08 March 2016
EMA/455316/2013
Information Technology

Electronic Application Form Data Exchange Standard 3.0

Supplementary Specification Annex 3 “Application for Renewal of Marketing Authorization” v.1.20.0.0

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1. INTRODUCTION

1.1. How to read this document

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

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

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

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

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

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

1.2. Sections Components

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

1.2.1 The Elements Mapping Table

This table describes how the mapping between the paper forms 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)

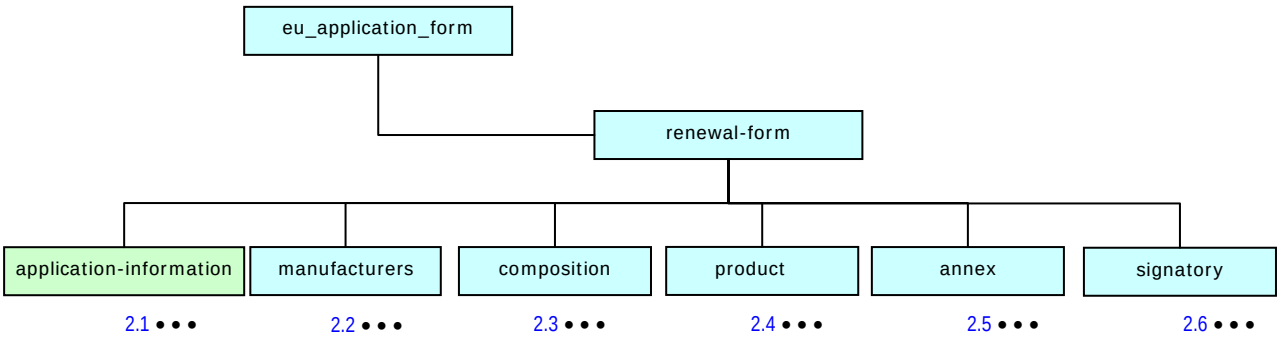
The diagrams of this version reflect the DES 3.0 standard described in the DES 3.0 Supplementary Specifications document. The ETD shows which are the concepts involved in the mapping of all the application form fields in the Element Mapping Table and the hierarchical constrains between them.

2. RENEWAL APPLICATION FORM

The “Renewal application form” 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/renewal-form		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2-1	APPLICATION FOR RENEWAL OF A MARKETING AUTHORISATION	application-information		See Section 2.1
E2-2	APPROVED MANUFACTURERS	manufacturers		See section 2.2
E2-3	QUALITATIVE AND QUANTITATIVE COMPOSITION IN TERMS OF THE ACTIVE SUBSTANCE(S) AND EXCIPIENT(S)	composition		See section 2.3
E2-4	Boxes for PRESENT / PROPOSED product information text	product		See section 2.4
E2-5	DOCUMENTS APPENDED TO THIS APPLICATION	annex		See section 2.5
E2-6	Signature/Declaration	signatory		See section 2.6
E2-7	Footer Section			See section 2.7

Element Tree Diagram

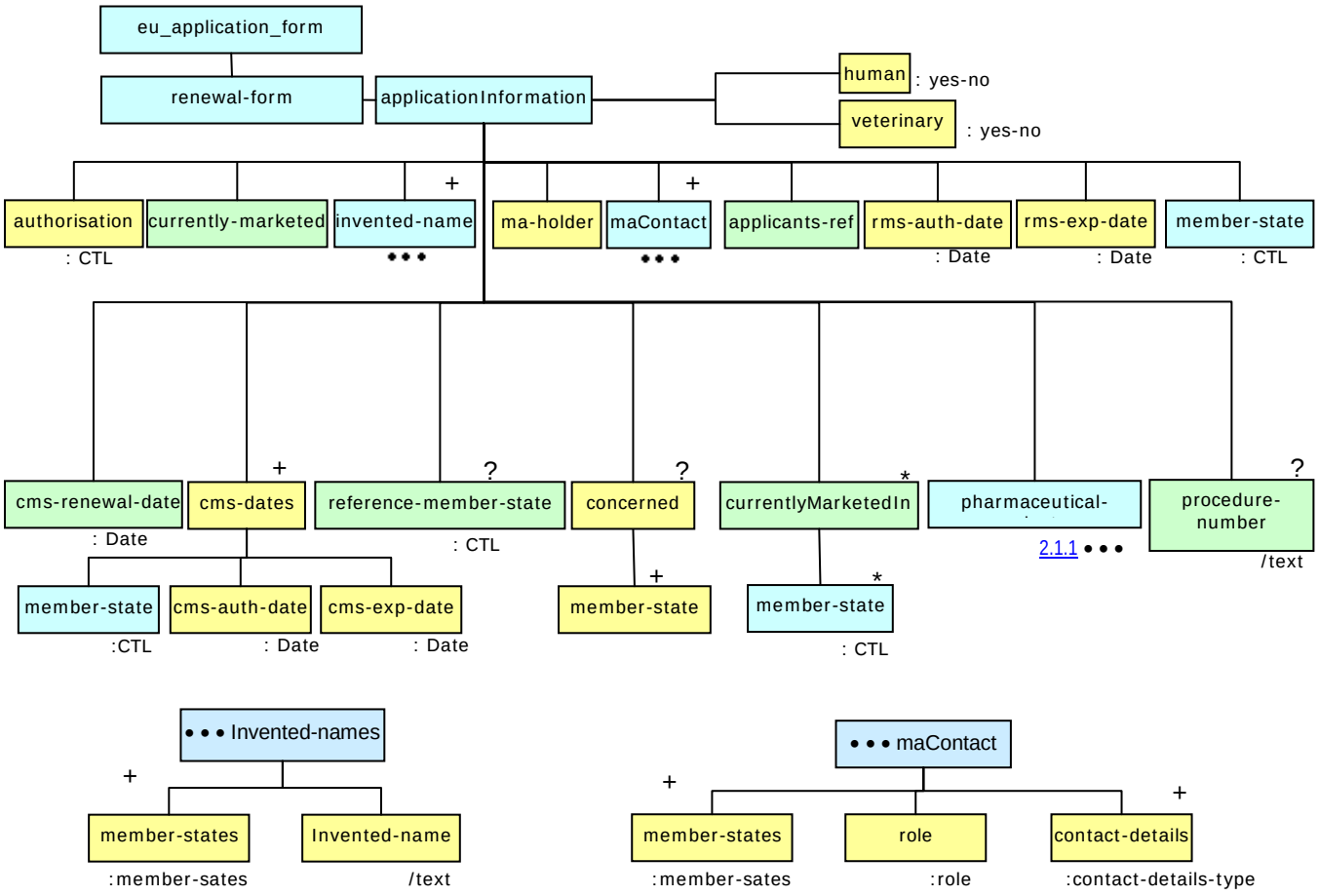


2.1. Application Information

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:renewal-form/maa:application-information /			
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E21-1	HUMAN	maa:human	Domain CTL > term id	B21-1
E21-2	VETERINARY	maa:veterinary	Domain CTL > term id	B21-1
E21-3	National Authorisation in MRP	maa:authorisation	mp-procedure > Procedure Type CTL	B21-2
E21-4	MRP Procedure Number	maa:procedure-number	MP Procedure>procedure Number	B21-2
E21-5	EU authorization	maa:authorisation	MP Procedure > Procedure Type CTL	B21-2
E21-6	National authorization only	maa:authorisation	MP Procedure > Procedure Type CTL	B21-2
E21-7	Referenced member state	maa:reference-member-state	MP Procedure > role > country CTL	B21-2
E21-8	Concerned member state	maa:concerned/maa:member-state	MP Procedure > role > country CTL	B21-2
E21-9	Is this product currently marketed	maa:currently-marketed	Product Marketing> is product marketed	B21-3, B521-3, B522-2
E21-10	In which member states			
E21-11	Member State	maa:currently-marketed-in/maa:member-state		B21-3
E21-12	Invented Name	maa:invented-names		
		maa:invented-name	Medicinal Product Group>invented name	
		maa:invented/maa:member-states/rdm:member-state		
E21-13	Pharmaceutical product section	maa:pharmaceutical-products		See Section 2.1.1
E21-14	Name and address of MA holder	maa:ma-holder/rdm:member-states/rdm:ref-member-state/rdm:name		
		maa:ma-holder//rdm:company-name	Application>Role> Organisation > name	
		maa:ma-holder/rdm:address1	Application>Role> Party > Contact Details > address line 1 (to address line 5)	
		maa:ma-holder/rdm:address2	Application>Role> Party > Contact Details > address line 2 (to address line 5)	
		maa:ma-holder/rdm:postcode	Application>Role> Party > Contact Details > postcode	
		maa:ma-holder /rdm:country	Application>Role> Party > Contact Details > Country CTL	
		maa:ma-holder /rdm:phone	Application>Role> Party> Contact Details > electronic contact	
		maa:ma-holder/rdm:fax	Application>Role> Party > Contact Details > electronic contact	
		maa:ma-holder/rdm:email	Application>Role> Party > Contact Details > electronic contact	
E21-15	Name and address of Contact			
		maa:maContact/maa:role/rdm:personal-title	Application>Role>Party>Person> Personal Title	
		maa:maContact/maa:role/rdm:given-name	Role>Party>Person> given name	
		maa:maContact/maa:role/rdm:family-name	Role>Party>Person> family name	
		maa:maContact/maa:member-states/rdm:member-state		
		maa:maContact/maa:contact-details/rdm:companyName	Role>Party>Person> Company name	
		maa:maContact/maa:contact-details/rdm:address	Role>Party>Contact Details > Address	
		maa:maContact/maa:contact-details/rdm:city	Role>Party>Contact Details > City	
		maa:maContact/maa:contact-	Role>Party>Contact Details >	

