Electronic Application Form Data Exchange Standard 3.0

Supplementary Specification Annex 2 "Variations Form" v.1.20.0.0

Table of contents

1. Introduction

1.1. How to read this document

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

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

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

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

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

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

1.2. Sections Components

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

1.2.1. The Elements Mapping Table

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

The table consists in 4 columns:

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

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

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

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

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

<u>**Colours**</u>

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.

- o "ignored" based on the decision of the RDM team not to map the element
- o "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.

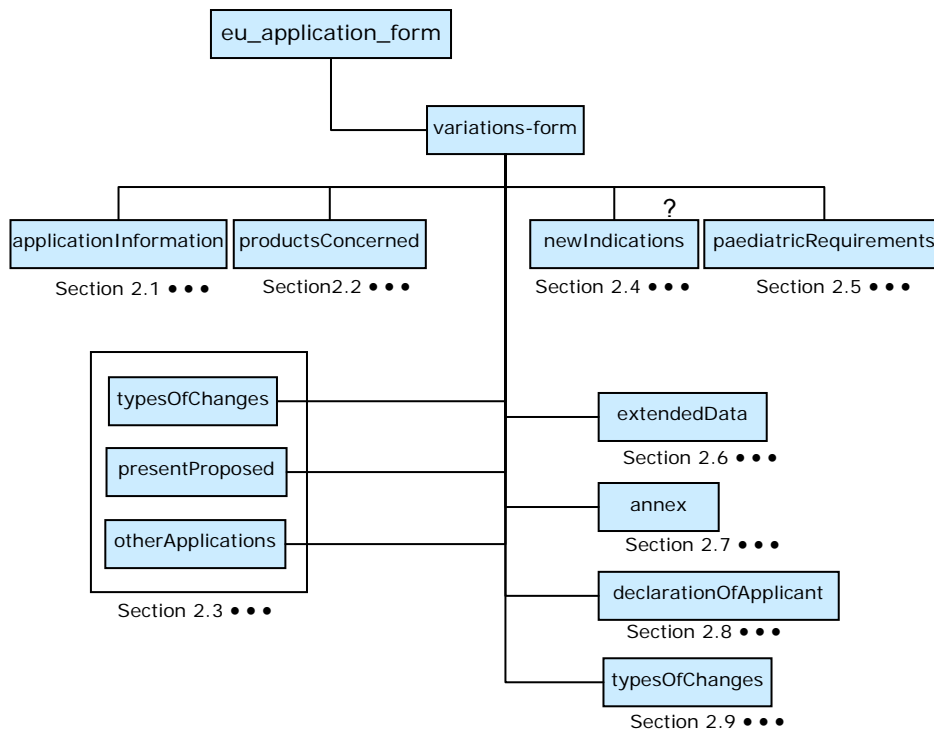The model is called "Element Tree Diagram" (ETD)

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. Variations Form

The "variations-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.

