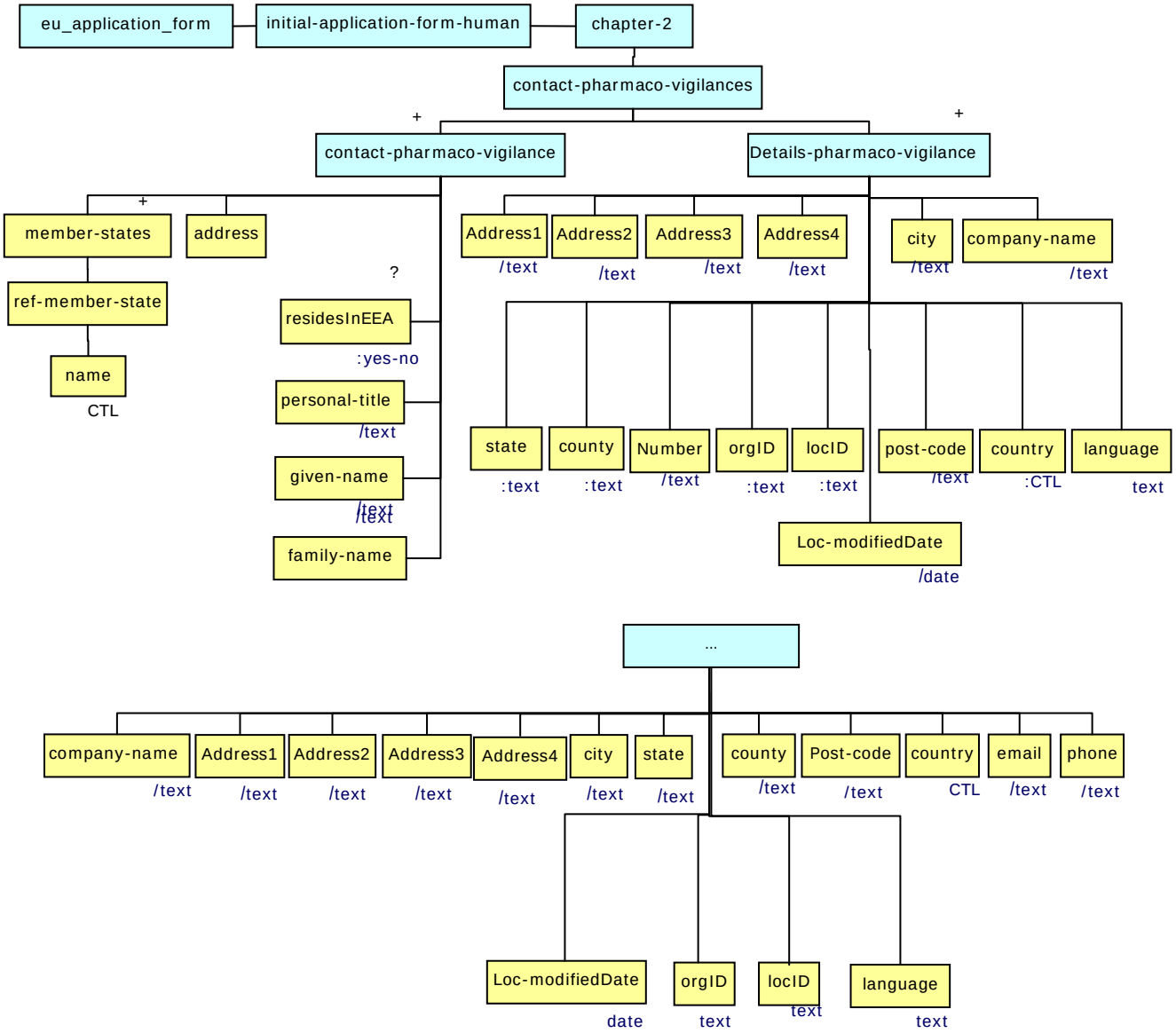
Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2343-1	E2343-1 to E2343-12	Optional.	Elements should be optional.	
B2343-2	E2343-1	hidden	If E2341-2 is selected then E2343-1 is visible If E2341-1 is selected then E2343-1 is invisible	

2.3.4.4 Summary of the applicant pharmacovigilance system

	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		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2344-1	Member states	maa:contact-pharmaco-vigilance/rdm:member-states/rdm:ref-member-state/rdm:name	Procedure Use > Role > Country CTL	B2344-1
E2344-2	Title	maa:contact-pharmaco-vigilance/rdm:personal-title	Role>Party>Person> Personal Title	
E2344-3	First name	maa:contact-pharmaco-vigilance/rdm:given-name	Role>Party>Person> given name	
E2344-4	Surname	maa:contact-pharmaco-vigilance/rdm:family-name	Role>Party>Person> family name	
E2344-5	Company name	maa:contact-pharmaco-vigilance/rdm:company-name	Role>Party>Organisation>Name	
E2344-6	Address1	maa:contact-pharmaco-vigilance/rdm:address1	Role>Party>Contact Details > Address	
		maa:contact-pharmaco-vigilance/rdm:address2		
		maa:contact-pharmaco-vigilance/rdm:address3		
		maa:contact-pharmaco-vigilance/rdm:address4		
E2344-7	city	maa:contact-pharmaco-vigilance/rdm:city	Role>Party>Contact Details > city	
E2344-8	Postcode	maa:contact-pharmaco-vigilance/rdm:post-code	Role>Party>Contact Details > Address> post code	
E2344-9	Country	maa:contact-pharmaco-vigilance/rdm:country	Role>Party>Contact Details > Address > Country CTL	
E2344-9a	state	maa:contact-pharmaco-vigilance/rdm: state		
E2344-9b	county	maa:contact-pharmaco-vigilance/rdm: county		
E2344-10	24H Telephone	maa:contact-pharmaco-vigilance/rdm:phone	Role>Party>Contact Details > Electronic Contact > electronic contact	
E2344-11a	orgID	maa:contact-pharmaco-vigilance/rdm: orgID		
E2344-11b	locID	maa:contact-pharmaco-vigilance/rdm: locID		
E2344-11c	Loc-modifiedDate	maa:contact-pharmaco-vigilance/rdm: loc-modifiedDate		
E2344-11d	langugae	maa:contact-pharmaco-vigilance /rdm:language		
E2344-12	E-mail	maa:contact-pharmaco-vigilance/rdm:email	Role>Party>Contact Details> Electronic Contact > electronic contact	
E2344-13	The above-mentioned qualified person resides6 in the EEA	maa:contact-pharmaco-vigilance/rdm:residesInEEA		
E2344-14	Pharmacovigilance system master file			
E2344-15	Number	maa:details-pharmaco-vigilance/maa:number		
E2344-16	Address1	maa:details-pharmaco-vigilance/rdm:address1	Role>Party>Contact Details > Address	
		maa:details-pharmaco-vigilance/rdm:address2		
		maa:details-pharmaco-vigilance/rdm:address3		
		maa:details-pharmaco-vigilance/rdm:address4		
E2344-16a	city	maa:details-pharmaco-vigilance/rdm:city		
E2344-16b	Postcode	maa:details-pharmaco-vigilance/rdm:post-code		
E2344-16c	Country	maa:details-pharmaco-vigilance/rdm:country		
E2344-17	state	maa:details-pharmaco-vigilance/rdm: state	Role>Party>Contact Details > Address> post code	
E2344-18	county	maa:details-pharmaco-vigilance/rdm:county	Role>Party>Contact Details > Address > Country CTL	

E2344-18a	orgID	maa:details-pharmaco-vigilance/rdm: orgID		
E2344-18b	locID	maa:details-pharmaco-vigilance/rdm: locID		
E2344-18c	Loc-modifiedDate	maa:details-pharmaco-vigilance/rdm: loc-modifiedDate		
E2344-18d	langugae	maa:details-pharmaco-vigilance /rdm:language		

Element Tree Diagram

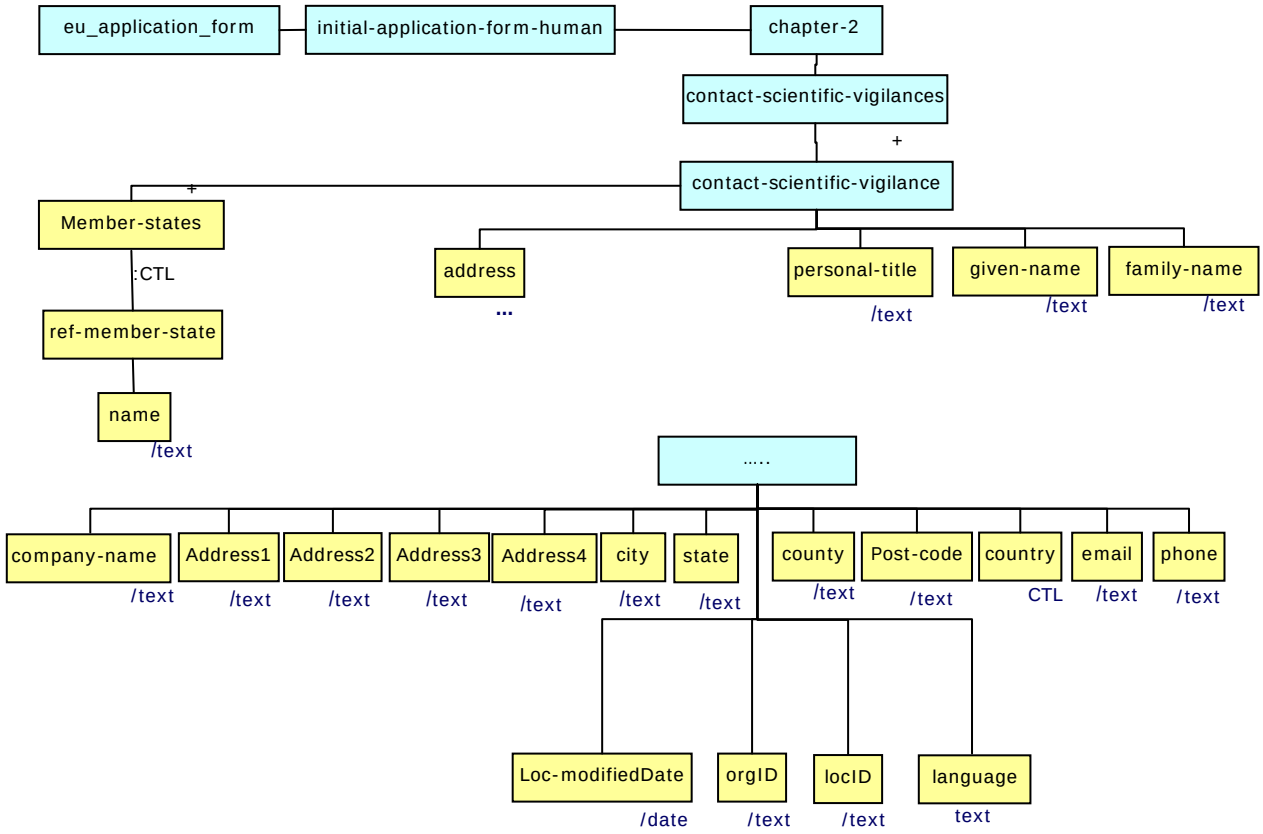


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2344-1	E2343-1	hidden	If E2341-2 is selected then E2344-1 is visible If E2341-1 is selected then E2344-1 is hidden	

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	Name of the contact person			
E2345-2	Title	rdm:personal-title	Role>Party>Person> Personal Title	
E2345-3	First name	rdm:given-name	Role>Party>Person> given name	
E2345-4	Surname	rdm:family-name	Role>Party>Person> family name	
E2345-5	Company name	rdm:company-name	Role>Party>Organisation>Name	
E2345-6	Address1	rdm:address1	Role>Party>Contact Details > Address	
		rdm:address2		
		rdm:address3		
		rdm:address4		
E2345-7	city	rdm:city	Role>Party>Contact Details > city	
E2345-7a	state	rdm:state		
E2345-7b	county	rdm:county		
E2345-8	Postcode	rdm:post-code	Role>Party>Contact Details > Address> post code	
E2345-9	Country	rdm:country	Role>Party>Contact Details > Address > Country CTL	
E2345-9a	orgID	rdm:orgID		
E2345-9b	locID	rdm:locID		
E2345-9c	Loc-modifiedDate	rdm:loc-modifiedDate		
E2345-9d	langugae	rdm:language		
E2345-10	Telephone	rdm:phone	Role>Party>Contact Details > Electronic Contact > electronic contact	
E2345-12	E-mail	rdm:email	Role>Party>Contact Details> Electronic Contact > electronic contact	
E2345-13	Member-states	rdm:member-states/rdm:ref-member-state/rdm:name	Procedure Use > Role > Country CTL	