		details/rdm:post-code	Post Code	
		maa:maContact/maa:contact-details/rdm:country	Role>Party>Contact Details > Address > Country CTL	
		maa:maContactmaa:contact-details/rdm:phone	Role>Party>Contact Details > Electronic contact>electronic contact	
		maa:maContact/maa:contact-details/rdm:fax	Role>Party>Contact Details > Electronic contact>electronic contact	
		maa:maContact/maa:contact-details/rdm:email	Role>Party>Contact Details > Electronic contact>electronic contact	
E21-16	Applicant's Reference	maa:applicants-ref	Application > applicant reference	
E21-17	First authorisation date in Reference Member State/Community	maa:rms-auth-date	MP Procedure > cms first auth date	
E21-18	Expiry date of current authorization in Reference Member State/Community	maa:rms-exp-date	MP Procedure > cms current auth expiry date	
E21-19	Concerned member state	maa:cms-dates/maa:member-state		
E21-20	First authorization in Concerned Member State to which application is made	maa:cms-dates/maa:cms-auth-date	MP Procedure > rms first auth date	B21-2
E21-21	Expiry date of current authorization in Concerned Member State	maa:cms-dates/maa:cms-exp-date	MP Procedure > rms current auth expiry date	B21-2
E21-22	Proposed Common Renewal Date	maa:cms-renewal-date	Procedure Use> proposed common renewal date	B21-2
E21-23	Attach annex	maa:attach-annex		B21-3

Element Tree Diagram



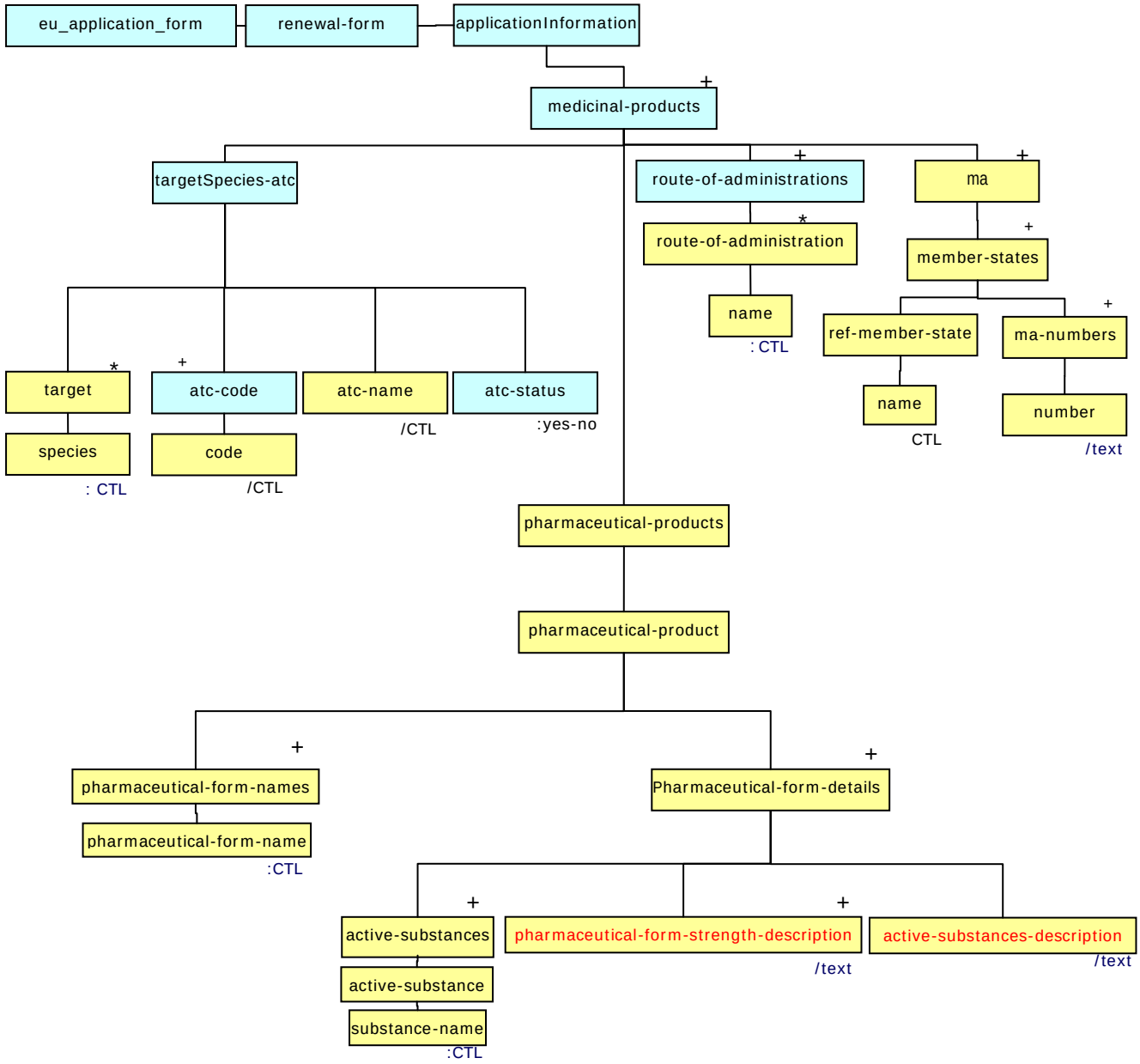
Business Rules

Rule ID	Element id(s)	Default BR	Rule	Effect(s)
B21-1	E21-1 (human), E21-2 (veterinary)	Mandatory	Elements are mutually Exclusive. Same applies to sections 2.5.1 and 2.5.2	Flag for either Human or Veterinary application.
B21-2	E21-3, E21-5, E21-6 (authorisation) E21-4, E21-7, E21-8, E21-20, E21-21, E21-22	Mandatory	E21-3, E21-5, E21-6 are mutually exclusive	If E21-3 is selected, E21-4, E21-7, E21-8, E21-20, E21-21, E21-22 are mandatory.
B21-3	E21-9 (currentlyMarketed) E21-11(currentlyMarketedIn/ memberState)	Mandatory	E21-9 has a binary value (“YES” or “NO”)	If E21-9 value is “YES”, then E21-11 is mandatory, If E21-9 value is “NO”, then E21-11 is hidden. If E21-9 is “YES” and E21-5 and not E21-4, then E21-23 is mandatory and E21-11 is optional.

2.1.1 Pharmaceutical Product

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:renewal-form/maa:applicationInformation/maa:medicinal-products			
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E211-1	Pharmaceutical form(s)	maa:pharmaceutical-products/maa: pharmaceutical-product/rdm:pharmaceutical-form-names/ rdm:pharmaceutical-form-name	Pharmaceutical Product > pharmaceutical Dose Form CTL	
E211-2	Strength(s)	maa:pharmaceutical-products maa:pharmaceutical-product/rdm:pharmaceutical-form-details/rdm:pharmaceutical-form-strength-description		B211-1
E211-3	Active Substance(s)	maa:pharmaceutical-products maa:pharmaceutical-product/maa: pharmaceutical-form-details/maa:active-substances-description		
E211-4	Active Substance	maa:pharmaceutical-products maa:pharmaceutical-product/ rdm:pharmaceutical-form-details/ rdm:active-substances/rdm-active-substance/ rdm:substance-name/rdm:name	Pharmaceutical Product > Ingredient > Substance CTL	
E211-5	Target Species	rdm:targetSpecies-atc rdm:target/maa:species	Target Population > Species CTL	B211-1
E211-6	ATC Code	rdm:targetSpecies-atc/rdm:atc/rdm:act-code/rdm:code	Medicinal Product > ATC Code CTL	
E211-7	Group	rdm:atc/rdm:act-code/rdm:code	Medicinal Product > ATC Code CTL	
E211-8	If no ATC code has been assigned, please indicate if an application for ATC code has been made	rdm:atc/rdm:atc-status		
E211-9	Route of Amdinistration	maa:route-of-administrations/rdm: route-of-administration/rdm:name	Medicinal Product >Pharmaceutical Product > Route of Administration CTL	
E211-10	Member state	maa:ma/rdm:member-states/rdm:ref-member-state/rdm:name		
E211-11	MA Number	maa:ma/rdm:member-states/rdm:ma-numbers/rdm:number	MP Authorisation > authorization number	

