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EMA/471653/2014
Information Technology

Electronic Application Form Data Exchange Standard 3.0

Supplementary Specification Annex 4 "Initial Veterinary Application Form" v1.26.0.0

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_vet_schema.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 veterinary 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 Technical Guide 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.

1.2.1. The Elements Mapping Table

This table describes the mapping between the paper form fields of a specific chapter and the elements of the DES 3.0 Model.
The table consists in 4 columns:

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

The minimal notation is always "<technical concept parent>/" in the common context and "<mapped-to element>" in the DES 3.0 column.
The description of the technical concept parent is in the DES 2.0 supplementary specifications sections 7.1 and 7.2
If there is no mapping, the DES 1.0 element remains in the form specific part of the model.

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

Colours
Text: Tells that the elements are not part of the RDM 3.0 and can be found only in DES 3.0 with no similarity in terms of definition.
Text: Tells that there is no existing mapping between the DES 3.0 and RDM 3.0. The missing mapping can be of two kinds.

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

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

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

1.2.2. The Business Rules Table

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

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

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

Rule: Description of the condition to be evaluated.

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

1.2.3. The Element Tree Diagram (ETD)

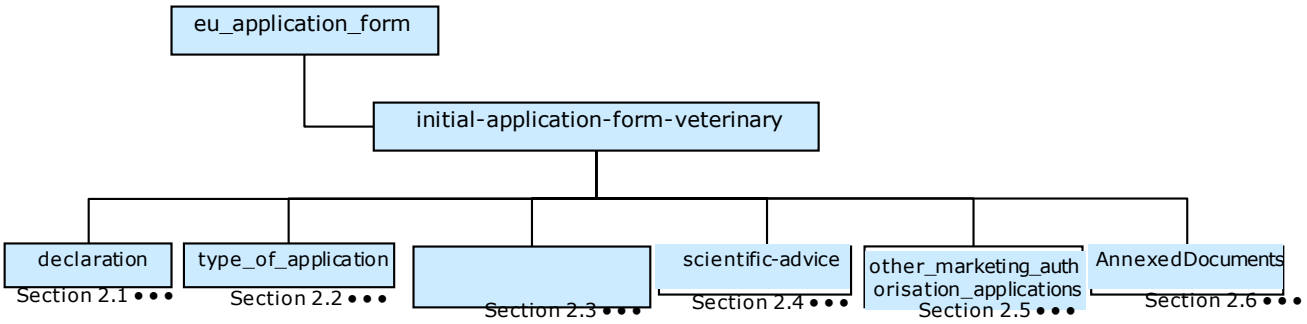
The data structure constraints are captured in a graphic approach to facilitate the reading and assessment by the business.
The model used refers to the one used by W3C (World Wide Web Consortium XML Specification DTD for its publication standard issued in 1998.
The model is called "Element Tree Diagram" (ETD)
The diagrams of this version reflect the DES 3.0 standard described in the DES 3.0 Supplementary Specifications document. The ETD shows which are the concepts involved in the mapping of all the application form fields in the Element Mapping Table and the hierarchical constrains between them.

2. Initial Application form

The "initial-application-form-veterinary" 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-veterinary/			
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2.1	DECLARATION AND SIGNATURE	maa:declaration	Application	See Section 2.1
E2.2	TYPE OF APPLICATION	maa:type_of_application	MP Procedure	See section 2.2
E2.3	MARKETING AUTHORISATION APPLICATION PARTICULARS	maa:marketing_authorisation_application_particulars		See Section 2.3
E2.4	SCIENTIFIC ADVICE	maa:scientific-advice	App Scientific Advice	See Section 2.4
E2.5	OTHER MARKETING AUTHORISATION APPLICATIONS	maa:other_marketing_authorisation_applications		See Section 2.5
E2.6	5. ANNEXED DOCUMENTS (WHERE APPROPRIATE)	maa:AnnexedDocuments		See Section 2.6

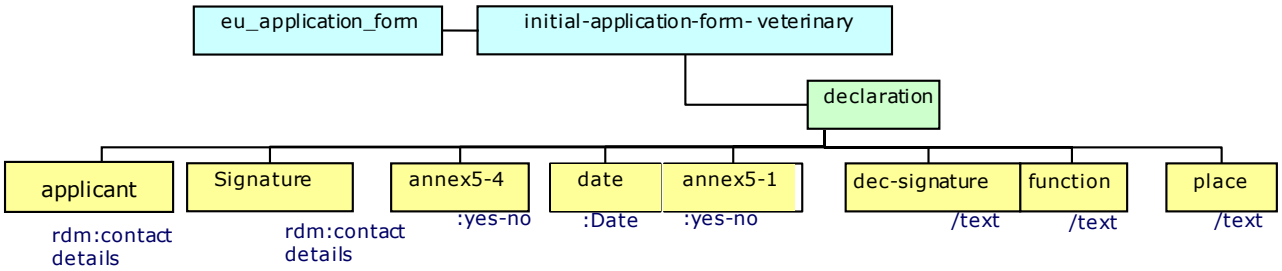
Element Tree Diagram



2.1. DECLARATION AND SIGNATURE

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa: initial-application-form-veterinary maa:declaration/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E21-12	Signatory	maa:dec-signature	Not mapped	
E21-12a	Applicant	maa:applicant		
E21-12b	Address	maa:applicant/rdm:Address		
E21-13	Title	maa:signature/rdm:personal-title	Role > Party > Person > Personal title	
E21-14	First name	maa:signature/rdm:given-name	Role > Party > Person > given name	
E21-15	Surname	maa:signature/rdm: family-name	Role > Party > Person > family name	
E21-16	Function	maa:function	Manufacturer MP> functions performed	
E21-17	Address	maa:signature/rdm:address	signature address	
E21-18	Date	maa:date	signature date	
E21-19	*Note: please attach letter of authorisation for communication/signing on behalf of the applicant in annex 5.4*	maa:annex5-4		
E21-20	*Note: if fees have been paid, attach proof of payment in Annex5.1 - see information on fee payments in the Notice to Applicants, Volume2A, chapter 7.*	maa:annex5-1		

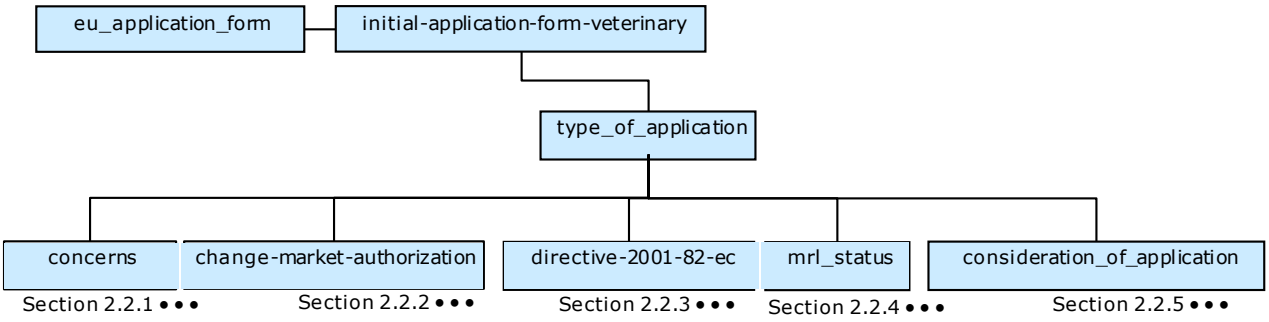
Element Tree Diagram



2.2. TYPE OF APPLICATION

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-veterinary/maa:type_of_application/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E22-1	THIS APPLICATION CONCERNS	maa:concerns		See section 2.2.1
E22-2	Is this an application for a change to your existing marketing authorisation leading to an extension as referred to in Annex II of Regulations (EC) no. 1084/2003 or 1085/2003, or any national legislation, where applicable?	maa:change-market-authorization		See section 2.2.2
E22-3	This application is submitted in accordance with the following article in Directive 001/82/EC or Regulation (EC) No 726/2004	maa:directive-2001-82-ec		See section 2.2.3
E22-4	MRL status (only for food producing species)	maa:mrl_status		See section 2.2.4
E22-5	Consideration of this application is also requested under the following article in Directive 2001/82/EC or Regulation (EC) no. 726/2004	maa:consideration_of_application		See section 2.2.5

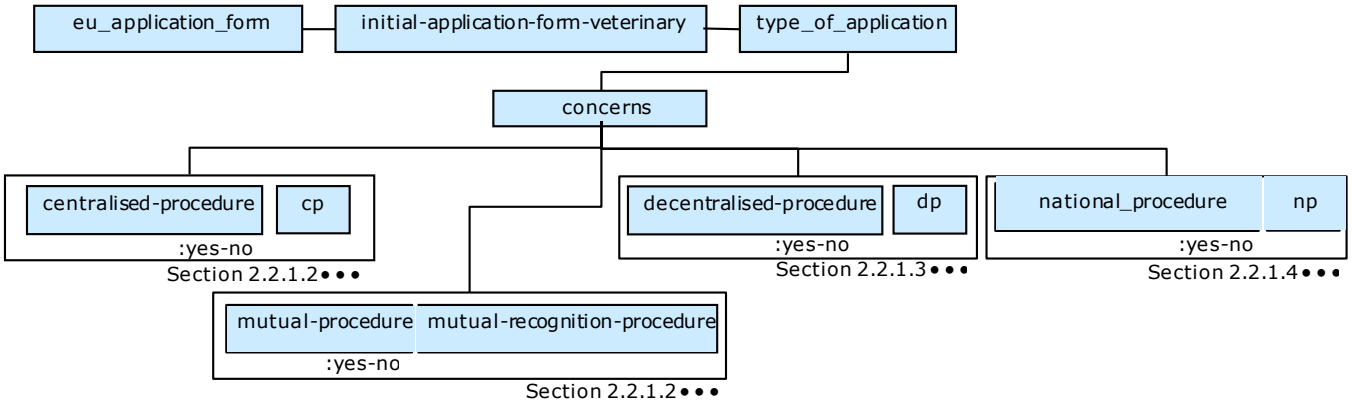
Element Tree Diagram



2.2.1. THIS APPLICATION CONCERNS

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-veterinary/maa:type_of_application/maa:concerns/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E221-1	A CENTRALISED PROCEDURE (according to Regulation (EC) No 726/2004)	maa:centralised-procedure maa:cp		B221-1
E221-2	A MUTUAL RECOGNITION PROCEDURE (according to Article 32(2) of Directives 2001/82/EC)	maa:mutual-procedure maa:mutual-recognition-procedure		B221-1
E221-3	A DECENTRALISED PROCEDURE (according to Article 32(3) of Directive 2001/82/EC)	maa:decentralised-procedure maa:dp		B221-1
E221-4	1.1.4 A NATIONAL PROCEDURE	maa:national_procedure maa:np		B221-1, B25-1

Element Tree Diagram

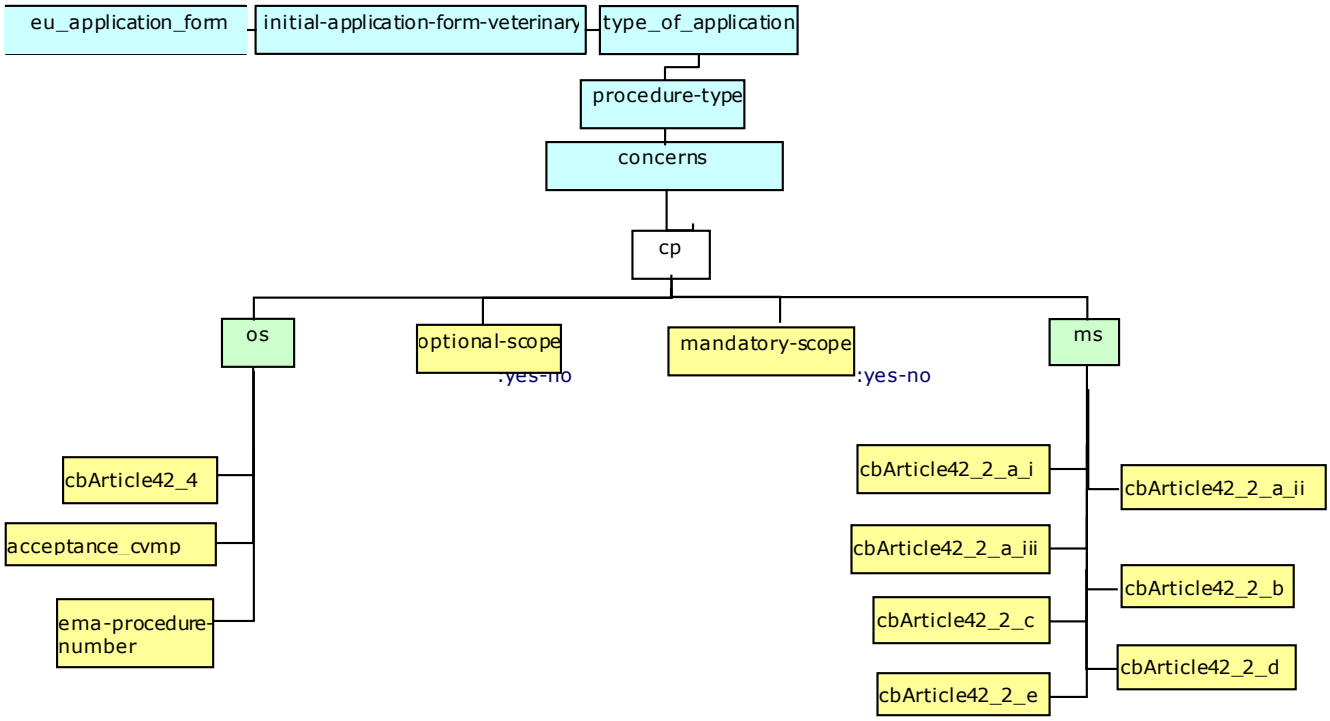


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B221-1	E221-1 to E221-4	Mandatory.	Mutually Exclusive.	

2.2.1.1. A CENTRALISED PROCEDURE (according to Regulation (EC) No 726/2004)

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-veterinary/maa:type_of_application/maa:concerns/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2211-1	A CENTRALISED PROCEDURE (according to Article 42 of Regulation (EC) 2019/6)	maa:centralised-procedure	Procedure Type CTL (Value="centralised")	
E2211-2	"Mandatory scope" (Article 42(2))	maa:cp/maa:mandatory-scope	Basis for Eligibility CTL	B2211-1
E2211-3	Article 42(2)(a)(i) of Regulation (EU) 2019/6	maa:cp/ms/cbArticle42_2_a_i	Basis for Eligibility CTL	B2211-2
E2211-4	Article 42(2)(a)(ii) of Regulation (EU) 2019/6	maa:cp/ms/cbArticle42_2_a_ii	Basis for Eligibility CTL	B2211-2
E2211-5	Article 42(2)(a)(iii) of Regulation (EU) 2019/6	maa:cp/ms/cbArticle42_2_a_iii	Basis for Eligibility CTL	B2211-2
E2211-6	Article 42(2)(b) of Regulation (EU) 2019/6	maa:cp/ms/cbArticle42_2_b	Basis for Eligibility CTL	B2211-2
E2211-7	Article 42(2)(c) of Regulation (EU) 2019/6	maa:cp/ms/cbArticle42_2_c	Basis for Eligibility CTL	B2211-2
E2211-8	Article 42(2)(d) of Regulation (EU) 2019/6	maa:cp/ms/cbArticle42_2_d	Basis for Eligibility CTL	B2211-2
E2211-9	Article 42(2)(e) of Regulation (EU) 2019/6	maa:cp/ms/cbArticle42_2_e	Basis for Eligibility CTL	B2211-2
E2211-10	"Optional scope" (Article 42(4))	maa:cp/maa:optional-scope	Basis for Eligibility CTL	B2211-1
E2211-11	Article 42(4) of Regulation (EU) 2019/6	maa:cp/maa:os/ maa:cbArticle42_4	Basis for Eligibility CTL	B2211-3
E2211-12	Date of acceptance/confirmation by CVMP	maa:cp/maa:os/ maa:accepatance_cvmp	Basis for Eligibility CTL	B2211-3
E2211-13	EMA procedure number	maa:cp/maa:os/ maa:ema-procedure-number	Basis for Eligibility CTL	B2211-4

Element Tree Diagram

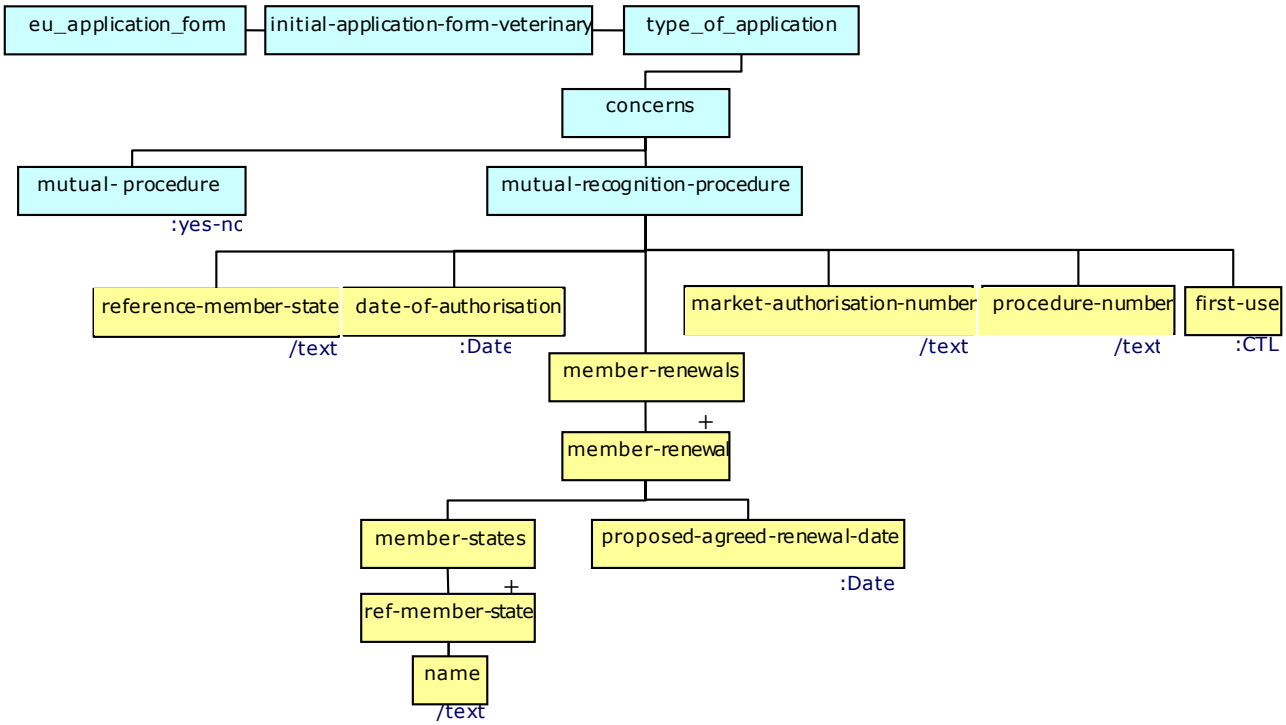


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2211-1	E2211-2, E2211-5, E2211-10	Mandatory.	Fields are mutually exclusive.	Can only have one of them active at a time.
B2211-2	E2211-4 to E2211-9	Mandatory if E2211-2 is selected.	Fields are mutually exclusive.	Can only have one of them active at a time.
B2211-3	E2211-11 to, E2211-12	Mandatory if E2211-10 isselected.	Fields are mutually exclusive.	Can only have one of them active at a time.
B2211-4	E2211-13	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-veterinary/maa:type_of_application/maa:concerns/		Application > MP Procedure >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2212-1	1.1.2 A MUTUAL RECOGNITION PROCEDURE	maa:mutual-procedure	Procedure Type CTL (Value=" mutual-recognition ")	
E2212-2	Reference Member State	maa:mutual-recognition-procedure/rdm:reference-member-state	Role > Country CTL	
E2212-3	Date of authorisation	maa:mutual-recognition-procedure/rdm:date-of-authorisation	previous auth date	
E2212-4	Marketing authorisation number	maa:mutual-recognition-procedure/rdm:market-authorisation-number	previous auth number	
E2212-5	Procedure number:	maa:mutual-recognition-procedure/rdm:procedure-number	procedure number	
E2212-6	First use	maa:mutual-recognition-procedure/rdm:first-use (Value=1)	Procedure Use CTL	B2212-1
E2212-7	Repeat use (Please also complete section 4.2)	maa:mutual-recognition-procedure/rdm:first-use (Value=2)	Procedure Use CTL	B2212-1, B222-2
E2212-8	Wave	maa:mutual-recognition-procedure/rdm:member-renewals/rdm:member-renewal	Procedure Use > waive id	B2212-2
E2212-9	Concerned Member State (specify)	maa:mutual-recognition-procedure/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	maa:mutual-recognition-procedure/rdm:member-renewals/ rmd:member-renewal/ rdm:proposed-agreed-renewal-date	Procedure Use > Proposed / agreed common renewal date	

Element Tree Diagram

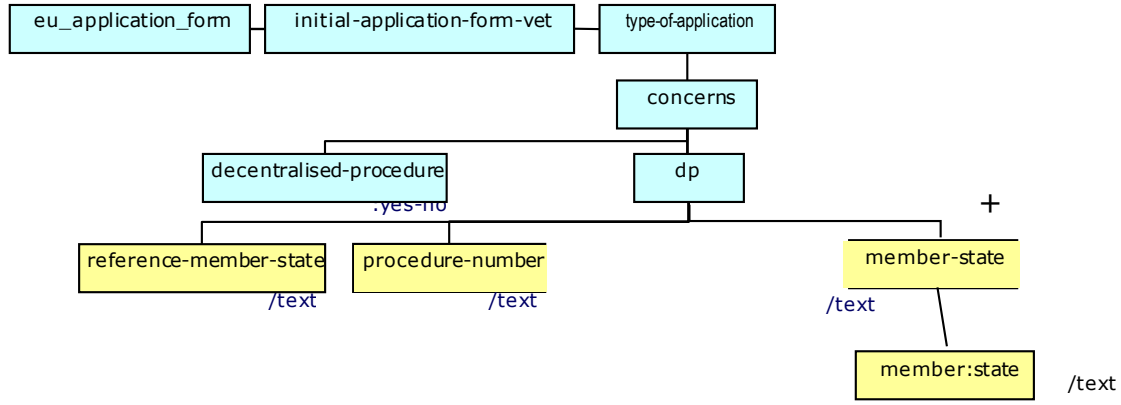


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2212-1	E2212-6 , E2212-7	Mandatory.	Mutually Exclusive.	
B2212-2	E2212-7 to E2212-10	If E2212-7 is selected, then E2212-8 to E2212-10 are mandatory.		

2.2.1.3. A DECENTRALISED PROCEDURE

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-veterinary/maa:type_of_application/maa:concerns/		Application > MP Procedure >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2213-1	1.1.3 A DECENTRALISED PROCEDURE	maa:decentralised-procedure	Procedure Type CTL (Value="decentralised")	
E2213-2	(according to Article 28(3) of Directives 2001/82/EC)			
E2213-3	Reference Member State	maa:reference-member-state	Procedure Use > Role > Country CTL	
E2213-4	Procedure number:	maa:procedure-number	Procedure number	
E2213-5	Concerned Member State (specify)	maa:member-state / maa:member-state	Procedure Use > Role > Country CTL	
E2213-6	If a waiver or amendment or PSUR-cycle is applied for, to harmonize with a substance birthdate, please specify:	maa:waiver	Procedure use > psur cycle waiver	
E2213-7	Proposed Common Renewal Date	maa:proposed-common-renewal-date	proposed-common-renewal-date	

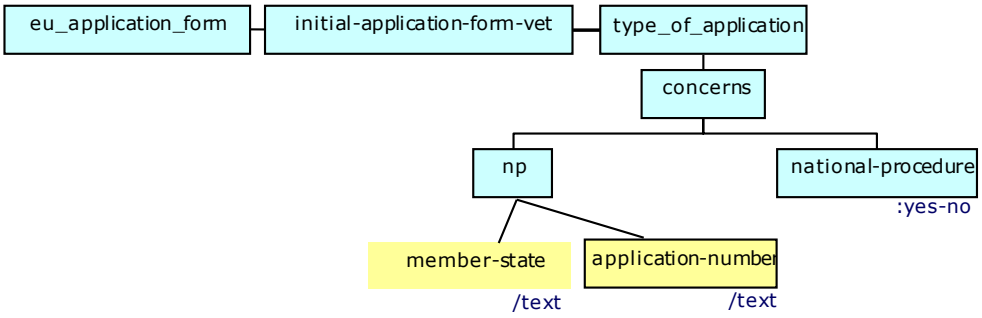
Element Tree Diagram



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:concerns		Application > MP Procedure >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2214-1	1.1.4 A NATIONAL PROCEDURE	maa;national_procedure	Procedure Type CTL (Value="national")	
E2214-2	Member State	maa:np/member-state	Role > Country CTL	
E2214-3	Application number (if available)	maa:np/application_number	previous app number	

Element Tree Diagram

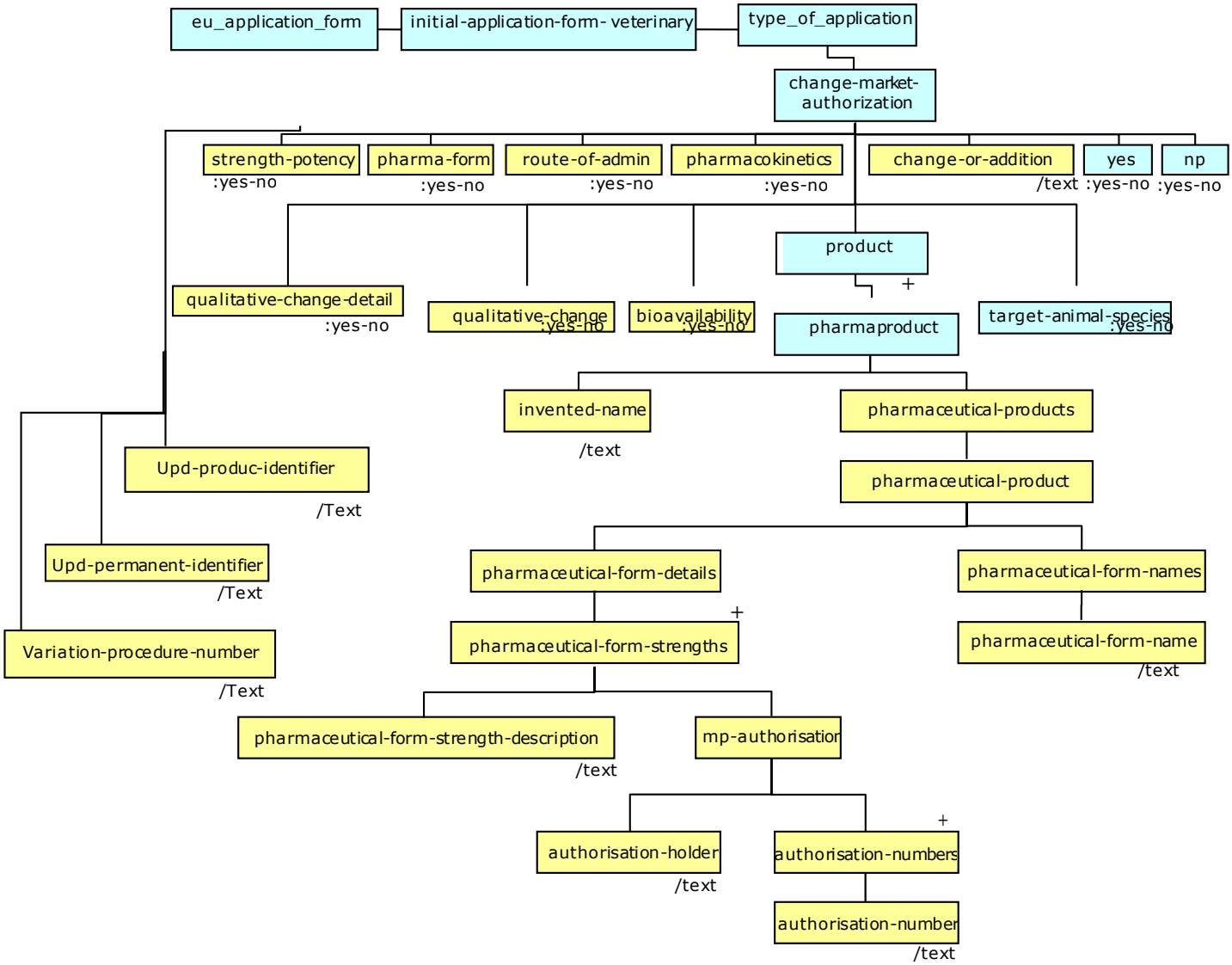


2.2.2. Application for a change to your existing marketing authorisation leading to an extension as referred to in Annex I of Commission Regulation (EC) no. 1234/2008, or any national legislation, where applicable?