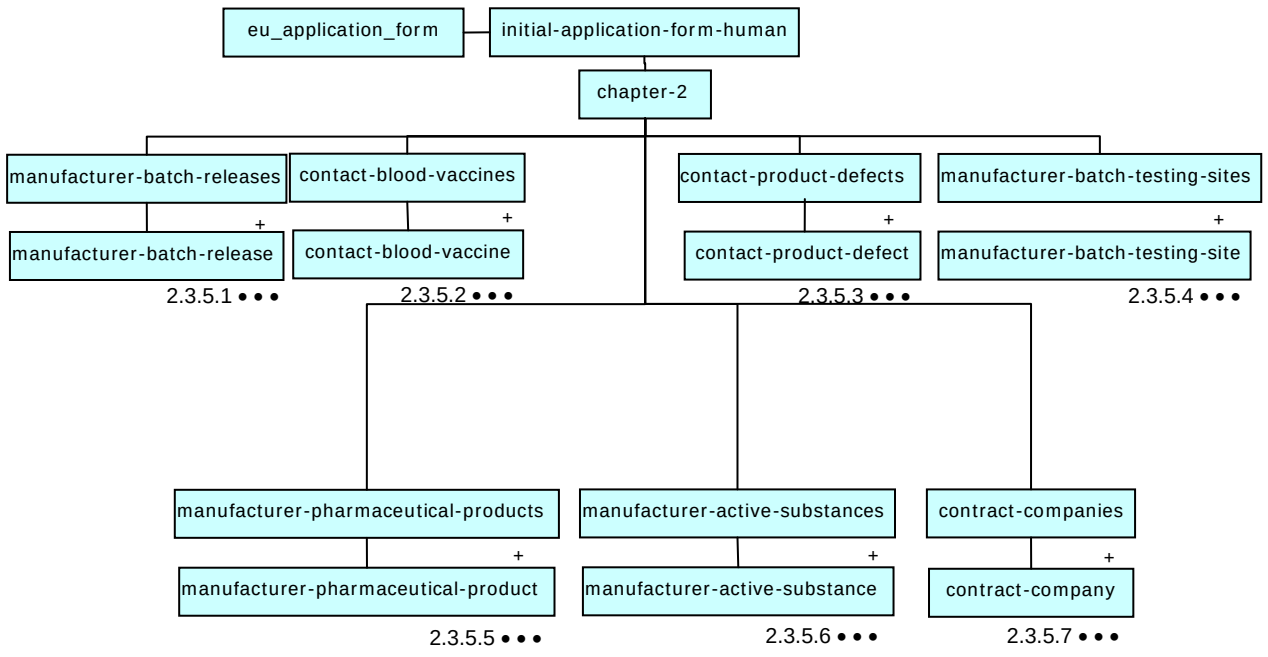
Element Tree Diagram



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 labeling 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-study		See Section 2.3.5.7

Element Tree Diagram

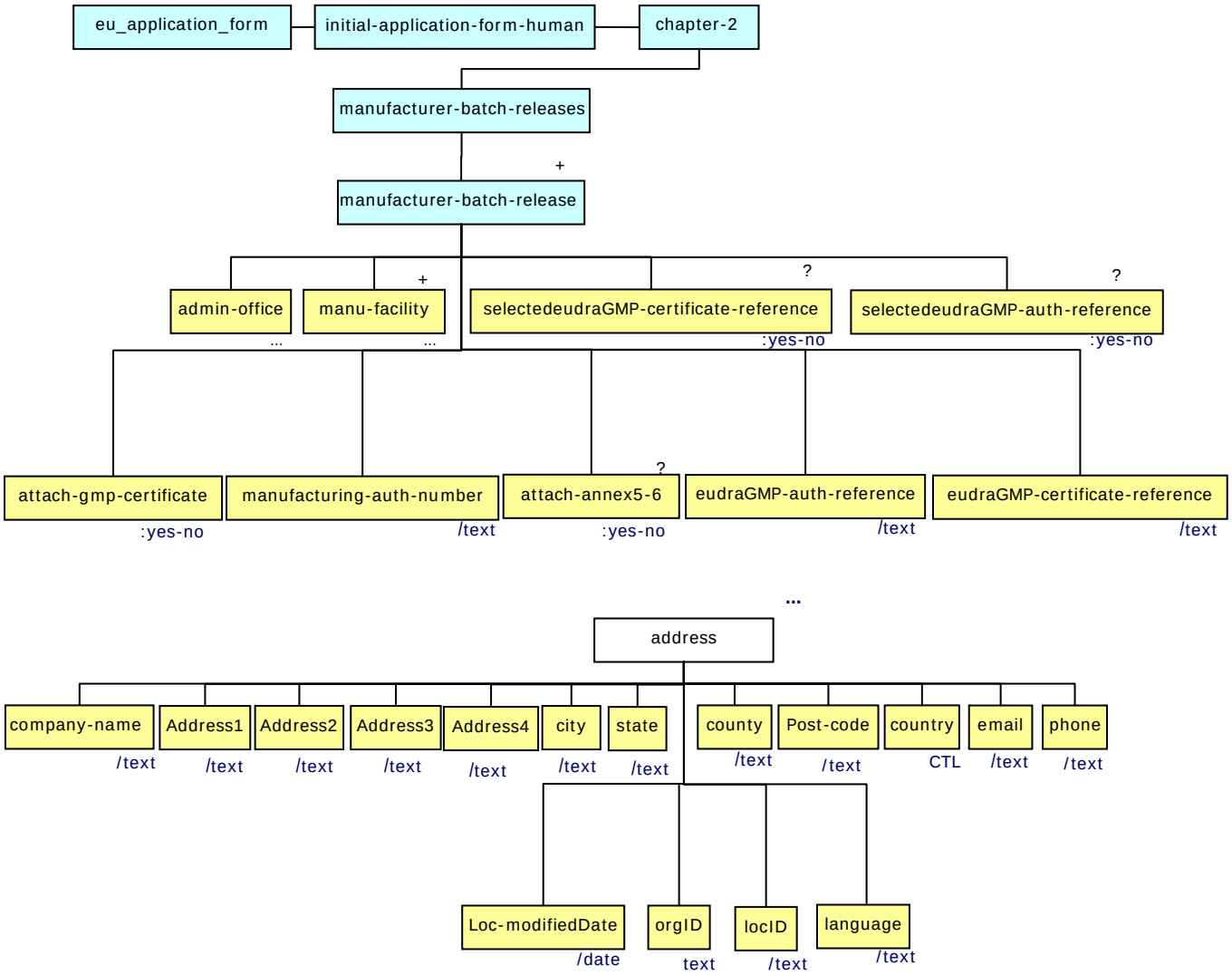


2.3.5.1 Authorised manufacturer(s) (or importer(s)) responsible for batch release in the EEA in accordance with Article 40 and Article 51 of Directive 2001/83/EC (as shown in the package leaflet and where applicable in the labeling of Annex II of the Commission Decision):

	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**
E2351-0	Package	rdm:package-responsible-manufacturer		
E2351-1	Do you have admin address and manufacturer address	maa:contact-details/rdm:admin-manu-address		B2351-5
E2351-2	Company name	rdm:/contact-details/rdm:admin-office/ rdm:company-name	Role>Party>Organisation>Name	B2351-5
E2351-3	Admin Office Address 1	rdm:/contact-details/ rdm:admin-office/rdm:address1	Role>Party>Contact Details > Address	B2351-5
		rdm:/contact-details/ rdm:admin-office/rdm:address2		
		rdm:/contact-details/ rdm:admin-office/rdm:address3		
		rdm:/contact-details/ rdm:admin-office/rdm:address4		
E2351-4	city	rdm:/contact-details/ rdm:admin-office/rdm:city	Role>Party>Contact Details > City	B2351-5
E2351-4a	state	rdm:/contact-details/ rdm:admin-office/rdm:state		
E2351-4b	county	rdm:/contact-details/ rdm:admin-office/rdm:county		
E2351-5	Postcode	rdm:/contact-details/ rdm:post-code	Role>Party>Contact Details > Address> post code	B2351-5
E2351-6	Admin Office Country	rdm:/contact-details/ rdm:admin-office/rdm:country	Role>Party>Contact Details > Address > Country CTL	B2351-5
E2351-6a	orgID	rdm:/contact-details/ rdm:admin-office/rdm:country		
E2351-6b	locID	rdm:/contact-details/ rdm:admin-office/rdm:locID		
E2351-6c	Loc-modifiedDate	rdm:/contact-details/ rdm:admin-office/rdm:loc-modifiedDate		
E2351-6d	langugae	rdm:/contact-details/ rdm:admin-office/rdm:language		
E2351-7	Admin Office Telephone	rdm:/contact-details/ rdm:admin-office/rdm:phone	Role>Party>Contact Details > Electronic Contact > electronic contact	B2351-5
E2351-9	Admin Office E-mail	rdm:/contact-details/ rdm:admin-office/rdm:email	Role>Party>Contact Details > Electronic Contact > electronic contact	B2351-5
E2351-10	Company name	rdm:/contact-details/ rdm:manu-facility/ rdm:company-name	Role>Party>Organisation>Name	B2351-5
E2351-11	Manufacturing Facility Address 1	rdm:/contact-details/ rdm:manu-facility/rdm:address1	Role>Party>Contact Details > address	B2351-5
		rdm:/contact-details/ rdm:manu-facility/rdm:address2		
		rdm:/contact-details/ rdm:manu-facility/rdm:address3		
		rdm:/contact-details/ rdm:manu-facility/rdm:address4		
E2351-12	City	rdm:/contact-details/ rdm:manu-facility/rdm:city	Role>Party>Contact Details > city	B2351-5
E2351-	Post code	rdm:/contact-details/		

12a		rdm:manu-facility/rdm: postcode		
E2351-12b	Manufacturing Facility Country	rdm:/contact-details/rdm:manu-facility/rdm:country		
E2351-13	state	rdm:/contact-details/rdm:manu-facility/rdm: state	Role>Party>Contact Details > Address> post code	B2351-5
E2351-14	county	rdm:/contact-details/rdm:manu-facility/rdm: county	Role>Party>Contact Details > Address > Country CTL	B2351-5
E2351-14a	orgID	rdm:/contact-details/rdm:manu-facility/rdm: orgID		
E2351-14b	locID	rdm:/contact-details/rdm:manu-facility/rdm: locID		
E2351-14c	Loc-modifiedDate	rdm:/contact-details/rdm:manu-facility/rdm: loc-modifiedDate		
E2351-14d	langugae	rdm:/contact-details/rdm:manu-facility/rdm:language		
E2351-15	Manufacturing Facility Telephone	rdm:/contact-details/ rdm:manu-facility/rdm:phone	Role>Party>Contact Details > Address > Country CTL	B2351-5
E2351-17	Manufacturing Facility E-mail	rdm:/contact-details/ rdm:manu-facility/rdm:email	Role>Party>Contact Details > Electronic Contact > electronic contact	B2351-5
E2351-18	Manufacturing Authorisation number	rdm:manufacturing-auth-number	Manufacturing auth number	
E2351-19	Attach copy of manufacturing authorisation(s) (Annex 5.6)	rdm:attach-annex5-6		B2351-1
E2351-20	Enter EudraGMDP document reference number	rdm:selectedeudraGMP-auth-reference		B2351-1, B2351-3
E2351-21	Enter EudraGMDP document reference number	rdm:eudraGMP-auth-reference	Eudragmp auth ref	B2351-3
E2351-22	Attach latest GMP certificate (Annex 5.9)	rdm:attach-gmp-certificate		B2351-2
E2351-23	Enter EudraGMDP document reference number	rdm:selectedeudraGMP-certificate-reference		B2351-2, B2351-4
E2351 24	Enter EudraGMDP document reference number	rdm:eudraGMP-certificate-reference	Eudragmp certificate ref no	B2351-4