Element Tree Diagram

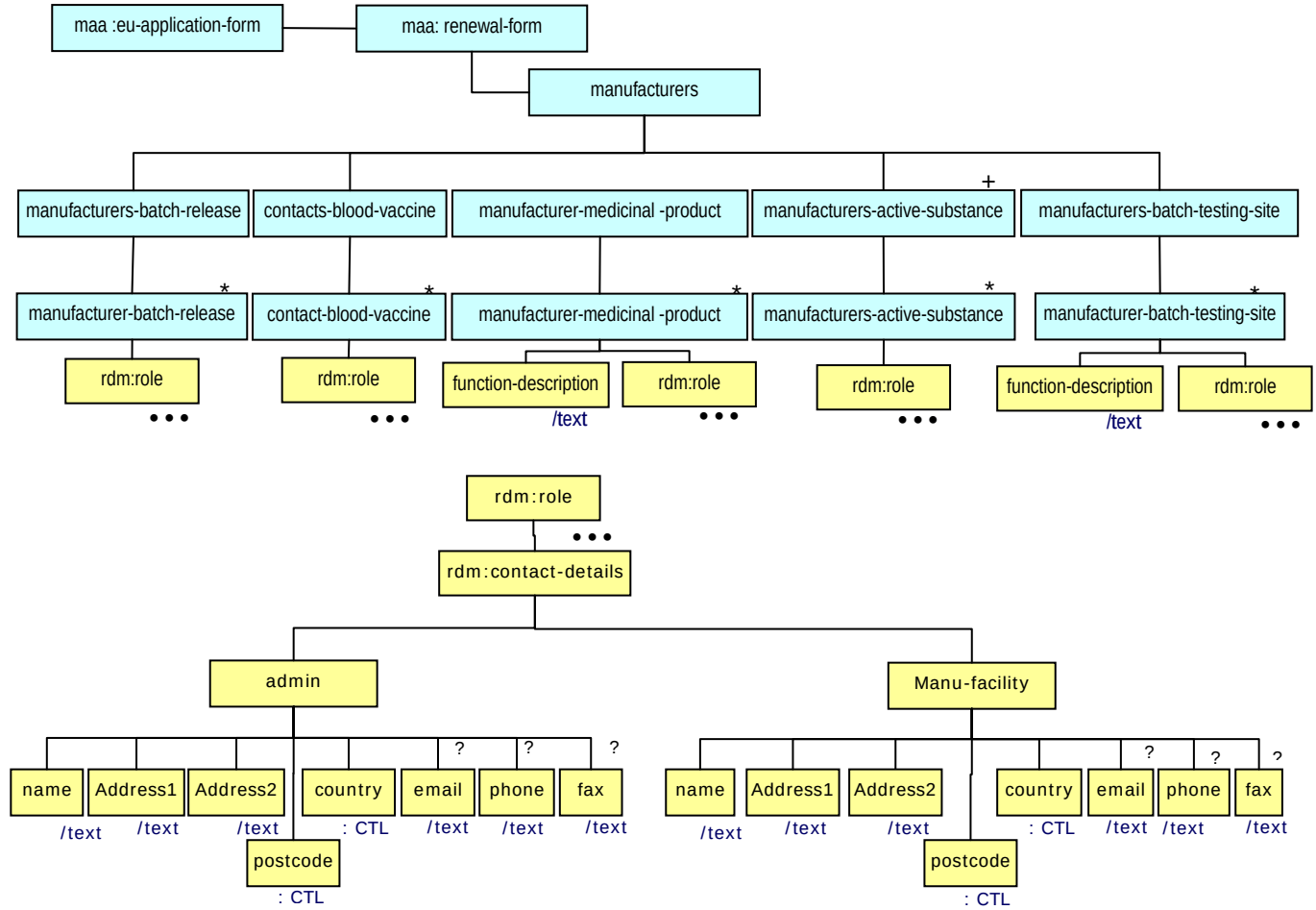


Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B211-1	E21-2, E211-7	optional	When E21-2 is selected (veterinary), E211-5 (targetSpecies) is visible and mandatory, else it is hidden and optional	

2.2. Approved Manufacturers

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:renewal-form/maa:manufacturers/			
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E22-1	Authorised manufacturer(s) (or importer) responsible for **batch release** in the EEA (in accordance with Articles 40 and 51 of Directive 2001/83/EC, as amended, or Articles 44 and 55 of Directive 2001/82/EC (as shown in the package leaflet and where applicable in the labelling or Annex II of the Decision)	maa: manufacturers-batch-release		See 2.2.1
E22-2	**For blood products and vaccines:** State laboratory or laboratory designated for official **batch release**, as accordance with Articles 111(1), 113, 114 (1)-(2) and 115 of Directive 2001/83/EC as amended.	maa: contacts-blood-vaccine		See 2.2.2, B22-1
E22-3	Site(s) in EEA or in countries where an MRA or other Community arrangements apply, where **batch control/testing** takes place, as required by Article 51 of Directive 2001/83/EC as amended or Article 55 of Directive 2001/82/EC, if different from above	maa: manufacturers-batch-testing-site		See 2.2.3 B22-1
E21-4	Manufacturer(s) of the **medicinal product** and site(s) of manufacture (including diluent and solvent manufacturing sites)	maa: manufacturers-medicinal-product		See 2.2.4
E21-5	Manufacturer(s) of the **active substance(s)** *Note: All manufacturing sites involved in the manufacturing process of each source of active substance should be listed. Broker or supplier details alone are not sufficient*	maa:manufacturers-active-substance		See 2.2.5

Element Tree Diagram



Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B22-1	E22-2	Optional	Not mandatory to complete sections E22-2 and E22-3. Depends upon product nature.	

2.2.1 Batch Release Approved Manufacturers

	Common DES 3.0 Context		**Common RDM Entry point**	
	maa:eu_application_form/maa:renewal-form/maa:manufacturers/maa:manufacturers-batch-release/maa:manufacturer-batch-release/		Application>	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E221-1	companydescription	maa:role/rdm:company-description		
E221-2	Do you have admin address and manufacturer address	maa:role/maa:contact-details/rdm:admin-manu-address		B221-1
E221-3	Company Name	maa:role/rdm:contact-details/rdm: admin-office/rdm:name	Manufacturer Batch Release > Role > Organisation > name	B221-1
E221-4	Admin Office Address 1	maa:role/rdm:contact-details/rdm: admin-office/rdm:address	Role> Party > Contact Details > address	B221-1
E221-5	Admin Office Address 2	maa:role/rdm:contact-details/rdm: admin-office/rdm:city	Role> Party > Contact Details > address city	B221-1
E221-6	Postcode	maa:role/rdm:contact-details/rdm: admin-office/rdm:postcode	Role> Party > Contact Details > postcode	B221-1
E221-7	Admin Office Country	maa:role/rdm:contact-details/rdm: admin-office/rdm:country	Role> Party > Contact Details > Country CTL	B221-1
E221-8	Admin Telephone	maa:role/rdm:contact-details/rdm: admin-office/rdm:phone	Role> Party> Contact Details > electronic contact	B221-1
E221-9	Admin Office Telefax	maa:role/rdm:contact-details/rdm: admin-office/rdm:fax	Role> Party > Contact Details > electronic contact	B221-1
E221-10	Admin Office E-mail	maa:role/rdm:contact-details/rdm: admin-office/rdm:email	Role> Party > Contact Details > electronic contact	B221-1
E221-11	Company Name	maa:role/rdm:contact-details/rdm:manu-facility/rdm:name	Manufacturer Batch Release > Role > Organisation > name	B221-1
E221-12	Manufacturing Facility Address 1	maa:role/rdm:contact-details/rdm:manu-facility/rdm:address	Role> Party > Contact Details > address	B221-1
E221-13	Manufacturing Facility Address 2	maa:role/rdm:contact-details/rdm:manu-facility/rdm:city	Role> Party > Contact Details > city	B221-1
E221-14	Postcode	maa:role/maa:contact-details/rdm: manu-facility/rdm:postcode	Role> Party > Contact Details > postcode	B221-1
E221-15	Manufacturing Facility Country	maa:role/rdm:contact-details/rdm:manu-facility/rdm:country	Role> Party > Contact Details > Country CTL	B221-1
E221-16	Manufacturing Facility Telephone	maa:role/rdm:contact-details/rdm:manu-facility/rdm:phone	Role> Party> Contact Details > electronic contact	B221-1
E221-17	Manufacturing Facility Telefax	maa:role/rdm:contact-details/rdm:manu-facility/rdm:fax	Role> Party > Contact Details > electronic contact	B221-1
E221-18	Manufacturing Facility E-mail	maa:role/rdm:contact-details/rdm:manu-facility/rdm:email	Role> Party > Contact Details > electronic contact	B221-1

Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B221-1	E221-2 to E221-18	Mandatory and visible	E221-2 is yes then E221-3 to E221-18 are visible else E221-3 to E221-10 are hidden	