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-veterinary/maa:type_of_application/maa:change-market-Authorisation		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remark**
E222-1	Yes	maa:yes(Value=1)	change in existing ma	B222-1, B222-2
E222-2	No *(complete section 1.3 and 1.4.)*	maa:no (Value=0)	change in existing ma	B222-1, B222-2
E222-2a	UPD Product Identifier (only relevant for MRP and CP)	maa:upd-product-identifier	Difference CTL	
E222-2b	UPD Permanent Identifier for the concerned national product(s)	maa:upd-permanent-identifier	Difference CTL	
E222-2c	Variation Procedure number(mandatory for MRP)	maa:variation-procedure-number	Difference CTL	
E222-3	Change of bioavailability	maa:bioavailability	Difference CTL	B222-2
E222-4	Change of pharmacokinetics	maa:pharmacokinetics	Difference CTL	B222-2
E222-5	Change or addition of a new strength/potency	maa:strength-potency	Difference CTL	B222-2
E222-6	Change or addition of a new pharmaceutical form	maa:pharma-form	Difference CTL	B222-2
E222-7	Change or addition of a new route of administration	maa:route-of-admin	Difference CTL	B222-2
E222-14	Change or addition of a food-producing target animal species	maa:target-animal-species	Difference CTL	B222-2
E222-8	Qualitative change in declared active substance not defined as a new active substance	maa:qualitative-change	Difference CTL	B222-2, B222-3
E222-9	Replacement by a different salt/ester, complex/derivative (same therapeutic moiety)	maa:qualitative-change-detail	Difference CTL	B222-3, B222-4
E222-10	Replacement by a different isomer, mixture of isomers, of a mixture by an isolated isomer	maa:qualitative-change-detail	Difference CTL	B222-3, B222-4
E222-11	Replacement of a biological substance or product of biotechnology	maa:qualitative-change-detail	Difference CTL	B222-3, B222-4
E222-12	modification of the vector used to produce the antigen or the source material, including a new master cell bank from a different source, where the clinical/safety characteristics are not significantly different;	maa:qualitative-change-detail	Difference CTL	B222-3, B222-4
E222-13	change to the extension solvent or the radio of herbal drug to herbal drug preparation	maa:qualitative-change-detail	Difference CTL	B222-3, B222-4
E222-14	Product (invented) name	maa:product/ rdm:pharmaproduct/ rdm:invented-name	Reference Medicinal Product > Medicinal Product>Pharmaceutical Product>Ingredient>Subs	B222-2
E222-15	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	B222-2
E222-16	Strength(s)	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	B222-2
E222-17	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	B222-2

E222-18	Marketing authorisation number	maa:product/ rdm:pharmaproduct/ rdm:pharmaceutical-products/ rdm:pharmaceutical-product/ rdm:pharmaceutical-form-details/rdm:pharmaceutical-form-strengths /rdm:authorisation-numbers/ rdm:authorisation-number	MP Authorisation > authorization number	B222-2

Element Tree Diagram

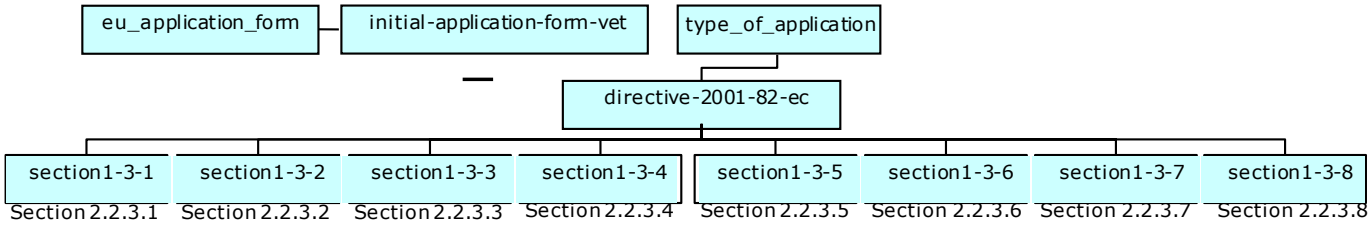


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B222-1	E222-1, E222-2	Mandatory.	Mutually Exclusive.	
B222-2	E222-1, E222-3 to E222-8, E222-14 to E222-19	E223-1 is Mandatory, rest are optional.	If E222-1 is selected, the rest are mandatory.	
B222-3	E222-8 to13	Optional	If E222-8 is selected, then the rest are required and visible	
B222-4	E222-8 to 32	Optional	Mutually Exclusive	
B222-5	E222-2a, E222-2b, E222-2c	Optional	Mutually Exclusive	

2.2.3. THIS APPLICATION IS SUBMITTED IN ACCORDANCE WITH THE FOLLOWING ARTICLE IN DIRECTIVE 2001/82/EC

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-veterinary/maa:type_of_application/maa:directive-2001-82-ec/		Application > MP Procedure >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E223-1	Article 12(3) application, (i.e. dossier with administrative, quality, safety and efficacy data*)	maa:section1-3-1		B223-1
E223-2	Article 13(1) Generic application	maa:section1-3-2		B223-1
E223-3	Article 13(3) hybrid application	maa:section1-3-3		B223-1
E223-4	Article 13(4) Similar biological application	maa:section1-3-4		B223-1
E223-5	Article 13a - Well established Veterinary use	maa:section1-3-5		B223-1
E223-6	Article 13b - Fixed combination application	maa:section1-3-6		B223-1
E223-7	Article 13c - Informed consent application	maa:section1-3-7		B223-1
E223-8	Article 13d - Immunological Veterinary Medicinal Product for which the results of certain trials are not being submitted	maa:section1-3-8		B223-1

Element Tree Diagram

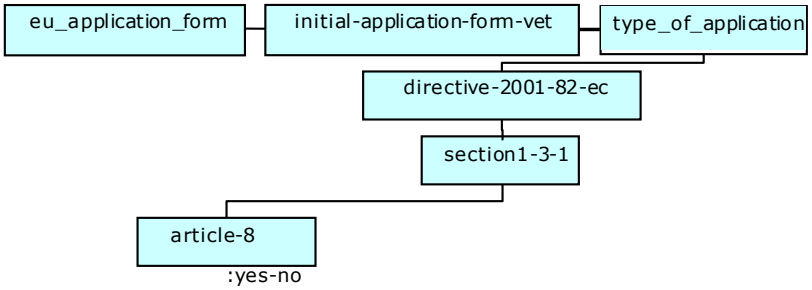


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B223-1	E223-1 to E223-8	Mandatory.	Mutually Exclusive.	

2.2.3.1. Article 12(3) application, (i.e. dossier with administrative, quality, safety and efficacy data)*

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-veterinary/maa:type_of_application/maa:directive-2001-82-ec/maa:section1-3-1/		Application	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2231-1	Article 12(3) application, (i.e. dossier with administrative, quality, safety and efficacy data*)	maa:article-8	Basis for Eligibility CTL	B223-1,

Element Tree Diagram



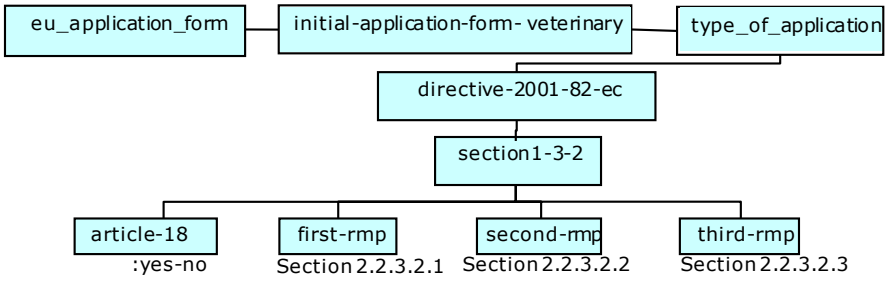
Business Rules

Rule ID	Element id(s)	Default BR	Rule	Effect(s)
B223-1	E2231-1 to 3	Optional	If E2231-1 is selected, the rest become required.	
B222-2	E2231-2 to 3	Optional	Mutually Exclusive.	

2.2.3.2. Article 13(1) Generic application

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-veterinary/maa:type_of_application/maa:directive-2001-82-ec/maa:section1-3-2/		Application > MP Procedure >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2232-1	Article 13(1) Generic application	maa:article-18	Basis for Eligibility CTL	B2232-1
E2232-2	*Veterinary 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-rmp		B2232-1
E2232-3	*Veterinary medicinal product authorised in the Union/Member State where the application is made or European reference medicinal product:*	maa:second-rmp		B2232-1
E2232-4	*Veterinary medicinal product which is or has been authorised in accordance with Union provision in forceand to which bioequivalence has been demonstrated by appropriate bioavailability studies*	maa:third-rmp		

Element Tree Diagram

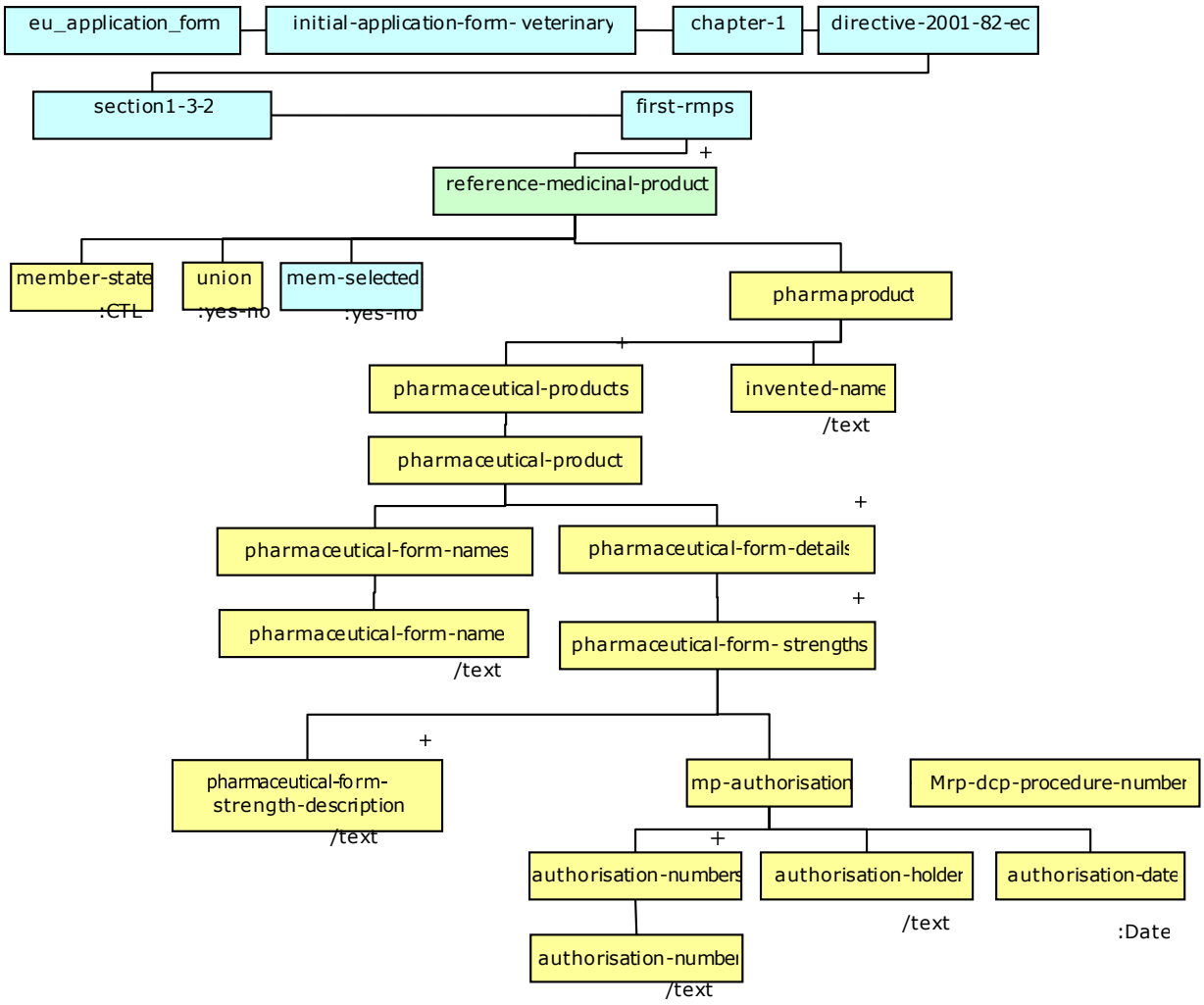


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2232-1	E2232-1 to 3	Optional	If E2232-1 is selected, the rest become required	

2.2.3.2.1. Veterinary 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-veterinary/maa:type_of_application/maa:directive-2001-82-ec/ maa:section1-3-2/maa:first-rmp/maa:reference-medicinal-product/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E22321-1	Product (Invented) name	rdm:pharmaproduct/rdm:invented-name	Reference Medicinal Product > Medicinal Product > Medicinal Product Name	
E22321-2	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	
E22321-3	Strength(s)	rdm: pharmaproduct/ rdm: pharmaceutical-products/rdm: pharmaceutical-product /rdm: pharmaceutical-form-details/rdm: pharmaceutical-form-strengths/rdm: pharmaceutical-form-strength-description	Ingredient	
E22321-4	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	
E22321-5	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	
E22321-6	Marketing authorisation granted by			
E22321-7	Union	rdm:community	MP Authorisation > Country CTL	B22321-1
E22321-8	Member State(EEA)	rdm:mem-selected		B22321-1, B22321-2
E22321-9	Member State(EEA)	rdm:member-state	MP Authorisation > Country CTL	B22321-1, B22321-2
E22321-10	Marketing Authorisation number(s)	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	
E22321-11	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		

Element Tree Diagram

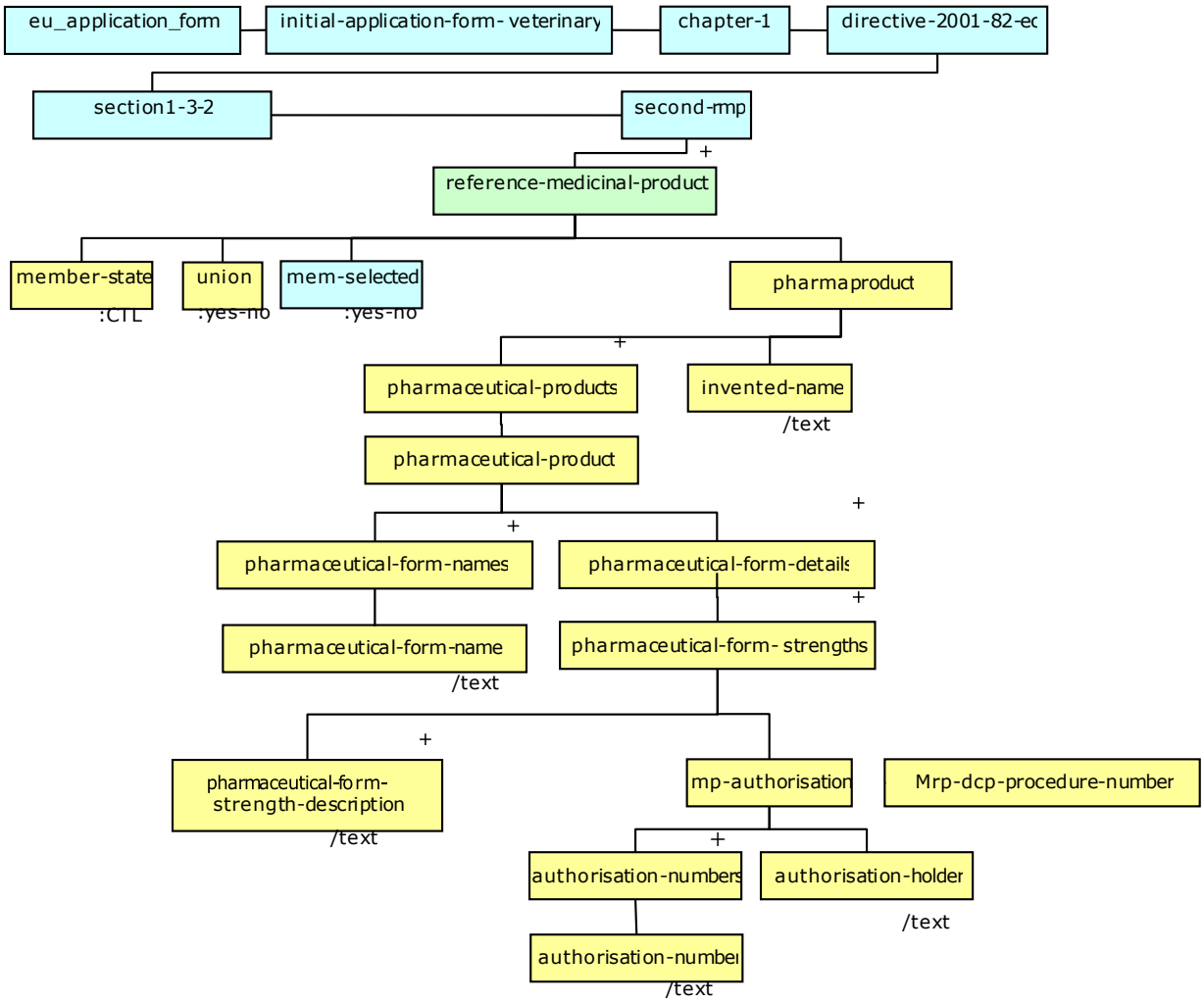


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B22321-1	E22321-7 to 8	Required	Mutually Exclusive	
B22321-2	E22321-8 to 9	Optional	If E22321-7 is selected, E22321-9 is required.	
B22321-3	E22321-11	Optional		

2.2.3.2.2. Veterinary 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-veterinary/maa:type_of_application/maa:directive-2001-82-ec/ maa:section1-3-2/maa:second-rmp/maa:reference-medicinal-product/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E22322-1	Product (Invented) name	rdm:pharmaproduct/rdm:invented-name	Reference Medicinal Product > Medicinal Product > Medicinal Product Name	
E22322-2	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	
E22322-3	Strength(s)	rdm: pharmaproduct/ rdm: pharmaceutical-products/rdm: pharmaceutical-product /rdm: pharmaceutical-form-details/rdm: pharmaceutical-form-strengths/rdm: pharmaceutical-form-strength-description	Ingredient	
E22322-4	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	
E22322-5	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	
E22322-10	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:mrp-dcp-procedure-number		
E22322-6	Marketing authorisation granted by			
E22322-7	Union	rdm:community	MP Authorisation > Country CTL	B22322-1
E22322-8	Member State(EEA)	rdm:mem-selected		B22322-1, B22322-2
E22322-9	Member State(EEA)	rdm:member-state	MP Authorisation > Country CTL	B22322-1, B22322-2

Element Tree Diagram

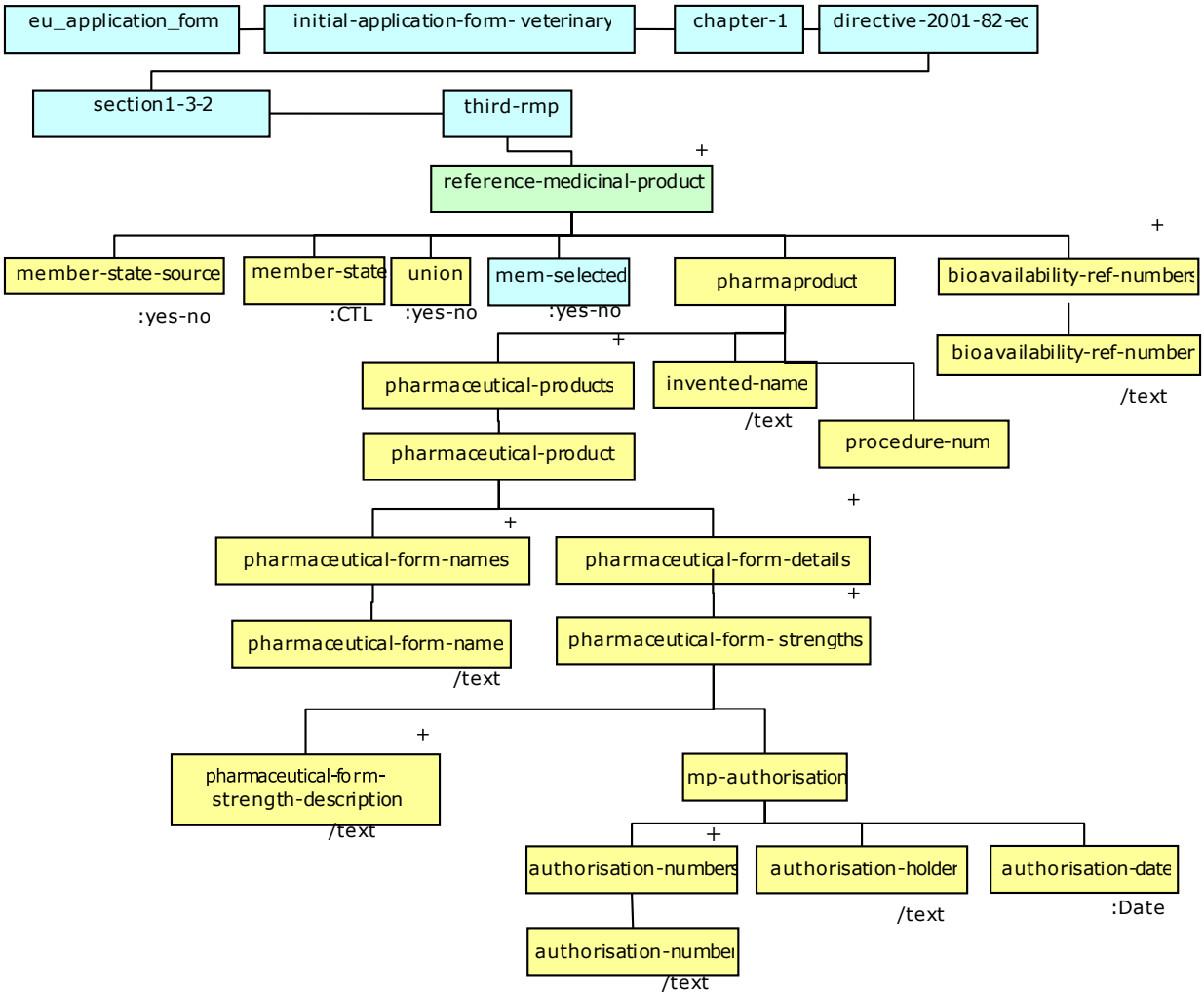


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B22322-1	E22322-7 to 8	Required	Mutually Exclusive	
B22322-2	E22322-8 to 9	Optional	If E22322-7 is selected, E22322-9 is required.	
B22322-2	E22322-10	Not visible	When E221-2 or E221-3 is selected, then E22322-10 is visible and mandatory	
B22322-3	E22322-10	Optional		

2.2.3.2.3. Veterinary medicinal product which is or has been authorised in accordance with Union provision 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-veterinary/maa:type_of_application/maa:directive-2001-82-ec/maa:section1-3-2/maa:third-rmp/maa:reference-medicinal-product/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E22323-1	Product (Invented) name	rdm:pharmaproduct/rdm:invented-name	Reference Medicinal Product > Medicinal Product > Medicinal Product Name	
E22323-2	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	
E22323-3	Strength(s)	rdm: pharmaproduct/ rdm:pharmaceutical-products/rdm:pharmaceutical-product /rdm:pharmaceutical-form-details/rdm:pharmaceutical-form-strengths/rdm:pharmaceutical-form-strength-description	Ingredient	
E22323-4	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	
E22323-5	Member State of source	rdm:member-state-source	Country CTL	
E22323-6	Marketing Authorisation granted by			
E22323-7	Union	rdm:community	MP Authorisation > Country CTL	B22323-1
E22323-8	Member State(EEA)	rdm:mem-selected		B22323-1, B22323-2
E22323-9	Member State(EEA)	rdm:member-state	MP Authorisation > Country CTL	B22323-1, B22323-2
E22323-10	Bioavailability study(ies) reference number(s)	rdm:bioavailability-ref-numbers/rdm:bioavailability-ref-number		
E22323-11	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	
E22321-13	Procedure number for MRP/DCP (if applicable)			
E22323-12	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	

Element Tree Diagram



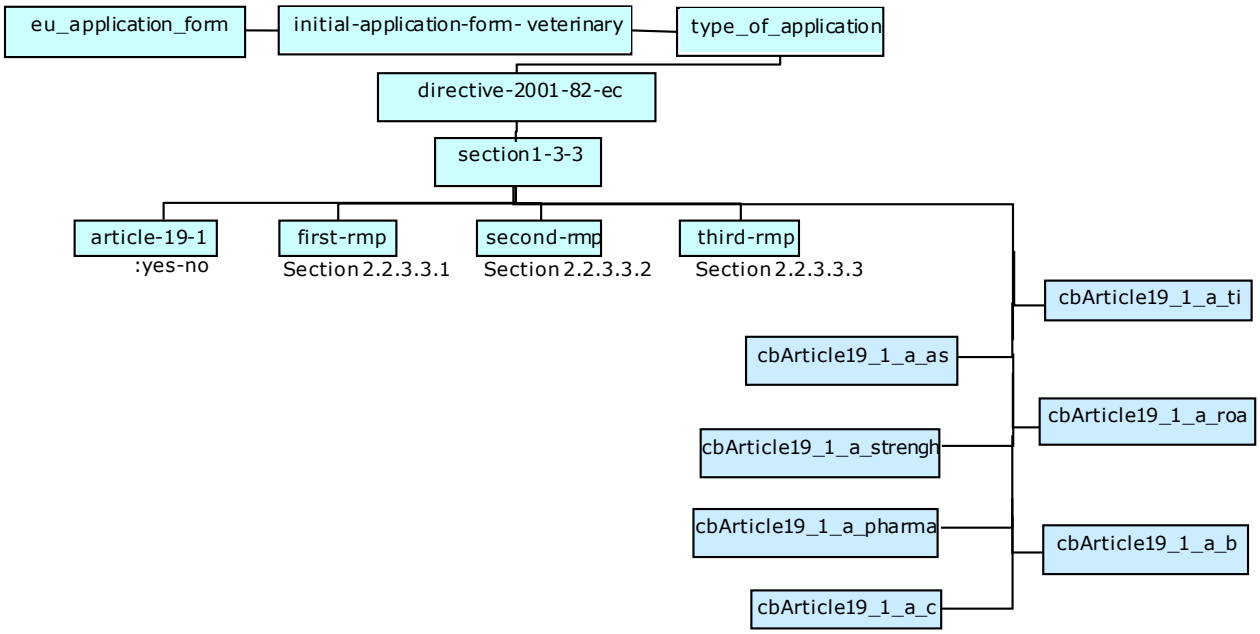
Business Rules

Rule ID	Element id(s)	Default BR	Rule	Effect(s)
B22323-1	E22323-7 to 8	Required	Mutually Exclusive	
B22323-2	E22323-8 to 9	Optional	If E22323-7 is selected, E22323-9 is required.	
B22321-3	E22321-13	Optional		

2.2.3.3. Article 13(3) hybrid application

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-veterinary/maa:type_of_application/maa:directive-2001-82-ec/maa:section1-3-3/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2233-1	Article 13(1) hybrid application	maa:article19-1	Basis for Eligibility CTL	B2233-1
E2233-2	(Article 19(1)(a) of Regulation (EU) 2019/6) - Hybrid application – change in active substance(s)	maa:cbArticle19_1_a_as		B2233-2
E2233-3	(Article 19(1)(a) of Regulation (EU) 2019/6) - Hybrid application – change in therapeutic indication(s)	maa:cbArticle19_1_a_ti		B2233-2
E2233-4	(Article 19(1)(a) of Regulation (EU) 2019/6) - Hybrid application - change in strength	maa:cbArticle19_1_a_strength		B2233-2
E2233-5	(Article 19(1)(a) of Regulation (EU) 2019/6) - Hybrid application – change in route of administration	maa:cbArticle19_1_a_roa		B2233-2
E2233-6	(Article 19(1)(a) of Regulation (EU) 2019/6) - Hybrid application – change in pharmaceutical form	maa:cbArticle19_1_a_pharma		B2233-2
E2233-7	(Article 19(1)(b) of Regulation (EU) 2019/6) - Hybrid application – bioavailability studies cannot be used to demonstrate bioequivalence	maa:cbArticle19_1_b		B2233-2
E2233-8	(Article 19(1)(c) of Regulation (EU) 2019/6) - Hybrid application – differences in raw materials or in manufacturing processes of biological VMPs	maa:cbArticle19_1_c		B2233-2
E2233-9	*Reference veterinary medicinal product which is or has been authorised for not less than 6/8/10 years in the EEA*	maa:first-rmp		B2233-1
E2233-10	*Reference veterinary medicinal product authorised in the Community/Member State where the application is made*	maa:second-rmp		B2233-1
E2233-11	*Veterinary medicinal product used in bioequivalence studies, where applicable*	maa:third-rmp		B2233-1