Element Tree Diagram

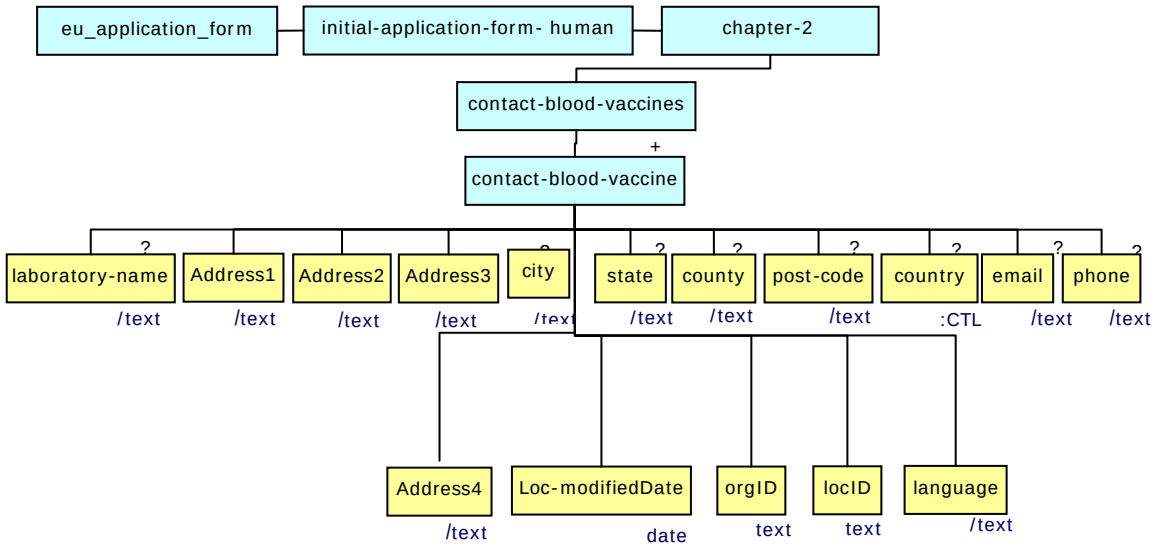


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2351-1	E2351-19, E2343-20	Mandatory.	Mutually Exclusive.	
B2351-2	E2351-22, E2351-23	Mandatory.	Mutually Exclusive.	
B2351-3	E2351-20, E2351-21	Mandatory, Optional.	If E2351-20 is selected, E2351-21 is mandatory.	
B2351-4	E2351-23, E2351-24	Mandatory, Optional.	If E2351-23 is selected, E2351-24 is mandatory.	
B2351-5	E2351-1 to E2351-17	mandatory and visible	E2351-1 is yes then E2351-3 to E2351-17 are visible else E2351-10 to E2351-17 are visible	

2.3.5.1.1 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	B2352-1
E2352-2	Address1	rdm:address	Role>Party>Contact Details > Address	B2352-1
E2352-3	Address2	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	B2352-1
E2352-6	Telephone	rdm:phone	Role>Party>Contact Details > Electronic Contact > electronic contact	B2352-1
E2352-8	E-mail	rdm:email	Role>Party>Contact Details> Electronic Contact > electronic contact	B2352-1
E2352-2	Admin Office Address 1	rdm:address1	Role>Party>Contact Details > Address	B2352-1
		rdm:address2		
		rdm:address3		
		rdm:address4		
E2352-3	city	rdm:city	Role>Party>Contact Details > City	B2352-1
E2352-4	state	rdm:state		
E2352-5	county	rdm:county		
E2352-6	Postcode	rdm:post-code	Role>Party>Contact Details > Address> post code	B2352-1
E2352-7	Country	rdm:country	Role>Party>Contact Details > Address > Country CTL	B2352-1
E2352-8	orgID	rdm:country		
E2352-9	locID	rdm:locID		
E2352-10	Loc-modifiedDate	rdm:loc-modifiedDate		
E2352-10a	langugae	rdm:language		
E2352-11	Telephone	rdm:phone	Role>Party>Contact Details > Electronic Contact > electronic contact	B2352-1
E2352-13	E-mail	rdm:email	Role>Party>Contact Details > Electronic Contact > electronic contact	B2352-1

Element Tree Diagram

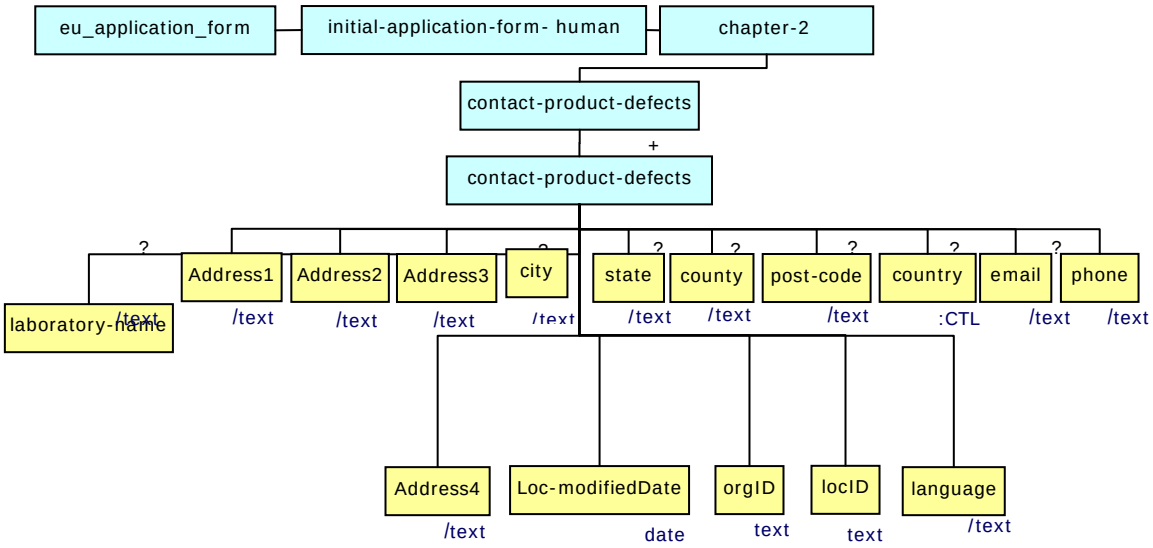


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2352-1	E2352-1 to E2352-13	Optional	Elements should be optional	

2.3.5.2 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	Company name	rdm:company-name	Role>Party>Organisation>Name	B2353-1
E2353-2	Title	rdm:personal-title	Role>Party>Person> Personal Title	B2353-1
E2353-3	First name	rdm:given-name	Role>Party>Person> given name	B2353-1
E2353-4	Surname	rdm:family-name	Role>Party>Person> family name	B2353-1
E2353-5	Address1	rdm:address1	Role>Party>Contact Details > Address	B2353-1
		rdm:address2		B2353-1
		rdm:address3		B2353-1
		rdm:address4		B2353-1
E2353-6	City	rdm:city	Role>Party>Contact Details > city	B2353-1
E2353-6a	state	rdm:state		B2353-1
E2353-6b	County	rdm:county		B2353-1
E2353-7	Postcode	rdm:post-code	Role>Party>Contact Details > Address> post code	B2353-1
E2353-8	Country	rdm:country	Role>Party>Contact Details > Address > Country CTL	B2353-1
E2353-8a	orgID	rdm:country		B2353-1
E2353-8b	locID	rdm:locID		B2353-1
E2353-8c	Loc-modifiedDate	rdm:loc-modifiedDate		B2353-1
E2353-8d	langugae	rdm:language		
E2353-9	24H Telephone	rdm:phone	Role>Party>Contact Details > Electronic Contact > electronic contact	B2353-1
E2353-11	E-mail	rdm:email	Role>Party>Contact Details> Electronic Contact > electronic contact	B2353-1

Element Tree Diagram

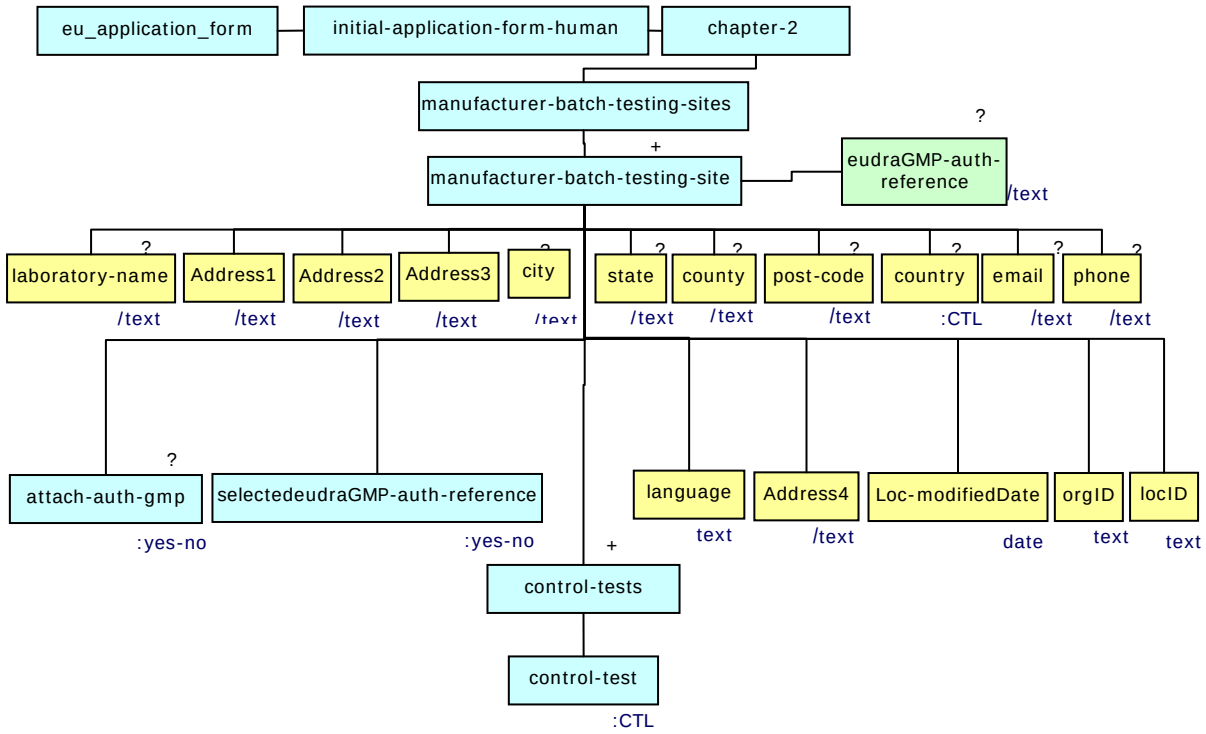


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2353-1	E2353-1 to E2353-11	Optional	Elements should be optional	

2.3.5.2.1 Batch control Testing arrangements Site(s) in the EEA or in countries where an MRA or other European Union 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	Address1	rdm:address1	Role>Party>Contact Details > Address	
		rdm:address2		
		rdm:address3		
		rdm:address4		
E2354-3	City	rdm:city	Role>Party>Contact Details > city	
E2354-4	state	rdm:state		
E2354-4a	County	rdm:county		
E2354-4b	postcode	rdm:post-code		
E2354-5	Country	rdm:country	Role>Party>Contact Details > Address > Country CTL	
E2354-5a	orgID	rdm:country		
E2354-5b	locID	rdm:locID		
E2354-5c	Loc-modifiedDate	rdm:loc-modifiedDate		
E2354-5d	langugae	rdm:language		
E2354-6	Telephone	rdm:phone	Role>Party>Contact Details > Electronic Contact > electronic contact	
E2354-8	E-mail	rdm:email	Role>Party>Contact Details> Electronic Contact > electronic contact	
E2354-9	control-test	rdm:control-tests/ rdm:control-test		
E2354-10	Brief description of control tests carried out by the laboratory(ies) concerned. (note: please see the `Compilation of Union Procedures on Inspections and Exchange of Information' document, (see pages - Interpretation of the Union Format for Manufacturer/Importer Authorisation): http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004706.pdf Site(s)	rdm:desc	control test carried	
E2354-11	Attach copy of manufacturing authorisation(s) or other proof of GMP compliance (Annex 5.6)	rdm:attach-auth-gmp		B2354-1
E2354-12	Enter EudraGMDP document reference number	rdm:selectedeudraGMP-auth-reference		B2354-1, B2354-2
E2354-13	Enter EudraGMDP document reference number	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.	