2.2.2 Approved Manufacturers for Blood Products and Vaccines

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:renewal-form/maa:manufacturers/maa:contacts-blood-vaccine/maa:contact-blood-vaccine/		Application>Role>	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E222-1	Laboratory Name	maa:role/rdm:name	Organisation > name	B222-2
E222-2	Do you have admin address and manufacturer address	maa:role/maa:contact-details/rdm:admin-manu-address		B222-1, B222-2
E222-3	Company Name	maa:role/rdm:contact-details/rdm: admin-office/rdm:name	Manufacturer Batch Release > Role > Organisation > name	B222-1, B222-2
E222-4	Admin Office Address 1	maa:role/rdm:contact-details/rdm: admin-office/rdm:address	Role> Party > Contact Details > address	B222-1, B222-2
E222-5	Admin Office Address 2	maa:role/rdm:contact-details/rdm: admin-office/rdm:city	Role> Party > Contact Details > address city	B222-1, B222-2
E222-6	Postcode	maa:role/rdm:contact-details/rdm: admin-office/rdm:postcode	Role> Party > Contact Details > postcode	B222-1, B222-2
E222-7	Admin Office Country	maa:role/rdm:contact-details/rdm: admin-office/rdm:country	Role> Party > Contact Details > Country CTL	B222-1, B222-2
E222-8	Admin Telephone	maa:role/rdm:contact-details/rdm: admin-office/rdm:phone	Role> Party> Contact Details > electronic contact	B222-1, B222-2
E222-9	Admin Office Telefax	maa:role/rdm:contact-details/rdm: admin-office/rdm:fax	Role> Party > Contact Details > electronic contact	B222-1, B222-2
E222-10	Admin Office E-mail	maa:role/rdm:contact-details/rdm: admin-office/rdm:email	Role> Party > Contact Details > electronic contact	B222-1, B222-2
E222-11	Company Name	maa:role/rdm:contact-details/rdm:manu-facility/rdm:name	Manufacturer Batch Release > Role > Organisation > name	B222-1, B222-2
E222-12	Manufacturing Facility Address 1	maa:role/rdm:contact-details/rdm:manu-facility/rdm:address	Role> Party > Contact Details > address	B222-1, B222-2
E222-13	Manufacturing Facility Address 2	maa:role/rdm:contact-details/rdm:manu-facility/rdm:city	Role> Party > Contact Details > city	B222-1, B222-2
E222-14	Postcode	maa:role/maa:contact-details/rdm: manu-facility/rdm:postcode	Role> Party > Contact Details > postcode	B222-1, B222-2
E222-15	Manufacturing Facility Country	maa:role/rdm:contact-details/rdm:manu-facility/rdm:country	Role> Party > Contact Details > Country CTL	B222-1, B222-2
E222-16	Manufacturing Facility Telephone	maa:role/rdm:contact-details/rdm:manu-facility/rdm:phone	Role> Party> Contact Details > electronic contact	B222-1, B222-2
E222-17	Manufacturing Facility Telefax	maa:role/rdm:contact-details/rdm:manu-facility/rdm:fax	Role> Party > Contact Details > electronic contact	B222-1, B222-2
E222-18	Manufacturing Facility E-mail	maa:role/rdm:contact-details/rdm:manu-facility/rdm:email	Role> Party > Contact Details > electronic contact	B222-1, B222-2

Business Rules

Rule ID	Element id(s)	Default BR	Rule	Effect(s)
B222-1	E222-2 to E222-18	Optional and visible	E222-2 is yes then E222-3 to E222-18 are visible else E222-3 to E222-10 are hidden	
B222-2	E222-1 to E222-18	Optional	E222-1 is not null then E222-3 to E222-18 are mandatory	

2.2.3 Batch controlled / Testing approved Manufacturers

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:renewal-form/maa:manufacturers/maa:manufacturers-batch-testing-site/maa:manufacturer-batch-testing-site/		Application>Role>	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E223-1	Do you have admin address and manufacturer address	maa:role/maa:contact-details/rdm:admin-manu-address		B223-1
E223-2	Company Name	maa:role/rdm:contact-details/rdm: admin-office/rdm:name	Manufacturer Batch Release > Role > Organisation > name	
E223-3	Admin Office Address 1	maa:role/rdm:contact-details/rdm: admin-office/rdm:address	Role> Party > Contact Details > address	B223-1
E223-3	Admin Office Address 2	maa:role/rdm:contact-details/rdm: admin-office/rdm:city	Role> Party > Contact Details > address city	B223-1
E223-4	Postcode	maa:role/rdm:contact-details/rdm: admin-office/rdm:postcode	Role> Party > Contact Details > postcode	B223-1
E223-5	Admin Office Country	maa:role/rdm:contact-details/rdm: admin-office/rdm:country	Role> Party > Contact Details > Country CTL	B223-1
E223-6	Admin Telephone	maa:role/rdm:contact-details/rdm: admin-office/rdm:phone	Role> Party> Contact Details > electronic contact	B223-1
E223-7	Admin Office Telefax	maa:role/rdm:contact-details/rdm: admin-office/rdm:fax	Role> Party > Contact Details > electronic contact	B223-1
E223-8	Admin Office E-mail	maa:role/rdm:contact-details/rdm: admin-office/rdm:email	Role> Party > Contact Details > electronic contact	B223-1
E223-9	Company Name	maa:role/rdm:contact-details/rdm:manu-facility/rdm:name	Manufacturer Batch Release > Role > Organisation > name	B223-1
E223-10	Manufacturing Facility Address 1	maa:role/rdm:contact-details/rdm:manu-facility/rdm:address	Role> Party > Contact Details > address	B223-1
E223-11	Manufacturing Facility Address 2	maa:role/rdm:contact-details/rdm:manu-facility/rdm:city	Role> Party > Contact Details > city	B223-1
E223-12	Postcode	maa:role/maa:contact-details/rdm: manu-facility/rdm:postcode	Role> Party > Contact Details > postcode	B223-1
E223-13	Manufacturing Facility Country	maa:role/rdm:contact-details/rdm:manu-facility/rdm:country	Role> Party > Contact Details > Country CTL	B223-1
E223-14	Manufacturing Facility Telephone	maa:role/rdm:contact-details/rdm:manu-facility/rdm:phone	Role> Party> Contact Details > electronic contact	B223-1
E223-15	Manufacturing Facility Telefax	maa:role/rdm:contact-details/rdm:manu-facility/rdm:fax	Role> Party > Contact Details > electronic contact	B223-1
E223-16	Manufacturing Facility E-mail	maa:role/rdm:contact-details/rdm:manu-facility/rdm:email	Role> Party > Contact Details > electronic contact	B223-1

Business Rules

Rule ID	Element id(s)	Default BR	Rule	Effect(s)
B223-1	E223-1 to E223-16	Optional and visible	E223-1 is yes then E223-2 to E223-16 are visible else E223-2 to E223-10 are hidden	

2.2.4 Medicinal Product Approved Manufacturers

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:renewal-form/maa:manufacturers/maa:manufacturers-medicinal-product/ maa:manufacturer-medicinal-product/		Application>	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E224-1	Do you have admin address and manufacturer address	maa:role/maa:contact-details/rdm:admin-manu-address		B224-1
E224-2	Company Name	maa:role/rdm:contact-details/rdm:admin-office/rdm:name	Manufacturer Batch Release > Role > Organisation > name	B224-1
E224-3	Admin Office Address 1	maa:role/rdm:contact-details/rdm:admin-office/rdm:address	Role> Party > Contact Details > address	B224-1
E224-3a	Admin Office Address 2	maa:role/rdm:contact-details/rdm:admin-office/rdm:city	Role> Party > Contact Details > address city	B224-1
E224-4	Postcode	maa:role/rdm:contact-details/rdm:admin-office/rdm:postcode	Role> Party > Contact Details > postcode	B224-1
E224-5	Admin Office Country	maa:role/rdm:contact-details/rdm:admin-office/rdm:country	Role> Party > Contact Details > Country CTL	B224-1
E224-6	Admin Office Telephone	maa:role/rdm:contact-details/rdm:admin-office/rdm:phone	Role> Party> Contact Details > electronic contact	B224-1
E224-7	Admin Office Telefax	maa:role/rdm:contact-details/rdm:admin-office/rdm:fax	Role> Party > Contact Details > electronic contact	B224-1
E224-8	Admin Office E-mail	maa:role/rdm:contact-details/rdm:admin-office/rdm:email	Role> Party > Contact Details > electronic contact	B224-1
E224-9	Company Name	maa:role/rdm:contact-details/rdm:manu-facility/rdm:name	Manufacturer Batch Release > Role > Organisation > name	
E224-10	Manufacturing Facility Address 1	maa:role/rdm:contact-details/rdm:manu-facility/rdm:address	Role> Party > Contact Details > address	B224-1
E224-11	Manufacturing Facility Address 2	maa:role/rdm:contact-details/rdm:manu-facility/rdm:city	Role> Party > Contact Details > city	B224-1
E224-12	Postcode	maa:role/maa:contact-details/rdm:manu-facility/rdm:postcode	Role> Party > Contact Details > postcode	B224-1
E224-13	Manufacturing Facility Country	maa:role/rdm:contact-details/rdm:manu-facility/rdm:country	Role> Party > Contact Details > Country CTL	B224-1
E224-14	Manufacturing Facility Telephone	maa:role/rdm:contact-details/rdm:manu-facility/rdm:phone	Role> Party> Contact Details > electronic contact	B224-1
E224-15	Manufacturing Facility Telefax	maa:role/rdm:contact-details/rdm:manu-facility/rdm:fax	Role> Party > Contact Details > electronic contact	B224-1
E224-16	Manufacturing Facility E-mail	maa:role/rdm:contact-details/rdm:manu-facility/rdm:email	Role> Party > Contact Details > electronic contact	B224-1
E224-17	Brief description of functions performed by manufacturer of dosage form/assembler, etc.(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	rdm:function-description		
E224-18	Manufacturer functions	rdm:manu-functions/ rdm: manu-function		

Business Rules

Rule ID	Element id(s)	Default BR	Rule	Effect(s)
B224-1	E224-1 to E224-16	mandatory and visible	E224-1 is yes then E224-2 to E224-16 are visible else E224-2 to E224-10 are hidden	