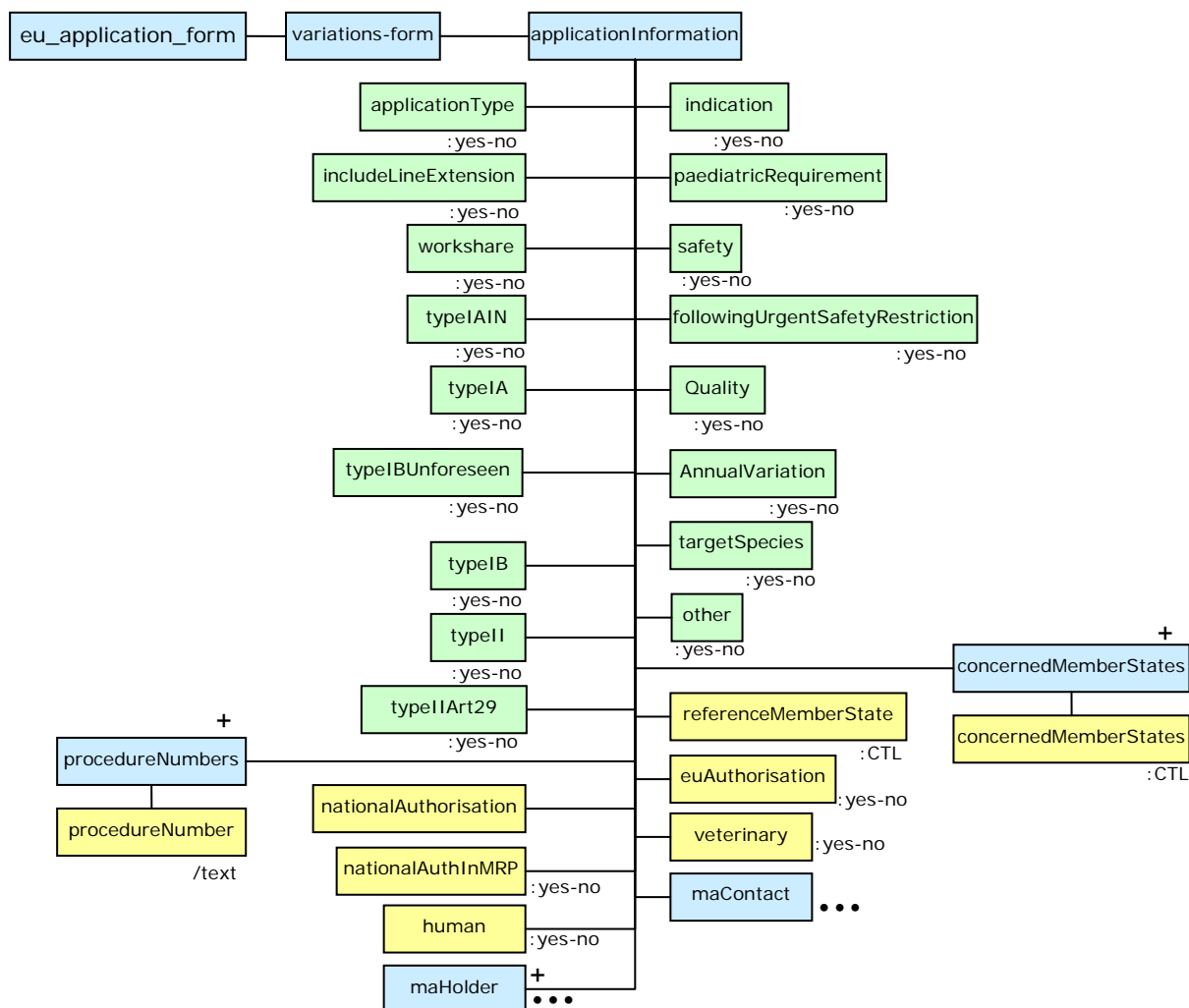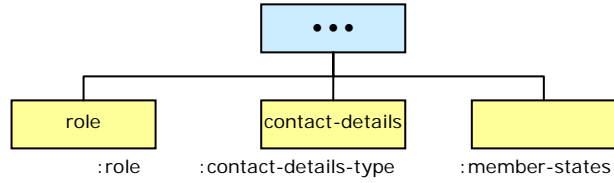|	**Common DES 3.0 Context**		**Common RDM Entry point**	
	maa:eu_application_form/maa:variations-form/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E2.1	APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION	maa:applicationInformation/		See Section 2.1
E2.2	PRODUCTS CONCERNED BY THIS APPLICATION	maa:productsConcerned/		See Section 2.2
E2.3	TYPE OF CHANGE(S)	maa:typesOfChanges/ and maa:presentProposed/ and maa:otherApplications/		See Section 2.3
E2.4	Type II Variations – new Indications – orphan medicinal product information	maa:newIndications/		See Section 2.4
E2.5	Type II Variations – Paediatric requirements	maa:paediatricRequirements/		See Section 2.5
E2.6	Type II variations – Extended data/market exclusivity	maa:extendedData/		See Section 2.6
E2.7	The following amended product information proposals are provided in the relevant sections of the EU-CTD format for NTA volume 6B format, where applicable:	maa:annex/		See Section 2.7
E2.8	DECLARATION OF APPLICANT	maa:declarationOfApplicant/		See Section 2.8
E2.9	Signatures	maa:Signatory/		See Section 2.9