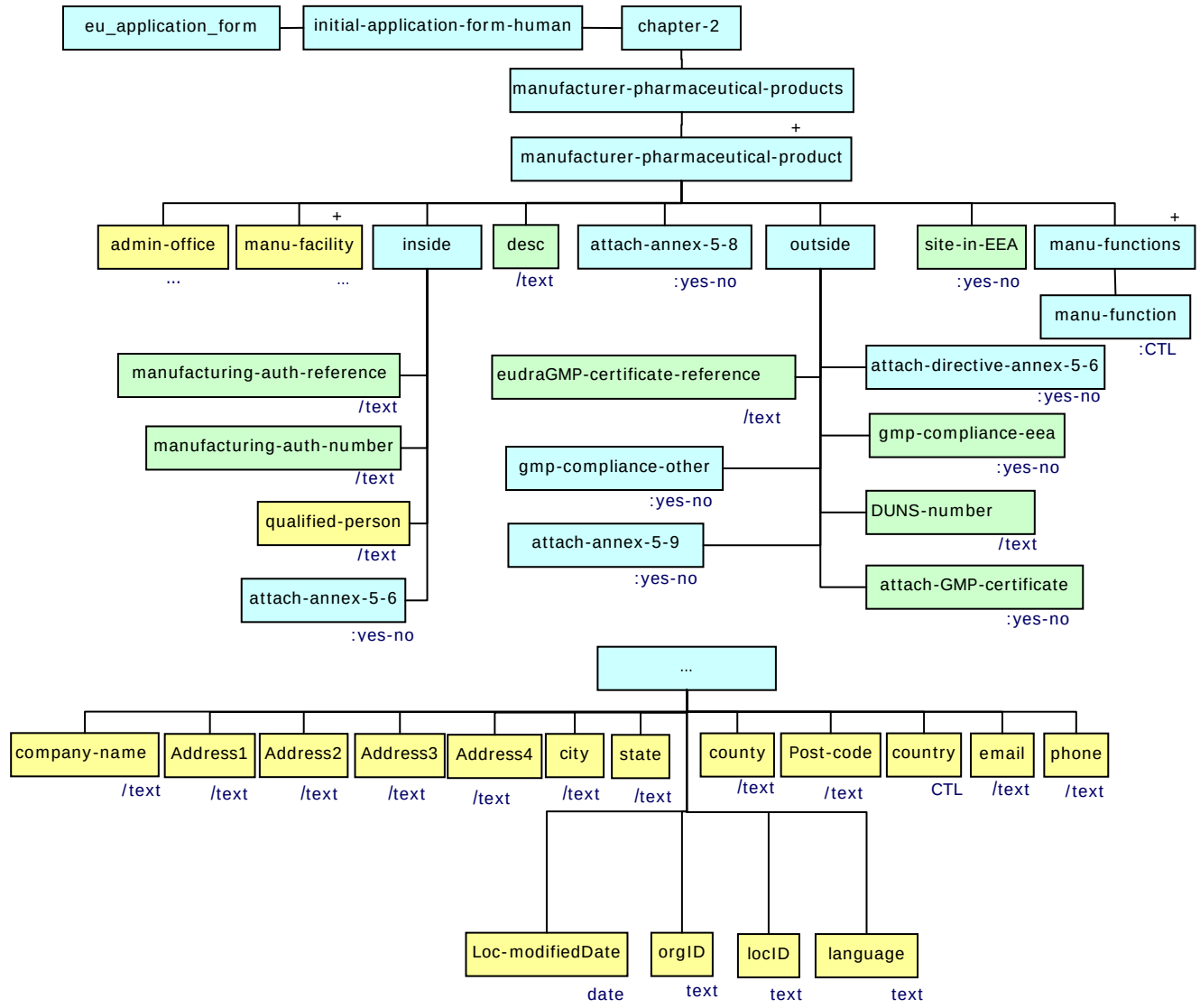
2.3.5.3 Manufacturer(s) of the medicinal product and site(s) of manufacture: *(Note: including manufacturing sites of any diluent/solvent presented in a separate container but forming part of the medicinal product, quality control/ in-process testing sites, and importer(s).For each site provide the relevant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

	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**
E2355-0	Description of the partial product	maa:partial-product-desc		
E2355-1	Do you have admin address and manufacturer address	maa:contact-details/rdm:admin-manu-address		B2355-12
E2355-2	Admin Office Address	rdm:/contact-details/rdm:admin-office/rdm:address1	Role>Party>Contact Details > Address	
		rdm:/contact-details/rdm:admin-office/rdm:address2		B2355-12
		rdm:/contact-details/rdm:admin-office/rdm:address3		B2355-12
		rdm:/contact-details/rdm:admin-office/rdm:address4		B2355-12
E2355-2a	city	rdm:/contact-details/rdm:admin-office/rdm:city	Role>Party>Contact Details > City	B2355-12
E2355-2b	state	rdm:/contact-details/rdm:admin-office/rdm:state		B2355-12
E2355-2c	county	rdm:/contact-details/rdm:admin-office/rdm:county		B2355-12
E2355-3	Postcode	rdm:/contact-details/rdm:post-code	Role>Party>Contact Details > Address> post code	B2355-12
E2355-4	Admin Office Country	rdm:/contact-details/rdm:admin-office/rdm:country	Role>Party>Contact Details > Address > Country CTL	
E2355-4a	orgID	rdm:/contact-details/rdm:admin-office/rdm:country		B2355-12
E2355-4b	locID	rdm:/contact-details/rdm:admin-office/rdm:locID		B2355-12
E2355-4c	Loc-modifiedDate	rdm:/contact-details/rdm:admin-office/rdm:loc-modifiedDate		B2355-12
E2355-4d	langugae	rdm:/contact-details/rdm:admin-office/rdm:language		
E2355-5	Admin Office Telephone	rdm:/contact-details/rdm:admin-office/rdm:phone	Role>Party>Contact Details > Electronic Contact > electronic contact	B2355-12
E2355-7	Admin Office E-mail	rdm:/contact-details/rdm:admin-office/rdm:email	Role>Party>Contact Details > Electronic Contact > electronic contact	B2355-12
E2355-7a	Company name	rdm:/contact-details/rdm:manu-facility/rdm:company-name	Role>Party>Organisation>Name	B2355-12
E2355-8	Manufacturing Facility Address	rdm:/contact-details/rdm:manu-facility/rdm:address1	Role>Party>Contact Details > Address	
		rdm:/contact-details/rdm:manu-facility/rdm:address2		
		rdm:/contact-details/rdm:manu-		B2355-1, B2355-2

		facility/rdm:address3		
		rdm:/contact-details/ rdm:manu-facility/rdm:address4		B2355-1, B2355-4, B2355-5
E2355-8a	City	rdm:/contact-details/ rdm:manu-facility/rdm:city	Role>Party>Contact Details > city	B2355-2, B2355-3
E2355-8b	Post code	rdm:/contact-details/ rdm:manu-facility/rdm:post-code		
E2355-8c	Manufacturing Facility Country	rdm:/contact-details/ rdm:manu-facility/rdm: country		B2355-2, B2355-3
E2355-8b	state	rdm:/contact-details/rdm:manu-facility/rdm:state	Role> Party > Contact Details > postcode	B2355-4
E2355-9	county	rdm:/contact-details/rdm:manu-facility/rdm: county	Role>Party>Contact Details > Address > Country CTL	B2355-4
E2355-9a	orgID	rdm:/contact-details/rdm:manu-facility/rdm: orgID		B2355-4
E2355-9b	locID	rdm:/contact-details/rdm:manu-facility/rdm: locID		
E2355-9c	Loc-modifiedDate	rdm:/contact-details/rdm:manu-facility /rdm:loc-modifiedDate		
E2355-9d	langugae	rdm:/contact-details/rdm:manu-facility /rdm:language		
E2355-10	Manufacturing Facility Telephone	rdm:/contact-details/ rdm:manu-facility/rdm:phone	Role>Party>Contact Details > Electronic Contact > electronic contact	B2355-12
E2355-12	Manufacturing Facility E-mail	rdm:/contact-details/ rdm:manu-facility/rdm:email	Role>Party>Contact Details > Electronic Contact > electronic contact	B2355-12
E2355-13	Brief description of functions performed. (note: please see the `Compilation of Union Procedures on Inspections and Exchange of Information' document, (see pages - Interpretation of the Union Format for Manufacturer/Importer Authorisation): http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004706.pdf Site(s)	rdm:desc		
E2355-13a	Manufacturer functions	rdm:manu-functions/ rdm: manu-function		
E2355-14	Site is in the EEA:	rdm:site-in-EEA	is site in eea	B2355-1, B2355-2
E2355-15	Site is outside the EEA:	rdm:site-in-EEA	is site in eea	B2355-1, B2355-4, B2355-5
E2355-16	Manufacturing authorisation number	rdm:inside/ rdm:manufacturing-auth-number	manufacturing auth number	B2355-2, B2355-3
E2355-17	Attach copy of manufacturing authorisation(s) (Annex 5.6)	rdm:inside/rdm:attach-annex-5-6		
E2355-18	Enter EudraGMDP document reference number	rdm:inside/rdm:manufacturing-auth-reference	eudragmp auth ref	B2355-2, B2355-3
E2355-19	Name of qualified person	rdm:inside/rdm:qualified-person	Role>Party>Person> given name	B2355-4
E2355-20	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		B2355-4

E2355-21	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?			B2355-4
E2355-23	Yes	rdm:outside/ rdm:gmp-compliance-eea	inspected by eea authority	B2355-4, B2355-5, B2355-6, B2355-7
E2355-24	No	rdm:outside/ rdm:gmp-compliance-eea	inspected by eea authority	B2355-4, B2355-5, B2355-6 B2355-9
E2355-25	Attach latest GMP certificate or other proof of GMP compliance	rdm:outside/rdm:attach-GMP-certificate		B2355-4, B2355-7, B2355-8 B2355-9
E2355-26	Enter EudraGMDP document reference number:	rdm:outside/ rdm:eudraGMP-certificate-reference	eudragmp certificate ref no	B2355-4, B2355-7, B2355-8, B2355-9
E2355-27	Has the site been inspected for GMP compliance by any other authority (including those of countries where MRA or other European Union arrangements apply but not within their respective territory)?			B2355-4,
E2355-28	Yes	rdm:outside/ rdm:gmp-compliance-other	inspected by other authority	B2355-4, B2355-5, B2355-9, B2355-10
E2355-29	No	rdm:outside/rdm:gmp-compliance-other	inspected by other authority	B2355-4, B2355-5, B2355-9
E2355-30	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		B2355-4, B2355-10
E2355-31	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		

Element Tree Diagram



Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2355-1	E2355-14, E2355-15	Mandatory.	Mutually Exclusive.	
B2355-2	E2355-14, E2355-16 to E2355-18	Mandatory.	If E2355-14 is selected, then the other fields are required.	
B2355-3	E2355-16, E2355-18	Optional.	Mutually Exclusive.	
B2355-4	E2355-15, E2355-20 to E2355-30	invisible	If E2355-15 is selected, then the other fields are visible.	
B2355-5	E2355-15, E2355-23 to E2355-24, E2355-28 to E2355-29	Optional.	If E2355-15 is selected, then the other fields are mandatory.	
B2355-6	E2355-23, E2355-24	Mandatory.	Mutually Exclusive.	
B2355-7	E2355-23, E2355-25 to E2355-26	Optional.	If E2355-23 is selected, then the rest are required.	
B2355-8	E2355-25, E2355-26	Optional.	Mutually Exclusive.	
B2355-9	E2355-24, E2355-25 to E2355-26	Invisible	If E2355-24 is selected, then the rest of the fields are invisible	
B2355-10	E2355-28, E2355-30	Optional	If E2355-28 is selected, then E2355-30 is mandatory	
B2355-11	E2355-28, E2355-30	Invisible.	If E2355-29 is selected, then E2355-30 is visible.	
B2355-12	E2355-1 to E2355-12	mandatory and visible	E2355-1 is yes then E2355-1a to E2355-12 are visible else E2355-1a to E2355-7 are hidden	