Element Tree Diagram



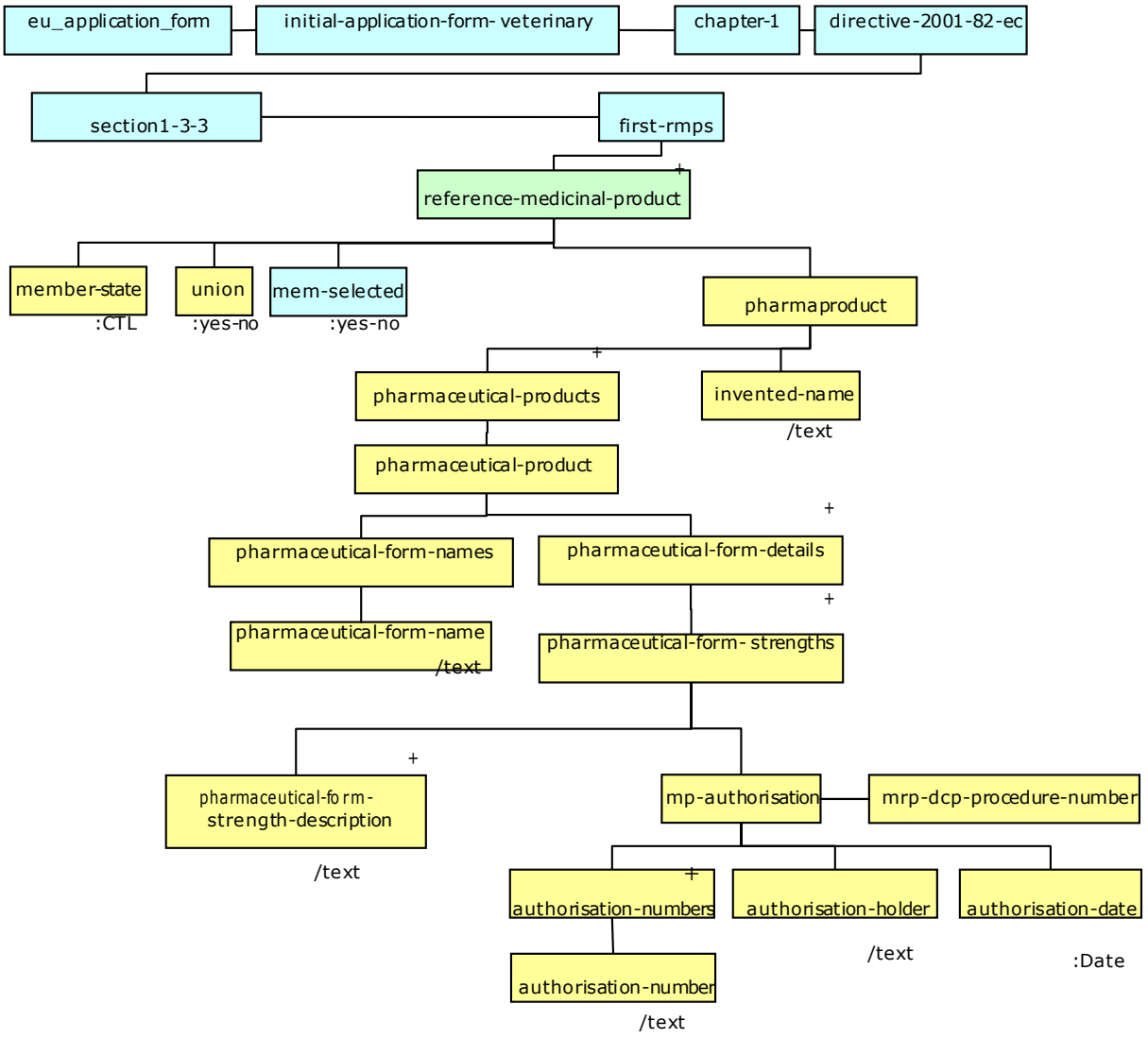
Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2233-1	E2233-1, E2233-9 to 11	Optional	If E2233-1 is selected, the rest become required	

B2233-2	E2233-12 to 8	Optional		

2.2.3.3.1. Veterinary medicinal product which is or has been authorised in accordance with Union provision 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-veterinary/maa:type_of_application/maa:directive-2001-82-ec/ maa:section1-3-3/maa:first-rmp/maa:reference-medicinal-product/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E22331-1	Product (Invented) name	rdm:pharmaproduct/rdm:invented-name	Reference Medicinal Product > Medicinal Product > Medicinal Product Name	
E22331-2	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	
E22331-3	Strength(s)	rdm: pharmaproduct/ rdm: pharmaceutical-products/rdm: pharmaceutical-product /rdm: pharmaceutical-form-details/rdm: pharmaceutical-form-strengths/rdm: pharmaceutical-form-strength-description	Ingredient	
E22331-4	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	
E22331-5	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	
E22331-6	Marketing authorisation granted by			
E22331-7	Union	rdm:community	MP Authorisation > Country CTL	B22331-1
E22331-8	Member State(EEA)	rdm:mem-selected		B22331-1, B22331-2
E22331-9	Member State(EEA)	rdm:member-state	MP Authorisation > Country CTL	B22331-2
E22331-9a	Marketing authorisation number(s)	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	
E22331-10	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:mrp-dcp-procedure-number		

Element Tree Diagram



Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B22331-1	E22331-7 to 8	Optional	Mutually Exclusive	
B22331-2	E22331-8 to 9	Optional	If E22331-8, then E22331-9 is required	
B22321-3	E22331-10	Optional		

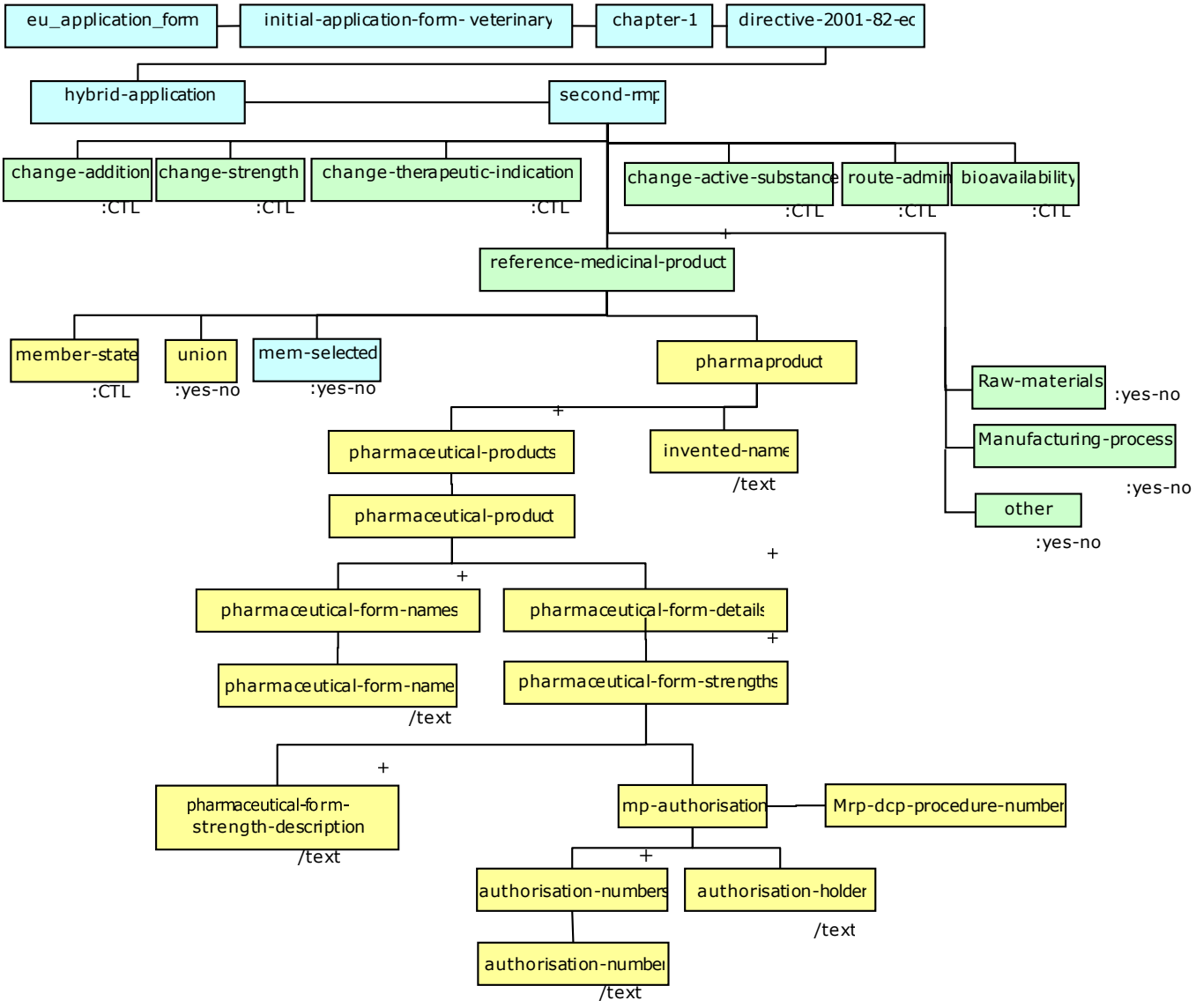
2.2.3.3.2. Veterinary medicinal product authorised in the Union/Member State where the application is made or European reference medicinal product

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-veterinary/maa:type_of_application/maa:directive-2001-82-ec/maa:section1-3-3/maa:second-rmp		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E22332-1	Product (Invented) name	maa:reference-medicinal-product/rdm:pharmaproduct/rdm:invented-name	Reference Medicinal Product > Medicinal Product > Medicinal Product Name	
E22332-2	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	
E22332-3	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	
E22332-4	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	
E22332-5	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	
E22322-18	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		
E22332-6	Marketing authorisation granted by			
E22332-7	Union	maa:reference-medicinal-product/rdm:community	MP Authorisation > Country CTL	B22332-1
E22332-8	Member State(EEA)	maa:reference-medicinal-product/rdm:mem-selected		B22332-1, B22332-2
E22332-9	Member State(EEA)	maa:reference-medicinal-product/rdm:member-state	MP Authorisation > Country CTL	B22332-2
E22332-10	Difference(s) compared to this reference veterinary medicinal product			
E22332-11	Changes in the active substance(s)	maa:change-active-substance	Difference CTL	B22332-3
E22332-12	Change in therapeutic indications	maa:change-therapeutic-indication	Difference CTL	B22332-3
E22332-13	Change in strength (quantitative change to the active substance(s))	maa:change-strength	Difference CTL	B22332-3
E22332-14	Change in pharmaceutical form	maa:change-addition	Difference CTL	B22332-3
E22332-15	Change in route of administration	maa:route-admin	Difference CTL	B22332-3
E22332-16	change(s) in the raw material(s) (compared to the reference	maa:raw-materials		

	biological veterinary medicinal product)			
E22332-17	change(s) in the manufacturing process(es) (compared to the reference biological veterinary medicinal product)	maa:manufacturing-process		
E22332-18	other	maa:other		
E22332-19	Bioequivalence cannot be demonstrated through bioavailability studies	maa:bioequilvalence	Difference CTL	B22332-3

E22332-20	Member States	maa:reference-medicinal-product rdm:member-states/rdm:ref-member-state/rdm:name	Procedure Use > Role > Country CTL	B22332-4

Element tree Diagram



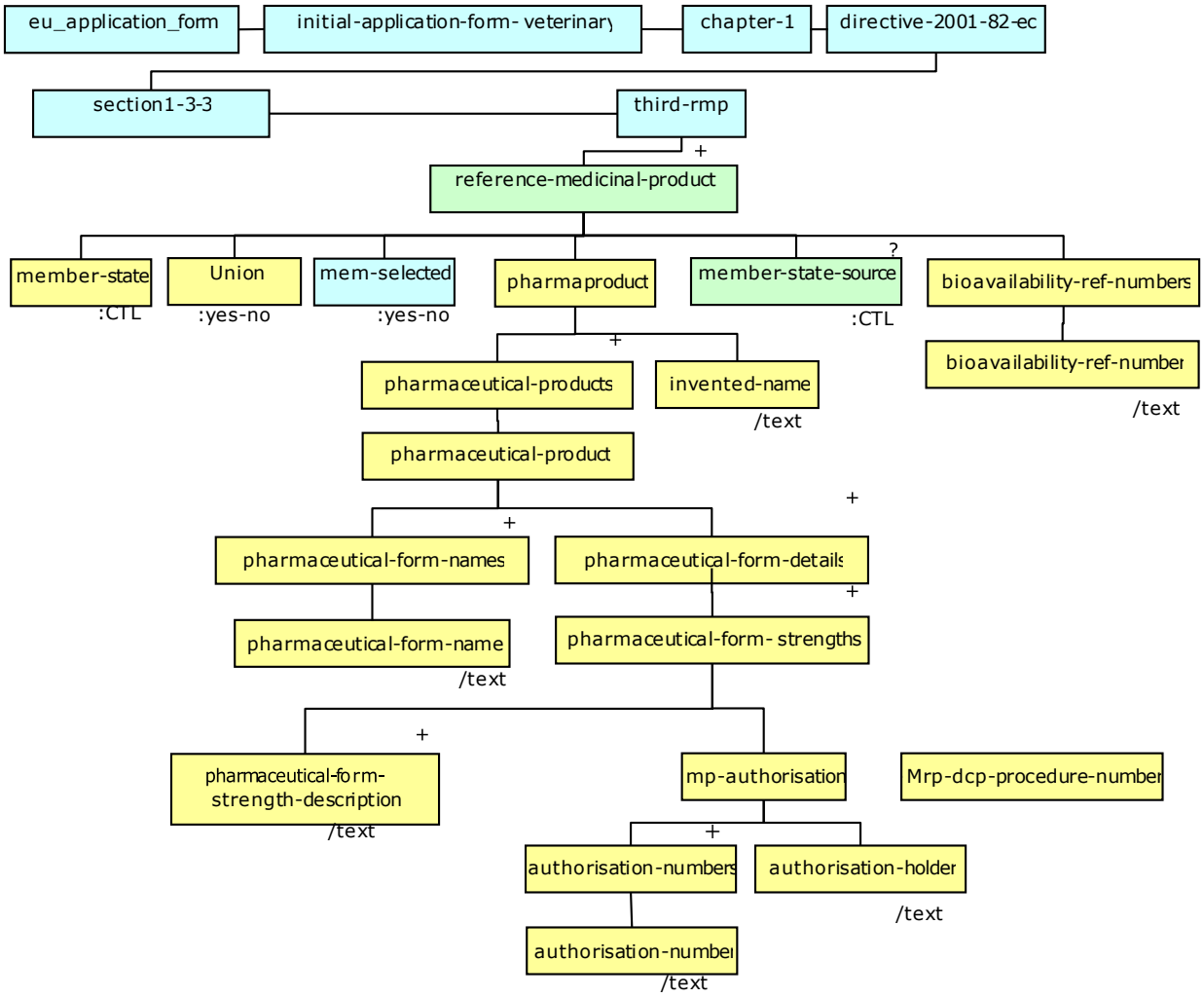
Business Rules

Rule ID	Element id(s)	Default BR	Rule	Effect(s)
B22332-1	E22332-7 to 8	Optional	Mutually Exclusive	
B22332-2	E22332-8 to 9	Optional	If E22332-8 is selected, then E22332-9 is required	
B22332-3	E22332-11 to 19	Mandatory	Mutually Exclusive	
B22332-4	E22332-20,	E22423-17 is not visible.	When E221-2 or E221-3 is selected, then E22332-17 is visible and mandatory	

2.2.3.3.3. Veterinary 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-veterinary/maa:type_of_application/maa:directive-2001-82-ec/maa:section1-3-3/maa:third-rmp/maa:reference-medicinal-product		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E22333-1	Product (Invented) name	rdm:pharmaproduct/rdm:invented-name	Reference Medicinal Product > Medicinal Product > Medicinal Product Name	
E22333-2	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	
E22333-3	Strength(s)	rdm: pharmaproduct/ rdm:pharmaceutical-products/rdm:pharmaceutical-product /rdm:pharmaceutical-form-details/rdm:pharmaceutical-form-strengths/rdm:pharmaceutical-form-strength-description	Ingredient	
E22333-4	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	
E22333-4a	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	
E22333-11	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		
E22333-5	Member State of source	rdm:member-state	Country CTL	
E22333-6	Marketing authorisation granted by			
E22333-7	Union	rdm:community	MP Authorisation > Country CTL	B22333-1
E22333-8	Member State(EEA)	rdm:mem-selected		B22333-1, B22333-2
E22333-9	Member State(EEA)	rdm:member-state	MP Authorisation > Country CTL	B22333-2
E22333-10	Study reference number	rdm:bioavailability-ref-numbers/rdm:bioavailability-ref-number	Reference Medicinal Product > study ref number	

Element Tree Diagram



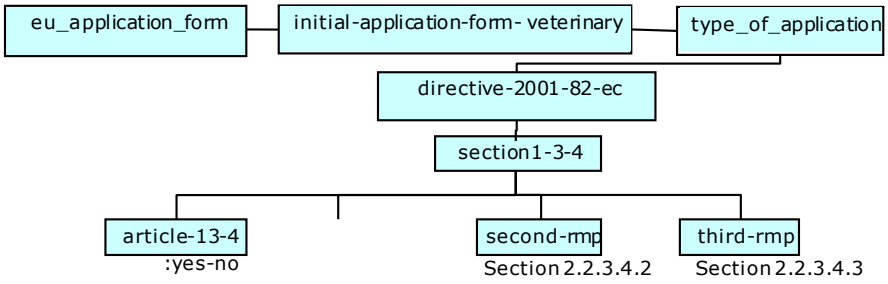
Business Rules

Rule ID	Element id(s)	Default BR	Rule	Effect(s)
B22333-1	E22333-7 to 8	Optional	Mutually Exclusive	
B22333-2	E22333-8 to 9	Optional	If E22333-8, then E22333-9 is required	
B22321-3	E22333-11	Optional		

2.2.3.4. Article 13(4) Similar biological application

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-veterinary/maa:type_of_application/maa:directive-2001-82-ec/maa:section1-3-4/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2234-1	Article 20 – Combination veterinary medicinal products	maa:article-20	Basis for Eligibility CTL	B2234-1
E2234-2	*Reference veterinary medicinal product authorised in the Community/Member State where the application is made*	maa:second-rmp		B2234-1
E2234-3	*Veterinary medicinal product used in bioequivalence studies where applicable*	maa:third-rmp		B2234-1

Element Tree Diagram

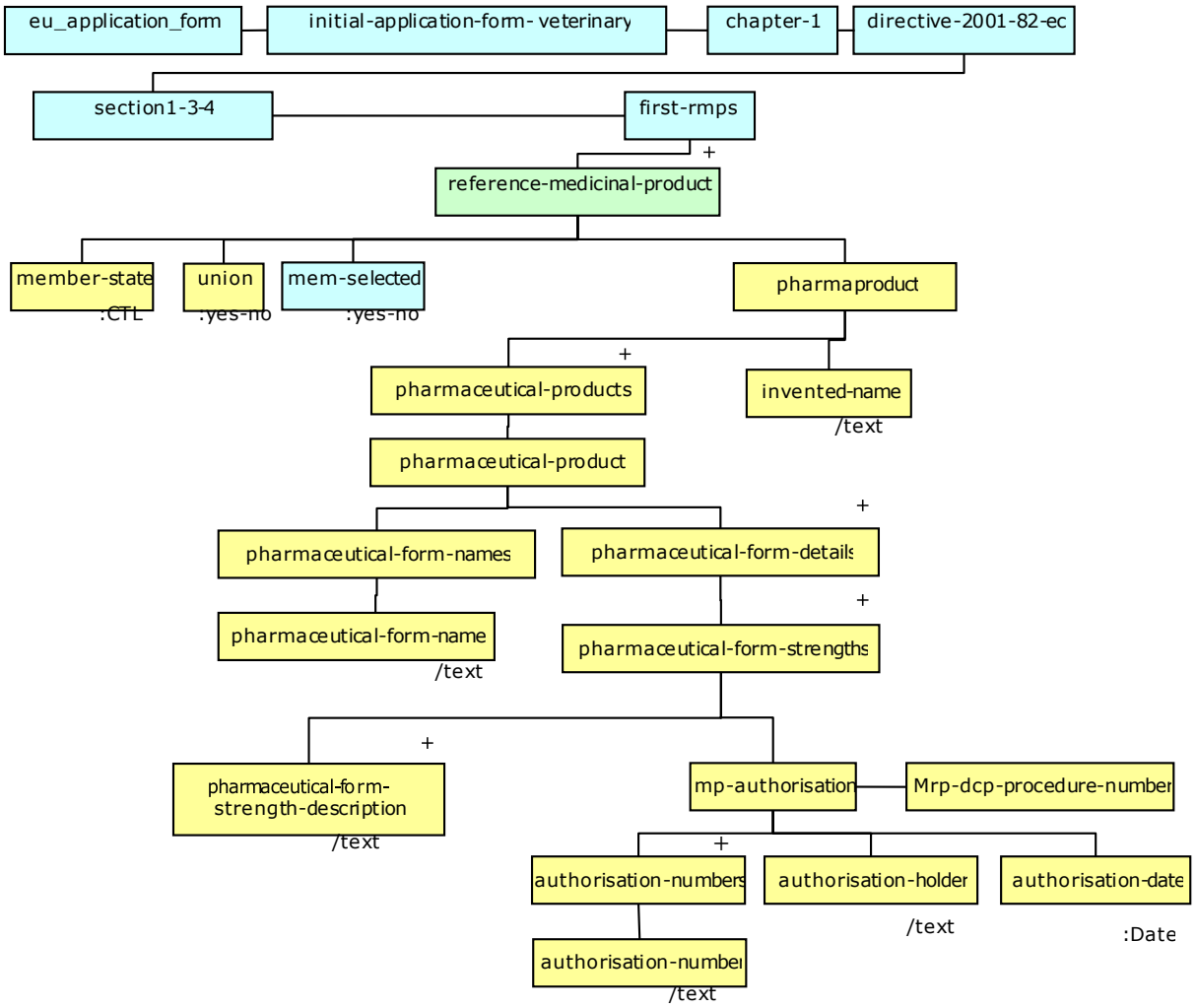


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2234-1	E2234-1 to 3	Optional	If E2234-1 is selected, the rest become required	

2.2.3.4.1. Reference veterinary 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-veterinary/maa:type_of_application/maa:directive-2001-82-ec/ maa:section1-3-4/maa:first-rmp/maa:reference-medicinal-product/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E22341-1	Product (Invented) name	rdm:pharmaproduct/rdm:invented-name	Reference Medicinal Product > Medicinal Product > Medicinal Product Name	
E22341-2	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	
E22341-3	Strength(s)	rdm:pharmaproduct/ rdm: pharmaceutical-products/rdm: pharmaceutical-product /rdm: pharmaceutical-form-details/rdm: pharmaceutical-form-strengths/rdm: pharmaceutical-form-strength-description	Ingredient	
E22341-4	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	
E22341-5	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	
E22341-6	Marketing authorisation granted by			
E22341-7	Union	rdm:community	MP Authorisation > Country CTL	B22341-1
E22341-8	Member State(EEA)	rdm:mem-selected		B22341-1, B22341-2
E22341-9	Member State(EEA)	rdm:member-state	MP Authorisation > Country CTL	B22341-2
E22341-10	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	
E22341-11	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		

Element Tree Diagram



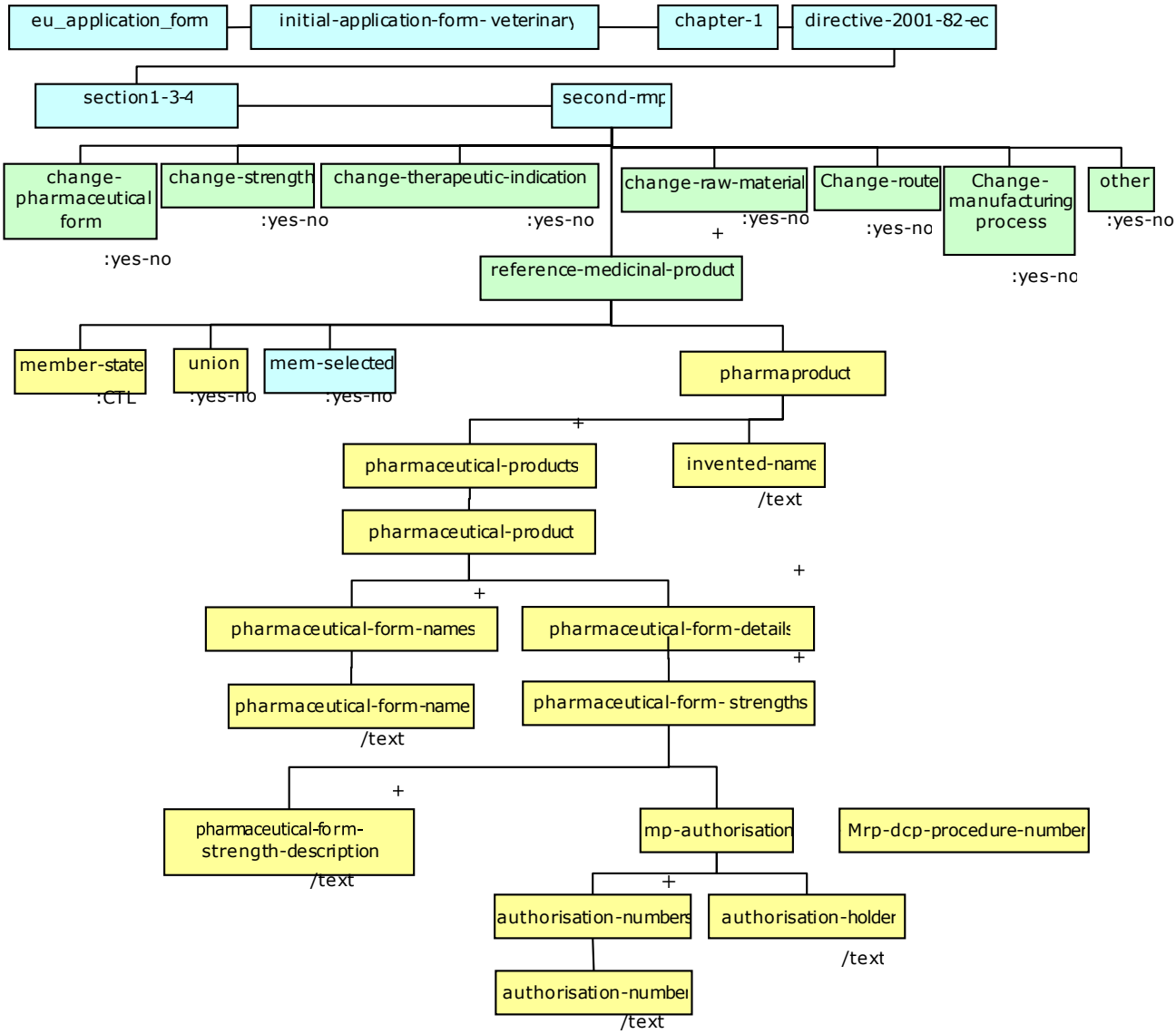
Business Rules

Rule ID	Element id(s)	Default BR	Rule	Effect(s)
B22341-1	E22341-7 to 8	Optional	Mutually Exclusive	
B22341-2	E22341-8 to 9	Optional	If E22341-8, then E22341-9 is required	
B22321-3	E22341-11	Optional		

2.2.3.4.2. Reference veterinary 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-veterinary/maa:type_of_application/maa:directive-2001-82-ec/maa:section1-3-4/maa:second-rmp		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E22342-1	Product (Invented) name	maa:reference-medicinal-product/ rdm:pharmaproduct/rdm:invented-name	Reference Medicinal Product > Medicinal Product > Medicinal Product Name	
E22342-2	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	
E22342-3	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	
E22342-4	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	
E22342-5	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	
E22342-18	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		
E22342-6	Marketing authorisation granted by			
E22342-7	Union	maa:reference-medicinal-product/ rdm:community	MP Authorisation > Country CTL	B22342-1
E22342-8	Member State(EEA)	maa:reference-medicinal-product/ rdm:mem-selected		B22342-1, B22342-2
E22342-9	Member State(EEA)	maa:reference-medicinal-product / rdm:member-state	MP Authorisation > Country CTL	B22342-2
E22342-10	Difference(s) compared to this reference medicinal product			
E22342-11	change-raw material	rdm:change-raw-substance		B22342-3
E22342-12	change-manufacturing process	rdm:manufacturing		B22342-3
E22342-13	change-therapeutic indication	rdm:change-therapeutic-indication		B22342-3
E22342-14	change-pharmaceutical form	rdm:change-addition		B22342-3
E22342-15	Change-strength	rdm:change-strength		B22342-3
E22342-16	Change - route	rdm:route-admin		B22342-3
E22342-17	other	rdm:other		B22342-3