Element Tree Diagram

2.1. APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION

Elem Id	Label	DES 3.0 Mapping	RDM 3.0 Mapping	Remarks
	Common DES 3.0 Context		**Common RDM Entry point**	
	maa:eu_application_form/maa:variations-form/maa:applicationInformation/		Application >	
E21-1	Human	maa:human	Domain CTL	B21-1
E21-2	Veterinary	maa:veterinary	Domain CTL	B21-1
E21-3	National Authorisation in MRP/DCP	maa:nationalAuthInMRP	Procedure Type CTL	
E21-4	EU Authorisation	maa:euAuthorisation	Procedure Type CTL	
E21-5	National Authorisation	maa:nationalAuthorisation	Procedure Type CTL	
E21-6	Variation procedure number(s)[1]:	maa:procedureNumbers/ maa:procedureNumber	MP Procedure > procedure number	
E21-7	Reference Member State / Reference Authority for worksharing	maa:.referenceMemberState	MP Procedure > Role > Country CTL	
E21-8	Concerned Member State(s)	maa:concernedMemberStates/ maa:concernedMemberState	MP Procedure > Role > Country CTL	
E21-9	Type of Application (tick all applicable options)			
E21-10	Single variation	maa:applicationType (value=1)	Var Grouping CTL	B21-2
E21-11	Grouping of variations	maa:applicationType (value=2)	Var Grouping CTL	B21-2, B21-3
E21-12	Include a line extension[3]	maa:includeLineExtension	Var Grouping CTL	B21-3
E21-13	Worksharing	maa:workshare	Var Grouping CTL	
E21-14	Type IA$_{IN}$	maa:typeIAIN	Var Type Summary CTL	B21-4
E21-15	Type IA	maa:typeIA	Var Type Summary CTL	B21-4
E21-16	Type IB unforeseen[2]	maa:typeIBUnforeseen	Var Type Summary CTL	B21-4, B21-5,
E21-17	Type IB	maa:typeIBForeseen	Var Type Summary CTL	B21-4, B21-5
E21-18	Type II	maa:typeII	Var Type Summary CTL	B21-4, B21-5, B24-1, B26-2
E21-19	Type II Art. 29[4]	maa:typeIIArt29	Var Type Summary CTL	B21-4, B21-5, B24-1, B26-2
E21-20	Change(s) concern(s) (for Type IB and Type II variations only, tick all changes applicable)			
E21-21	Indication	maa:indication	Var Domain Summary CTL	B21-5, B24-1
E21-22	Paediatric Requirements	maa:paediatricIndication	Var Domain Summary CTL	B21-5, B24-1
E21-23	Safety	maa:safety	Var Domain Summary CTL	B21-5, B21-6
E21-24	Following Urgent Safety Restriction	maa:followingUrgentSafetyRestriction	Var Domain Summary CTL	B21-6
E21-25	Quality	maa:Quality	Var Domain Summary CTL	B21-5
E21-26	Annual variation for human influenza vaccines	maa:AnnualVariation	Var Domain Summary CTL	B21-5
E21-27	Non-food producing target species	maa:targetSpecies	Var Domain Summary CTL	B21-5
E21-28	Other	maa:other	Var Domain Summary CTL	B21-5
E21-29	Name and address of the Applicant/MA Holder[5]			
E21-30	Company Name	maa:maHolder/maa:role/rdm:name	Application > Party > Organisation > Name	
E21-31	Address1	maa:maHolder/maa:contact-details/rdm:address	Application > Role> Party>Contact Details > Address	
E21-32	Address2	maa:maHolder/maa:contact-details /rdm:city	Application > Role> Party>Contact Details > City	
E21-33	PostCode	maa:maHolder/maa:contact-details/rdm:post-code	Application > Role> Party>Contact Details > Post Code	
E21-34	Country	maa:maHolder/maa:contact-details rdm:country	Application > Role> Party>Contact Details > Address > Country CTL	
E21-35	Name and address of contact person[6]			
E21-36	Title	maa:maContact/maa:role/rdm:personal-title	Role>Party>Person> Personal Title	
E21-37	First name	maa:maContact/maa:role/rdm:given-name	Role>Party>Person> given name	
E21-38	Surname	maa:maContact/maa:role/rdm:family-name	Role>Party>Person> family name	