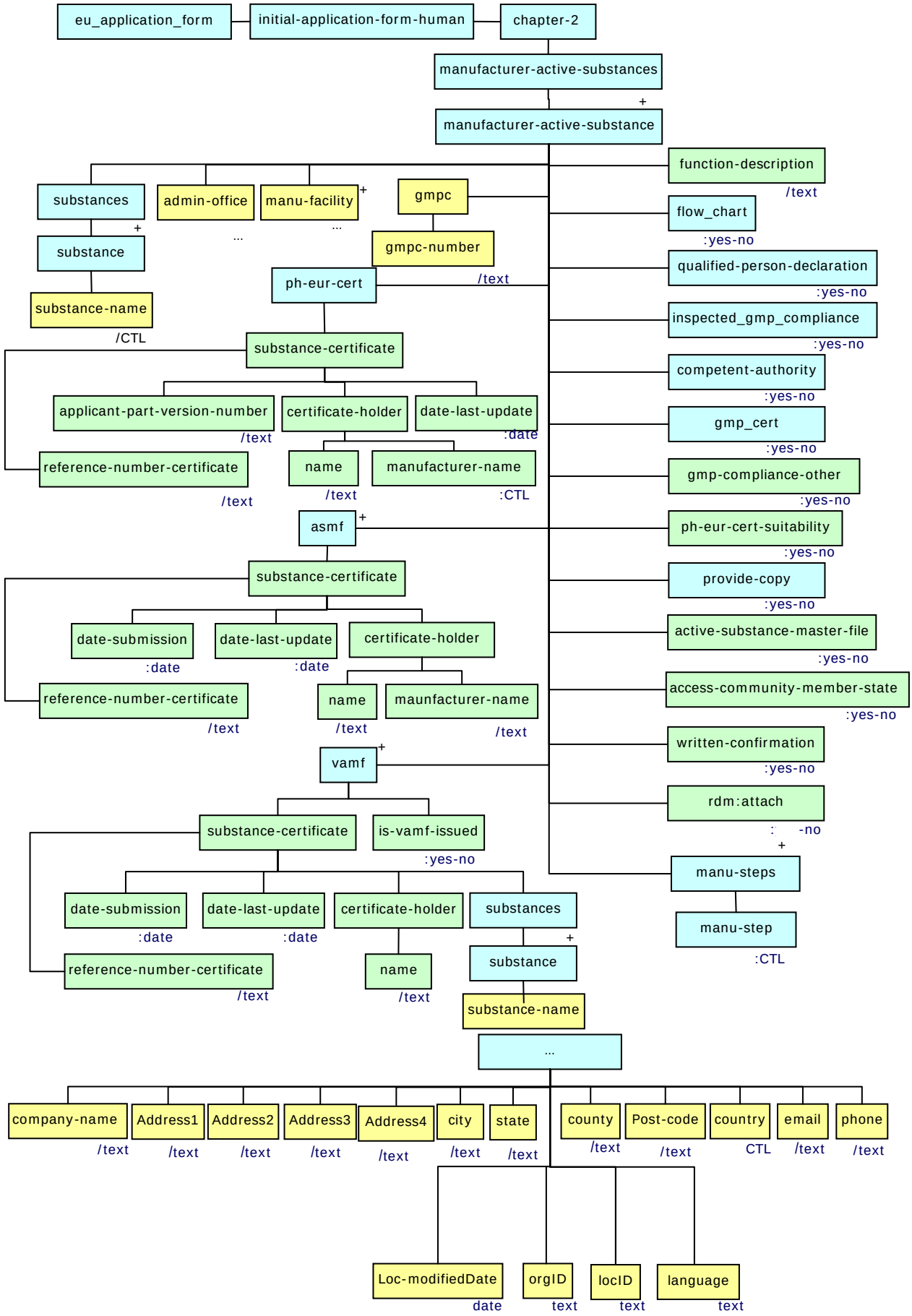
2.3.5.4 Manufacturer(s) of the active substance(s) and site(s) of manufacture *Note: All manufacturing sites involved the manufacturing process of each source of active substance, including quality control/ in-process testing sites, should be listed. Broker or supplier details alone are not acceptable. 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**
E2356-0	Description of the company	maa: company-description		
E2356-1	Active Substance	rdm:active-substances/ rdm:active-substance/ rdm:substance-name	Medicinal Product > Pharmaceutical Product > Ingredient > Substance CTL > term id	
E2356-2	Do you have admin address and manufacturer address	maa:role/maa:contact-details/rdm:admin-manu-address		B2356-12
E2356-2a	Company Name	rdm:/contact-details/ rdm:admin-office/ rdm:company-name	Role > Party > Organisation> Name	B2356-12
E2356-3	Admin Office Address 1	rdm:/contact-details/ rdm:admin-office/rdm:address1	Role>Party>Contact Details > Address	B2356-12
		rdm:/contact-details/ rdm:admin-office/rdm:address2		
		rdm:/contact-details/ rdm:admin-office/rdm:address3		
		rdm:/contact-details/ rdm:admin-office/rdm:address4		
E2356-3a	city	rdm:/contact-details/ rdm:admin-office/rdm:city	Role>Party>Contact Details > city	B2356-12
E2356-3b	state	rdm:/contact-details/ rdm:admin-office/rdm:state		
E2356-3c	county	rdm:/contact-details/ rdm:admin-office/rdm:county		
E2356-3b	Postcode	rdm:/contact-details/ rdm:post-code	Role> Party > Contact Details > electronic contact	B2356-12
E2356-4	Admin Office Country	rdm:/contact-details/ rdm:admin-office/rdm:country	Role>Party>Contact Details > Address > Country CTL	B2356-12
E2356-4a	orgID	rdm:/contact-details/ rdm:admin-office/rdm:country		
E2356-4b	locID	rdm:/contact-details/ rdm:admin-office/rdm:locID		
E2356-4c	Loc-modifiedDate	rdm:/contact-details/ rdm:admin-office/rdm:loc-modifiedDate		
E2356-4d	langugae	rdm:/contact-details/ rdm:admin-office/rdm:language		
E2356-5	Admin Office Telephone	rdm:/contact-details/ rdm:admin-office/rdm:phone	Role>Party>Contact Details > Electronic Contact > electronic contact	B2356-12
E2356-7	Admin Office E-mail	rdm:/contact-details/ rdm:admin-office/rdm:email	Role>Party>Contact Details > Electronic Contact > electronic contact	B2356-12
E2356-7a	Company Name	rdm:/contact-details/ rdm:manu-facility/ rdm:company-name	Role > Party > Organisation> Name	B2356-12
E2356-8	Manufacturing Facility Address 1	rdm:/contact-details/ rdm:manu-facility/rdm:address1	Role>Party>Contact Details > Address	B2356-12
		rdm:/contact-details/ rdm:manu-facility/rdm:address2		
		rdm:/contact-details/ rdm:manu-facility/rdm:address3		
		rdm:/contact-details/ rdm:manu-facility/rdm:address4		
E2356-8a	City	rdm:/contact-details/ rdm:manu-facility/ rdm:city	Role>Party>Contact Details > City	B2356-12
E2356-8b	Post code	rdm:/contact-details/ rdm:manu-facility/rdm: postcode		
E2356-8c	state	rdm:/contact-details/rdm:manu-facility/rdm: state		

E2356-8d	County	rdm:/contact-details/rdm:manu-facility/rdm: county		
E2356-9	Manufacturing Facility Country	rdm:/contact-details/ rdm:manu-facility/ rdm:country	Role>Party>Contact Details > Address > Country CTL	B2356-12
E2356-9a	orgID	rdm:/contact-details/rdm:manu-facility/rdm: orgID		
E2356-9b	locID	rdm:/contact-details/rdm:manu-facility/rdm: locID		
E2356-9c	Loc-modifiedDate	rdm:/contact-details/rdm:manu-facility/rdm: loc-modifiedDate		B2356-12
E2356-9d	langugae	rdm:/contact-details/rdm:manu-facility /rdm:language		
E2356-10	Manufacturing Facility Telephone	rdm:/contact-details/ rdm:manu-facility/rdm:phone	Role>Party>Contact Details > Electronic Contact > electronic contact	B2356-12
E2356-12	Manufacturing Facility E-mail	rdm:/contact-details/ rdm:manu-facility/rdm:email	Role>Party>Contact Details > Electronic Contact > electronic contact	B2356-12
E2356-13	Brief description of manufacturing steps performed by manufacturing site: (note: please see the `Compilation of Union Procedures on Inspections and Exchange of Information' document, (see pages - Interpretation of the Union Format for Manufacturer/Importer Authorisation): http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004706.pdf Site(s)	rdm:function-description	Manufacturing steps	
E2356-13a	Manufacturer steps	rdm:manu-steps/rdm: manu-step		
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 principles and 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 European Union 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				
E2356-20				
E2356-21	Attach latest GMP certificate in Annex 5.9	rdm:gmp_cert		B2356-2, B2356-3
E2356-22	EudraGMDP document 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	Name of the CEP holder	rdm:ph-eur-cert/rdm:substance-certificate/rdm:certificate-holder/rdm:name	Role > Party > Organisation> Name	B2356-7
E2356-33	Name of the manufacturer	rdm:ph-eur-cert/rdm:substance-certificate/rdm:certificate-holder/rdm:manufacturer-name	Role > Party > Organisation> Name	B2356-7
E2356-34	CEP 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 an 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	Name of the ASMF holder	rdm:asmf/rdm:substance-certificate/rdm:certificate-holder/rdm:name	European Drug Master File > Substance CTL	B2356-9
E2356-41	Name of the manufacturer	rdm:asmf/rdm:substance-certificate/rdm:certificate-holder/rdm:manufacturer-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	Applicant part version number	rdm:asmf/rdm:substance-certificate/rdm:Applicant-part-version-number	European Drug Master File > Version ?	B2356-9
E2356-44	Date of submission	rdm:asmf/rdm:substance-certificate/rdm:date-submission	European Drug Master File > Submission date	B2356-9
E2356-45	Date of last update	rdm:asmf/rdm:substance-certificate/rdm:date-last-update	European Drug Master File > Last update date	B2356-9
E2356-46	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
E2356-47	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
E2356-48	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?			
E2356-49	Yes	rdm:vamf/rdm:is-vamf-issued (Value=1)	Vaccine Antigen Master File>is certificate issued	B2356-10
E2356-50	No	rdm:vamf/rdm:is-vamf-issued (Value=0)	Vaccine Antigen Master File>is certificate issued	B2356-10
E2356-51	Active Substance	rdm:vamf/rdm:substance-certificate/rdm:active-substances/ rdm:active-substance/ rdm:substance-name	Vaccine Antigen Master File> Medicinal Product > Pharmaceutical Product > Ingredient > Substance CTL > term id	
E2356-52	Name of the VAMF Certificate Holder/VAMF Applicant	rdm:vamf/rdm:substance-certificate/rdm:certificate-holder/rdm:name	Role > Party > Organisation> Name	
E2356-53	Reference number of Application/ Certificate	rdm:vamf/rdm:substance-certificate/rdm:reference-number-certificate	Vaccine Antigen Master File>reference Number	
E2356-54	Date of submission (if pending)	rdm:vamf/rdm:substance-certificate/rdm:date-submission	Vaccine Antigen Master File > submission date	
E2356-55	Date of approval or last update (if approved)	rdm:vamf/rdm:substance-certificate/rdm:date-last-update	Vaccine Antigen Master File > last update date	
E2356-56	Provide copy in (Annex 5.20)	rdm:attach		

Element Tree Diagram



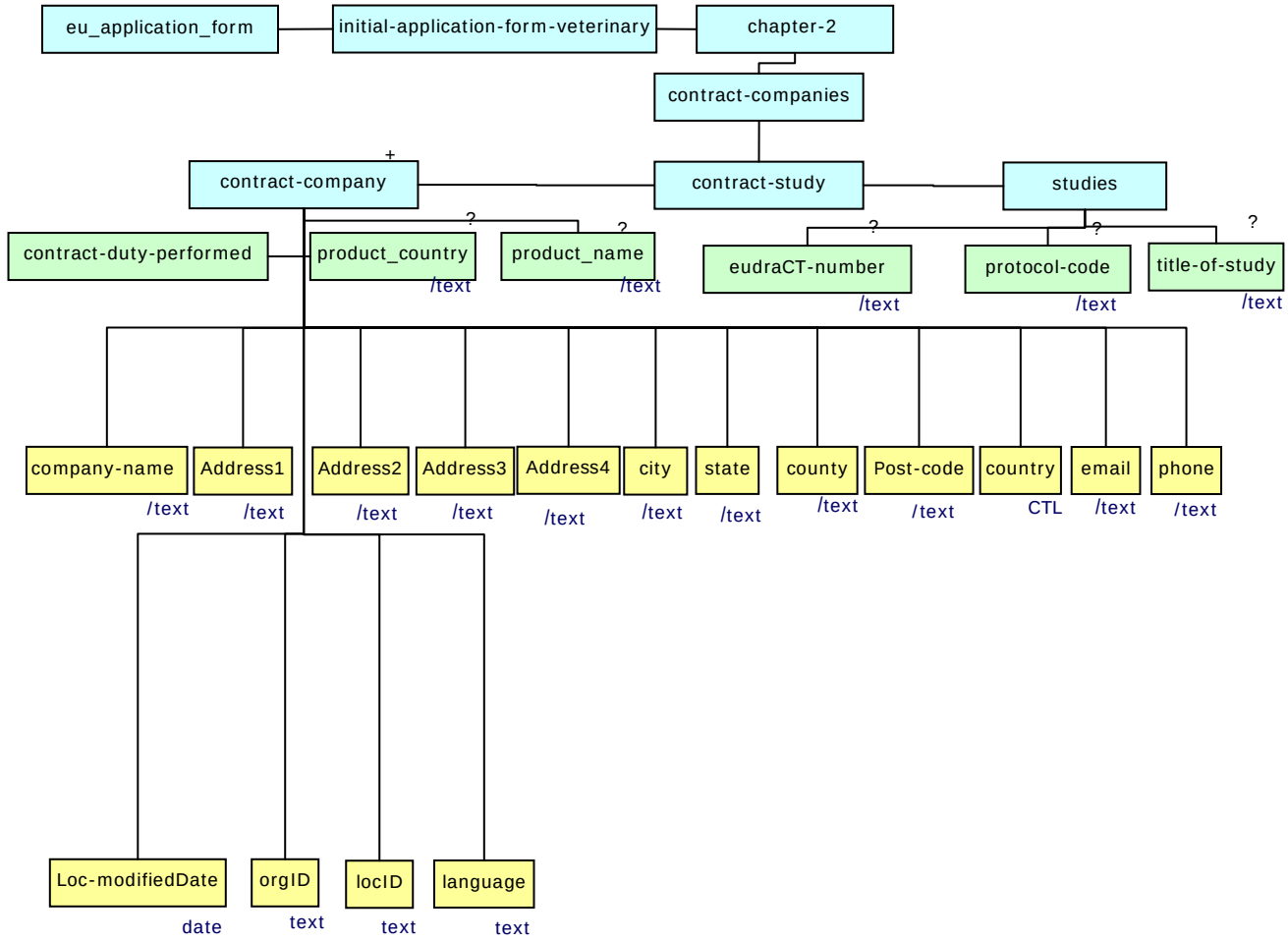
Business Rules

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, E2356-17 is 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 E2356-56	E2356-48 is Mandatory, Rest are optional.	If E2356-48 is selected, the rest are required.	
B2356-12	E2356-2 to E2356-12	mandatory and visible	E2356-2 is yes then E2356-3 to E2356-12 are visible else E2356-8 to E2356-12 are hidden	