Element Tree Diagram

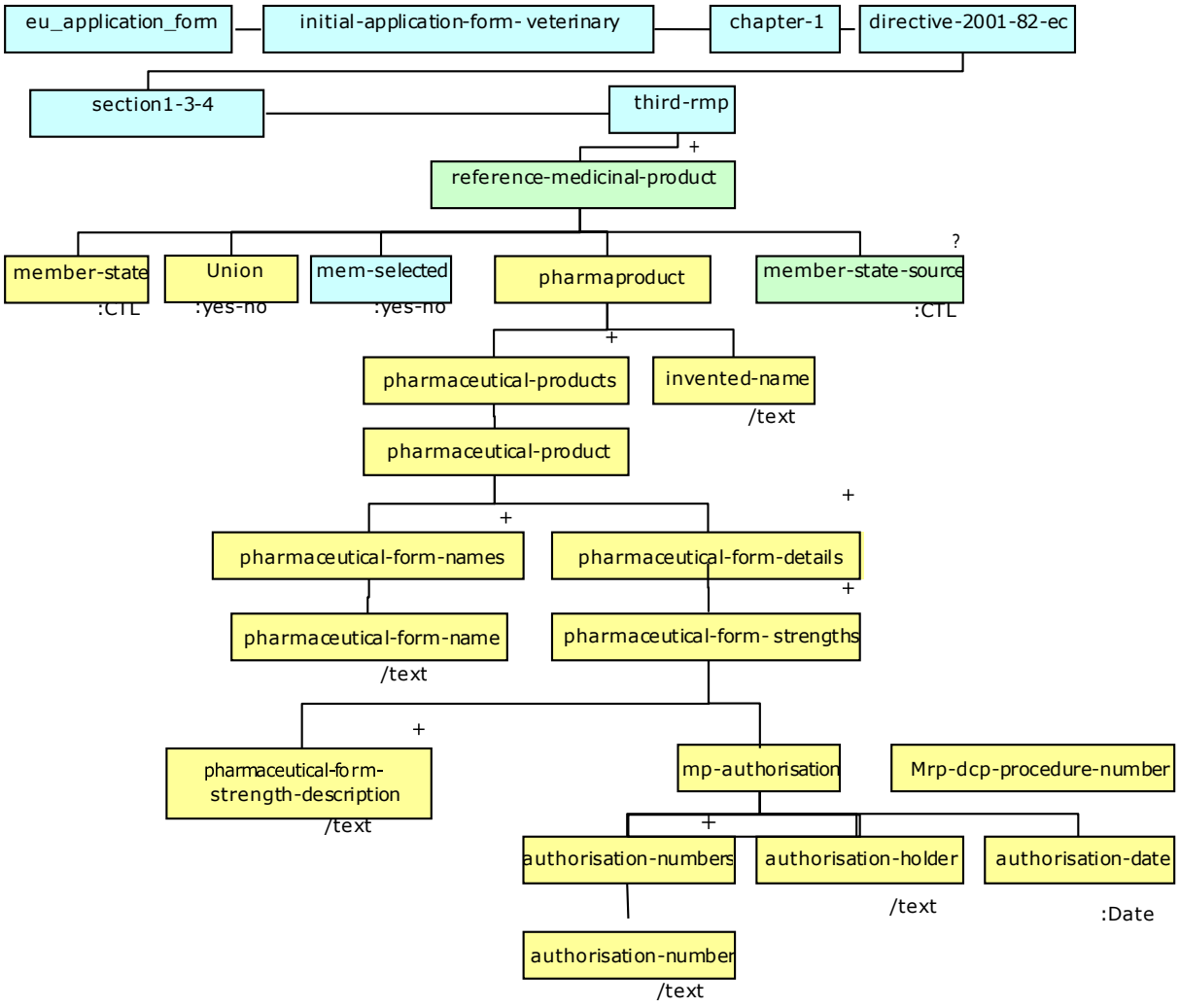


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B22342-1	E22342-7 to 8	Optional	Mutually Exclusive	
B22342-2	E22342-8 to 9	Optional	If E22342-8, then E22342-9 is required	
B22342-3	E22342-11 to 17	Mandatory	Mutually Exclusive	
B22321-4	E22342-18	Optional		

2.2.3.4.3. Veterinary 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-veterinary/maa:type_of_application/maa:directive-2001-82-ec/maa:section1-3-4/maa:third-rmp/maa:reference-medicinal-product/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E22343-1	Product (Invented) name	rdm:pharmaproduct/rdm:invented-name	Reference Medicinal Product > Medicinal Product > Medicinal Product Name	
E22343-2	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	
E22343-3	Strength(s)	rdm: pharmaproduct/ rdm: pharmaceutical-products/rdm: pharmaceutical-product /rdm: pharmaceutical-form-details/rdm: pharmaceutical-form-strengths/rdm: pharmaceutical-form-strength-description	Ingredient	
E22343-4	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	
E22343-5	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 > authorisation date	
E22343-6	Marketing authorisation granted by			
E22343-7	Union	rdm:community	MP Authorisation > Country CTL	B22343-1
E22343-8	Member State(EEA)	rdm:mem-selected		B22343-1, B22343-2
E22343-9	Member State(EEA)	rdm:member-state	MP Authorisation > Country CTL	B22343-2
E22343-10	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	
E22343-11	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		

Element Tree Diagram



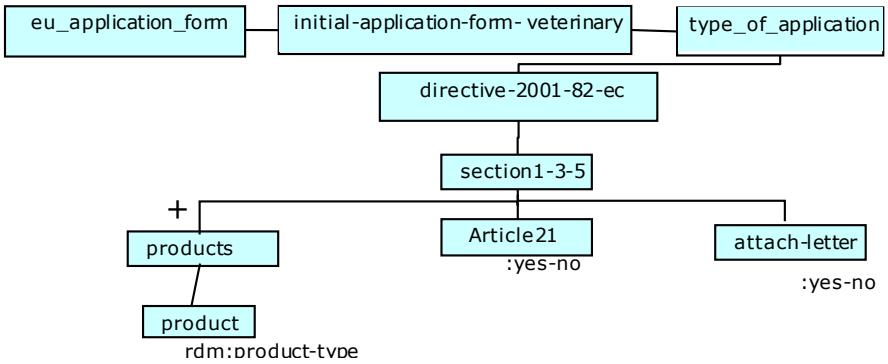
Business Rules

Rule ID	Element id(s)	Default BR	Rule	Effect(s)
B22343-1	E22343-7 to 8	Optional	Mutually Exclusive	
B22343-2	E22343-8 to 9	Optional	If E22343-8, then E22343-9 is required	
B22321-3	E22343-11	Optional		

2.2.3.5. Article 13a - Well established Veterinary use

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-veterinary/maa:type_of_application/maa:directive-2001-82-ec/maa:section1-3-5/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2235-1	Article 21 – Informed consent application	maa:article21	Basis for Eligibility CTL	
E2235-2	*Authorised product in the Union/Member State where the application is made*	maa:products		
E2235-3	Attach letter of consent from marketing authorisation holder of the authorised product	maa:attach-letter		

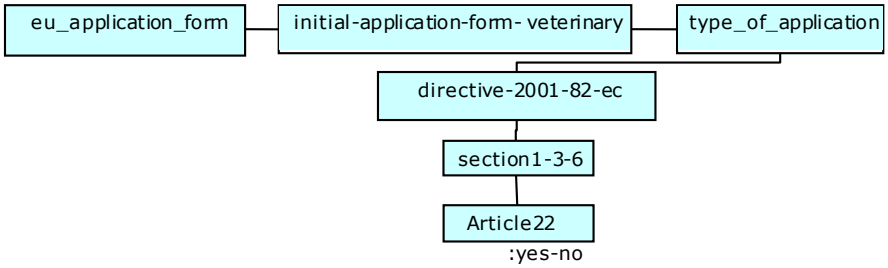
Element tree Diagram



2.2.3.6. Article 13b - Fixed combination application

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-veterinary/maa:type_of_application/maa:directive-2001-82-ec/maa:section1-3-6/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2236-1	Article 22 – Bibliographic application	maa:article22	Basis for Eligibility CTL	

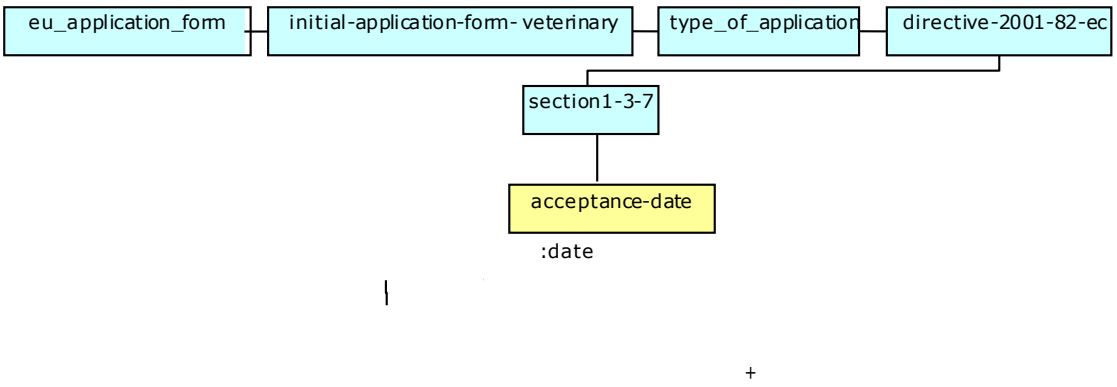
Element Tree Diagram



2.2.3.7. Article 13c - Informed consent application

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-veterinary/maa:type_of_application/maa:directive-2001-82-ec/maa:section1-3-7/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2237-1	Article 23 – Applications for limited markets	maa:article23	Basis for Eligibility CTL	
E2237-7	Date of acceptance/confirmation by CVMP or National Competent Authority	maa:accepatance-date		

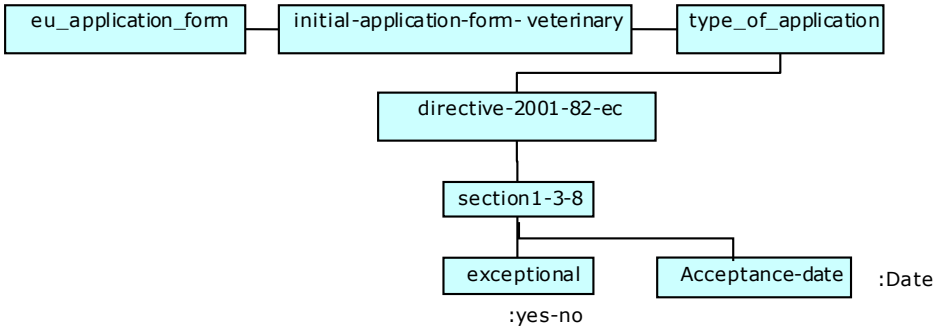
Element Tree Diagram



2.2.3.8. Article 13d - Immunological Veterinary Medicinal Product for which the results of certain trials are not being submitted

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-veterinary/maa:type_of_application/maa:directive-2001-82-ec/maa:section1-3-8/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2235-1	Exceptional Circumstances	maa:exceptional	Basis for Eligibility CTL	
E2235-2	Date of acceptance/confirmation by CVMP or National Competent Authority	maa:acceptance-date		

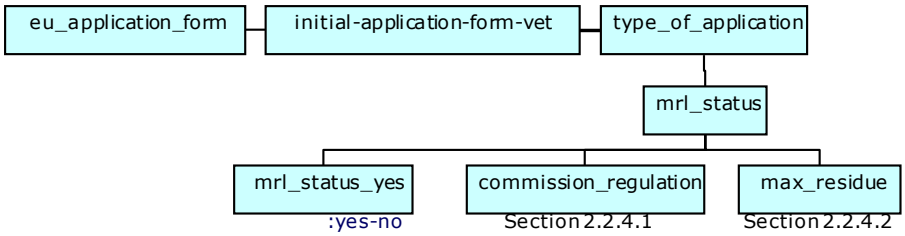
Element Tree Diagram



2.2.4. MRL status (only for food producing species)

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-veterinary/maa:type_of_application/maa:mrl_status/		Application > MP Procedure >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E223-1	Maximum Residue Limits (MRL) according to Commission Regulation (EU) No 37/2010	maa:commission_regulation		
E223-2	Application for a Maximum Residue Limit has been made to the EMA	maa:max_residue		
E223-3	Check box	maa:mrl_status_yes		B223-1

Element Tree Diagram



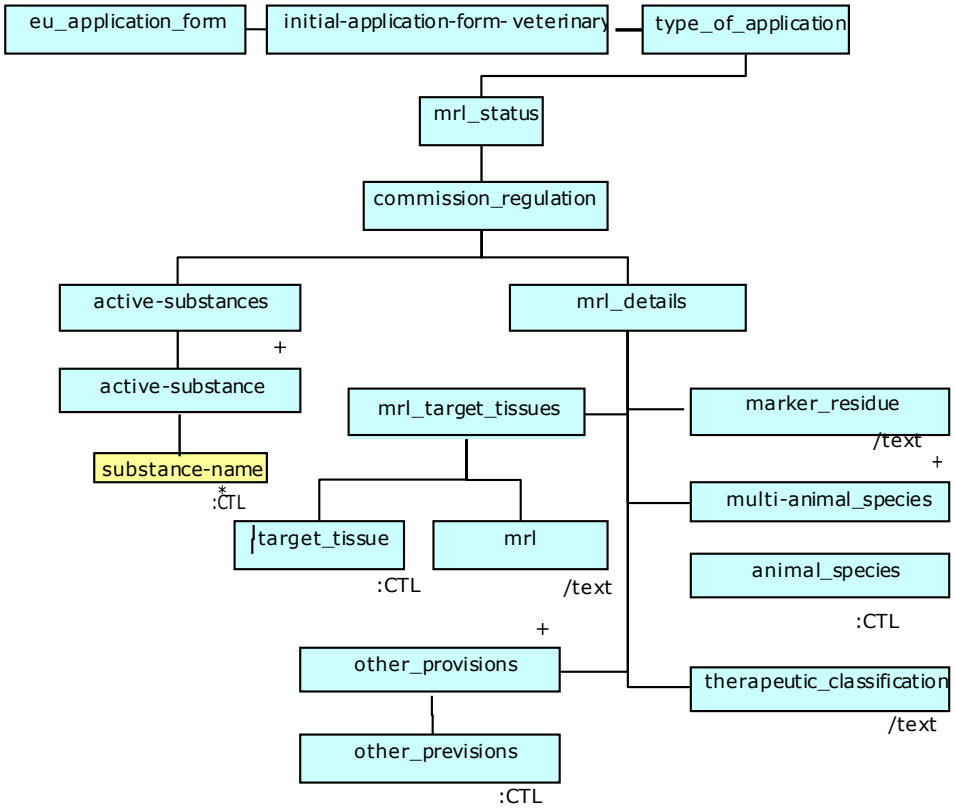
Business Rules

Rule ID	Element id(s)	Default BR	Rule	Effect(s)
B223-1	E223-3	Optional	If E223-3 is selected then E2241-1 to E2242-5 is visible	E2241-1 to E2242-5

2.2.4.1. Maximum Residue Limits (MRL) according to Commission Regulation (EU) No 37/2010

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-veterinary/maa:type_of_application/maa:mrl_status/maa:commission_regulation/		Application > MRL	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2241-1	Active Substance(s)	maa:active-substances/maa:active-substance/rdm:substance-name	Ingredient > Substance CTL, Ingredient > IngredientRole CTL	B223-1
E2241-2	Marker residue	maa:mrl_details/maa:marker_residue		B223-1
E2241-3	Animal species	maa:mrl_details/maa:multi-animal_species/maa:animal_species	Target Population > Species CTL	B223-1
E2241-4	MRL	maa:mrl_details/maa:mrl_target_tissues/maa:mrl	Maximum Residue Limit	B223-1
E2241-5	Target Tissue	maa:mrl_details/maa:mrl_target_tissues/maa:target_tissue	Tissue CTL	B223-1
E2241-6	Other Provisions	maa:mrl_details/maa:other_provisions/maa:other_previsions		B223-1
E2241-7	Therapeutic classification	maa:mrl_details/maa:therapeutic_classification		B223-1

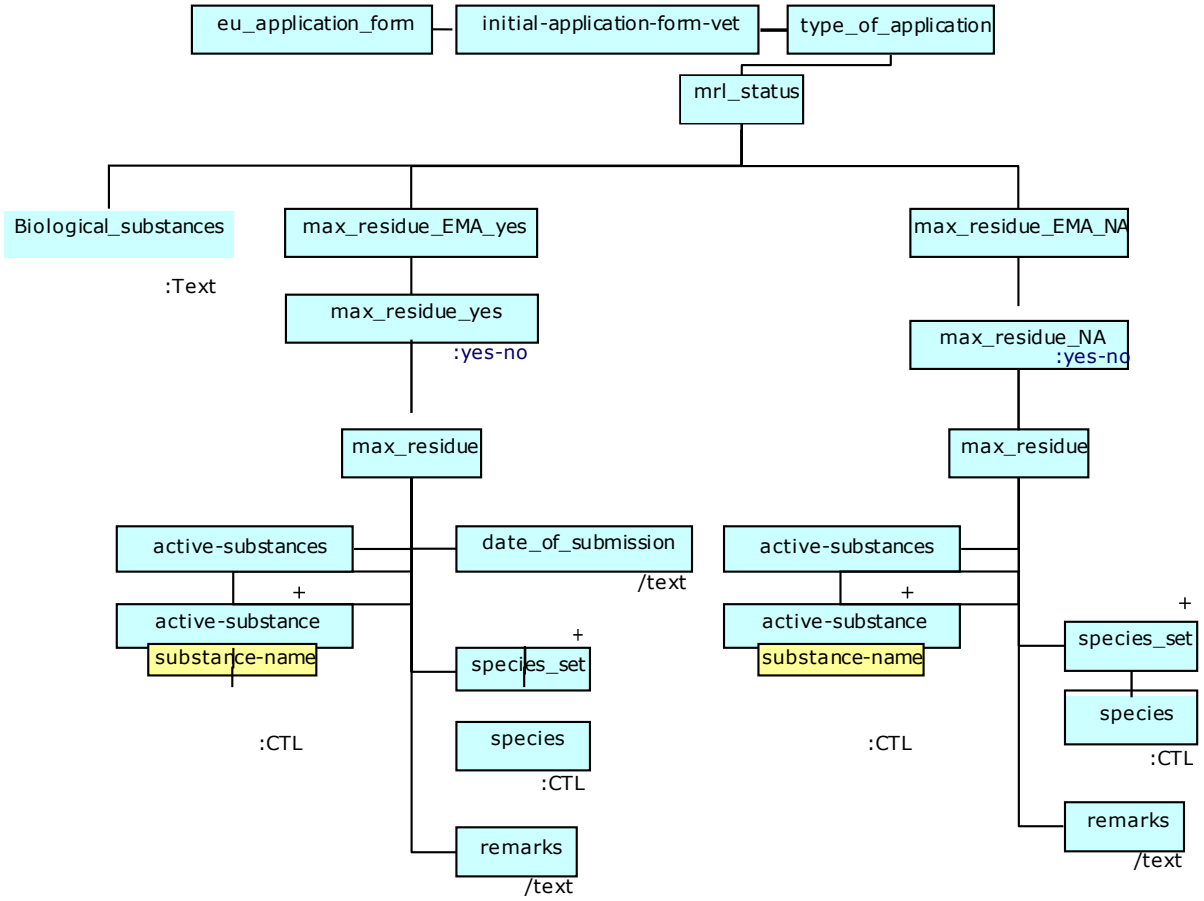
Element Tree Diagram



2.2.4.2. Application for a Maximum Residue Limit has been made to the EMA

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-veterinary/maa:type_of_application/maa:mrl_status		Application > MRL >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2242-1	Active Substance(s)	maa:max_residue/maa:active-substances/maa:active-substance/rdm:substance-name	Ingredient > Substance CTL, Ingredient > IngredientRole CTL	B223-1
E2242-2	Date of Submission	maa:max_residue/maa:date_of_submission	Emea submission date	B223-1
E2242-3	Species	maa:max_residue/maa:species_set/maa:species	Species CTL	B223-1
E2242-4	Remarks	maa:max_residue/maa:remarks	mrl remarks	B223-1
E2242-4a	biological substance	maa:biological_substances		
E2242-5	Application for a Maximum Residue Limit has been made to the EMA: Yes – not applicable	maa:max_residue_EMA_Yes		B223-1
E2242-6	Application for a Maximum Residue Limit has been made to the EMA: Yes – not applicable	maa:max_residue_EMA_NA		B223-1

Element Tree Diagram

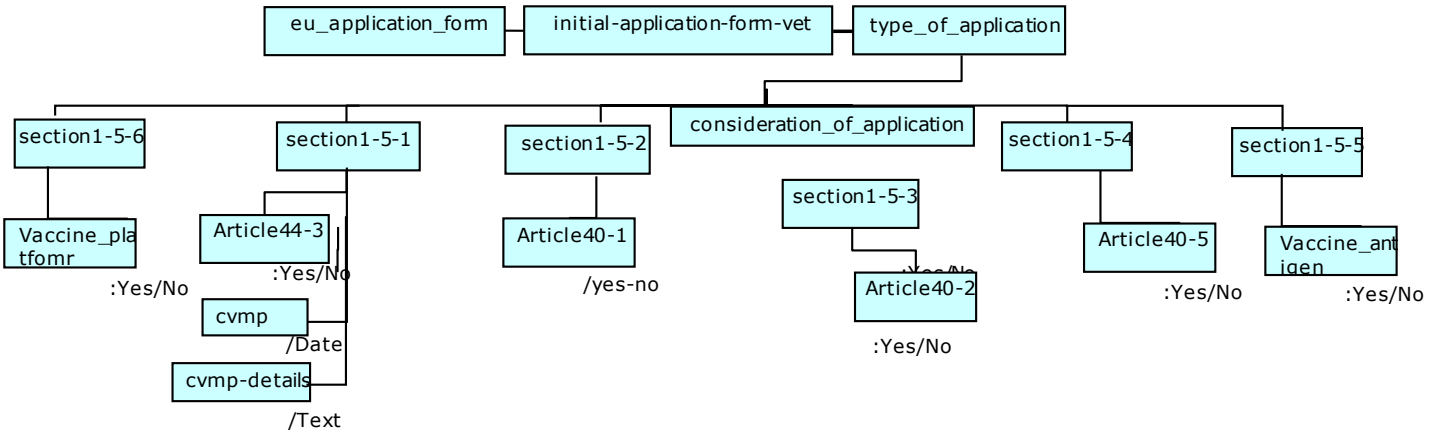


2.2.5. Consideration of this application is also requested under the following article in Directive 2001/82/EC or Regulation (EC) no. 726/2004

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-veterinary/maa:type_of_application/maa:consideration_of_application/		Application > MP Procedure >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E225-1	Accelerated assessment procedure	maa:section1-5-1/ maa:article44-3		B225-1
E225-1a	Date of acceptance by CVMP	maa:cvmp		
E225-1b		maa:cvmp		
E225-2	Article 40(1) of Regulation (EU) 2019/6 (where the first MA is granted for >1 species referred to in point (a) or (b) of Article 39(1), or a variation is approved in accordance with Article 67 which adds another species referred to in point (a) or (b) of Article 39(1), the period of the protection provided for in Article 39 shall be prolonged by one year for each additional target species, provided that, in the case of a variation, the application has been submitted at least three years before expiration of the protection period laid down in point (a) or (b) of Article 39(1))	maa:section1-5-2/ maa:article40-1		B225-1, B225-2
E225-5	Article 40(2) of Regulation (EU) 2019/6 (where the first MA is granted for >1 species referred to in point (d) of Article 39(1), or a variation is approved in accordance with Article 67 which adds another species not referred to in point (a) of Article 39(1), the period of the protection provided for in Article 39 shall be prolonged by four years, provided that, in the case of a variation, the application has been submitted at least three years before expiration of the protection period laid down in point (d) of Article 39(1))	maa:section1-5-3/ maa:article40-2		B225-1
E225-6	Article 40(4) of Regulation (EU) 2019/6 (where an applicant for a marketing authorisation or for a variation submits an MRL application in accordance with Regulation (EC) No 470/2009, together with safety and residues tests and pre-clinical studies and clinical trials during the application procedure, other applicants shall not refer to results of those tests, studies and	maa:section1-5-4/ maa:article40-5		B225-1

	trials for a period of 5 years from the granting of the MA for which they were carried out))			
	Article 40(5) of Regulation (EU) 2019/6 (if a variation involving a change to the pharmaceutical form, administration route or dosage is approved, and additionally assessed to have met a criterion within this Article, the results of the concerned pre-clinical studies or clinical trials shall benefit from four years protection)	maa:section1-5-5/vaccine-antigen		
	Vaccine antigen master file Note: centralised procedure only according to Section V.2.3.1 of Annex II to Regulation (EU) 2019/6	maa:section1-5-6/vaccine_platform		

Element Tree Diagram

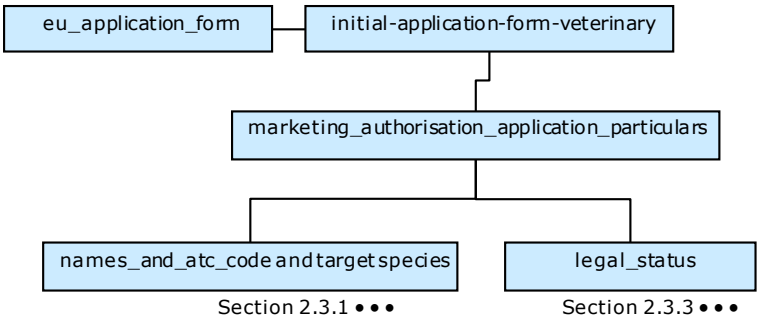


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B225-1	E225-1, 2	Optional	Mutually Exlusive	
B225-2	E225-2	Optional	If E225-2 is selected, E225-3 and E225-4 are visible	

2.3. MARKETING AUTHORISATION APPLICATION PARTICULARS

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-veterinary/maa:marketing_authorisation_application_particulars/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E23-1	NAME(S), ATC VET CODE and TARGET SPECIES	maa:names_and_atc_code		
E23-2	STRENGTH, PHARMACEUTICAL FORM, ROUTE OF ADMINISTRATION, CONTAINER AND PACK SIZES			
E23-3	LEGAL STATUS	maa:legal_status		
E23-4	MARKETING AUTHORISATION HOLDER / CONTACT PERSONS / COMPANY			
E23-5	MANUFACTURERS			
E23-6	QUALITATIVE AND QUANTITATIVE COMPOSITION			