2.2.5 Active Substance(s) Approved Manufacturers

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:renewal-form/maa:manufacturers/ maa:manufacturers-active-substance/maa:manufacturer-active-substance/maa:manufacturers		Application> Manufacturer Substance > Role	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E225-0	Name of active substance	rdm:active-substances/rdm:active-substance/rdm:substance-name	Ingredient > Substance CTL	
E225-1	Do you have admin address and manufacturer address	maa:role/maa:contact-details/rdm:admin-manu-address		B225-1
E225-2	Company Name	maa:role/rdm:contact-details/rdm:admin-office/rdm:name	Manufacturer Batch Release > Role > Organisation > name	
E225-3	Admin Office Address	maa:role/rdm:contact-details/rdm:admin-office/rdm:address	Role> Party > Contact Details > address line 1 (to address line 5)	B225-1
E225-4	Postcode	maa:role/rdm:contact-details/rdm:admin-office/rdm:postcode	Role> Party > Contact Details > electronic contact	B225-1
E225-5	Admin Office Country	maa:role/rdm:contact-details/rdm:admin-office/rdm:country	Role> Party > Contact Details > Country CTL	B225-1
E225-6	Admin Office Telephone	maa:role/rdm:contact-details/rdm:admin-office/rdm:phone	Role> Party> Contact Details > electronic contact	B225-1
E225-7	Admin Office Telefax	maa:role/rdm:contact-details/rdm:admin-office/rdm:fax	Role> Party > Contact Details > electronic contact	B225-1
E225-8	Admin Office E-mail	maa:role/rdm:contact-details/rdm:admin-office/rdm:email	Role> Party > Contact Details > electronic contact	B225-1
E225-9	Company Name	maa:role/rdm:contact-details/rdm:manu-facility/rdm:name	Manufacturer Batch Release > Role > Organisation > name	
E225-10	Manufacturing Facility Address	maa:role/rdm:contact-details/rdm:manu-facility/rdm:address	Role> Party > Contact Details > address line 1 (to address line 5)	B225-1
E225-11	Postcode	maa:role/maa:contact-details/rdm:manu-facility/rdm:postcode	Role> Party > Contact Details > electronic contact	B225-1
E225-12	Manufacturing Facility Country	maa:role/rdm:contact-details/rdm:manu-facility/rdm:country	Role> Party > Contact Details > Country CTL	B225-1
E225-13	Manufacturing Facility Telephone	maa:role/rdm:contact-details/rdm:manu-facility/rdm:phone	Role> Party> Contact Details > electronic contact	B225-1
E225-14	Manufacturing Facility Telefax	maa:role/rdm:contact-details/rdm:manu-facility/rdm:fax	Role> Party > Contact Details > electronic contact	B225-1
E225-15	Manufacturing Facility E-mail	maa:role/rdm:contact-details/rdm:manu-facility/rdm:email	Role> Party > Contact Details > electronic contact	B225-1

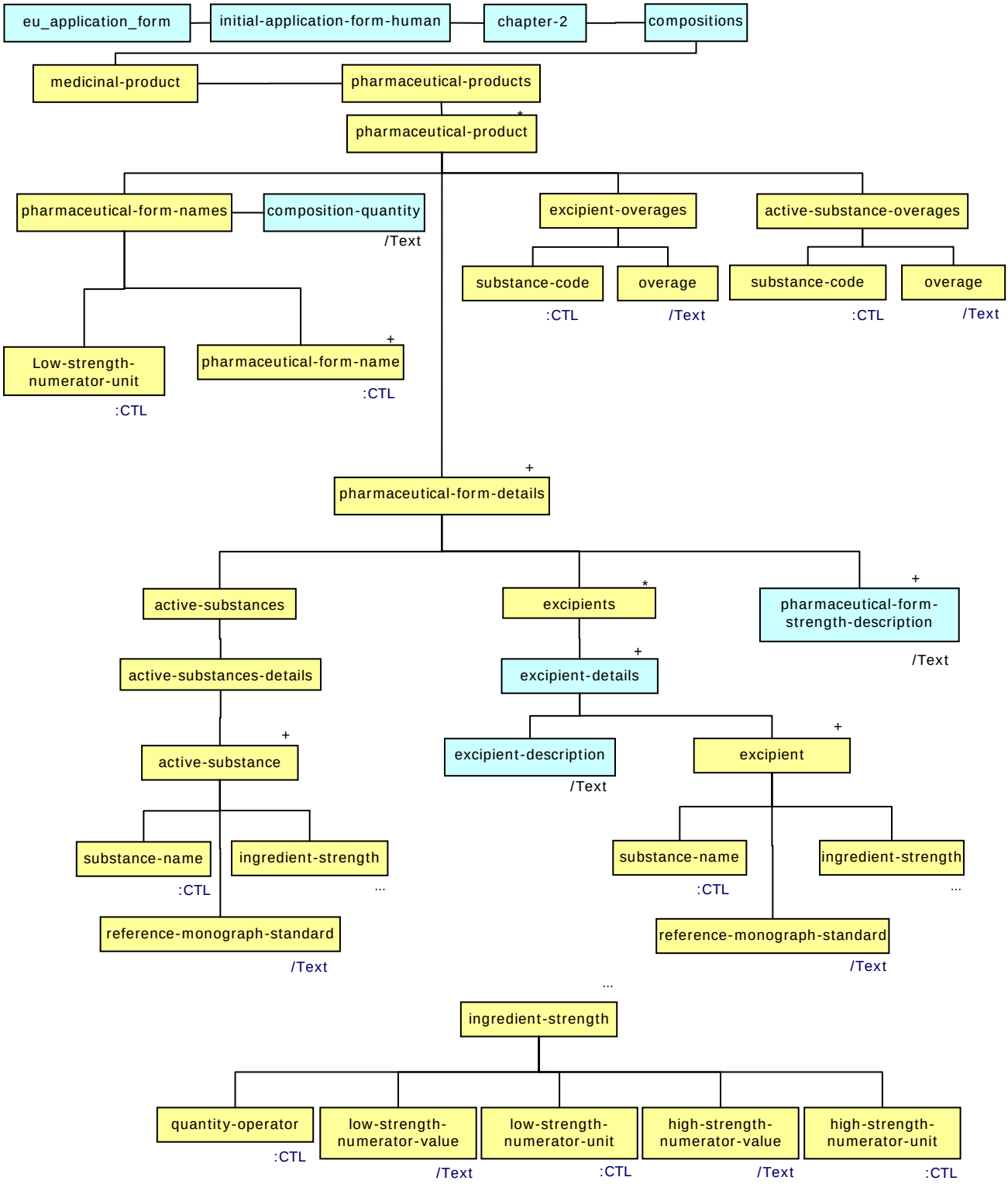
Business Rules

Rule ID	Element id(s)	Default BR	Rule	Effect(s)
B225-1	E225-1 to E225-15	mandatory and visible	E225-1 is yes then E225-2 to E225-145 are visible else E225-2 to E225-8 are hidden	

2.3. QUALITATIVE AND QUANTITATIVE COMPOSITION IN TERMS OF THE ACTIVE SUBSTANCE(S) AND EXCIPIENT(S)

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:renewal-form/maa:composition/ /rdm:medicinal-product/rdm:pharmaceutical-products/rdm:pharmaceutical-product/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E23-1	A note should be given as to which quantity the composition refers (e.g. 1 capsule)	rdm:pharmaceutical-form-names/rdm:composition-quantity		
E23-2	composition-unit	rdm:pharmaceutical-form-names/rdm:Low-strength-numerator-unit		
E23-3	Pharmaceutical Form	rdm:pharmaceutical-form-names/rdm:pharmaceutical-form-name	Pharmaceutical Dose Form CTL > term id	
E23-4	Strength	rdm:pharmaceutical-form-details/rdm:pharmaceutical-form-strength-description		
E23-5	Name of active substance	rdm:pharmaceutical-form-details/rdm:active-substances/rdm: active-substances-details/rdm:active-substance/rdm:substance-name	Ingredient > Substance CTL	
E23-6	Quantity / Unit	rdm:pharmaceutical-form-details/rdm:active-substances/ rdm: active-substances-details/rdm:active-substance/rdm:ingredient-strength	Ingredient > Unit CTL	
E23-7	Reference / Monograph Standard	rdm:pharmaceutical-form-details/rdm:active-substances/ rdm: active-substances-details/rdm:active-substance/rdm:reference-monograph-standard	??	
E23-8	Name of Excipient	rdm:pharmaceutical-form-details/rdm:excipients / rdm:excipients-details/rdm:excipient /rdm:substance-name	Ingredient > Substance CTL	
E23-9	Quantity / Unit	rdm:pharmaceutical-form-details/rdm:excipients / rdm:excipients-details/rdm:excipient /rdm:ingredient-strength	Ingredient > Unit CTL	
E23-10	Reference / Monograph Standard	rdm:pharmaceutical-form-details/rdm:excipients / rdm:excipients-details/rdm:excipient /rdm:reference-monograph-standard	??	
E23-11	Active Substance	rdm:pharmaceutical-form-details/rdm:active-substance-overages/rdm:substance-code	Ingredient > Substance CTL	
E23-12	Overage	rdm:active-substance-overages/rdm:overage	Ingredient > Overage	
E23-13	Excipient	rdm:excipient-overages/rdm:excipient-code	Ingredient > Substance CTL	
E23-14	Overage	rdm:excipient-overages /rdm:overage	Ingredient > Overage	