2.3.5.5Contract 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-study/		Application > Contract Company CT >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2357-1	Company Name	rdm:contract-company/ rdm:company-name	Role > Party > Organisation> Name	
E2357-2	Address	rdm:contract-company/ rdm:address1	Role>Party>Contact Details > Address	
		rdm:contract-company/ rdm:address2		
		rdm:contract-company/ rdm:address3		
		rdm:contract-company/ rdm:address4		
E2357-3	City	rdm:contract-company/ rdm:city	Role>Party>Contact Details > Address > City	
E2357-3a	state	rdm:contract-company/ rdm:state		
E2357-3b	county	rdm:contract-company/ rdm:county		
E2357-4	PostCode	rdm:contract-company/ rdm:post-code	Role>Party>Contact Details > Address > post code	
E2357-5	Country	rdm:contract-company/ rdm:country	Role>Party>Contact Details > Address > Country CTL	
E2357-5a	orgID	rdm:contract-company/ rdm:orgID		
E2357-5b	locID	rdm:contract-company/ rdm:locID		
E2357-5c	loc-modifiedDate	rdm:contract-company/ rdm:loc-modifiedDate		
E2357-5d	langugae	rdm:contract-company/ rdm:language		
E2357-6	Telephone	rdm:contract-company/ rdm:phone	Role>Party>Contact Details > Electronic Contact > electronic contact	
E2357-8	E-mail	rdm:contract-company/ rdm:email	Role>Party>Contact Details > Electronic Contact > electronic contact	
E2357-9	Duty performed according to contract	rdm:contract-company/ rdm:contract-duty-performed	Duty performed	

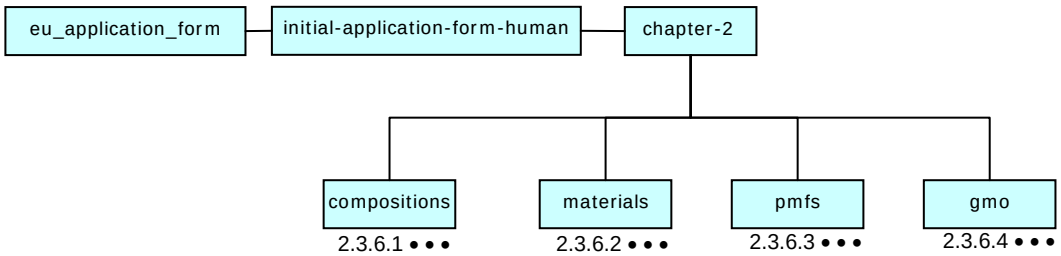
Element Tree Diagram



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 Quantitative 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

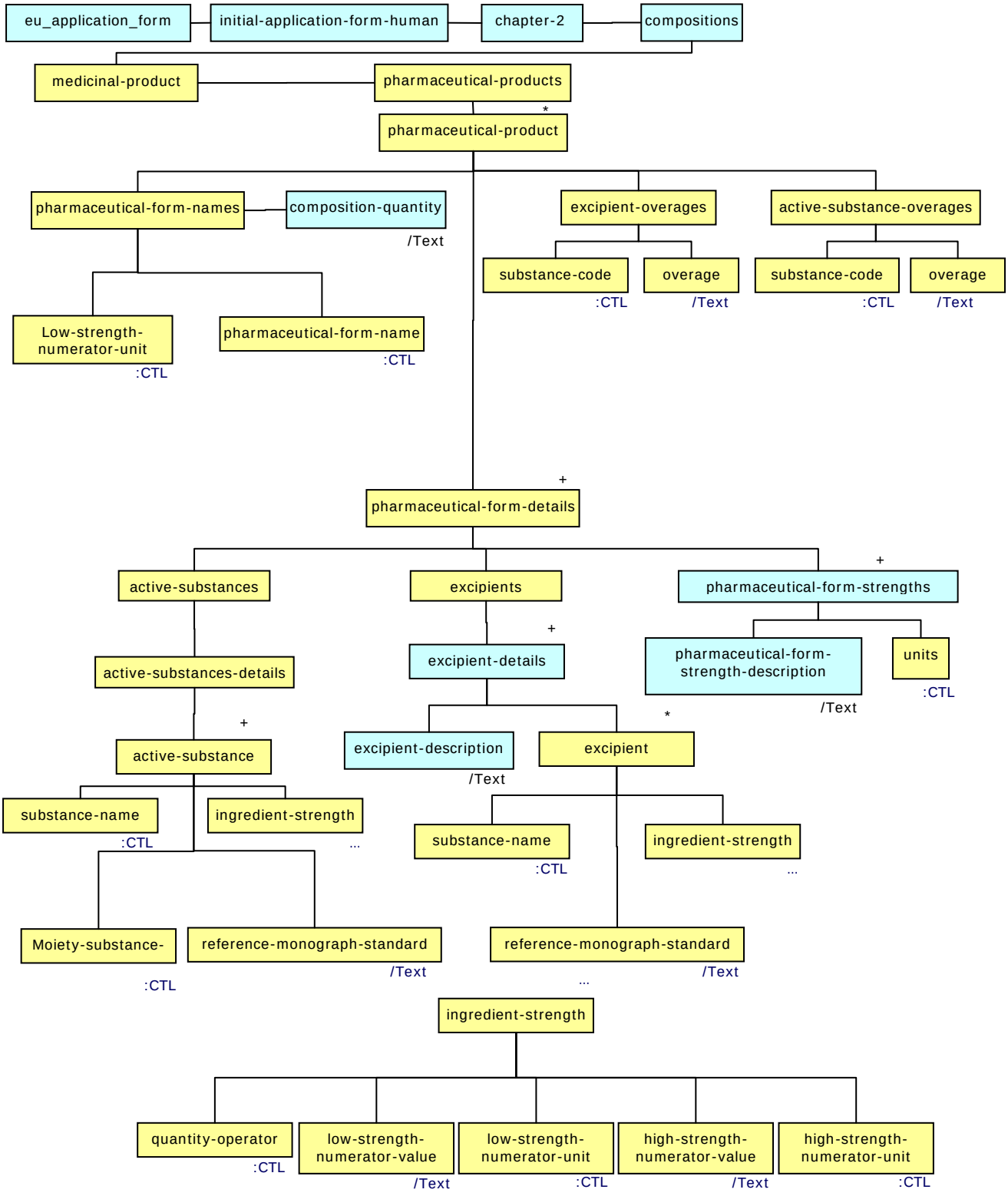


2.3.6. 1 Qualitative and Quantitative composition in terms of the active substance(s) and the excipient(s)

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-human/maa:chapter-2/maa:compositions/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)	rdm:pharmaceutical-form-names/rdm:composition-quantity		
E2361-2	composition-unit	rdm:pharmaceutical-form-names/rdm:Low-strength-numerator-unit		
E2361-3	Pharmaceutical Form	rdm:pharmaceutical-form-names/rdm:pharmaceutical-form-name/	Pharmaceutical Dose Form CTL > term id	
E2361-4	Strength	rdm:pharmaceutical-form-details/rdm:pharmaceutical-form-strengths/ rdm:pharmaceutical-form-strength-description		
E2361-4a	Units	rdm:pharmaceutical-form-details/rdm:pharmaceutical-form-strengths/ rdm:units		
E2361-5	Name of active substance	rdm:pharmaceutical-form-details/rdm:active-substances/ rdm: active-substances-details/rdm:active-substance/rdm:substance-name	Ingredient > Substance CTL	
E2361-5a	Base active moiety	rdm:pharmaceutical-form-details/rdm:active-substances/ rdm: active-substances-details/rdm:active-substance/rdm:moiety-substance-name	Ingredient > Substance CTL	
E2361-6	Quantity / Unit	rdm:pharmaceutical-form-details/rdm:active-substances/ rdm: active-substances-details/rdm:active-substance/rdm:ingredient-strength	Ingredient > Unit CTL	
E2361-7	Reference / Monograph Standard	rdm:pharmaceutical-form-details/rdm:active-substances/ rdm: active-substances-details/rdm:active-substance/rdm:reference-monograph-standard	??	
E2361-8	Name of Excipient	rdm:pharmaceutical-form-details/rdm:excipients / rdm:excipients-details/rdm:excipient /rdm:substance-name	Ingredient > Substance CTL	
E2361-9	Quantity / Unit	rdm:pharmaceutical-form-details/rdm:excipients / rdm:excipients-details/rdm:excipient /rdm:ingredient-strength	Ingredient > Unit CTL	
E2361-10	Reference / Monograph Standard	rdm:pharmaceutical-form-details/rdm:excipients / rdm:excipients-details/rdm:excipient /rdm:reference-monograph-standard	??	
E2361-11	Active Substance	rdm:pharmaceutical-form-details/rdm:active-substance-overages/rdm:substance-code	Ingredient > Substance CTL	
E2361-12	Overage	rdm:active-substance-overages/rdm:overage	Ingredient > Overage	

E2361-13	Excipient	rdm:excipient-overages/rdm:excipient-code	Ingredient > Substance CTL	
E2361-14	Overage	rdm:excipient-overages /rdm:overage	Ingredient > Overage	

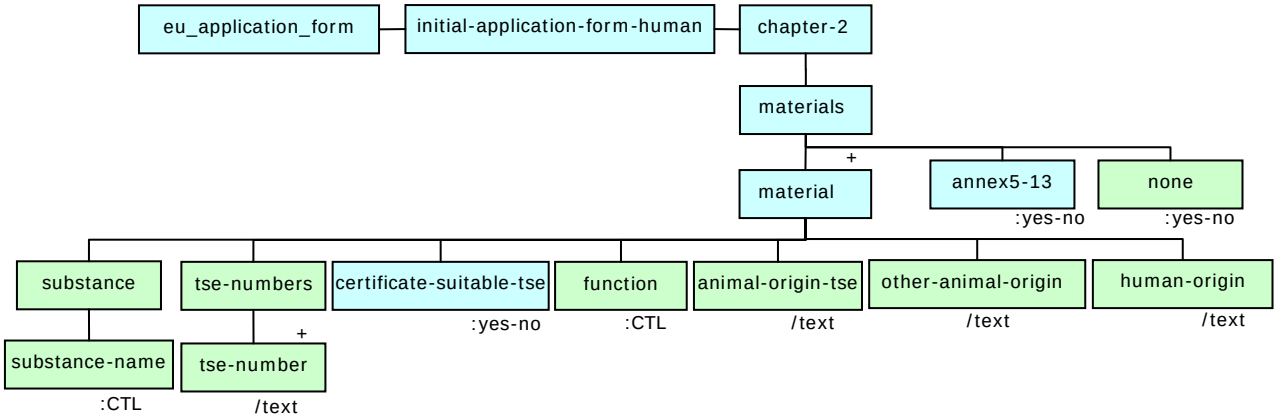
Element Tree Diagram



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

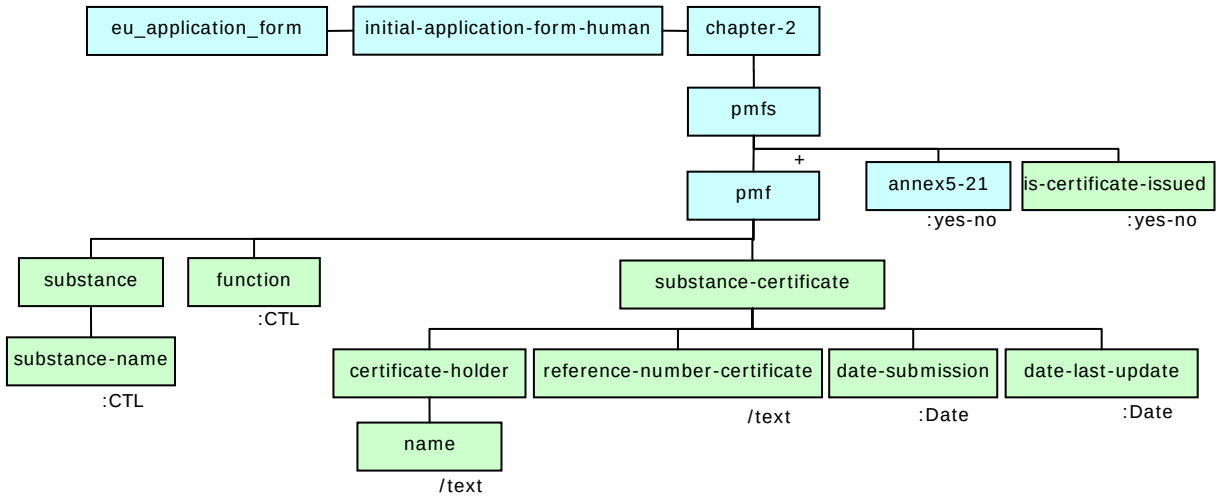


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2362-1	E2362-1, E2362-2 to E2362-11	Mandatory.	If E2362-1 is selected then the rest are optional.	
B2362-2	E2362-4 to E2362-6	Optional.	Mutually Exclusive.	
B2362-3	E2362-7 to E2362-9	Optional.	Mutually Exclusive.	
B2362-4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