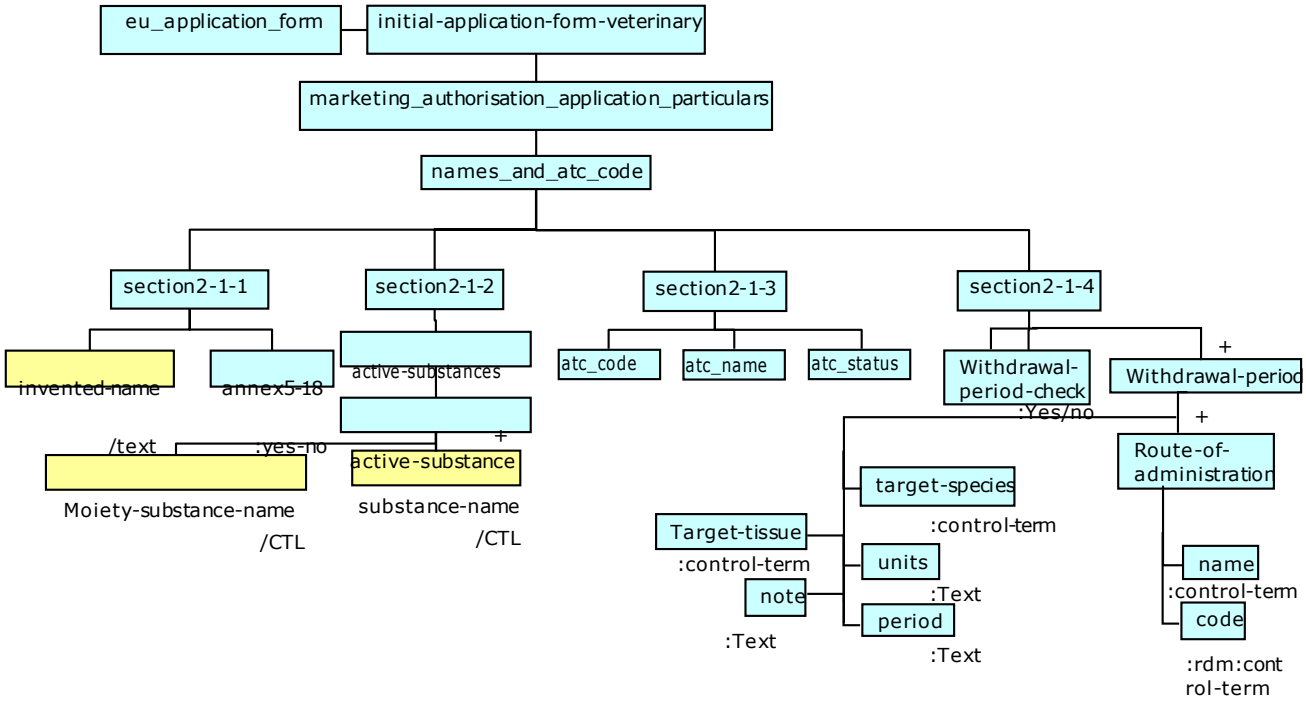
Element Tree Diagram



2.3.1. NAME(S), ATC VET CODE AND TARGET SPECIES

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-veterinary/maa:marketing_authorisation_application_particulars/maa:names_and_atc_code/		Application > MP Procedure >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E231-1	Proposed (invented) name of the veterinary medicinal product in the European Union / Member State / Iceland / Liechtenstein / Norway	maa:section2-1-1/ maa:invented-name	Substance CTL	
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 5.18	maa:section2-1-1/ maa:annex5-18		
E231-3	Active substance(s) if applicable including salt or hydrate*.	maa:section2-1-2/ maa:active-substances/ maa:active-substance/ rdm:substance-name	Substance CTL	
E231-9	Base/active moiety of the active substance(s)	maa:section2-1-2/ maa:active-substances/ maa:active-substance/ rdm:moiety-substance-name		
E231-10	Substance type (e.g. chemical substance, recombinant biological substance)	maa:substanceType		
E231-11	*For applications submitted in accordance with Art. 12(3) of Directive 2001/82/EC:*			
E231-12	Claim for new active substance(s)	Maa :new-active-substance		
E231-13	known active substance(s)	Maa :known-active-substance		
E231-14	Attach letter	Maa :attach-letter		
E231-4	Pharmacotherapeutic group (Please use current ATC vet code)			
E231-5	Group	maa:section2-1-3/ maa:atc/maa:atc_name	ATC Group CTL	
E231-6	ATC Vet code	maa:section2-1-3/ maa:atc/maa:atc_code	ATC Group CTL	
E231-7	Please indicate if the application for the ATC Vet Code is still pending	maa:section2-1-3/ maa:atc/maa:atc-status		
E231-8	Withdrawal period (Only for food-producing species)	maa:section2-1-4/ maa:withdrawal-period-check		
E231-9		maa:section2-1-4/ maa:withdrawal-period		
E231-10	Route of Administration	maa:section2-1-4/ maa:withdrawal-period/maa:route-of-administration/name	Species CTL	
E231-11		maa:section2-1-4/ maa:withdrawal-period/maa:route-of-administration/code	Species CTL	
E231-12	Target species	maa:section2-1-4/ maa:withdrawal-period/maa:target-species	Species CTL	
E231-13	Tissue	maa:section2-1-4/ maa:withdrawal-period/maa:target-tissue	Species CTL	
E231-14	Period	maa:section2-1-4/ maa:withdrawal-period/maa:period		
E231-15	Units	maa:section2-1-4/ maa:withdrawal-period/maa:units		
E231-16	Note	maa:section2-1-4/ maa:withdrawal-period/maa:note		

Element Tree Diagram

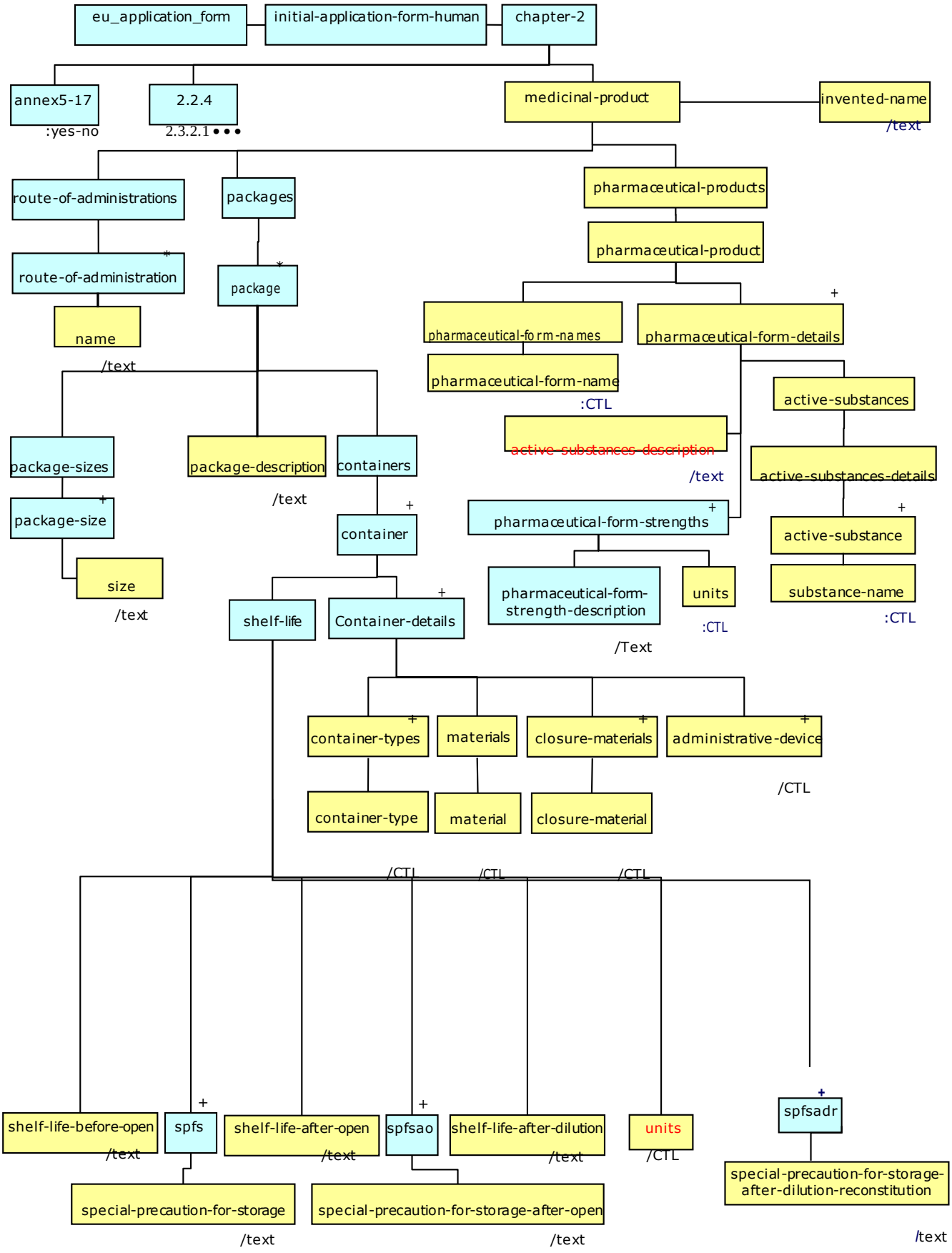


2.3.2. STRENGTH, PHARMACEUTICAL FORM, ROUTE OF ADMINISTRATION, CONTAINER AND PACK SIZES

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-veterinary/maa:marketing_authorisation_application_particulars/		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 > Pharmaceutida 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	
E232-7a	Target species	rdm:medicinal-product/maa:route-of-administrations/rdm:route-of-administration/rdm:target_species/rdm:species	Species 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/ rdm:container-details/ rdm:material	Package > Immediate Container > Container CTL	
E232-15	Closure	rdm:medicinal-product/maa:packages/rdm:package	Package > Immediate Container > Container	B232-1

		/rdm:containers/rdm:container/ rdm:container-details/rdm: closure-material	CTL	
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
E232-21a	Proposed storage conditions after reconstitution or dilution	rdm:medicinal-product/ maa:packages/rdm:package/rdm:containers/rdm:container/rdm:shelf-life/rdm:spfsadr/rdm:special-precaution-for-storage-after-dilution-reconstitution	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



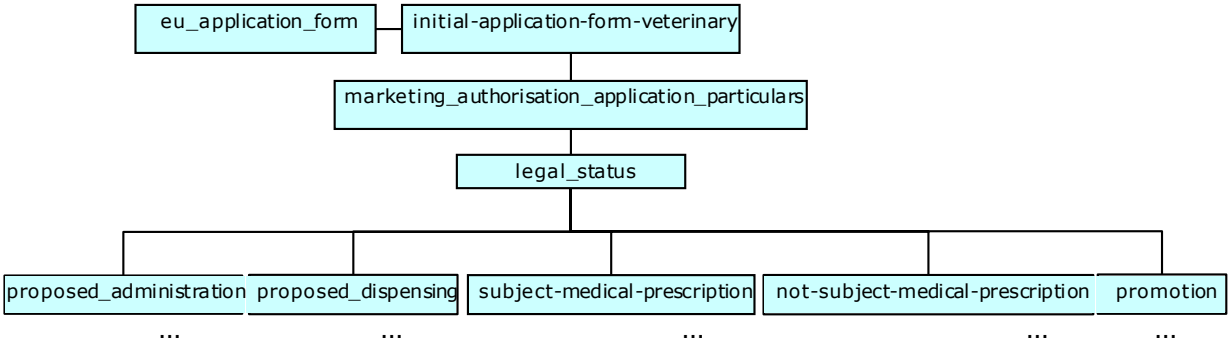
Business Rules

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.	

2.3.3. LEGAL STATUS

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-veterinary/maa:marketing_authorisation_application_particulars/maa:legal_status/		Application > Medicinal Product >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E233-1	Proposed administration	maa:proposed_administration		
E233-2	Proposed dispensing/classification	maa:proposed_dispensing		
E233-3	For veterinary products subject to medical prescriptions	maa:subject-medical-prescription		
E233-4	Supply for products not subject to medical prescription	maa:not-subject-medical-prescription		
E233-5	Promotion for product not subject to medical prescription	maa:promotion		

Element Tree Diagram

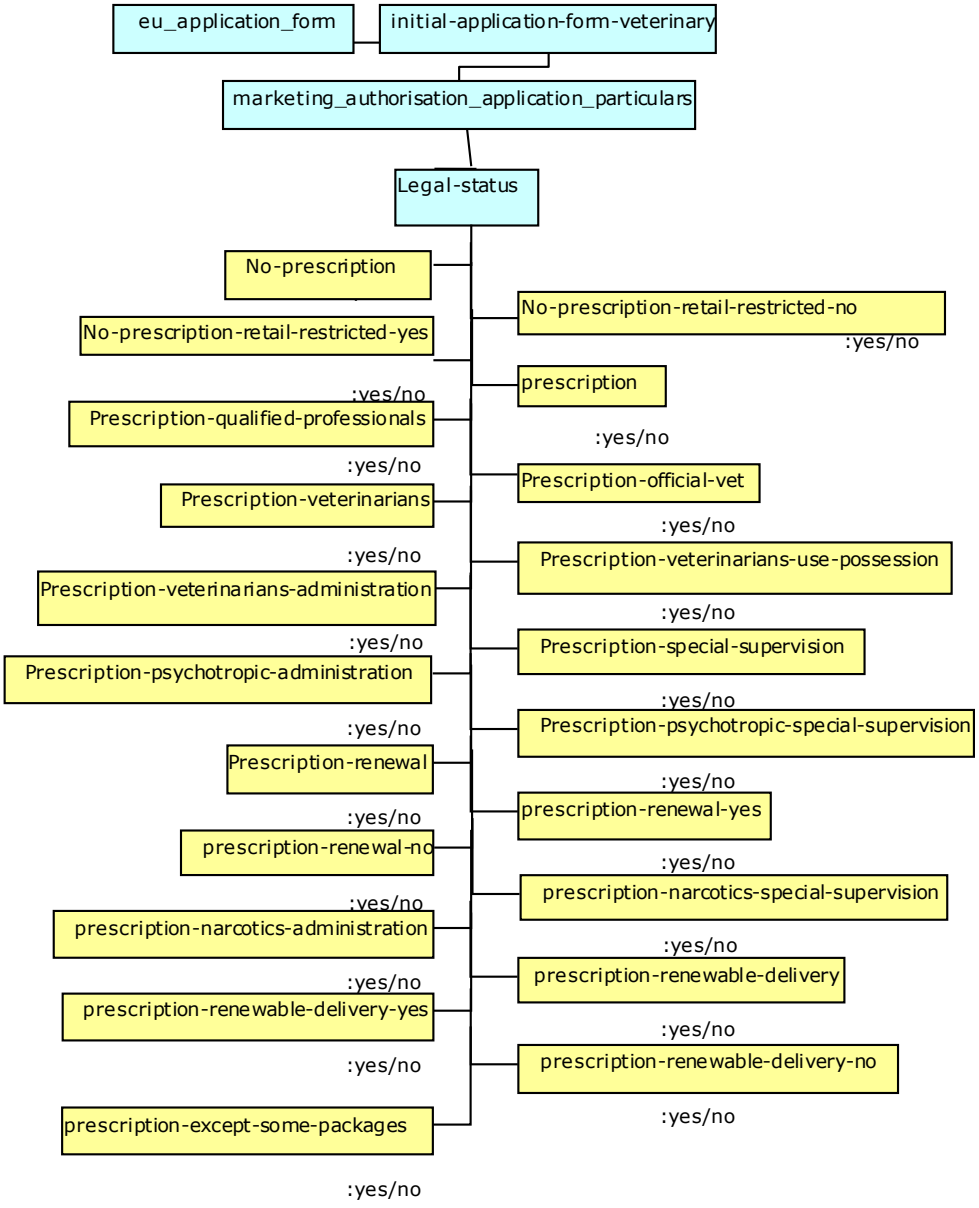


2.3.3.1. Proposed administration

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-veterinary/maa:marketing_authorisation_application_particulars/maa:legal_status/		Application > Medicinal Product	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2331-1	Veterinary medicinal product not subject to veterinary prescription	maa:no-prescription	Route of Administration CTL	
E2331-2	Veterinary medicinal product not subject to veterinary prescription, retail not restricted by national law	maa:no-prescription-retail-restricted-no		
E2331-3	Veterinary medicinal product not subject to veterinary prescription, retail restricted by national law	maa:no-prescription-retail-restricted-yes		
E2331-4	Veterinary medicinal product subject to veterinary prescription	maa:prescription		
E2331-5	Veterinary medicinal product subject to prescription by qualified professional	maa:prescription-qualified-professionals		
E2331-6	Veterinary medicinal product subject to specific restrictions - Use and administration exclusively by official veterinary services	maa:prescription-official-vet		
E2331-7	Veterinary medicinal product subject to specific restrictions - Use and	maa:prescription-veterinarians		

	administration exclusively by veterinarians			
E2331-8	Use and possession exclusively by veterinarians	maa:prescription-veterinarians-use-possession		
E2331-9	Administration exclusively by veterinarians	maa:prescription-veterinarians-administration		
E2331-10	Veterinary medicinal product subject to specific restrictions - For use under veterinary or special supervision	maa:prescription-special-supervision		
E2331-11	Psychotropic - Use and administration exclusively by veterinarians	maa:prescription-psychotropic-administration		
E2331-12	Psychotropic - For use under veterinary or special supervision	maa:prescription-psychotropic-special-supervision		
E2331-13	Veterinary medicinal product subject to renewal or not renewal veterinary prescription	maa:prescription-renewal		
E2331-14	Veterinary medicinal product not subject to renewal veterinary prescription	maa:prescription-renewal-yes		
E2331-15	Veterinary medicinal product subject to renewal veterinary prescription	maa:prescription-renewal-no		
E2331-16	Narcotics - For use under veterinary or special supervision	maa:prescription-narcotics-special-supervision		
E2331-17	Narcotics - Use and administration exclusively by veterinarians	maa:prescription-narcotics-administration		
E2331-18	Veterinary medicinal product on veterinary prescription for renewable delivery or non-renewable delivery	maa:prescription-renewable-delivery		
E2331-19	Veterinary medicinal product for renewable delivery	maa:prescription-renewable-delivery-yes		
E2331-20	Veterinary medicinal product for non-renewable delivery	maa:prescription-renewable-delivery-no		
E2331-21	Veterinary medicinal product subject to veterinary prescription except for some pack sizes	maa:prescription-except-some-packages		

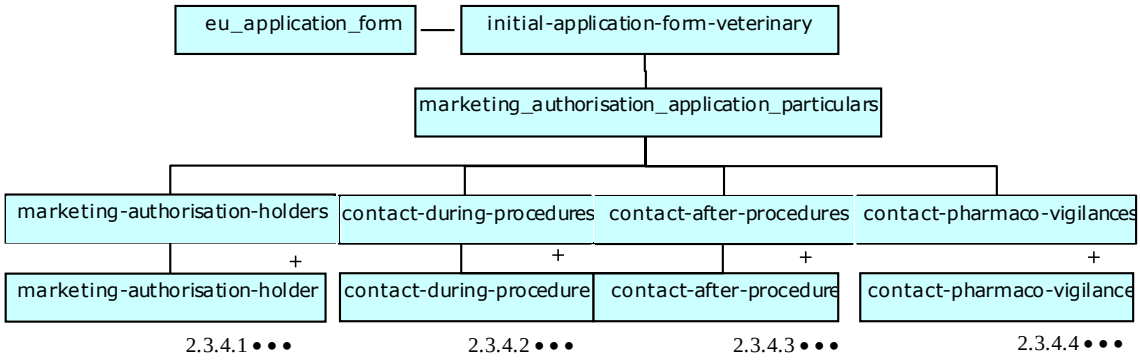
Element Tree Diagram



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-veterinary/maa:c :marketing_authorisation_application_particulars/		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 MS	maa:marketing-authorisation-holders/maa:marketing-authorisation-holder		See Section 2.3.4.1
E234-2	Person/company authorised for communication on behalf of the applicant during the procedure in the European Union /each MS	maa:contact-during-procedures/maa:contact-during-procedure/		See Section 2.3.4.2
E234-3	Person/company authorised for communication between the marketing authorisation holder and the competent authorities after authorisation if different from 2.4.2 in European Union /each MS	maa:contact-after-procedures/maa:contact-after-procedure/		See Section 2.3.4.3
E234-4	Qualified person in the EEA for Pharmacovigilance	maa:contact-pharmaco-vigilances/maa:contact-pharmaco-vigilance/		See Section 2.3.4.4
	Address	maa:contact-pharmaco-vigilances/maa:contact-pharmaco-vigilance/contact-details		
	PSMF reference number ((PSMF) reference number/ identifier as assigned by the QPPV shall be specified)	maa:contact-pharmaco-vigilances/maa:contact-pharmaco-vigilance/reference-number		
	PSMF location	maa:contact-pharmaco-vigilances/maa:contact-pharmaco-vigilance/pharma-system-address		

Element Tree Diagram



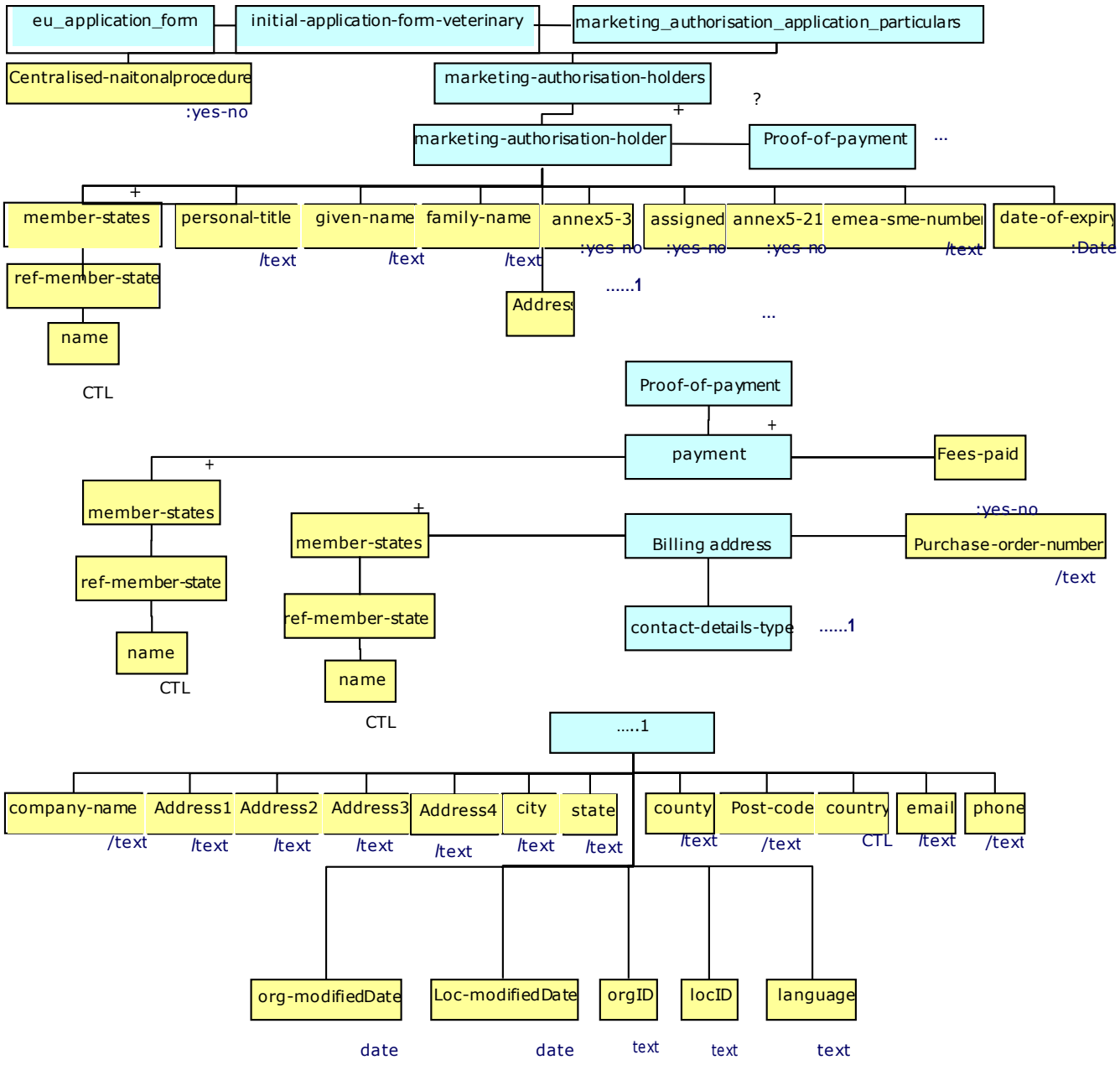
2.3.4.1. Proposed marketing authorisation holder/person legally responsible for placing the product on the market in the Community/each Member State

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-veterinary /maa:marketing_authorisation_application_particulars/maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/		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	Org-modifiedDate	maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:org-modifiedDate		
E2341-8e	language	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-	MAH for Placing Product>Role>Party>Person> given	B2341-4

		holder/rdm:given-name	name	
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 EMEA?			
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	EMEA-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 5.21)	maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:sme-status/rdm:annex5-21		
E2341-23	Proof of payment (when relevant; not applicable for centralised procedure)			
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)			
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-holder/rdm:city	MAH for Placing Product>Role>Party>Contact Details > city	B2341-5
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	Org-modifiedDate	maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:org-modifiedDate		
E2341-34e	language	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



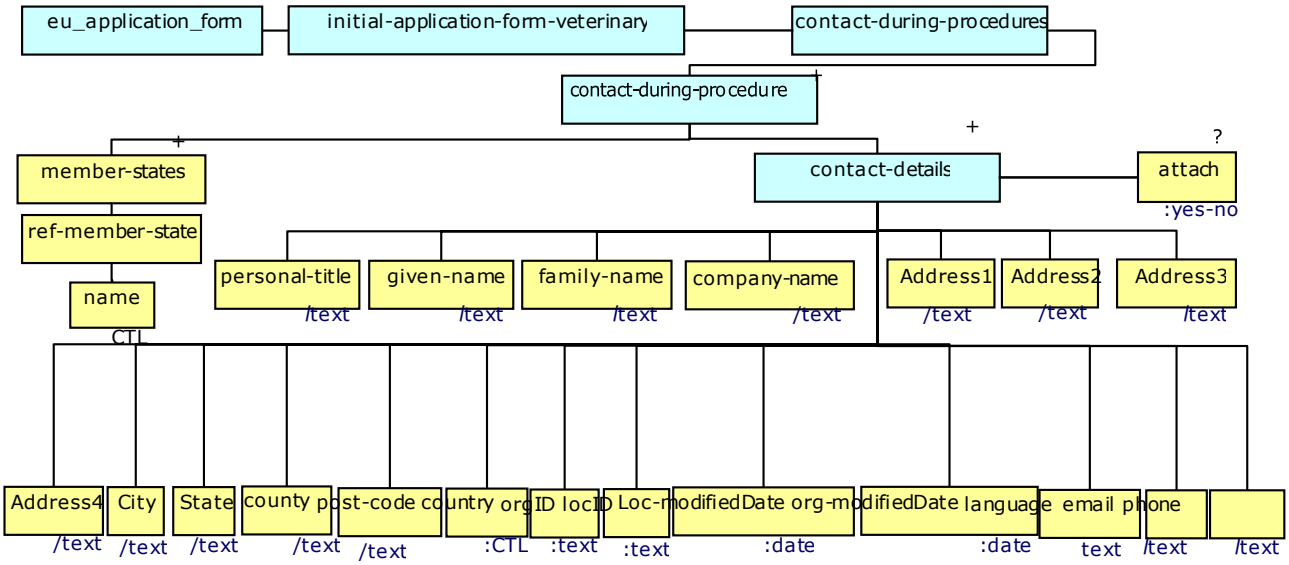
Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2341-1	E2341-18, E2341-19	Mandatory.	Mutually Exclusive.	
B2341-2	E2341-18, E2341-20 to E2341-22	Mandatory.	If E2341-18 is selected, then the rest are mandatory, else they are hidden.	
B2341-3	E2341-1, E2341-2, E2341-3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

2.3.4.2. Person/company authorised for communication on behalf of the applicant during the procedure in the European Union/each Member State

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa: initial-application-form-veterinary /maa:marketing_authorisation_application_particulars/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 rdm:contact-details/rdm:address2 rdm:contact-details/rdm:address3 rdm:contact-details/rdm:address4	Role>Party>Contact Details > Address	
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	Org-modifiedDate	rdm:contact-details/rdm:org-modifiedDate		
E2342-9e	language	rdm:contact-details/rdm:language		
E2342-10	Telephone	rdm:contact-details/rdm:phone	Role>Party>Contact Details > Electronic Contact > electronic contact	
E2342-12	E-mail	rdm:contact-details/rdm:email	Role>Party>Contact Details> Electronic Contact > electronic contact	
E2342-13	If different to 2.4.1 above, Attach letter of authorisation (Annex 5.4)	rdm:contact-details/rdm:attach		

Element Tree Diagram



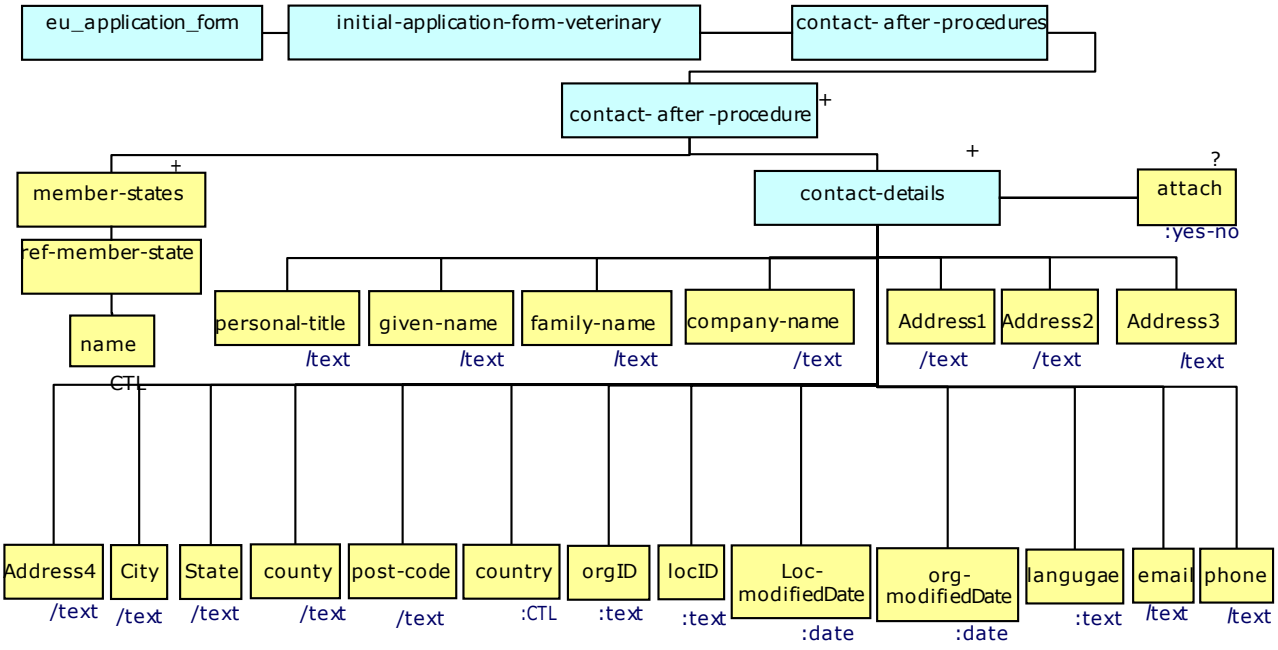
Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2342-1	E2341-1	hidden	If E2341-2 is selected then E2342-1 is visible If E2341-1 is selected then E2342-1 is invisible	