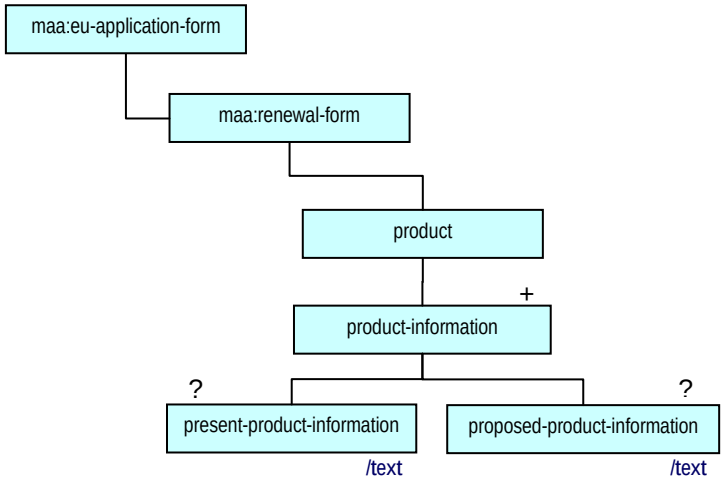
Element Tree Diagram



2.4. Boxes for PRESENT / PROPOSED product information text

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:renewal-form/maa:product/maa:product-information/		Application > Application Proposal	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E24-1	PRESENT PRODUCT INFORMATION TEXT	maa:present-product-information	present product info	
E24-2	PROPOSED PRODUCT INFORMATION TEXT	maa:proposed-product-information	proposed product info	

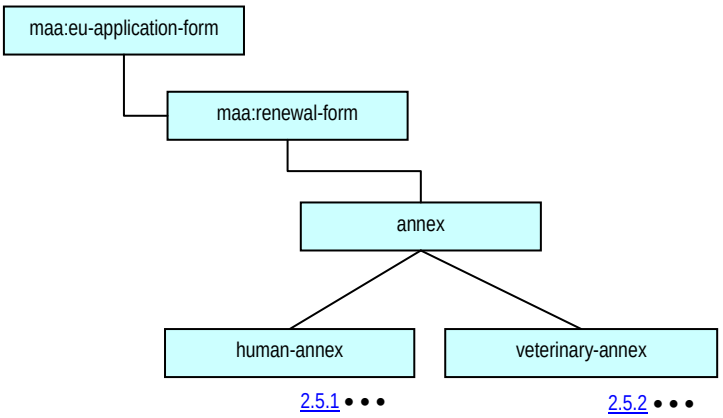
Element Diagram



2.5. DOCUMENTS APPENDED TO THIS APPLICATION

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_formmaa:renewal-form/maa:annex/			
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E25-1	FOR HUMAN MEDICINAL PRODUCTS ONLY	maa:human-annex		See Section 2.5.1
E25-2	FOR VETERINARY MEDICINAL PRODUCTS ONLY	maa:veterinary-annex		See Section 2.5.2

Element Diagram



2.5.1 FOR HUMAN MEDICINAL PRODUCTS ONLY

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:renewal-form/maa:annex/maa:human-annex/		-	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E251-1	Module 1			B521-2
E251-2	1.0 Cover Letter	maa:cover-letter		B521-2
E251-3	1.1 Comprehensive table of content	maa:table-of-content		B521-2
E251-4	1.2 Renewal Application Form with the following annexes:	maa:following-annexes		B521-2
E251-5	A list of all authorised product presentations for which renewal is sought in tabular format	maa:product-presentations		B521-2
E251-6	Details on contact persons:	maa:contact-persons-details		B521-2
E251-7	• Qualified person in the EEA for Pharmacovigilance	maa:EEA-for-Pharmacovigilance		B521-2
E251-8	• Contact person in the EEA with overall responsibility for product defects and recalls	maa:EEA-overall-responsibility		B521-2
E251-9	• Contact person for scientific service in the EEA in charge of information about the medicinal product	maa:EEA-charge-of-information		B521-2
E251-10	List of EU Member States / Norway / Iceland where the product is on the market and indicating for each country which presentations are marketed and the launch date	maa:EU-Member-States		B521-2, B521-3
E251-11	Chronological list of all post-authorisation submissions since grant of the Marketing authorisation or last renewal: a list of all approved or pending Type IA/IB and Type II variations, Extensions, Art 61(3) Notifications, USR, giving the procedure number (where applicable), date of submission, date of approval (if approved) and brief description of the change.	maa:post-authorisation-submissions		B521-2, B251-1
E251-12	Chronological list of Follow-up measures, and for Community Authorisations only, any Specific Obligations submitted since grant of marketing authorisation or last renewal indicating scope, status, date of submission and date when issue has been resolved (where applicable)	maa:community-authorisations		B521-2, B251-1
E251-13	Revised list of all remaining Follow-up measures/post-authorisation commitments, and for Community Authorisations only any Specific Obligations and signed letter of commitment (where applicable)	maa:post-authorisation-commitments		B521-2, B251-1
E251-14	A statement, or when available, a certificate of GMP compliance, not more than three years old, for the manufacturer(s) of the medicinal product listed in the application issued by an EEA competent authority or MRA partner authority. A reference to the Community EudraGMP database will suffice, once this is available	maa:certificate-of-GMP-compliance		B521-2
E251-15	For manufacturing sites of the medicinal product not located in the EEA or in the territory of an MRA partner, a list of the most recent GMP inspections carried out by other authorities indicating the date, inspection team and outcome	maa:most-recent-GMP		B521-2, B251-1
E251-16	A declaration by the Qualified Person (QP) of each of the manufacturing authorisation holders (i.e. located in the EEA) listed in the application form where the active substance(s) is used as a starting material, that the active substance(s) is manufactured in accordance with the guidelines on good manufacturing practice for starting materials as adopted by the Community5	maa:qualified-person		B521-2, B251-1
E251-17	Where different, a declaration by the Qualified Person (QP) of the manufacturing authorisation holder(s) listed in the application form as responsible for batch release, that the active substance(s) is manufactured in accordance with the guidelines on good manufacturing practice for starting materials as adopted by the Community5	maa:starting-materials		B521-2, B251-1
E251-18	1.3.1 SPC, Labelling and Package Leaflet	maa:labelling-package		B521-2
E251-19	1.3.3 Specimen (for Community Authorisations only)	maa:specimen		B521-2

E251-20	1.4 Information about the expert	maa:expert-Information		B521-2
E251-21	1.4.1 Quality (incl. Signature + CV)	maa:quality		B521-2
E251-22	1.4.2 Non-clinical (incl. Signature + CV) – if applicable (for Community Authorisations only)	maa:non-clinical		B521-2, B251-1
E251-23	1.4.3 Clinical (incl. Signature + CV)	maa:clinical		B521-2, B251-1
E251-28	Summary of Pharmacovigilance System (where applicable)	maa: phv-summary		
E251-29	Risk Management Plan (where applicable)	maa:risk-management-plan		
E251-24	Module 2			B521-2, B251-1
E251-25	2.3 Quality Overall Summary (Quality Expert Statement)	maa:quality-expert-statement		B521-2, B251-1
E251-26	2.4 Non-clinical Overview (Non-clinical Expert Statement) – if applicable (for Community Authorisations only)	maa:non-clinical-overview		B521-2, B251-1
E251-27	2.5 Clinical Overview (Clinical Expert Statement)	maa:clinical-overview		B521-2

Business Rules

Rule ID	Element id(s)	Default BR	Rule	Effect(s)
B251-1	E251-11 to E251-13 E251-15, E251-17, E251-22, E251-26	Optional	These elements are optional. The rest are mandatory	
B521-2	E251-1 to E251-27	Mandatory	All mapped elements have a binary (0, 1) data type	
B521-3	E21-9, E251-10	E21-9 is mandatory, E251-10 is optional	If E21-9 is selected (Value="yes"), then E251-10 is required	