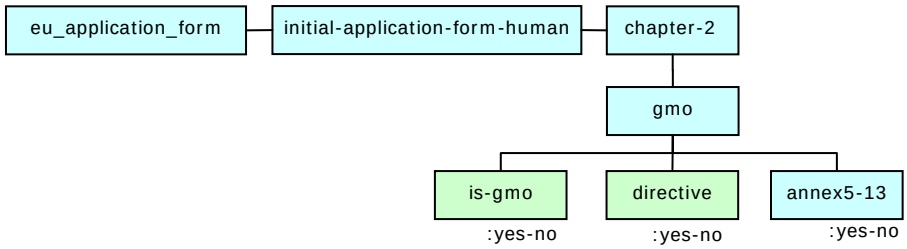
Business Rules

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



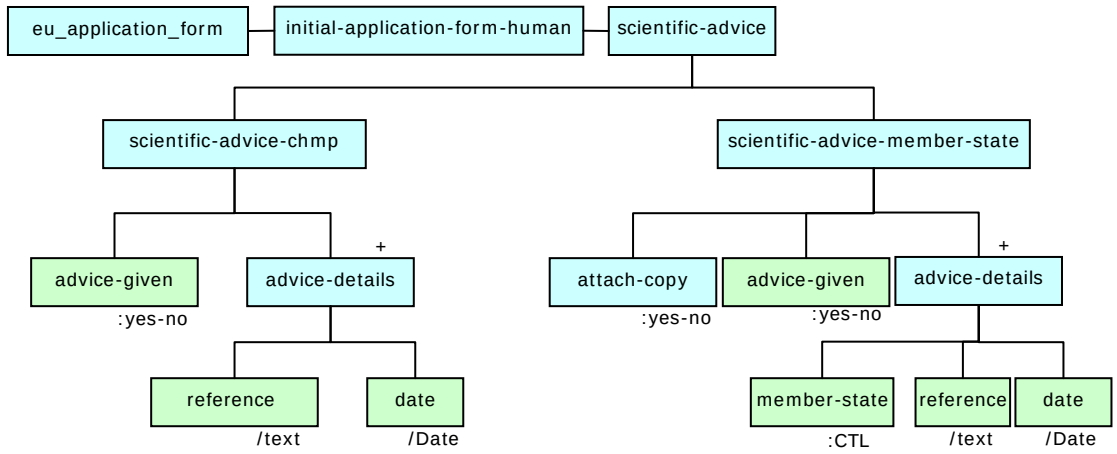
Business Rules

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



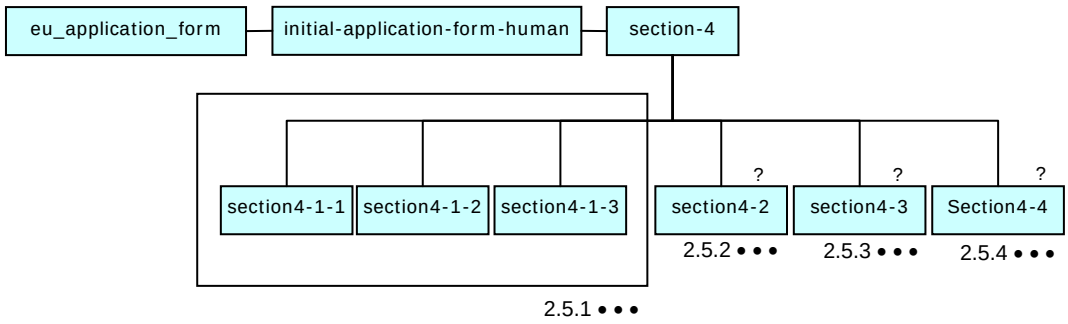
Business Rules

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

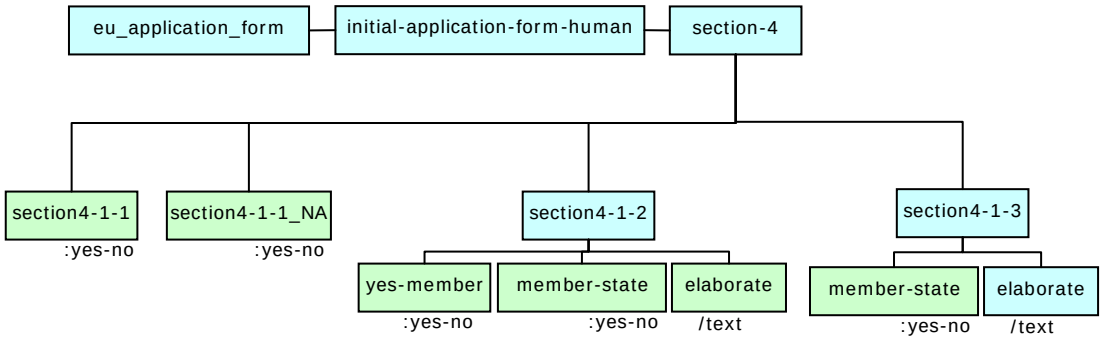
Element Tree Diagram



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
E251-3a	Not applicable	maa:section4-1-1_NA (Value=1)		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, B252-1
E251-13	No	maa:section4-1-3/ maa:yes-member (Value=0)	was auth refused	B251-6
E251-14	*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



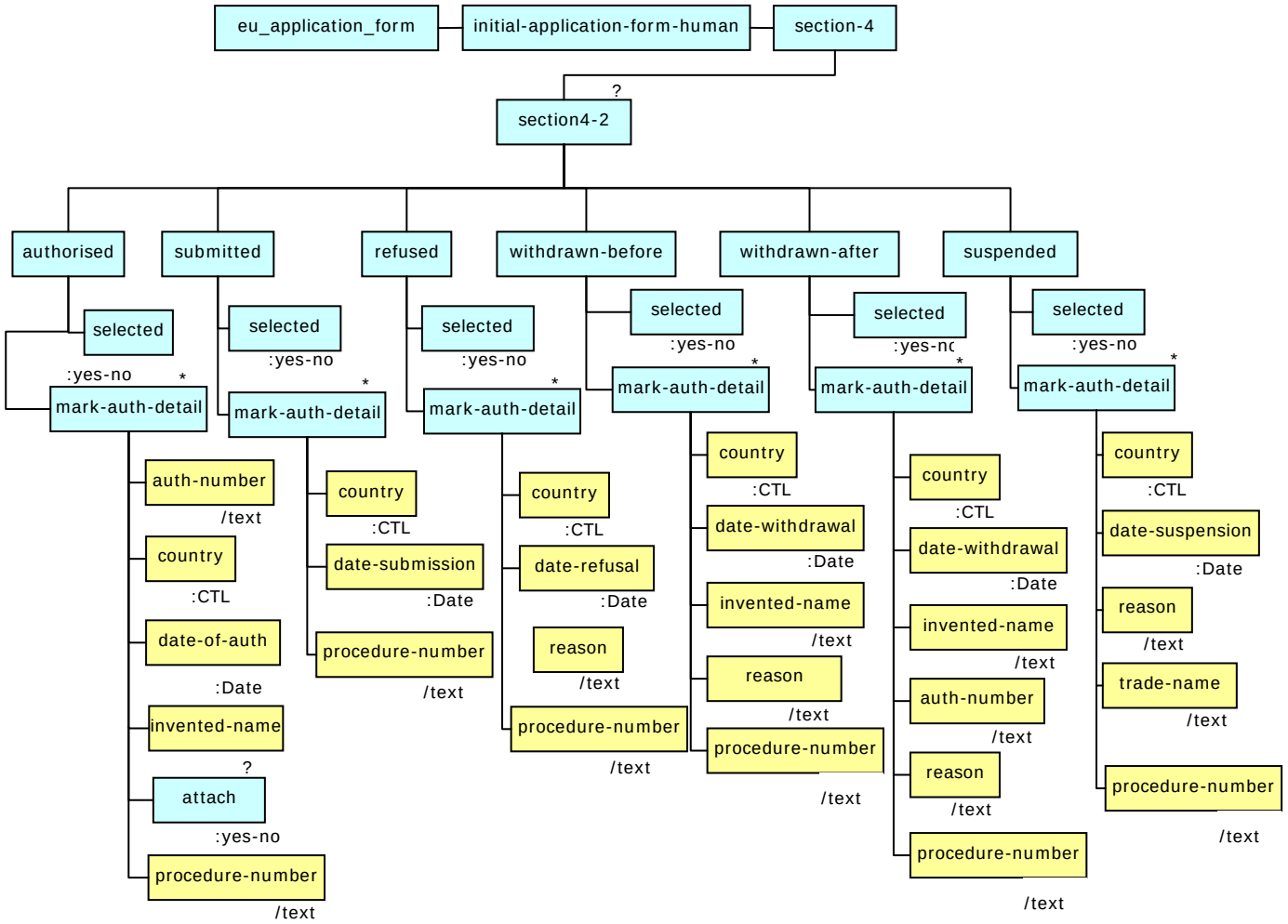
Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B251-1	E251-2, E251-3a	Mandatory.	Mutually Exclusive.	
B251-2	E251-5, E251-6	Mandatory.	Mutually Exclusive.	
B251-3	E251-5, E251-7 to E251-10	E251-5 is mandatory, rest are optional.	If E251-5 is selected, then the other 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.	

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	marketing authorisation number	maa:authorised/rdm:mark-auth-detail/rdm:auth-number	MP Authorisation > authorisation number	B252-2
E252-6	Procedure number of MRP/DCP	maa:authorised/rdm:mark-auth-detail/procedure-number	MP Authorisation > MP Procedure > procedure number	B252-2
E252-7	Attach marketing authorisation (Annex 5.15)	maa:authorised/rdm:mark-auth-detail/rdm:attach		B252-2
E252-8	Submitted	maa:pending/rdm:selected	Authorisation Status CTL	B252-3
E252-9	Country	maa:pending/rdm:mark-auth-detail/rdm:country	MP Authorisation > Country CTL	B252-3
E252-10	Date of submission	maa:pending/rdm:mark-auth-detail/rdm:date-submission	Application > submission date	B252-3
E252-11	Procedure number of MRP/DCP	maa:pending/rdm:mark-auth-detail/procedure-number	MP Authorisation > MP Procedure > procedure number	B252-3
E252-12	Refused	maa:refused/selected	Authorisation Status CTL	B252-7
E252-13	Country	maa:refused/rdm:mark-auth-detail/rdm:country	MP Authorisation > Country CTL	B252-7
E252-14	Date of refusal	maa:refused/rdm:mark-auth-detail/rdm:date-refusal	MP Authorisation > authorisation date	B252-7
E252-15	Procedure number of MRP/DCP	maa:refused/rdm:mark-auth-detail/procedure-number	MP Authorisation > MP Procedure > procedure number	B252-7
E252-16	Reason for refusal	maa:refused/rdm:mark-auth-detail/reason-refusal		B252-7
E252-17	Withdrawn (by applicant before authorisation)	maa:withdrawn-before/rdm:selected	Authorisation Status CTL	B252-4
E252-18	Country	maa:withdrawn-before/rdm:mark-auth-detail/rdm:country	MP Authorisation > Country CTL	B252-4
E252-19	Date of withdrawal	maa:withdrawn-before/rdm:mark-auth-detail/rdm:date-withdrawal	MP Authorisation > authorisation date	B252-4
E252-20	Invented name	maa:withdrawn-before/rdm:mark-auth-detail/rdm:invented-name	Medicinal Product Group > invented name	B252-4
E252-21	Reason for withdrawal	maa:withdrawn-before/rdm:mark-auth-detail/rdm:reason	MP Authorisation > authorisation description	B252-4
E252-22	Procedure number of MRP/DCP	maa:withdrawn-before/rdm:mark-auth-detail/procedure-number	MP Authorisation > MP Procedure > procedure number	B252-4
E252-23	Withdrawn (by applicant after authorisation)	maa:withdrawn-after/rdm:selected	Authorisation Status CTL	B252-5
E252-24	Country	maa:withdrawn-after/ rdm:mark-auth-detail/rdm:country	MP Authorisation > Country CTL	B252-5
E252-25	Date of withdrawal	maa:withdrawn-after/ rdm:mark-auth-detail/rdm:date-withdrawal	MP Authorisation > authorisation date	B252-5
E252-26	Authorisation number	maa:withdrawn-after/ rdm:mark-auth-detail/rdm:auth-number	MP Authorisation > authorisation number	B252-5
E252-27	Invented name	maa:withdrawn-after/ rdm:mark-auth-detail/rdm:invented-name	Medicinal Product Group > invented name	B252-5
E252-28	Reason for withdrawal	maa:withdrawn-after/ rdm:mark-auth-detail/rdm:reason	MP Authorisation > authorisation description	B252-5
E252-29	Procedure number of MRP/DCP	maa:withdrawn-after/rdm:mark-auth-detail/procedure-number	MP Authorisation > MP Procedure > procedure number	B252-5
E252-30	Suspended/revoked (by competent authority)	maa:suspended/rdm:selected	Authorisation Status CTL	B252-6