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 European Union/each Member State

	Common DES 3.0 Context		**Common RDM Entry point**	
	maa:eu_application_form/maa:initial-application-form-veterinary/ maa: marketing_authorisation_application_particulars/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		

E2343-9c	Org-modifiedDate	rdm:contact-details/rdm:org-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 E2343-13	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	

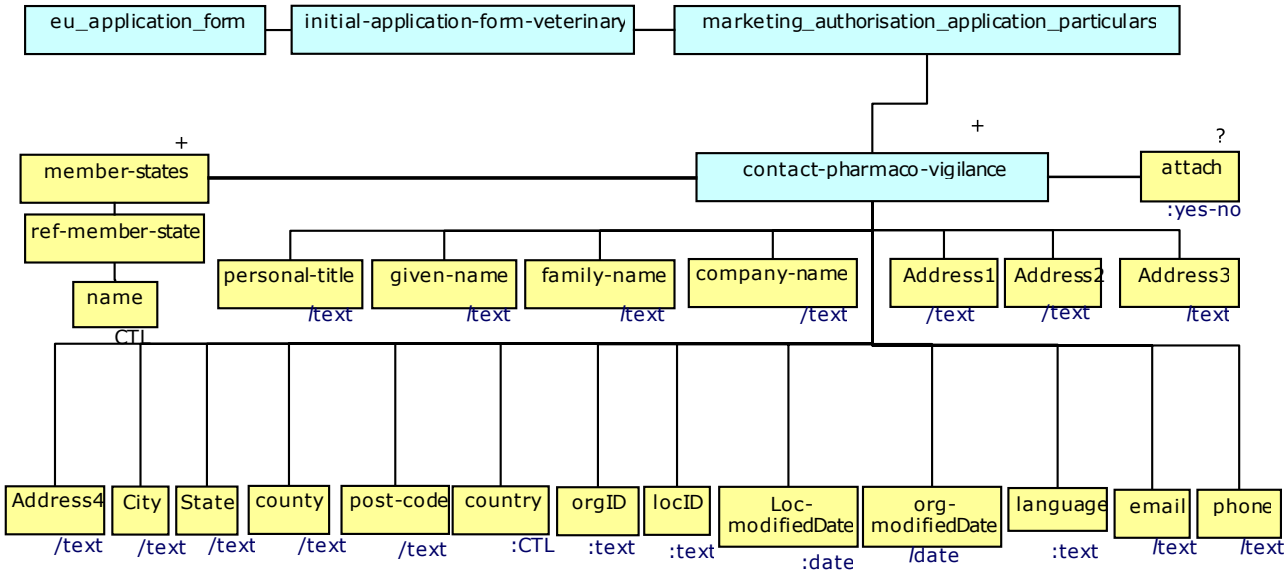
2.3.4.4. Qualified person in the EEA for Pharmacovigilance

	Common DES 3.0 Context		**Common RDM Entry point**	
	maa:eu_application_form/maa: initial-application-form-veterinary /maa:marketing_authorisation_application_particulars/maa:contact-pharmaco-vigilances/maa:contact-pharmaco-vigilance/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2344-1	Member states	rdm:member-states/rdm:ref-member-state/rdm:name	Procedure Use > Role > Country CTL	B2344-1
E2344-2	Title	rdm:personal-title	Role>Party>Person> Personal Title	
E2344-3	First name	rdm:given-name	Role>Party>Person> given name	
E2344-4	Surname	rdm:family-name	Role>Party>Person> family name	
E2344-5	Company name	rdm:company-name	Role>Party>Organisation>Name	
E2344-6	Address1	rdm:address1		

		rdm:address2 rdm:address3 rdm:address4	Role>Party>Contact Details > Address	

E2344-7	city	rdm:city	Role>Party>Contact Details > city	
E2344-7a	state	rdm:state		
E2344-7b	county	rdm:county		
E2344-8	Postcode	rdm:post-code	Role>Party>Contact Details > Address> post code	
E2344-9	Country	rdm:country	Role>Party>Contact Details > Address > Country CTL	
E2344-9a	orgID	rdm:orgID		
E2344-9b	locID	rdm:locID		
E2344-9c	Loc-modifiedDate	rdm:loc-modifiedDate		
E2344-9c	Org-modifiedDate	rdm:org-modifiedDate		
E2344-9c	language	rdm:language		
E2344-10	Telephone	rdm:phone	Role>Party>Contact Details > Electronic Contact > electronic contact	
E2344-12	E-mail	rdm:email	Role>Party>Contact Details> Electronic Contact > electronic contact	
E2344-12	The above-mentioned qualified person resides[6] in the EEA	rdm:residesInEEA		
E2344-13	The qualified person is registered with Eudravigilance	rdm:qualifiedPerson		
E2344-14	Attach detailed description of the pharmacovigilance system (Annex 5.20)	rdm:attach		

Element Tree Diagram

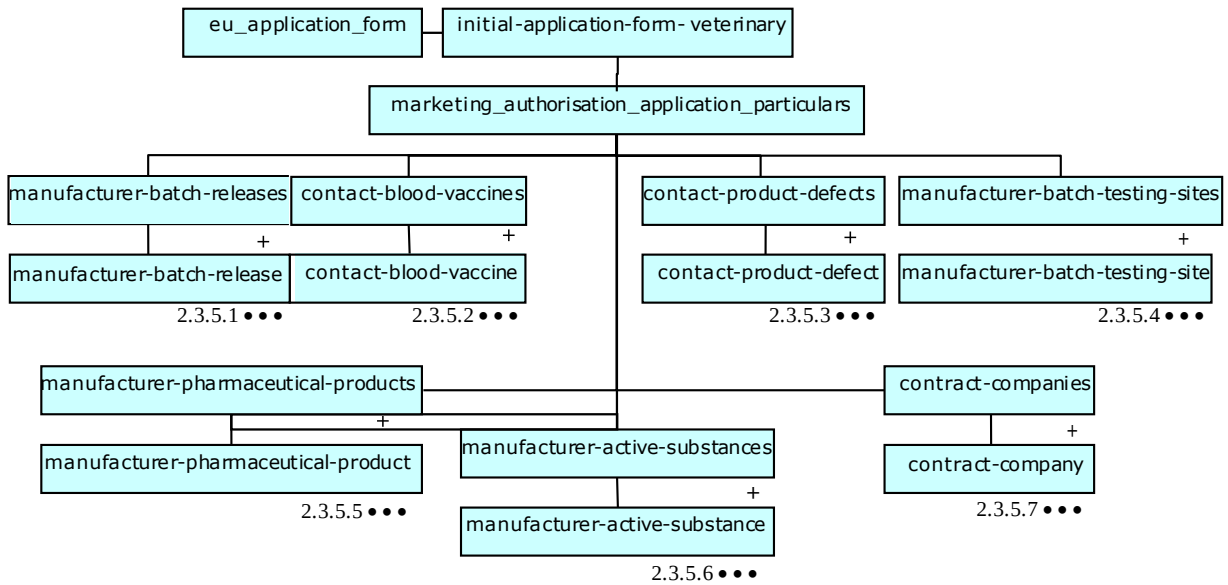


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2344-1	E2343-1	hidden	If E2341-2 is selected then E2344-1 is visible If E2341-1 is selected then E2344-1 is hidden	

2.3.5. MANUFACTURERS

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-veterinary /maa:marketing_authorisation_application_particulars/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E235-1	Authorised manufacturer(s) (or importer) responsible for batch release in the EEA in accordance with Article 55 and Article 53 of Directive 2001/82/EC (as shown in the package leaflet and where applicable in the labelling or Annex II of the Commission Decision)	maa:manufacturer-batch-releases/maa:manufacturer-batch-release/		See Section 2.3.5.1
E235-2	For Vaccines: Details of the state laboratory or laboratory designated for that purpose (OMCL) where the official batch protocol review (Article 81 of Directive 2001/82/EC) or the official control authority batch release Article 82 of Directive 2001/82/EC) takes place.	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. Sites in EEA or in countries where an MRA or other Community arrangements apply where batch control/testing takes place (if different from 2.5.1) as required by Article 55 of Directive 2001/82/EC	maa:manufacturer-batch-testing-sites/maa:manufacturer-batch-testing-site/		See Section 2.3.5.4
E235-5	Manufacturer(s) of the veterinary 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 veterinary medicinal product)*	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

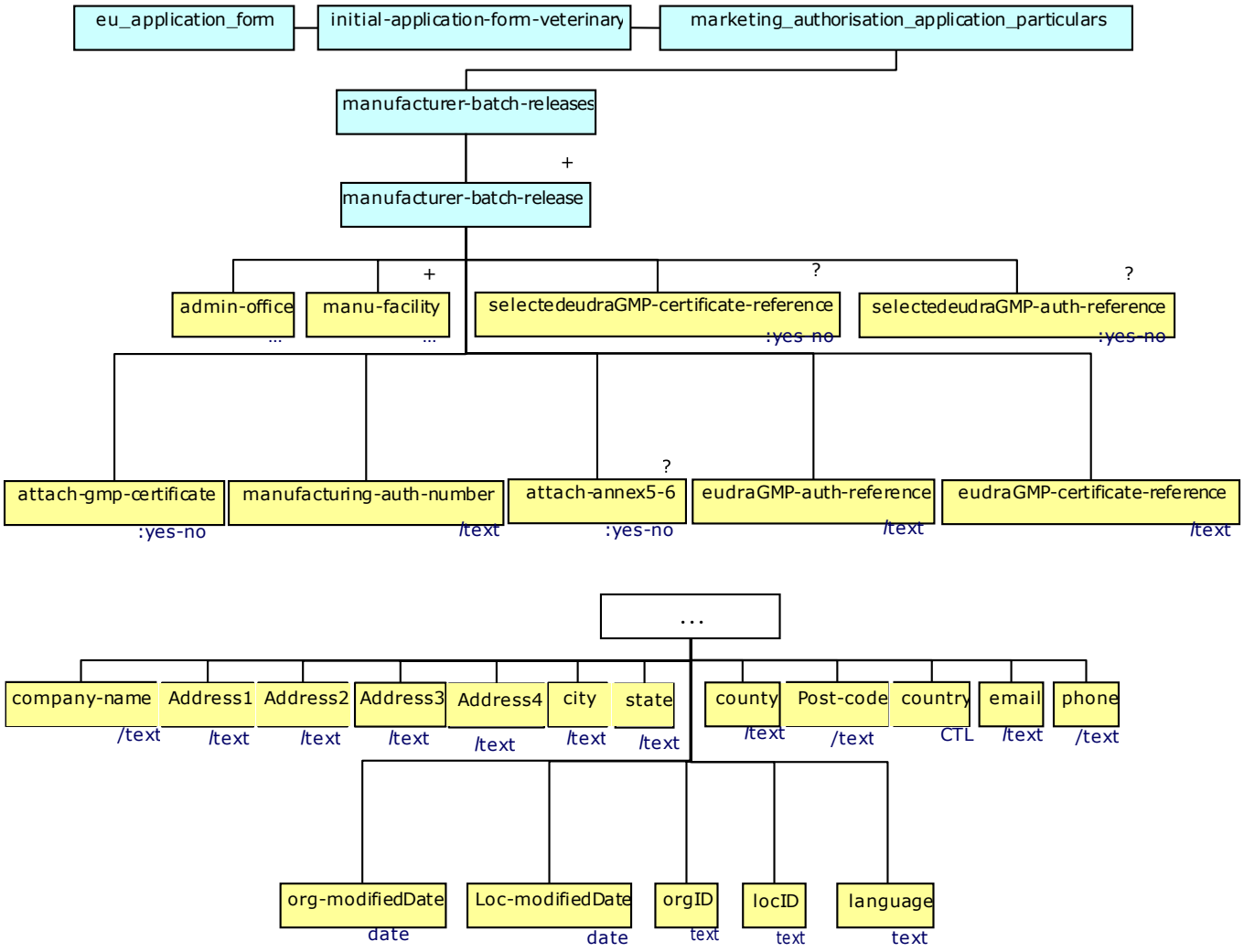


2.3.5.1. Authorised manufacturer(s) (or importer) responsible for batch release in the EEA in accordance with Article 55 and Article 53 of Directive 2001/82/EC (as shown in the package leaflet and where applicable in the labelling or Annex II of the Commission Decision)

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-veterinary/maa:marketing_authorisation_application_particulars/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	Company description	rdm:package-responsible-manufacturer		
E2351-1	Do you have admin address and manufacturer address	maa:contact-details/rdm:admin-manu-address		B2351-5
E2351-1a	Company name	rdm:/contact-details/rdm:admin-office/rdm:company-name	Role>Party>Organisation>Name	B2351-5
E2351-2	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		
E2351-2a	city	rdm:/contact-details/rdm:admin-office/rdm:city	Role>Party>Contact Details > City	B2351-5
E2351-2b	state	rdm:/contact-details/rdm:admin-office/rdm:state		
E2351-2c	county	rdm:/contact-details/rdm:admin-office/rdm:county		
E2351-3	Postcode	rdm:/contact-details/rdm:post-code	Role>Party>Contact Details > Address> post code	B2351-5
E2351-4	Admin Office Country	rdm:/contact-details/rdm:admin-office/rdm:country	Role>Party>Contact Details > Address > Country CTL	B2351-5
E2351-4a	orgID	rdm:/contact-details/rdm:admin-office/rdm:country		
E2351-4b	locID	rdm:/contact-details/rdm:admin-office/rdm:locID		
E2351-4c	Loc-modifiedDate	rdm:/contact-details/rdm:admin-office/rdm:loc-modifiedDate		
E2351-4d	Org-modifiedDate	rdm:/contact-details/rdm:admin-office/rdm:org-modifiedDate		
E2351-4e	language	rdm:/contact-details/rdm:admin-office /rdm:language		
E2351-5	Admin Office Telephone	rdm:/contact-details/rdm:admin-office/rdm:phone	Role>Party>Contact Details > Electronic Contact > electronic contact	B2351-5
E2351-7	Admin Office E-mail	rdm:/contact-details/rdm:admin-office/rdm:email	Role>Party>Contact Details > Electronic Contact > electronic contact	B2351-5
E2351-7a	Company name	rdm:/contact-details/rdm:manu-facility/rdm:company-name	Role>Party>Organisation>Name	B2351-5
E2351-8	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		

E2351-8a	City	rdm:/contact-details/ rdm:manu-facility/rdm:city	Role>Party>Contact Details > city	B2351-5
E2351-8b	Post code	rdm:/contact-details/ rdm:manu-facility/rdm: postcode	Role>Party>Contact Details > Address> post code	B2351-5
E2351-9	Manufacturing Facility Country	rdm:/contact-details/rdm:manu-facility/rdm:country	Role>Party>Contact Details > Address > Country CTL	B2351-5
E2351-9a	state	rdm:/contact-details/rdm:manu-facility/rdm: state		
E2351-9b	county	rdm:/contact-details/rdm:manu-facility/rdm: county		
E2351-11a	orgID	rdm:/contact-details/rdm:manu-facility/rdm: orgID		
E2351-11b	locID	rdm:/contact-details/rdm:manu-facility/rdm: locID		
E2351-11c	Loc-modifiedDate	rdm:/contact-details/rdm:manu-facility/rdm: loc-modifiedDate		
E2351-11d	Org-modifiedDate	rdm:/contact-details/rdm:manu-facility/rdm: org-modifiedDate		
E2351-11e	language	rdm:/contact-details/rdm:manu-facility/rdm:language		
E2351-10	Manufacturing Facility Telephone	rdm:/contact-details/ rdm:manu-facility/rdm:phone	Role>Party>Contact Details > Address > Country CTL	B2351-5
E2351-12	Manufacturing Facility E-mail	rdm:/contact-details/ rdm:manu-facility/rdm:email	Role>Party>Contact Details > Electronic Contact > electronic contact	B2351-5
E2351-13	Manufacturing Authorisation number	rdm:manufacturing-auth-number	Manufacturing auth number	
E2351-14	Attach copy of manufacturing authorisation(s) (Annex 5.6)	rdm:attach-annex5-6		B2351-1
E2351-15	Enter EudraGMDP document reference number	rdm:selectedeudraGMP-auth-reference		B2351-1, B2351-3
E2351-16	Enter EudraGMDP document reference number	rdm:eudraGMP-auth-reference	Eudragmp auth ref	B2351-3
E2351-17	Attach latest GMP certificate (Annex 5.9)	rdm:attach-gmp-certificate		B2351-2
E2351-18	Enter EudraGMDP document reference number	rdm:selectedeudraGMP-certificate-reference		B2351-2, B2351-4
E2351-19	Enter EudraGMDP document reference number	rdm:eudraGMP-certificate-reference	Eudragmp certificate ref no	B2351-4

Element Tree Diagram

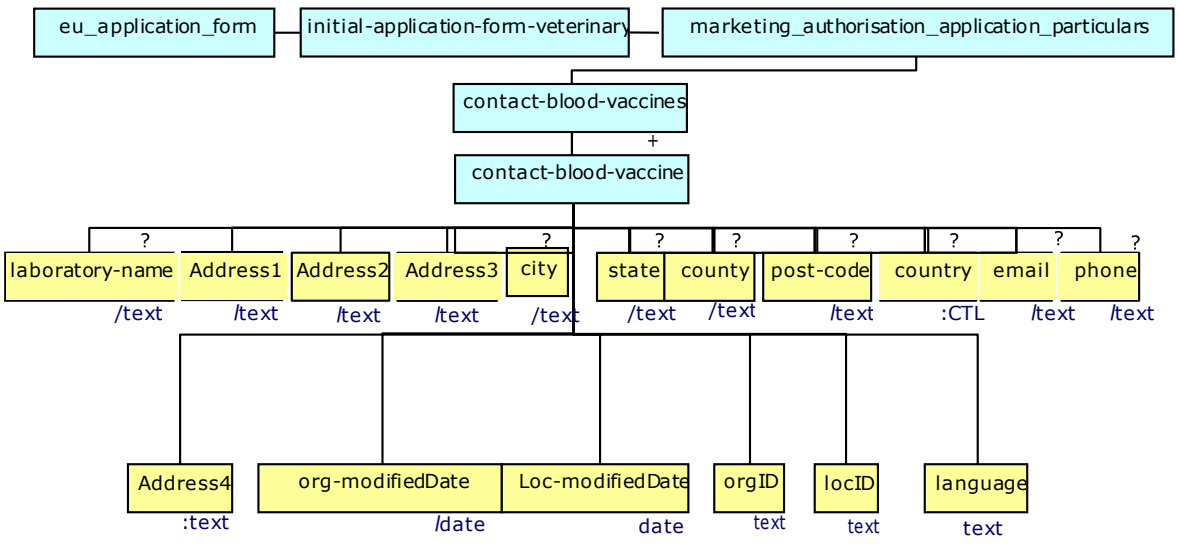


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2351-1	E2351-14, E2343-15	Mandatory.	Mutually Exclusive.	
B2351-2	E2351-17, E2351-18	Mandatory.	Mutually Exclusive.	
B2351-3	E2351-15, E2351-16	Mandatory, Optional.	If E2351-15 is selected, E2351-16 is mandatory.	
B2351-4	E2351-18, E2351-19	Mandatory, Optional.	If E2351-18 is selected, E2351-19 is mandatory.	
B2351-5	E2351-1 to E2351-12	mandatory and visible	E2351-1 is yes then E2351-1a to E2351-12 are visible else E2351-1a to E2351-7 are hidden	

2.3.5.1.1 *Official batch release For Vaccines: Details of Official Medicines Control Laboratory (OMCL) or laboratory designated the purpose of official batch release (in accordance with Article 81 and 82 of Directive 2001/82/EC as amended)*

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-veterinary /maa:marketing_authorisation_application_particulars/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 rdm:address2 rdm:address3 rdm:address4	Role>Party>Contact Details > Address	B2352-1
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	Org-modifiedDate	rdm:org-modifiedDate		
E2352-10b	language	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

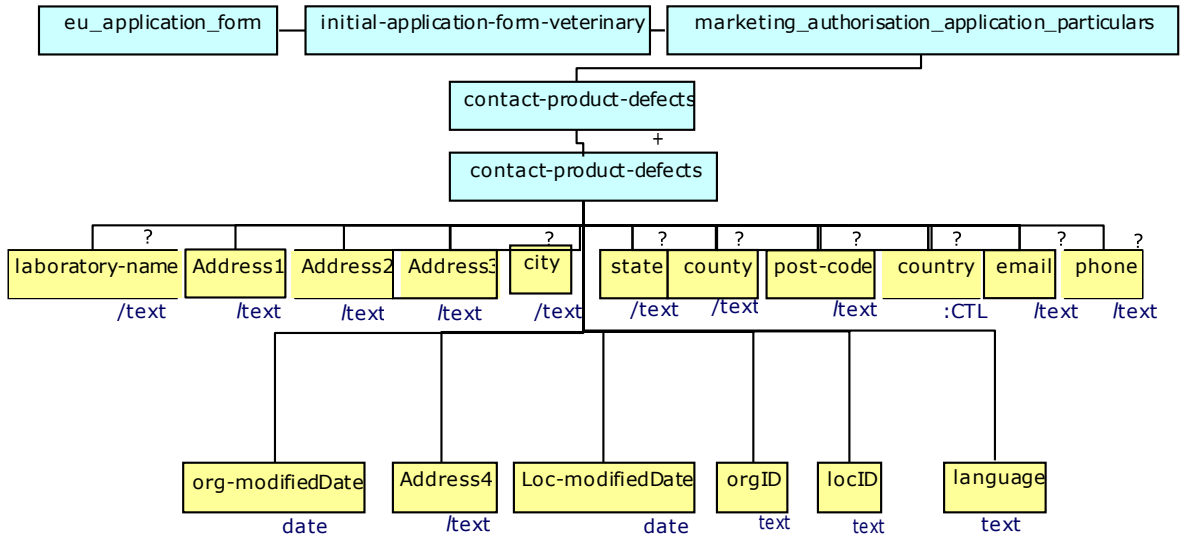


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2352-1	E2352-1 to E2352-13	Optional	Elements should be optional	

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-veterinary/maa:marketing_authorisation_application_particulars/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 rdm:address2 rdm:address3 rdm:address4	Role>Party>Contact Details > Address	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	Org-modifiedDate	rdm:org-modifiedDate		B2353-1
E2353-8e	language	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

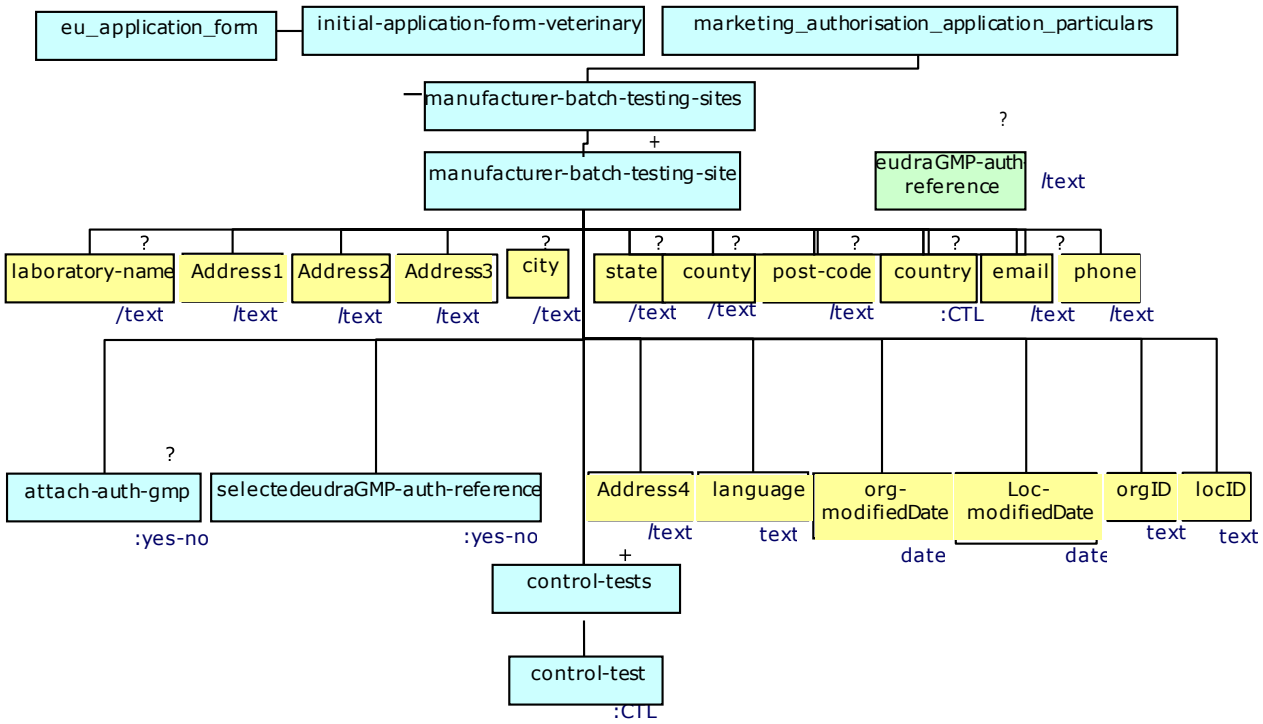


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2353-1	E2353-1 to E2353-11	Optional	Elements should be optional	

2.3.5.2.1 Batch control/Testing arrangements Sites in EEA or in countries where an MRA or other European Union arrangements apply where batch control/testing takes place as required by Article 55 of Directive 2001/82/EC.

	Common DES 3.0 Context		**Common RDM Entry point**	
	maa:eu_application_form/maa:initial-application-form-veterinary/ maa:marketing_authorisation_application_particulars/ 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 rdm:address2 rdm:address3 rdm:address4	Role>Party>Contact Details > Address	
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	Org-modifiedDate	rdm:org-modifiedDate		
E2354-5e	language	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	E2352-9 is Mandatory, E2352-10 is Optional.	If E2352-11 is selected then E2352-12 is mandatory.	