2.5.2 FOR VETERINARY MEDICINAL PRODUCTS ONLY

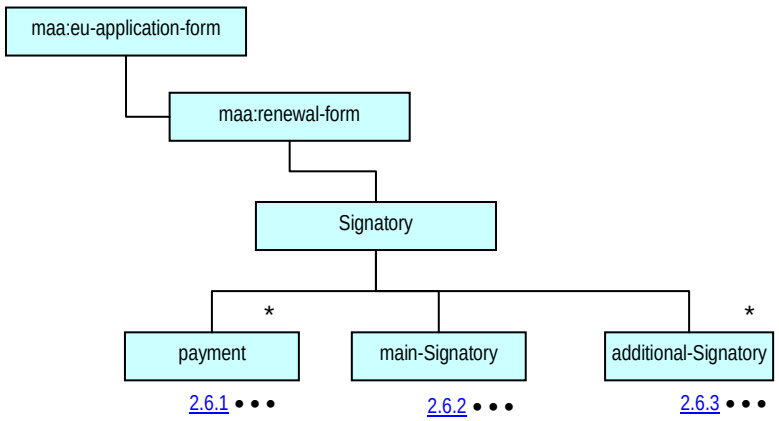
	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:renewal-form/maa:annex/maa:veterinary-annex/		-	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E252-1	1 Cover Letter	maa:cover-letter		B252-1
E252-2	1.1 Comprehensive table of content	maa:table-of-content		B252-1
E252-3	2 Renewal Application Form with the following annexes:	maa:following-annexes		B252-1
E252-4	2.1 List of all authorised product presentations for which renewal is sought in tabular format	maa:product-presentations		B252-1
E252-5	2.2 Details on contact persons:	maa:contact-persons-details		B252-1
E252-6	• Qualified person in the EEA for Pharmacovigilance and the QP for Pharmacovigilance in the MS, if different	maa:EEA-for-Pharmacovigilance		B252-1
E252-7	• Contact person in the EEA with overall responsibility for product defects and recalls	maa:EEA-overall-responsibility		B252-1
E252-8	• Contact person at the address of the Marketing Authorisation Holder (if different from the address of the contact person during the procedure)	maa:EEA-charge-of-information		B252-1
E252-9	2.3 List of EU Member States / Norway / Iceland where the product is on the market and indicating for each country which presentations are marketed and the launch date	maa:EU-Member-States		B252-1, B522-2
E252-10	2.4 Chronological list of all post authorisation submissions (variations, extensions etc.), follow-up measures and, for Community Authorisations only, any Specific Obligations submitted since grant of marketing authorisation or last renewal indicating scope, status, date of submission and date when issue has been resolved	maa:post-authorisation-submissions		B252-1
E252-11	2.5 Revised list of all remaining Follow-up measures and , for Community Authorisations only, any Specific Obligations and signed letter of commitment (where applicable)	maa:community-authorisations		B252-1
E252-12	2.6 Proof of payment of fee, where relevant	maa:proof-of-payment		B252-1
E252-13	2.7 A statement, or when available, a certificate of GMP compliance, not more than three years old, for the manufacturer(s) of the medicinal product listed in the application issued by an EEA competent authority or MRA partner authority.	maa:certificate-of-GMP-compliance		B252-1
E252-14	2.8 In addition, for manufacturing sites of the medicinal product not located in the EEA or in the territory of an MRA partner, a list of the most recent GMP inspections carried out by other authorities indicating the date, inspection team and outcome.	maa:most-recent-GMP		B252-1
E252-15	2.9 A declaration by the Qualified Person (QP) of each of the manufacturing authorisation holders (i.e. located in the EEA) listed in the application form where the active substance(s) is used as a starting material, that the active substance(s) is manufactured in accordance with the guidelines on good manufacturing practice for starting materials as adopted by the Community [6]	maa:qualified-person		B252-1
E252-16	2.10 Where different, a declaration by the Qualified Person (QP) of the manufacturing authorisation holder(s) listed in the application form as responsible for batch release, that the active substance(s) is manufactured in accordance with the guidelines on good manufacturing practice for starting materials as adopted by the Community[6]	maa:starting-materials		B252-1
E252-17	3 SPC, Labelling and Package Leaflet	maa:labelling-package		B252-1
E252-18	4 Quality expert statement, including:	maa:quality-expert-statement		B252-1
E252-19	4.1 Currently authorised specifications for the active substance and the finished product	maa:authorised-specifications-active-substance		B252-1
E252-20	4.2 Qualitative and quantitative composition in terms of the active substance(s) and the excipient(s)	maa:composition		B252-1
E252-21	5 Clinical expert statement	maa:clinical-expert-statement		B252-1
E252-22	6 Safety expert statement	maa:safety-expert-statement		B252-1
E252-23	7 Periodic Safety Update Report and Summary Bridging Report if applicable	maa:periodic-safety-update		B252-1
E252-24	8 Declaration of current TSE status	maa:TSE-status		B252-1

Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B252-1	E252-1 to E251-24	Mandatory	All mapped elements have a binary (0, 1) data type	
B522-2	E21-9, E252-9	E21-9 is mandatory, E251-9 is optional	If E21-9 is selected (value="yes"), then E252-9 is required	

2.6. SIGNATURE/DECLARATION

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_formmaa:renewal-form/maa:Signatory/			
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E26.1	I hereby make application for the above Marketing Authorisation to be renewed. I declare that the quality of the product, in respect of the methods of preparation and control, has been regularly updated by variation procedure to take account of technical and scientific progress in accordance with Article 23 of Directive 2001/83/EC or Article 27 (1) of Directive 2001/82/EC or Article 16 of Regulation (EC) No 726/2004. The product conforms with current CHMP/CVMP quality guidelines where relevant. I confirm that no changes have been made to the product particulars other than those approved by the Competent Authority.	-	-	-
E26.2	Payment Section (No label)	rdm:payment		See Section 2.6.1
E26.3	Main Signatory Section (No label)	rdm:main-Signatory		See section 2.6.2
E26.4	Additional Signatories Section (No label)	rdm:additional-Signatory		See section 2.6.3