E252-31	Country	maa:suspended/rdm:mark-auth-detail/rdm:country	MP Authorisation > Country CTL	B252-6
E252-32	Date of suspension/revocation	maa:suspended/rdm:mark-auth-detail/rdm:date-suspension	MP Authorisation > authorisation date	B252-6
E252-33	Reason for suspension/revocation	maa:suspended/rdm:mark-auth-detail/rdm:reason	MP Authorisation > authorisation description	B252-6
E252-34	Invented name	maa:suspended/rdm:mark-auth-detail/rdm:invented-name	Medicinal Product Group > invented name	B252-6
E252-35	Procedure number of MRP/DCP	maa:suspended/rdm:mark-auth-detail/procedure-number	MP Authorisation > MP Procedure > procedure number	B252-6

Element Tree Diagram

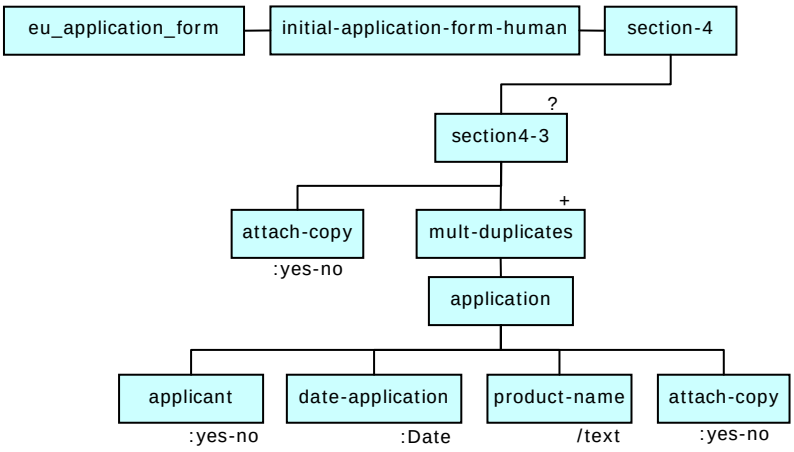


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B252-1	E251-1, E251-5, E251-12	Mandatory.	If one of the fields are selected, section 2.5.2 is mandatory.	
B252-2	E252-1 to E252-6	E252-1 mandatory, rest are optional.	If E252-1 is selected, then the rest are mandatory.	
B252-3	E252-8 to E252-11	E252-8 mandatory, rest are optional.	If E252-8 is selected, then the rest are mandatory.	
B252-4	E252-17 to E252-22	E252-17 mandatory, rest are optional.	If E252-17 is selected, then the rest are mandatory.	
B252-5	E252-23 to E252-29	E252-23 mandatory, rest are optional.	If E252-23 is selected, then the rest are mandatory.	
B252-6	E252-30 to E252-35	E252-30 mandatory, rest are optional.	If E252-35 is selected, then the rest are mandatory.	
B252-7	E252-12 to E252-16	E252-12 mandatory, rest are optional.	If E252-12 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(submitted simultaneously or subsequently to the original product) 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	Procedure number for MRP/DCP (if applicable)	maa:mult-duplicates/ maa:application/maa:procedure-number		
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 letter from the Commission services, for centralised procedures only (Annex 5.16)	maa:attach-copy		

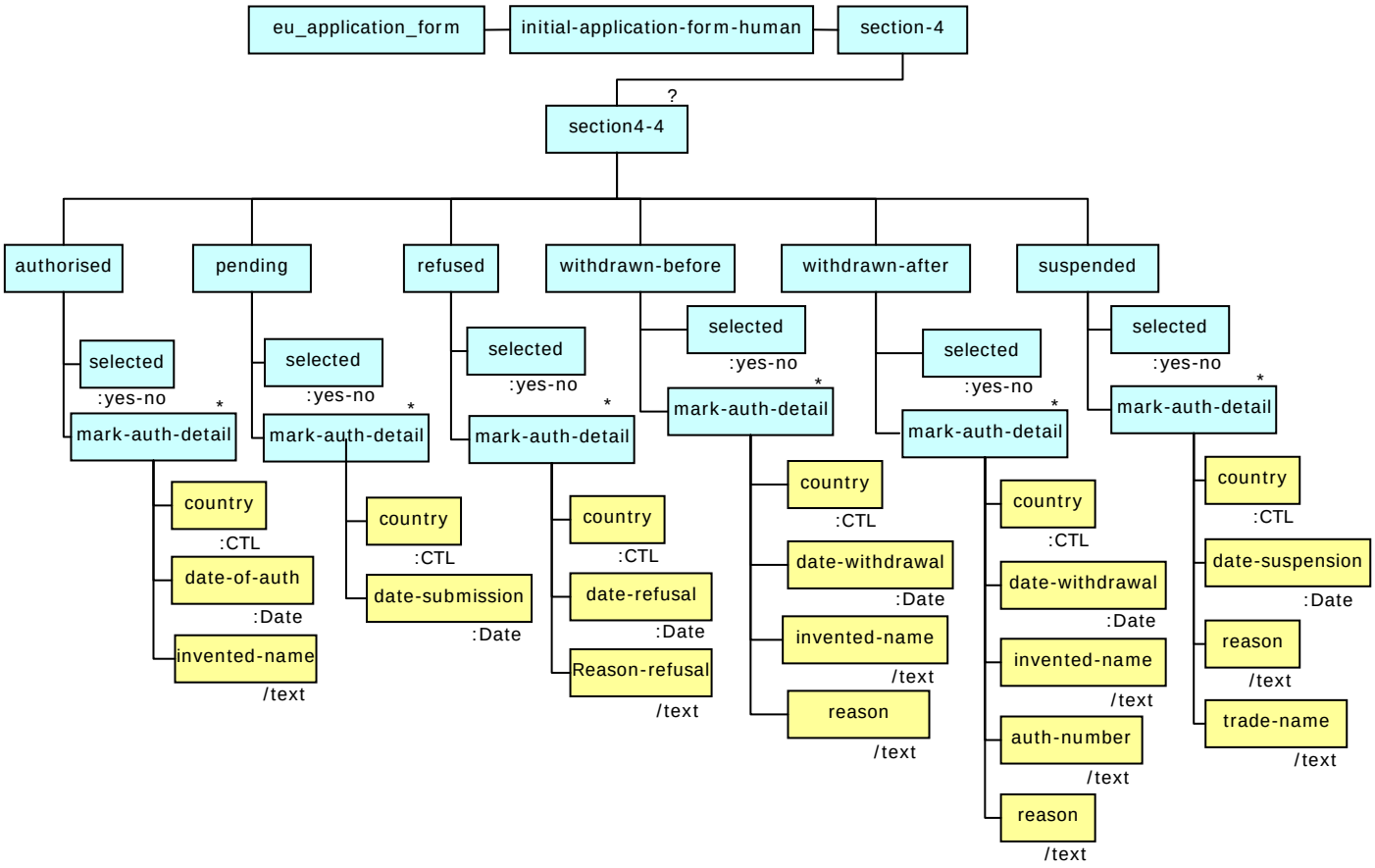
Element Tree Diagram



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 having the same pharmaceutical form).

	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	Reason for refusal	maa:refused/rdm:mark-auth-detail/rdm:reason-refusal	MP Authorisation > authorisation description	B254-3
E254-13	Withdrawn (by applicant before authorisation)	maa:withdrawn-before/rdm:selected	Authorisation Status CTL	B254-4
E254-14	Country	maa:withdrawn-before/rdm:mark-auth-detail/rdm:country	MP Authorisation > Country CTL	B254-4
E254-15	Date of withdrawal	maa:withdrawn-before/rdm:mark-auth-detail/rdm:date-withdrawal	MP Authorisation > authorisation date	B254-4
E254-16	Invented name	maa:withdrawn-before/rdm:mark-auth-detail/rdm:invented-name	Medicinal Product Group > invented name	B254-4
E254-17	Reason for withdrawal	maa:withdrawn-before/rdm:mark-auth-detail/rdm:reason	MP Authorisation > authorisation description	B254-4
E254-18	Withdrawn (by applicant after authorisation)	maa:withdrawn-after/rdm:selected	Authorisation Status CTL	B254-5
E254-19	Country	maa:withdrawn-after/ rdm:mark-auth-detail/rdm:country	MP Authorisation > Country CTL	B254-5
E254-20	Date of withdrawal	maa:withdrawn-after/ rdm:mark-auth-detail/rdm:date-withdrawal	MP Authorisation > authorisation date	B254-5
E254-21	Authorisation number	maa:withdrawn-after/ rdm:mark-auth-detail/rdm:auth-number	MP Authorisation > authorisation number	B254-5
E254-22	Invented name	maa:withdrawn-after/ rdm:mark-auth-detail/rdm:invented-name	Medicinal Product Group > invented name	B254-5
E254-23	Reason for withdrawal	maa:withdrawn-after/ rdm:mark-auth-detail/rdm:reason	MP Authorisation > authorisation description	B254-5
E254-24	Suspended/revoked (by competent authority)	maa:suspended/rdm:selected	Authorisation Status CTL	B254-6
E254-25	Country	maa:suspended/rdm:mark-auth-detail/rdm:country	MP Authorisation > Country CTL	B254-6
E254-26	Date of suspension/revocation	maa:suspended/rdm:mark-auth-detail/rdm:date-suspension	MP Authorisation > authorisation date	B254-6
E254-27	Reason for suspension/revocation	maa:suspended/rdm:mark-auth-detail/rdm:reason	MP Authorisation > authorisation description	B254-6
E254-28	Trade name	maa:suspended/rdm:mark-auth-detail/rdm:invented-name	Medicinal Product Group > invented name	B254-6

Element Tree Diagram



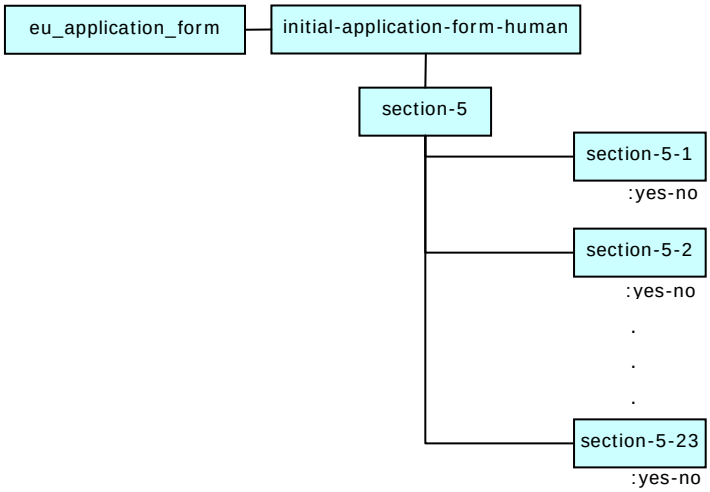
Business Rules

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 E254-12	E254-9 mandatory, rest are Optional.	If E254-9 is selected, then the rest are mandatory.	
B254-4	E254-13 to E254-17	E254-13 mandatory, rest are Optional.	If E254-13 is selected, then the rest are mandatory.	
B254-5	E254-18 to E254-23	E254-18 mandatory, rest are Optional.	If E254-18 is selected, then the rest are mandatory.	
B254-6	E254-24 to E254-28	E254-24 mandatory, rest are Optional.	If E254-24 is selected, then the rest are mandatory.	

2.6. ANNEXED DOCUMENTS (WHERE APPROPRIATE)

	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		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 European Union 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	Letter by Commission services regarding multiple applications.	maa:section5-16		
E26-17	List of Mock-ups or Samples/specimens sent with the application, as appropriate (see EMA/CMDh websites).	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 principles and guidelines of 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). The declaration should refer to an audit and the date of the audit.	maa:section5-22		
E26-23	Evidence and justification to support the claim of new active substance status in the Union for applications based on Article 8(3) of Directive 2001/83/EC.	maa:section5-23		

Element Tree Diagram



3. About this Document

3.1. Definitions, Acronyms, and Abbreviations

Acronyms

Name	Definition
cms	concerned member state
DCP	DeCentralised Procedure
DTD	Data Type Definition
ETD	Element Tree Diagem
EU	European Community
EudraGMPD	Eudra Good Manufacturing & Distribution Practice
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