2.3.5.3. Manufacturer(s) of the veterinary medicinal product and site(s) of manufacture:

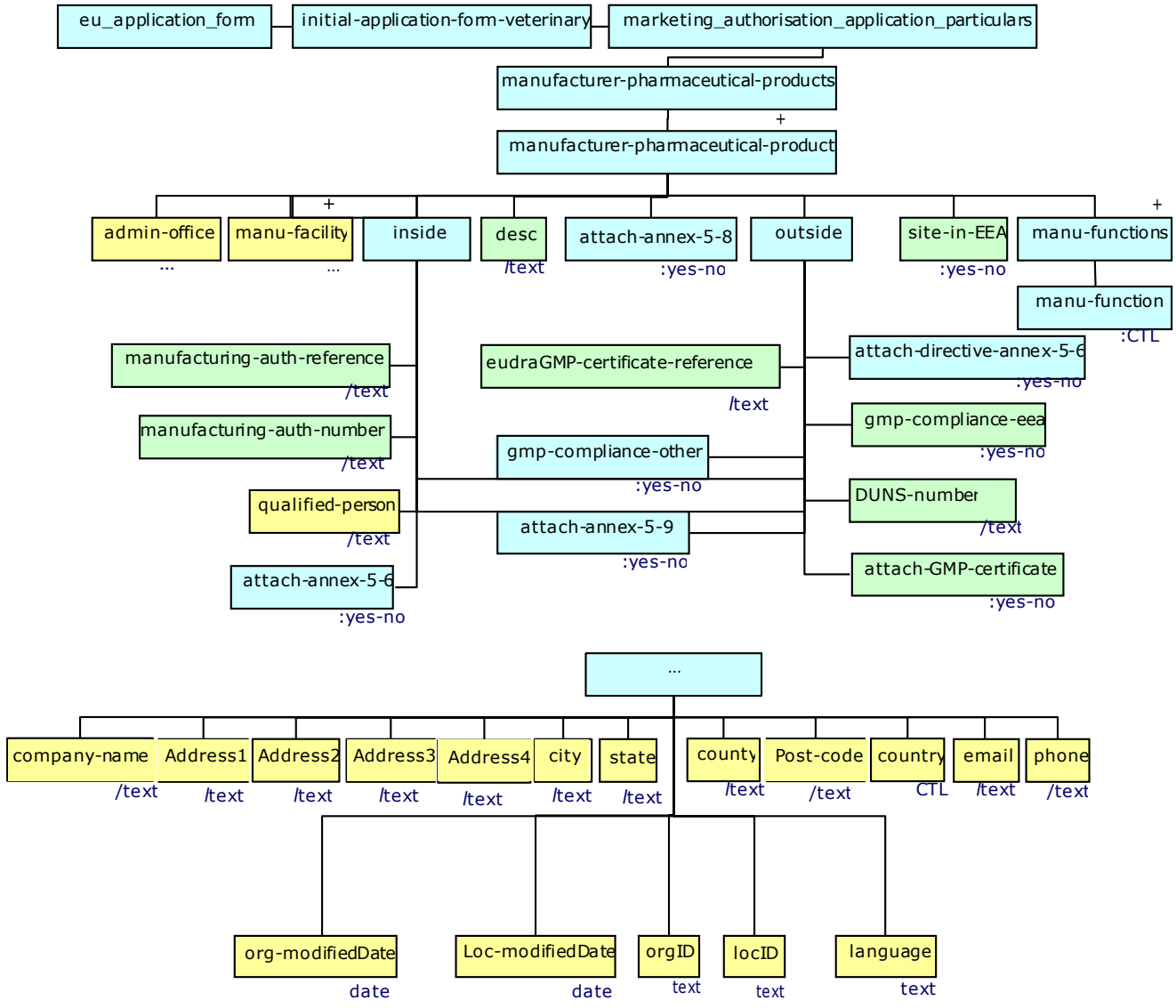
(Note: including manufacturing sites of any diluent/solvent presented in a separate container but forming part of the veterinary medicinal product)

	Common DES 3.0 Context		**Common RDM Entry point**	
	maa:eu_application_form/maa:initial-application-form-veterinary/maa:marketing_authorisation_application_particulars/maa:manufacturer-pharmaceutical-products/maa:manufacturer-pharmaceutical-product/		Application > Manufacturer MP >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2355-1	Do you have admin address and manufacturer address	maa:contact-details/rdm:admin-manu-address		B2355-12
E2355-1a	Company name	rdm:/contact-details/rdm:admin-office/rdm:company-name	Role>Party>Organisation>Name	B2355-12
E2355-2	Admin Office Address	rdm:/contact-details/rdm:admin-office/rdm:address1	Role>Party>Contact Details > Address	B2355-12
		rdm:/contact-details/rdm:admin-office/rdm:address2		
		rdm:/contact-details/rdm:admin-office/rdm:address3		
		rdm:/contact-details/rdm:admin-office/rdm:address4		
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		
E2355-2c	county	rdm:/contact-details/rdm:admin-office/rdm:county		
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	B2355-12
E2355-4a	orgID	rdm:/contact-details/rdm:admin-office/rdm:country		
E2355-4b	locID	rdm:/contact-details/rdm:admin-office/rdm:locID		
E2355-4c	Loc-modifiedDate	rdm:/contact-details/rdm:admin-office/rdm:loc-modifiedDate		
E2355-4d	Org-modifiedDate	rdm:/contact-details/rdm:admin-office/rdm:org-modifiedDate		
E2355-4e	language	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	B2355-12
		rdm:/contact-details/rdm:manu-facility/rdm:address2		
		rdm:/contact-details/rdm:manu-facility/rdm:address3		
		rdm:/contact-details/rdm:manu-facility/rdm:address4		
E2355-8a	City	rdm:/contact-details/rdm:manu-facility/rdm:city	Role>Party>Contact Details > city	B2355-12
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		

E2355-8b	state	rdm:/contact-details/rdm:manu-facility/rdm:state	Role > Party > Contact Details > postcode	B2355-12
E2355-9	county	rdm:/contact-details/rdm:manu-facility/rdm: county	Role >Party>Contact Details > Address > Country CTL	B2355-12
E2355-9a	orgID	rdm:/contact-details/rdm:manu-facility/rdm: orgID		
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	Org-modifiedDate	rdm:/contact-details/rdm:manu-facility/rdm: org-modifiedDate		
E2355-9e	language	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
E2355-22	D-U-N-S number	rdm:outside/DUNS-number		
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	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.*

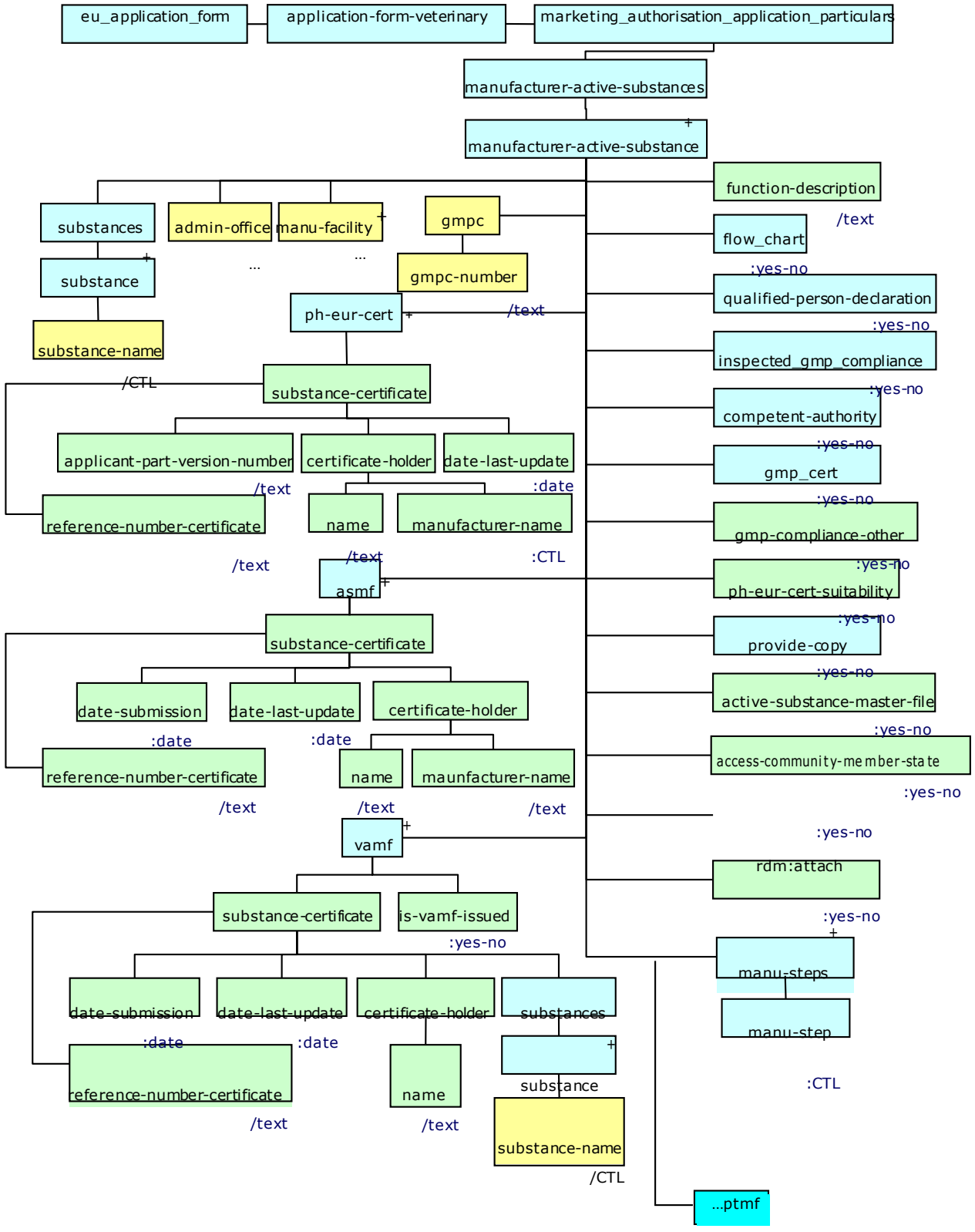
	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-veterinary/ maa:marketing_authorisation_application_particulars/maa:manufacturer-active-substances/maa:manufacturer-active-substance-vet/		Application > Manufacturer Substance	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
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: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	Org-modifiedDate	rdm:/contact-details/ rdm:admin-office/rdm:org-modifiedDate		
E2356-4e	language	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		Role>Party>Contact Details > Postcode	B2356-12
E2356-9a	orgID	rdm:/contact-details/rdm:manu-		

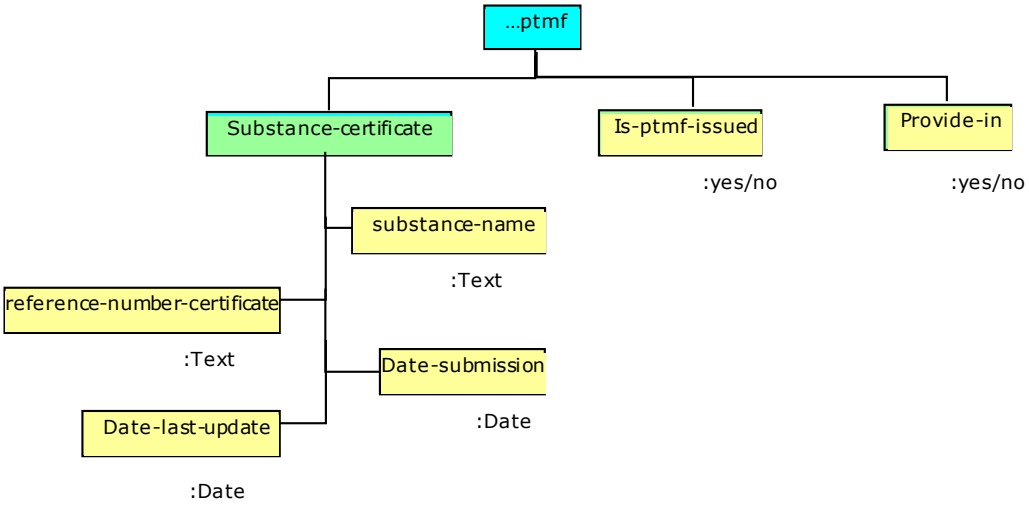
		facility/rdm: orgID		
E2356-9b	locID	rdm:/contact-details/rdm:manu-facility/rdm: locID		
E2356-9c	Loc-modifiedDate	rdm:/contact-details/rdm:manu-facility/rdm: loc-modifiedDate	Role>Party>Contact Details > Electronic Contact > electronic contact	B2356-12
E2356-9d	Org-modifiedDate	rdm:/contact-details/rdm:manu-facility/rdm: org-modifiedDate	Role>Party>Contact Details > Electronic Contact > electronic contact	B2356-12
E2356-9e	language	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	
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		
E2356-19				
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/	PH Eur Certificate > last	B2356-7

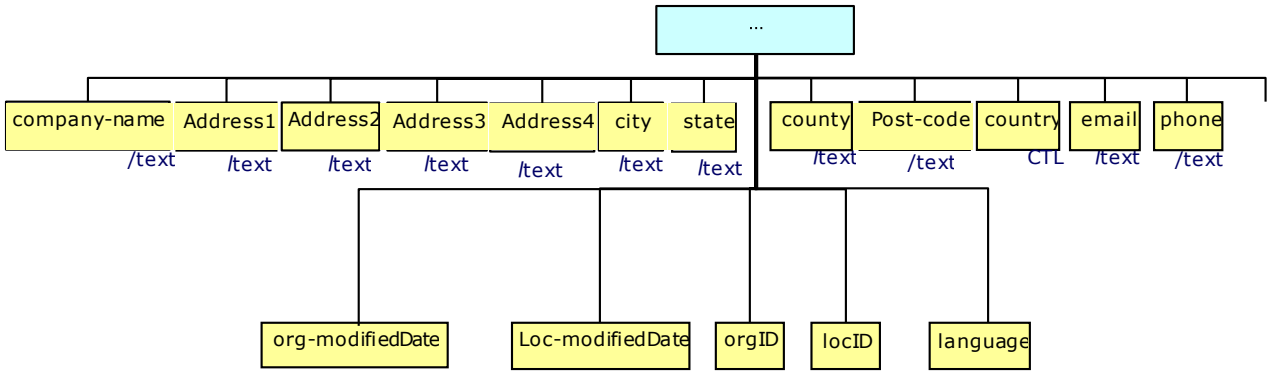
		rdm:substance-certificate/ rdm:date-last-update	update date	
E2356-36	Is an Active Substance Master File to be used for the active substance(s)?			
E2356-38	Yes	rdm:active-substance-master-file (Value=1)	European Drug Master File > used for active substance	B2356-8, B2356-9
E2356-39	No	rdm:active-substance-master-file (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
E2356-57	Address	rdm:/contact-details/rdm:address1		
E2356-58	Postcode	rdm:/contact-details/rdm:postcode		
E2356-59	Country	rdm:/contact-details/rdm:country		
E2356-60	Telephone	rdm:/contact-details/rdm:telephone		
E2356-61	E-Mail	rdm:/contact-details/rdm:email		
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
E2356-48	Is an EMA 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		
E2356-57	Is an EMA certificate for a Vaccine Platform Technology Master File (PTMF) issued or submitted in accordance with Regulation (EU) 2019/6 (Annex II), being used for this MAA?			
E2356-58	Yes	rdm:ptmf/rdm:is-ptmf-issued(Value = 1)		
E2356-59	No	rdm:ptmf/rdm:is-ptmf-issued(Value = 0)		
E2356-60	Name of the PTMF Certificate Holder / PTMF Applicant	rdm:ptmf/substance-certificate/rdm:active-substances/ rdm:active-substance/ rdm:substance-name		
E2356-62	Reference number of Application / Certificate	Rdm:ptmf /rdm:substance-certificate/rdm:reference-number-certificate		
E2356-63	Date of submission (if pending)	rdm:ptmf /rdm:substance-certificate/rdm:date-submission		
E2356-64	Date of approval or last update (if approved)	rdm:ptmf /rdm:substance-certificate/rdm:date-last-update		

E2356-65	Provide copy in	rdm:provide-copy		

Element Tree Diagram




...ptmf
Substance-certificate
Is-ptmf-issued
:yes/no
Provide-in
:yes/no
substance-name
:Text
reference-number-certificate
:Text
Date-submission
:Date
Date-last-update
:Date


...
company-name
/text
Address1
/text
Address2
/text
Address3
/text
Address4
/text
city
/text
state
/text
county
/text
Post-code
/text
country
CTL
email
/text
phone
/text
org-modifiedDate
Loc-modifiedDate
orgID
locID
language

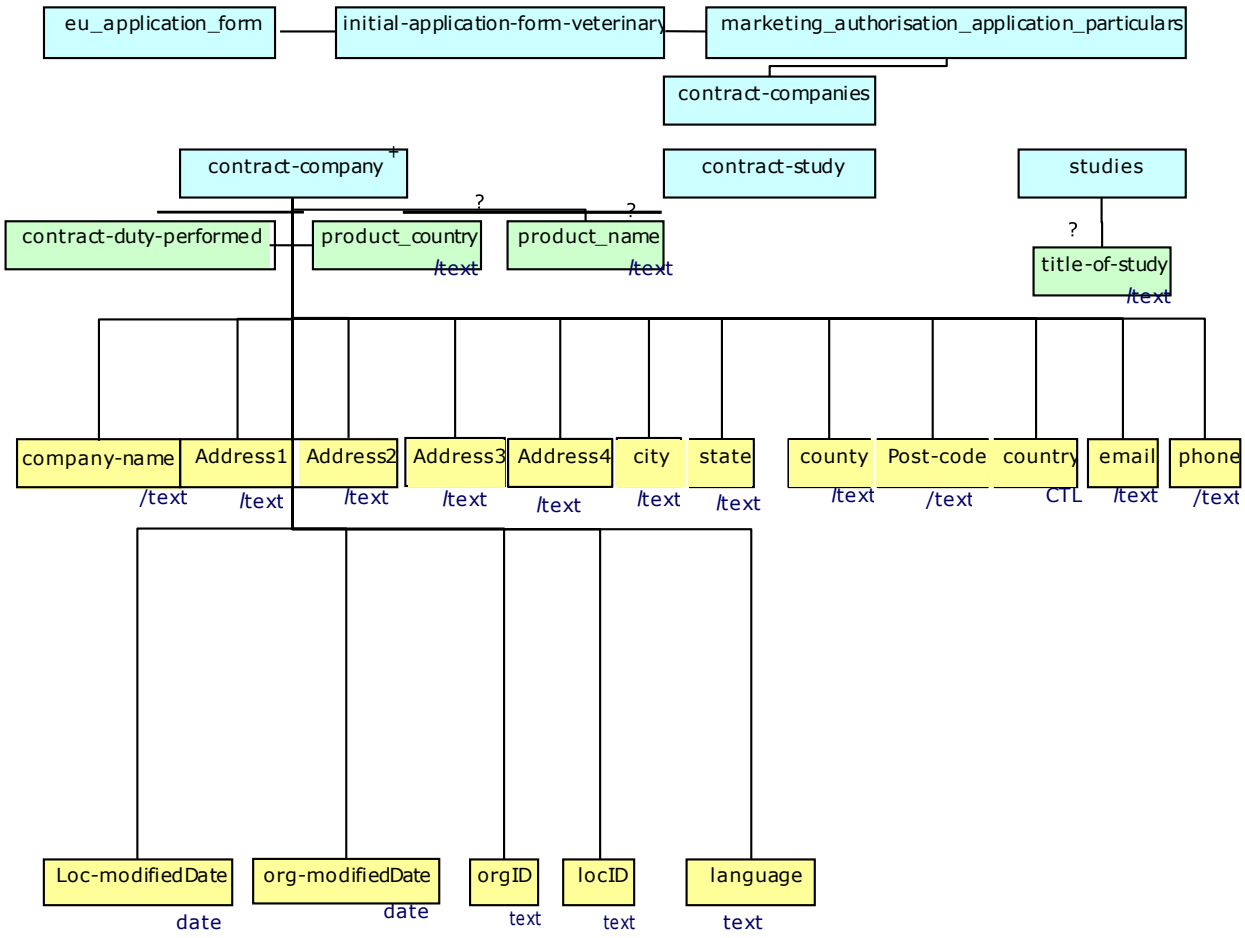
Business Rules

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 E2356-2a to E2356-12 are visible else E2356-2a to E2356-7 are hidden	

2.3.5.5. Contract companies used for clinical trial(s), bioavailabity or bioequivalence trials. For each contract company, state where analytical tests are performed and where efficacy data are collected and give

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-veterinary/ maa:marketing_authorisation_application_particulars/maa:contract-companies/maa:contract-study/		Application > Cotract 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	Org-modifiedDate	rdm:contract-company/ rdm:org-modifiedDate		
E2357-5e	language	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	
E2357-10	Name of product	rdm:contract-company/ rdm:product_name	Protocol code	
E2357-11	Country of product	rdm:contract-company/ rdm:product_country	Eudract number	
E2357-11	For each contract company, state where analytical tests are performed and where clinical data are collected and give:	rdm:studies/rdm:title-of-study	Study title	

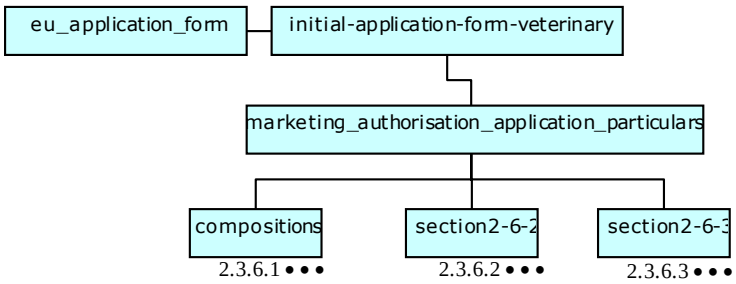
Element Tree Diagram



2.3.6. QUALITATIVE AND QUANTITATIVE COMPOSITION

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-veterinary/ maa:marketing_authorisation_application_particulars/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E236-1	Qualitative and Quantittative 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 origin contained or used in the manufacturing process of the veterinary medicinal product?	maa:section2-6-2/		See Section 2.3.6.2
E236-3	Does the veterinary medicinal product contain or consist of Genetically Modified Organisms(GMOs) within the meaning of Directive 2001/18/EC?	maa:section2-6-3		See Section 2.3.6.3

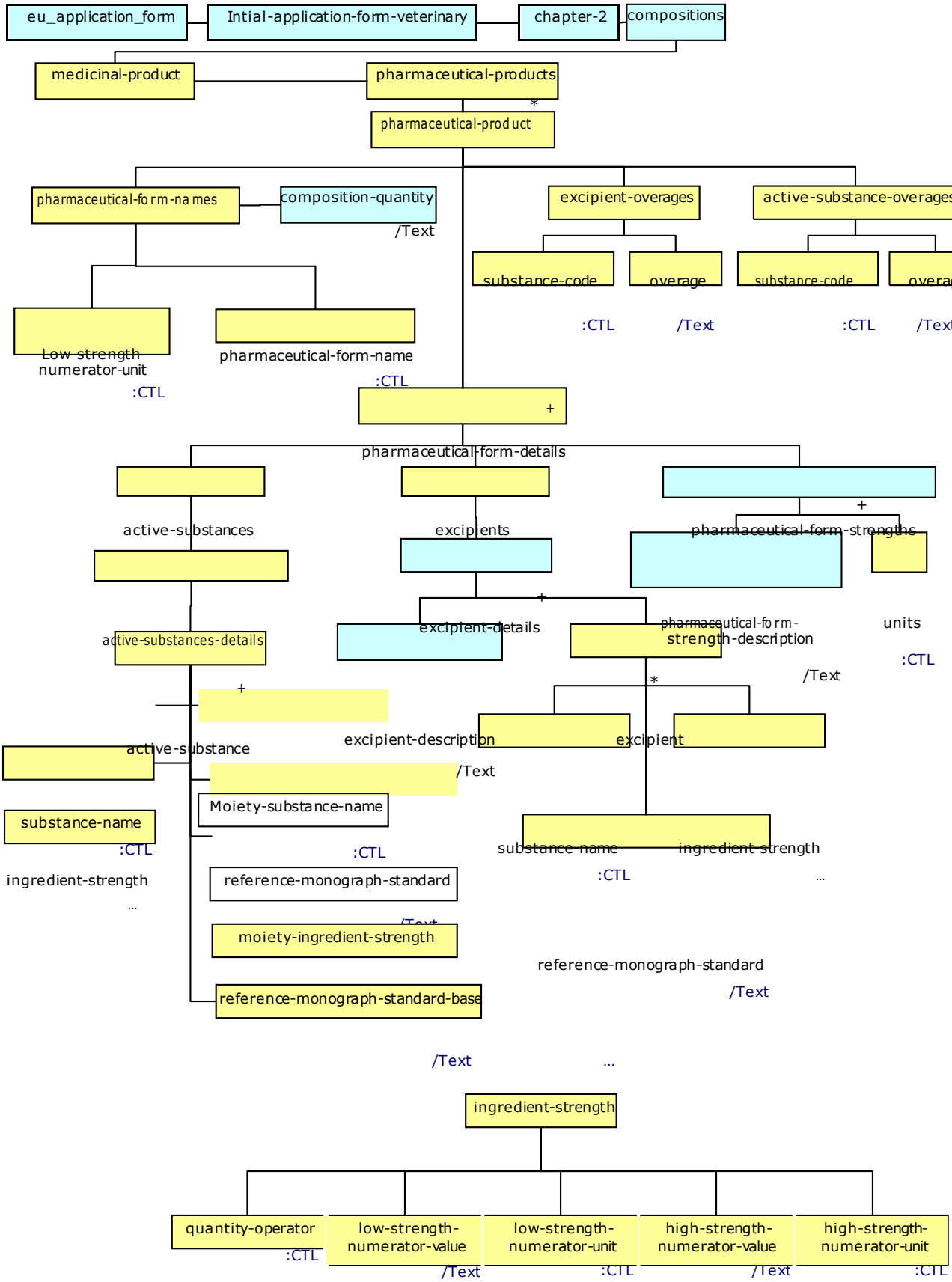
Element Tree Diagram



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: application-form-veterinary /maa:chapter-2/maa:compositions/maa:composition/rdm:medicinal-product/rdm:pharmaceutical-products/rdm:pharmaceutical-product/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2361-1	Dosage form unit 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-strength-description		
E2361-4a	Units	rdm:pharmaceutical-form-details /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		
E2361-5b	Quantity / Unit	rdm:pharmaceutical-form-details/rdm:active-substances/ rdm:active-substances-details/ rdm:active-substance/ rdm:moiety-ingredient-strength		
E2361-5c	Reference / Monograph Standard	rdm:pharmaceutical-form-details/rdm:active-substances/ rdm:active-substances-details/ rdm:active-substance/ rdm:reference-monograph-standard-base		
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

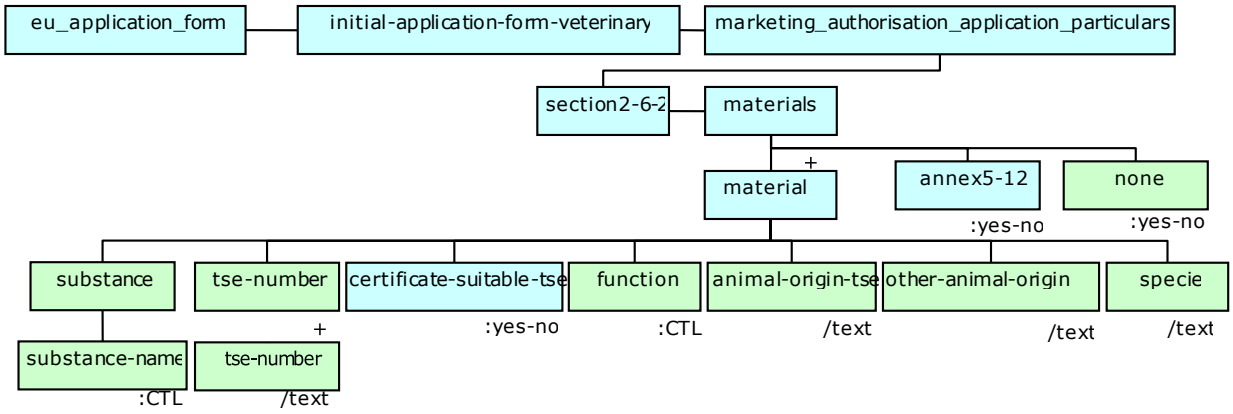


2.3.6.2.