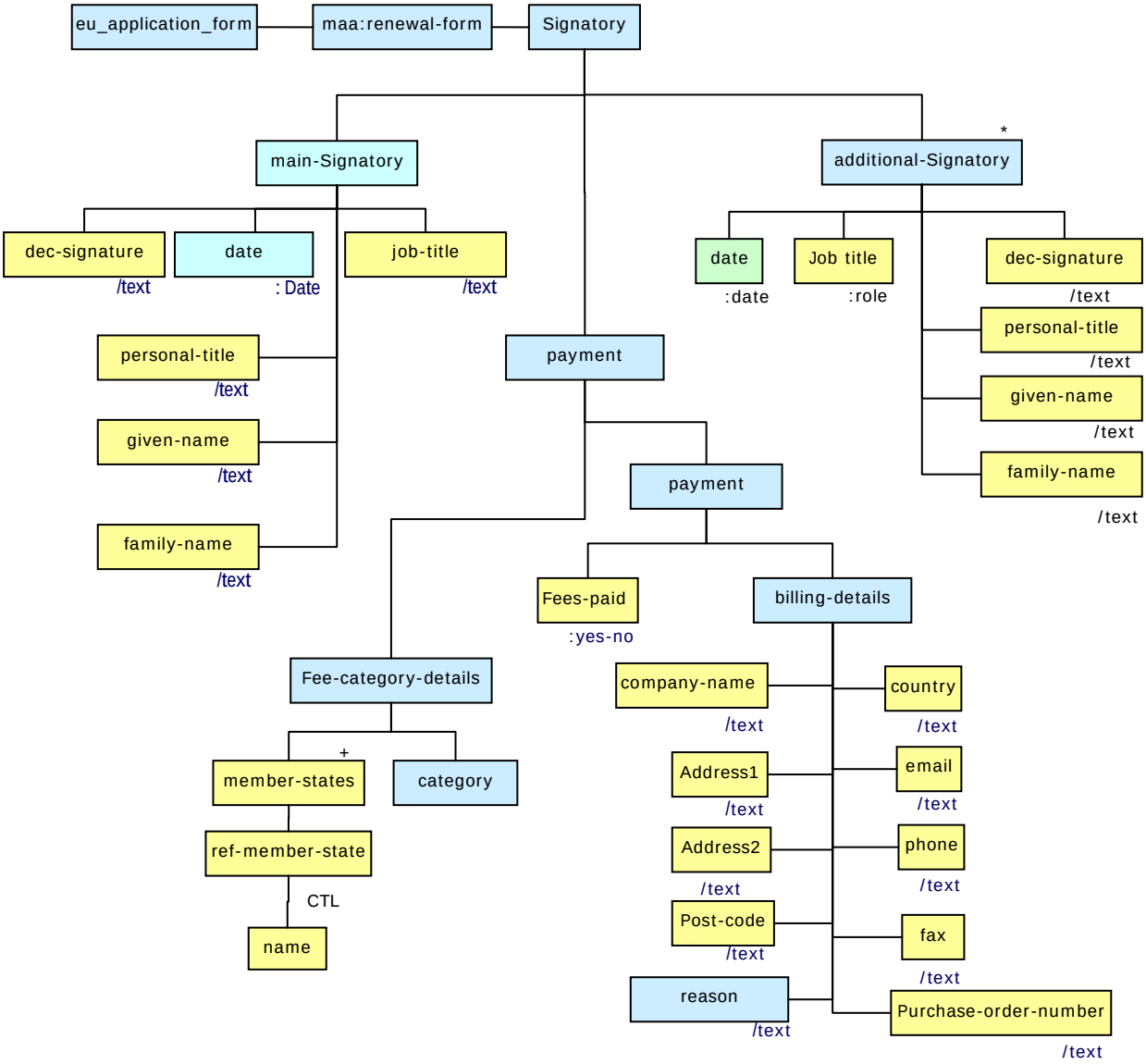
Element Diagram



2.6.1 Payment Section

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_formmaa:renewal-form/maa:Signatory/maa:payment			
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E261.1	Proof of payment (when relevant)			B261-1
E261.2	Have all relevant fees been prepaid to competent authorities?			
E261.3	Yes	maa:payment/maa:fees-paid (1)		B261-1, B261-2, B261-3
E261.4	No	maa:payment/maa:fees-paid (0)		B261-1, B261-2, B261-3
E261.5	For Member States	maa:payment/maa:fee-category-details/rdm:member-states/rdm:ref-member-state/rdm:name		B261-1, B261-2, B261-3
E261.6	Please specify fee category under National rules	maa: payment/maa: fee-category-details/maa:category		B261-1, B261-2, B261-3
E261.7	Please specify the reasons according to National requirements (exemption or later payment).	maa:payment/maa:payment/ maa:billingdetails/ maa:reason		B261-1, B261-2, B261-3
E261.8	Billing address (when relevant)			B261-1, B261-2, B261-3
E261.9	For Member States	maa:payment/maa:payment/maa:billing-details /rdm:member-states/rdm:ref-member-state/rdm:name		B261-1, B261-2, B261-3
E261.10	Company Name	maa:payment/maa:payment/maa:billing-details/ rdm:contact-details-type/maa:company-name		B261-1, B261-2, B261-3
E261.11	VAT Number	maa:payment/maa:payment/maa:billing-details/maa:VAT-number		B261-1, B261-2, B261-3
E261.12	Address1	maa:payment/maa:payment/maa:billing-details/ rdm:contact-details-type/rdm:address	Role>Party>Contact Details > Address	B261-1, B261-2, B261-3
E261.13	Address2	maa:payment/maa:payment/maa:billing-details/ rdm:contact-details-type/rdm:city	Role>Party>Contact Details > city	B261-1, B261-2, B261-3
E261.14	Postcode	maa:payment/maa:payment/maa:billing-details/ rdm:contact-details-type/rdm:postcode	Role>Party>Contact Details > postcode	B261-1, B261-2, B261-3
E261.15	Country	maa:payment/maa:payment/maa:billing-details/ rdm:contact-details-type/rdm:country	Role>Party>Contact Details > Address > Country CTL	B261-1, B261-2, B261-3
E261.16	Telephone	maa:payment/maa:payment/maa:billing-details/ rdm:contact-details-type/rdm:phone	Role>Party>Contact Details > Electronic Contact > electronic contact	B261-1, B261-2, B261-3
E261.17	Telefax	maa:payment/maa:payment/maa:billing-details/ rdm:contact-details-type/rdm:fax	Role>Party>Contact Details > Electronic Contact > electronic contact	B261-1, B261-2, B261-3
E261.18	E-mail	maa:payment/maa:payment/maa:billing-details/ rdm:contact-details-type/rdm:email	Role>Party>Contact Details> Electronic Contact > electronic contact	B261-1, B261-2, B261-3
E261.19	Purchase Order (PO) Number	maa:payment/maa:payment/maa:billing-details/Purchase-order-number		B261-1, B261-2, B261-3

Element Diagram



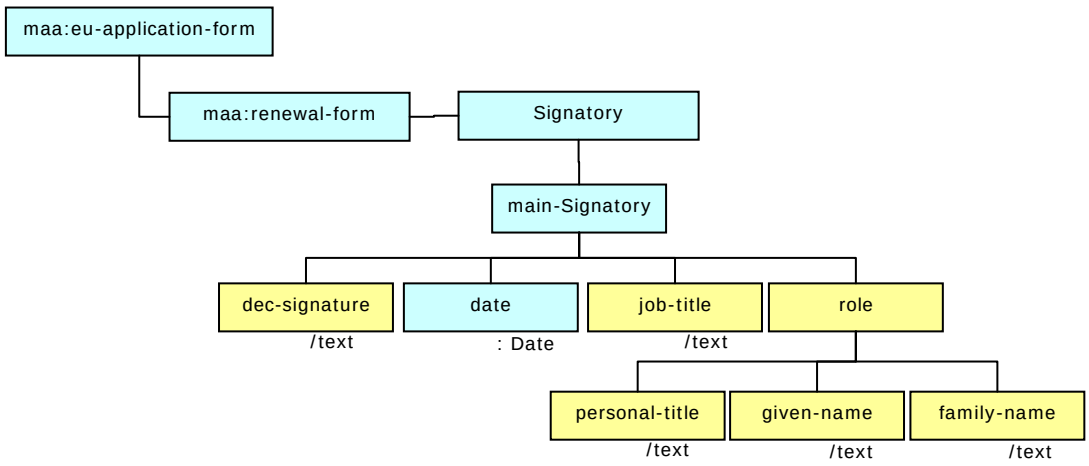
Business Rules

Rule ID	Element id(s)	Default BR	Rule	Effect(s)
B261-1	E261.1, E261.2, E261.19		If E261.1 is selected (value = 1), then E261.2 – 261.19 are visible.	If E261.1 is not selected (value = 0), then E261.2 – E261.18 are invisible.
B261-2	E261.3, E261.4, E261.19		If E261.3 is selected (value = 1), then E261.5 - E261.6 is visible.	If E261.3 is selected (value = 0), then E261.7, … E2616.19 is invisible, rest are visible
B261-3	E261.3, E261.4, E261.19		If E261.4 is selected (value = 0), then E261.7, … E2616.19 is visible	If E261.4 is not selected (value = 1), then E261.5 - E261.6 is invisible, rest are visible

2.6.2 Main Signatory Section

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_formmaa:renewal-form/maa:Signatory/rdm:main-Signatory			
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E262.1	Main Signatory	rdm: dec-signature	Application>Role>Party>Person>given name	Is this the same as First name?
E262.2	Title	rdm:role/rdm:personal-title	Application>Role>Party>Person>personal title	
E262.3	First name	rdm:role/rdm:given-name	Application>Role>Party>Person>given name	Is this the same as Main Signatory?
E262.4	Surname	rdm:role/rdm:family-name	Application>Role>Party>Person>family name	
E262.5	Status (Job Title)	rdm:job-title	Application>Role>Party>Person>job title	
E262.6	Date	rdm:date	Application > signature date	

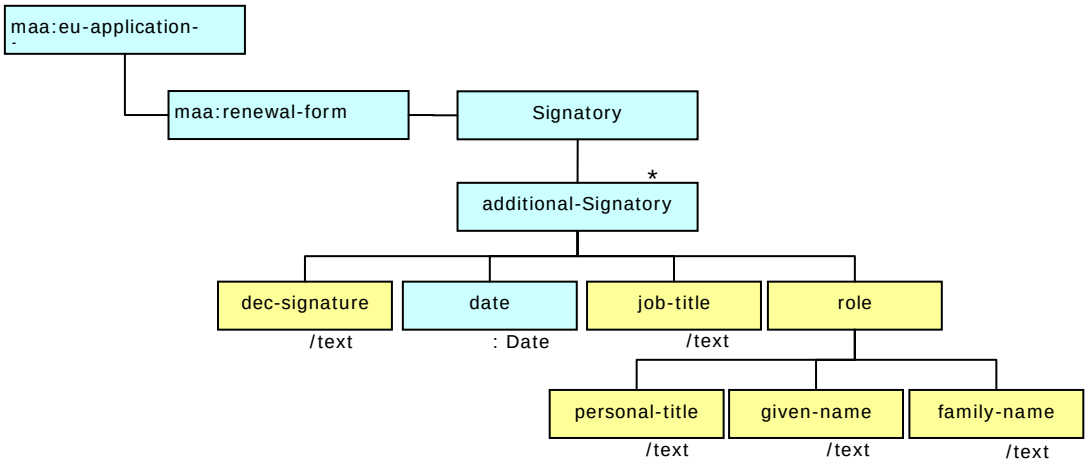
Element Diagram



2.6.3 Additional Signatories Section

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_formmaa:renewal-form/maa:Signatory/rdm:additional-Signatory			
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E263.1	Signatory	rdm: dec-signature	Application>Role>Party>Person>given name	Is this the same as First name?
E263.2	Title	rdm:role/rdm:personal-title	Application>Role>Party>Person>personal title	
E263.3	First name	rdm:role/rdm:given-name	Application>Role>Party>Person>given name	Is this the same as Signatory?
E263.4	Surname	rdm:role/rdm:family-name	Application>Role>Party>Person>family name	
E263.5	Status (Job Title)	rdm:job-title	Application>Role>Party>Person>job title	
E262.6	Date	rdm:date	Application > signature date	

Element Diagram



2.7. Footer Section

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_formmaa:renewal-form/maa:Signatory/rdm:additional-Signatory			
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E27.1	[1] Human Medicinal Products: Number to be completed by the Marketing Authorisation Holder, reflecting the correct sequential Mutual Recognition Procedure Number according to Volume 2A, Chapter 2, 7. Numbering System for the Procedures for Mutual Recognition as published on the Website of the European Commission (http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/homev2.htm) Veterinary Medicinal Products: Renewal number to be issued by the Reference Member State before submission of the application according to the corresponding CMD(v) Best Practice Guide (http://www.hma.eu)	-	-	-
E27.2	[2] For centrally authorised products a list of EU Member States / Norway / Iceland where the product is on the market should be provided in a separate appendix	-	-	-
E27.3	[3] For centrally authorised products this information, including packaging and pack size(s), should be provided in tabular format in a separate appendix (cf. Annex A to CHMP/CVMP Opinion)	-	-	-
E27.4	[4] As specified in section 2.4.3 in Part 1A. If different, attach letter of authorisation	-	-	-
E27.5	[5 & 6] Where more than one Qualified Person (QP) is involved, a single declaration by one of the QPs that the active substance(s) used as a starting material are manufactured in accordance with the guidelines on good manufacturing practice for starting materials as adopted by the Community, may be submitted provided that: • The declaration makes it clear that it is signed on behalf of all the involved QPs. • The arrangements are underpinned by a technical agreement as described in Chapter 7 of the GMP Guide and the QP providing the declaration is the one identified in the agreement as taking specific responsibility for the GMP compliance of the active substance manufacturer(s).	-	-	-

3. ABOUT THIS DOCUMENT

3.1. Definitions, Acronyms, and Abbreviations

3.1.1 Acronyms

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