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

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-veterinary/ maa:marketing_authorisation_application_particulars/maa:section2-6-2/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2362-1	NONE	maa:materials/maa:none	Manufacturing Material > is material used	B2362-1
E2362-2	Active Substance	maa:materials/maa:material/maa:substance/rdm:substance-name	Manufacturing Material > material name	B2362-1
E2362-3				
E2362-4	Active Substance	maa:materials/maa:material/function (Value=1)	Material Function CTL	B2362-1, B2362-2
E2362-5	Excipient (incl. starting materials used in manufacture of the active substance/excipient),	maa:materials/maa:material/function (Value=2)	Material Function CTL	B2362-1, B2362-2
E2362-6	Reagent / Culture Medium (incl. those used in the preparation of master and working cell banks)	maa:materials/maa:material/function (Value=3)	Material Function CTL	B2362-1, B2362-2
E2362-7	Animal Origin Susceptible to TSE as defined in section 2 (scope) of the Note for Guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products.	maa:materials/maa:material/animal-origin-tse	Material Origin CTL	B2362-1, B2362-3
E2362-8	Other Animal Origin	maa:materials/maa:material/other-animal-origin	Material Origin CTL	B2362-1, B2362-3
E2362-9	Species	maa:materials/maa:material/maa:specie		B2362-1, B2362-3
E2362-10	Certificate of suitability for TSE	maa:materials/maa:material/maa:certificate-suitable-tse		B2362-1, B2362-4
E2362-11	TSE number	maa:materials/maa:material/maa:tse-number	Manufacturing Material > 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:materials/maa:annex5-12		

Element Tree Diagram

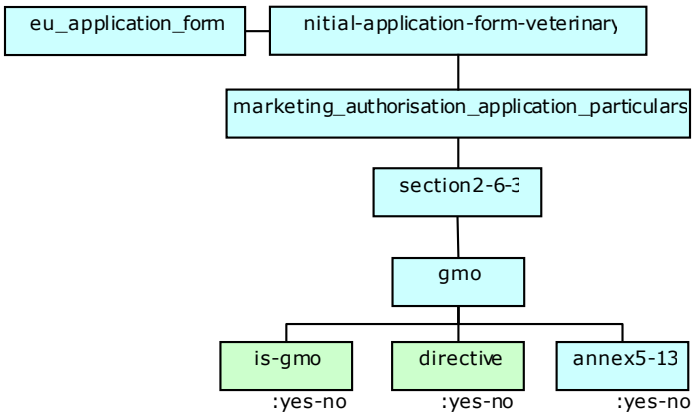


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B2362-1	E2362-1, E2362-2 to E2362-11	Mandatory.	If E2362-1 is selected then the rest are optional.	
B2362-2	E2362-4 to E2362-6	Optional.	Mutually Exclusive.	
B2362-3	E2362-7 to E2362-9	Optional.	Mutually Exclusive.	
B2362-4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

2.3.6.3. Does the veterinary 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-veterinary/ maa:marketing_authorisation_application_particulars/maa:section2-6-3/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		

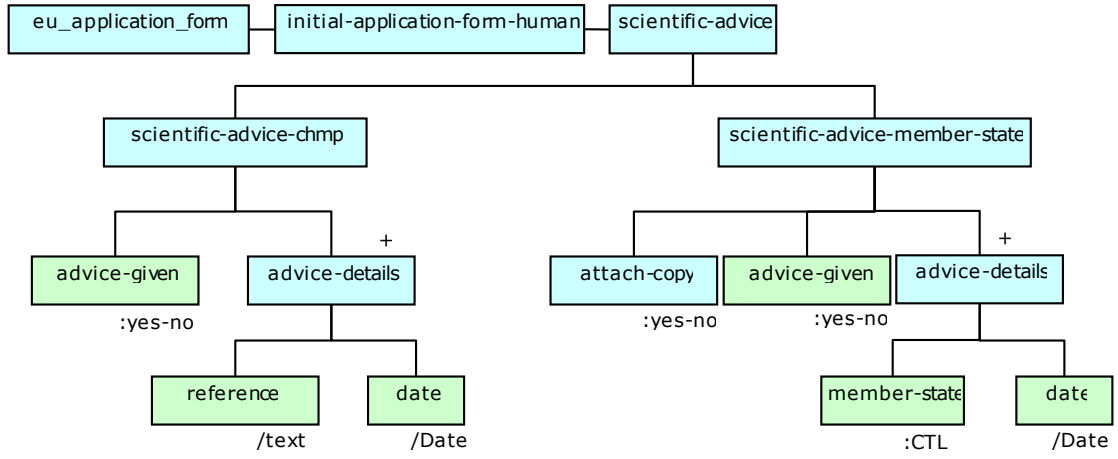
Element Tree Diagram



2.4. SCIENTIFIC ADVICE

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:initial-application-form-veterinary/ 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 given by the CVMP for this veterinary 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	Date	rdm:scientific-advice-chmp/ rdm:advice-details/rdm:date	scientific advice date	B24-2
E24-5	Reference of the scientific advice letter	rdm:scientific-advice-chmp/ rdm:advice-details/rdm:reference	scientific advice ref	B24-2
E24-6	Attach copy of scientific advice(s) (Annex 5.14)	rdm:scientific-advice-member-state/rdm:attach-copy		
E24-7	Was there scientific recommendation(s) given by Member State(s) for this veterinary medicinal product?			
E24-8	Yes	rdm:scientific-advice-member-state/rdm:advice-given	scientific Advice Source CTL	B24-3,B24-4
E24-9	No	rdm:scientific-advice-member-state/rdm:advice-given	scientific Advice Source CTL	B24-3
E24-10	Date	rdm:scientific-advice-member-state/rdm:advice-details/rdm:date	scientific advice date	B24-4
E24-11	Member State	rdm:scientific-advice-member-state/rdm:advice-details/ rdm:member-state	Country CTL	B24-4

Element Tree Diagram

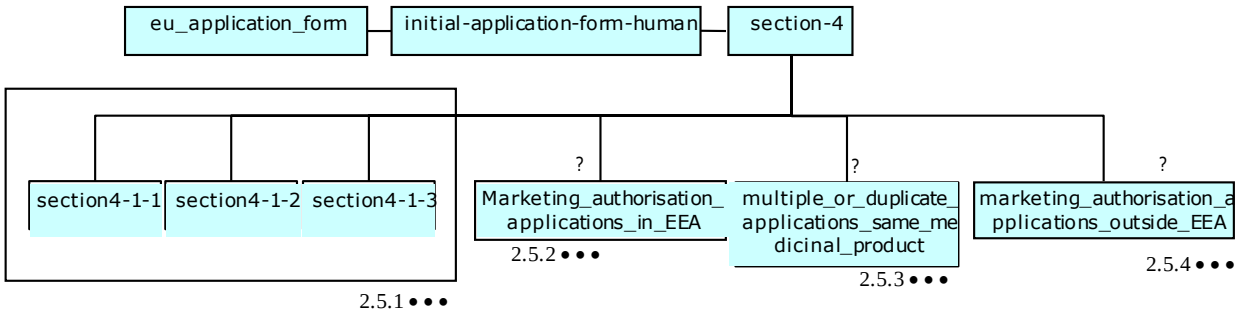


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B24-1	E24-2, E24-3	Mandatory	Mutually Exclusive	
B24-2	E24-2, E24-4, E24-5	Mandatory	If E24-2 is selected, then the others are required	
B24-3	E24-8, E24-9	Mandatory	Mutually Exclusive	
B24-4	E24-8, E24-10 to E24-11	E24-8 is Mandatory, rest are optional	If E24-8 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-veterinary/ maa:other_marketing_authorisation_applications/		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 2001/82/EC	maa:section4-1-1 and maa:section4-1-2 and maa:section4-1-3		See Section 2.5.1 B25-1
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:Marketing_authorisation_applications_in_EEA		See Section 2.5.2
E25-3	For multiple/duplicate applications of the same veterinary medicinal product:	maa:multiple_or_duplicate_applications_same_medicinal_product		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:marketing_authorisation_applications_outside_EEA		See Section 2.5.4

Element Tree Diagram

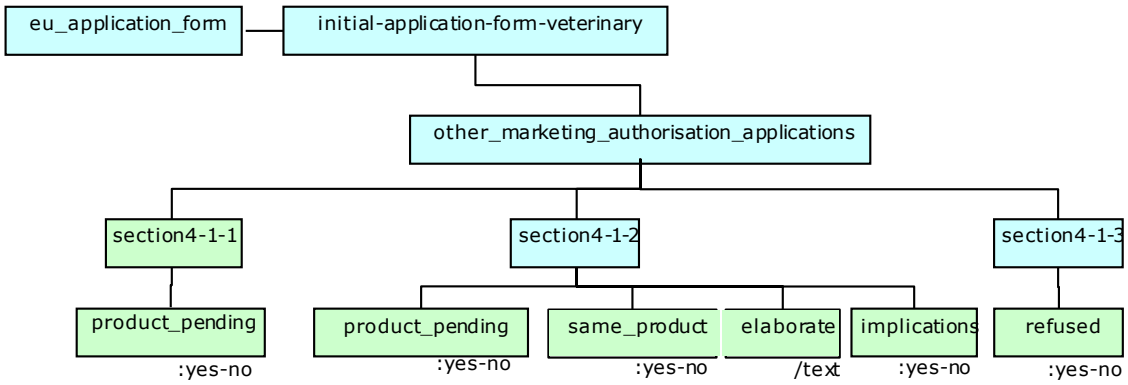


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B25-1	E25-1, E221-4	Optional	If E221-4 is selected, then E25-1 is required.	

2.5.1. FOR NATIONAL/MRP/DCP APPLICATIONS, PLEASE COMPLETE THE FOLLOWING IN ACCORDANCE WITH ARTICLE 12(1) OF DIRECTIVE 2001/82/EC

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/ maa:initial-application-form-veterinary/ maa:other_marketing_authorisation_applications/		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[4] product is pending?			
E251-2	Yes	maa:section4-1-1 /maa:product_pending (Value=1)	app pending in other ms	B251-1, B252-1
E251-3	No	maa:section4-1-1 /maa:product_pending (Value=0)	app pending in other ms	B251-1
E251-4	Is there another Member state(s) where an authorisation is granted for the same[4] product?			
E251-5	Yes	maa:section4-1-2/ maa:same_product (Value=1)	is auth granted in other ms	B251-2, B251-3, B252-1
E251-6	No	maa:section4-1-2/ maa:same_product (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 21 or 22 of Directive 2001/82/EC shall apply)?			B251-3
E251-8	Yes	maa:section4-1-2/ maa:implications (Value=1)	are there differences	B251-3, B251-4, B251-5
E251-9	No	maa:section4-1-2/ maa:implications (Value=0)	are there differences	B251-3, B251-4
E251-10	If yes, 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[4] product?			
E251-12	Yes	maa:section4-1-3/ maa:refused (Value=1)	was auth refused	B251-6, B252-1
E251-13	No	maa:section4-1-3/ maa:refused (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

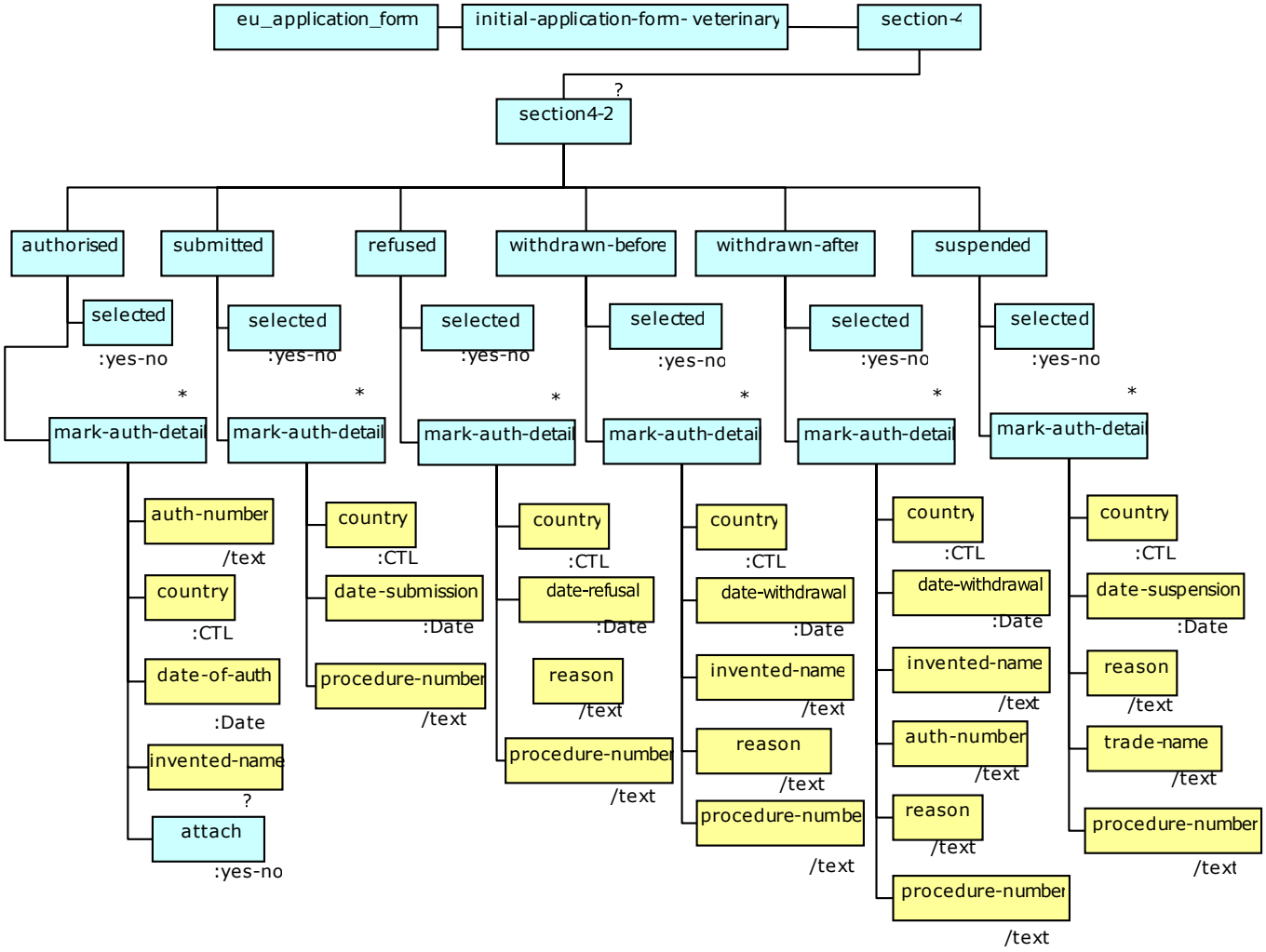
Rule ID	Element id(s)	Default BR	Rule	Effect(s)
B251-1	E251-2, E251-3a	Mandatory.	Mutually Exclusive.	
B251-2	E251-5, E251-6	Mandatory.	Mutually Exclusive.	
B251-3	E251-5, E251-7 to E251-10	E251-5 is mandatory, rest are optional.	If E251-5 is selected, then the other fields are required.	
B251-4	E251-8, 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-veterinary/ maa:other_marketing_authorisation_applications/ maa: Marketing_authorisation_applications_in_EEA/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E252-1	Authorised	maa:authorised/rdm:selected	Authorisation Status CTL	B252-2
E252-2	Country	maa:authorised/rdm:mark-auth-detail/rdm:country	MP Authorisation > Country CTL	B252-2
E252-3	Date of authorisation	maa:authorised/rdm:mark-auth-detail/rdm:date-of-auth	MP Authorisation > authorisation date	B252-2
E252-4	Invented name	maa:authorised/rdm:mark-auth-detail/rdm:invented-name	Medicinal Product Group > invented name	B252-2
E252-5	Authorisation number	maa:authorised/rdm:mark-auth-detail/rdm:auth-number	MP Authorisation > authorisation number	B252-2
E252-6	Attach marketing authorisation (Annex 5.15)	maa:authorised/rdm:attach		B252-2
E252-7	Submitted	maa:pending/rdm:selected	Authorisation Status CTL	B252-3
E252-8	Country	maa:pending/rdm:mark-auth-detail/rdm:country	MP Authorisation > Country CTL	B252-3
E252-9	Date of submission	maa:pending/rdm:mark-auth-detail/rdm:date-submission	Application > submission date	B252-3
E252-10	Procedure number of MRP/DCP	maa:pending/rdm:mark-auth-detail/procedure-number	MP Authorisation > MP Procedure > procedure number	B252-3
E252-11	Refused	maa:refused/selected	Authorisation Status CTL	B252-4
E252-12	Country	maa:refused/rdm:mark-auth-detail/rdm:country	MP Authorisation > Country CTL	B252-4
E252-13	Date of refusal	maa:refused/rdm:mark-auth-detail/rdm:date-refusal	MP Authorisation > authorisation date	B252-4
E252-14	Reason for refusal	maa:refused/rdm:mark-auth-detail/rdm:reason	MP Authorisation > authorisation description	B252-4
E252-15	Procedure number of MRP/DCP	maa:pending/rdm:mark-auth-detail/procedure-number	MP Authorisation > MP Procedure > procedure number	B252-4
E252-16	Withdrawn (by applicant before authorisation)	maa:withdrawn-before/rdm:selected	Authorisation Status CTL	B252-5
E252-17	Country	maa:withdrawn-before/rdm:mark-auth-detail/rdm:country	MP Authorisation > Country CTL	B252-5
E252-18	Date of withdrawal	maa:withdrawn-before/rdm:mark-auth-detail/rdm:date-withdrawal	MP Authorisation > authorisation date	B252-5
E252-19	Invented name	maa:withdrawn-before/rdm:mark-auth-detail/rdm:invented-name	Medicinal Product Group > invented name	B252-5
E252-20	Reason for withdrawal	maa:withdrawn-before/rdm:mark-auth-detail/rdm:reason	MP Authorisation > authorisation description	B252-5
E252-21	Procedure number of MRP/DCP	maa:pending/rdm:mark-auth-detail/procedure-number	MP Authorisation > MP Procedure > procedure number	B252-5
E252-22	Withdrawn (by applicant after authorisation)	maa:withdrawn-after/rdm:selected	Authorisation Status CTL	B252-6
E252-23	Country	maa:withdrawn-after/ rdm:mark-auth-detail/rdm:country	MP Authorisation > Country CTL	B252-6
E252-24	Date of withdrawal	maa:withdrawn-after/ rdm:mark-auth-detail/rdm:date-withdrawal	MP Authorisation > authorisation date	B252-6
E252-25	Authorisation number	maa:withdrawn-after/ rdm:mark-auth-detail/rdm:auth-number	MP Authorisation > authorisation number	B252-6
E252-26	Invented name	maa:withdrawn-after/ rdm:mark-auth-detail/rdm:invented-name	Medicinal Product Group > invented name	B252-6
E252-27	Reason for withdrawal	maa:withdrawn-after/ rdm:mark-auth-detail/rdm:reason	MP Authorisation > authorisation description	B252-6
E252-28	Procedure number of MRP/DCP	maa:pending/rdm:mark-auth-detail/procedure-number	MP Authorisation > MP Procedure > procedure number	B252-6
E252-29	Suspended/revoked (by competent authority)	maa:suspended/rdm:selected	Authorisation Status CTL	B252-7
E252-30	Country	maa:suspended/rdm:mark-auth-detail/rdm:country	MP Authorisation > Country CTL	B252-7
E252-31	Date of suspension/revocation	maa:suspended/rdm:mark-auth-detail/rdm:date-suspension	MP Authorisation > authorisation date	B252-7
E252-32	Reason for suspension/revocation	maa:suspended/rdm:mark-auth-detail/rdm:reason	MP Authorisation > authorisation description	B252-7

E252-33	Invented name	maa:suspended/rdm:mark-auth-detail/rdm:invented-name	Medicinal Product Group > invented name	B252-7
E252-34	Procedure number of MRP/DCP (if applicable)	maa:pending/rdm:mark-auth-detail/procedure-number	MP Authorisation > MP Procedure > procedure number	B252-7

Element Tree Diagram

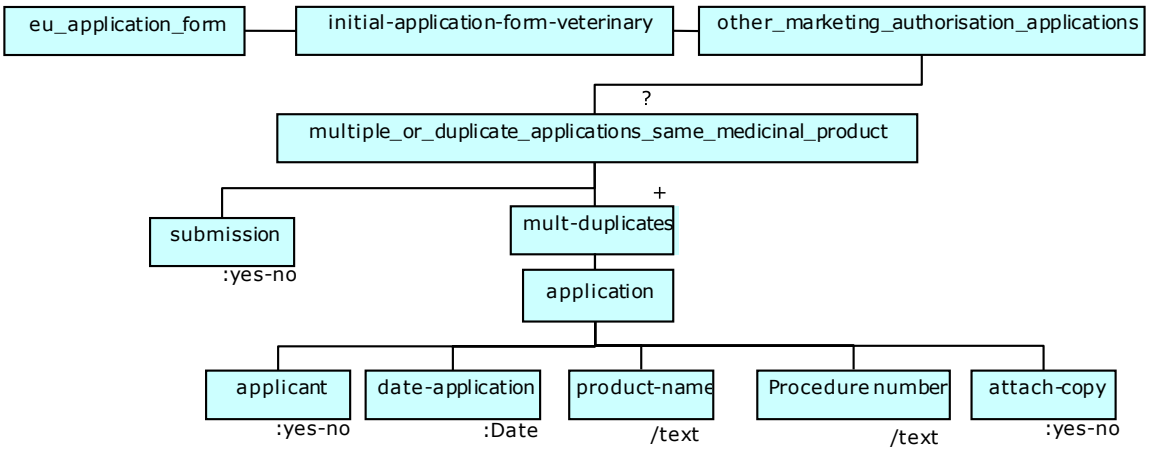


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B252-1	E251-1, E251-5, E251-12	Mandatory.	If one of the fields are selected, section 2.5.2 is mandatory.	
B252-2	E252-1 to E252-6	E252-1 mandatory, rest are optional.	If E252-1 is selected, then the rest are mandatory.	
B252-3	E252-7 to E252-10	E252-7 mandatory, rest are optional.	If E252-7 is selected, then the rest are mandatory.	
B252-4	E252-11 to E252-15	E252-13 mandatory, rest are optional.	If E252-11 is selected, then the rest are mandatory.	
B252-5	E252-16 to E252-21	E252-16 mandatory, rest are optional.	If E252-16 is selected, then the rest are mandatory.	
B252-6	E252-22 to E252-28	E252-22 mandatory, rest are optional.	If E252-22 is selected, then the rest are mandatory.	
B252-7	E252-29 to E252-34	E252-29 mandatory, rest are optional.	If E252-22 is selected, then 8the rest are mandatory.	

2.5.3. FOR MULTIPLE APPLICATIONS OF THE SAME VETERINARY MEDICINAL PRODUCT

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/ maa:initial-application-form-veterinary/ maa:other_marketing_authorisation_applications/ maa:multiple_or_duplicate_applications_same_medicinal_product/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E253-1	Multiple applications submitted Simultaneously or Subsequently to the initial application/MA for:	maa:submission		
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 letter from the Commission services, for centralised procedures only (Annex 5.16)	maa:mult-duplicates/ maa:application/maa:date-application /maa:attach-copy		

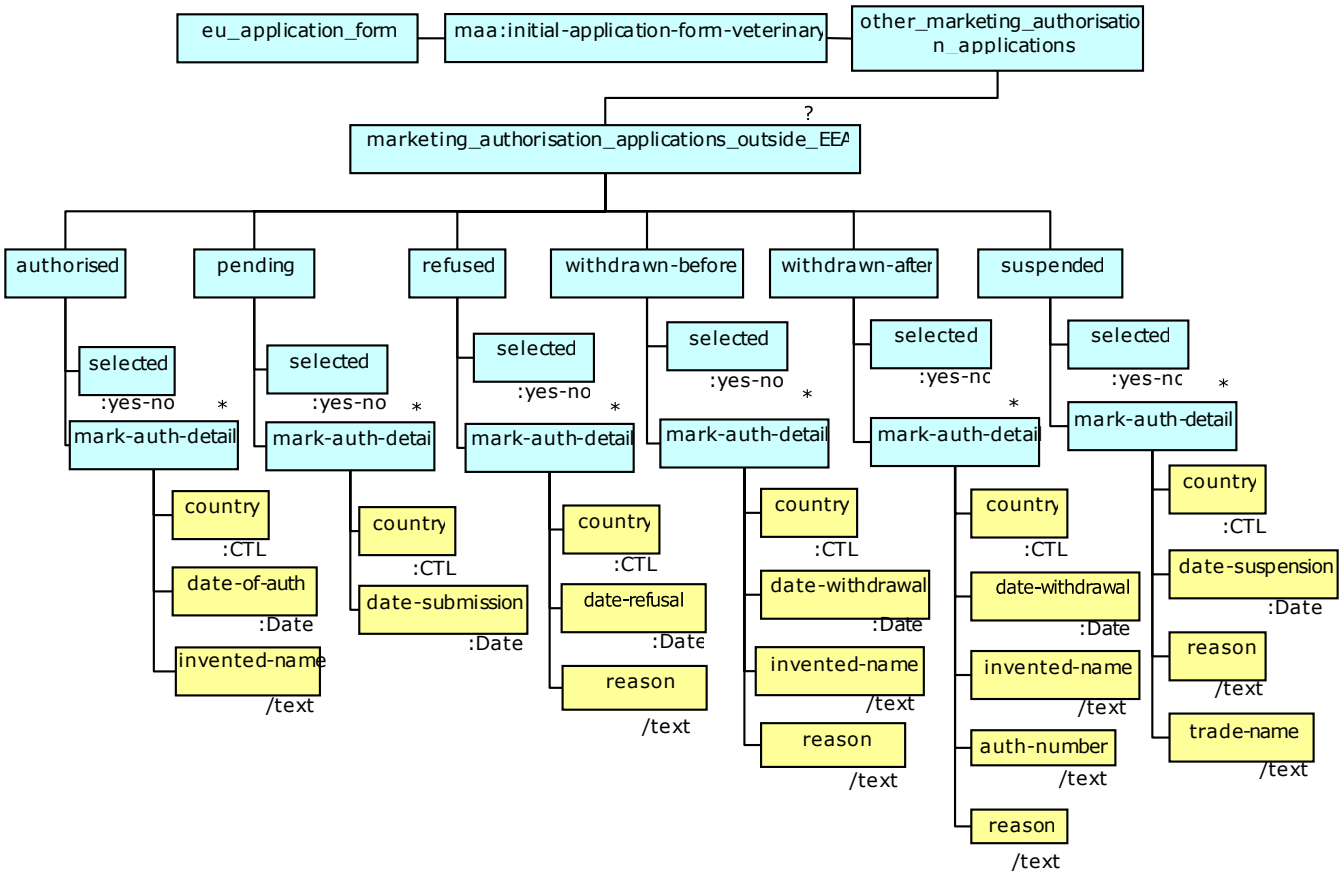
Element Tree Diagram



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-veterinary/ maa:other_marketing_authorisation_applications/ maa:marketing_authorisation_applications_outside_EEA/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E254-1	Authorized	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
E252-12	Reason for refusal	maa:refused/rdm:mark-auth-detail/rdm:reason	MP Authorisation > authorisation description	B252-3
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	Invented name	maa:suspended/rdm:mark-auth-detail/rdm:invented-name	Medicinal Product Group > invented name	B254-6

Element Tree Diagram



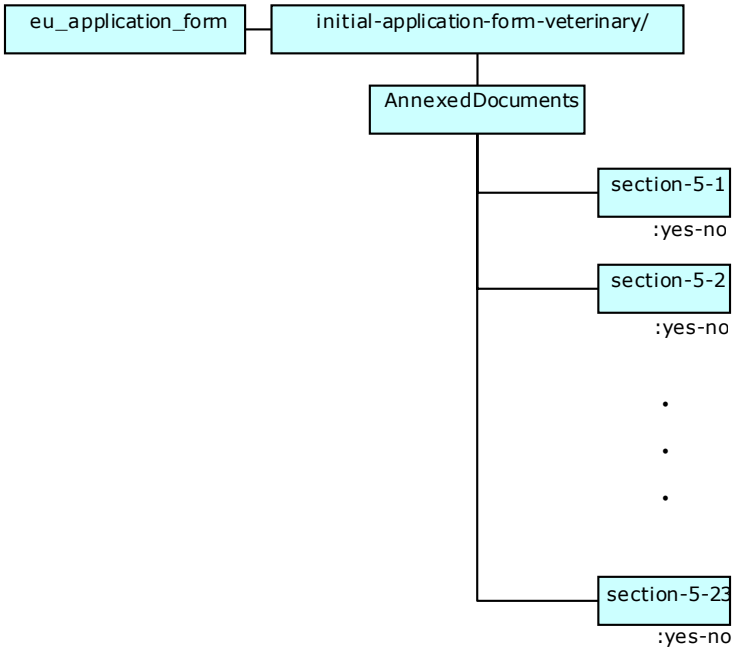
Business Rules

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	E254-12 mandatory, rest are Optional.	If E254-12 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-veterinary/ maa:AnnexedDocuments		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 veterinary 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	(empty)			
E26-6	Manufacturing Authorisation required under Article 44 of Directive 2001/82/EC (or equivalent, outside of the EEA where MRA or other Community arrangements apply). A reference to EudraGMDP will suffice when available.	maa:section5-6		
E26-7	(empty)			
E26-8	Flow-chart indicating all sites involved in the manufacturing process of the veterinary medicinal product or active substance (including sites involved in sampling and testing for batch release of products manufactured in third countries). Note: ALL manufacturing and control sites mentioned throughout the dossier MUST be consistent regarding their names, detailed addresses and activities	maa:section5-8		
E26-9	GMP certificate(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) (Drug 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 2001/82/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 CVMP or Member State.	maa:section5-14		
E26-15	Copy of Marketing Authorisation(s) required under Article 44 of Directive 2001/82/EC in the EEA and the equivalent in third countries on request (a photocopy of the pages which give the marketing authorisation number, the date of authorisation and the page which has been signed by the authorising competent authority will suffice).	maa:section5-15		
E26-16	Letter from 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/CMDv website).	maa:section5-17		
E26-18	List of proposed (invented) names and marketing authorisation holders in the concerned member states.	maa:section5-18		
E26-19	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 each of the manufacturing authorisation holders (i.e. located in EEA) listed in Section 2.5.2 where the active substance is used as a starting material that the active substance is manufactured in compliance with the detailed guidelines on good manufacturing practice for starting materials. Alternatively, such declaration may be signed by one Qualified Person on behalf of all QPs involved (provided this is clearly indicated). The declaration should refer to an audit and the date of the audit.	maa:section5-19		
E26-20	Detailed description of the Pharmacovigilance system and, where appropriate, the risk management system that the Applicant will put in place.	maa:section5-20		
E26-21	Copy of 'Qualification of SME Status'.	maa:section5-21		
E26-22	Evidence and justification to support the claim of new active substance status in the European Union for applications based on Article 12(3) of Directive 2001/82/EC	maa:section5-22		
E26-23	Copy of EMA certificate for a Vaccine Antigen Master File	maa:section5-23		

Element Tree Diagram



3. About this Document

3.1. Definitions, Acronyms, and Abbreviations

3.1.1. Acronyms

Name	Definition
CMS	Concerned Member State
DCP	DeCentralised Procedure
DTD	Data Type Definition
ETD	Element Tree Diagem
EU	European Community
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