E21-39	Company Name	maa:maContact/maa:contact-details/rdm:companyName	Role>Party>Person> Company name	
E21-40	Address1	maa:maContact/maa:contact-details/rdm:address	Role>Party>Contact Details > Address	
E21-41	Address2	maa:maContact/maa:contact-details/rdm:city	Role>Party>Contact Details > City	
E21-42	PostCode	maa:maContact/maa:contact-details/rdm:post-code	Role>Party>Contact Details > Post Code	
E21-43	Country	maa:maContact/maa:contact-details/rdm:country	Role>Party>Contact Details > Address > Country CTL	
E21-44	Telephone	maa:maContactmaa:contact-details/rdm:phone	Role>Party>Contact Details > Electronic contact>electronic contact	
E21-45	Telefax	maa:maContact/maa:contact-details/rdm:fax	Role>Party>Contact Details > Electronic contact>electronic contact	
E21-46	Email	maa:maContact/maa:contact-details/rdm:email	Role>Party>Contact Details > Electronic contact>electronic contact	

Element Tree Diagram

Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B21-1	E21-1, E21-2	Mandatory	Mutually Exclusive	
B21-2	E21-10, E21-11	Mandatory	Mutually Exclusive	
B21-3	E21-11, E21-12	E21-11 is mandatory , E21-12 is optional	If E21-11 is selected, then E21-12 is displayed but not required.	
B21-4	E21-14 to E21-19	Mandatory	At least one mandatory, more than one allowed	
B21-5	E21-21 to E21-23, E21-25 to E21-28, E21-16 to E21-19	Mandatory	If any of E21-16 to E21-19 are selected, then at least one of E21-21 to E21-23, E21-25 to E21-28 is required, more than one are allowed	
B21-6	E21-23, E21-24	E21-23 is Mandatory, E21-24 is optional	If E21-23 is selected, then E21-24 is displayed but it is still optional	

2.2. PRODUCTS CONCERNED BY THIS APPLICATION

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:variations-form/maa:productsConcerned/maa:products/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E22-1	MRP Variation Number[8]	maa:redBox/maa:variationNumber		
E22-2	Active Substance(s)	maa:redBox/maa:activeSubstances		
E22-3	ActiveSubstance	maa:redBox/maa:activeSubstances/maa:active-substance/maa:substance-name/maa:name		
E22-4	Member States	maa:redBox/maa:bluebox/maa:memberState		
E22-5	MA Number[8]	maa:redBox/maa:bluebox/maa:greebox/maa:maNumbers/maa:maNumber		
E22-6	Invented Name	maa:redBox/maa:bluebox/maa:greebox/maa:inventedName		
E22-7	MA Holder Name	maa:redBox/maa:bluebox/maa:greebox/maa:maHolderName		
E22-8	Pharmaceutical Form name	maa:redBox/maa:bluebox/maa:greebox/maa:pharmaceutical-form-name		
E22-9	Strength	maa:redBox/maa:bluebox/maa:greebox/maa:strength		
E22-10	Units	maa:redBox/maa:bluebox/maa:greebox/maa:units		

Element Tree Diagram

2.3. TYPE OF CHANGE(S)

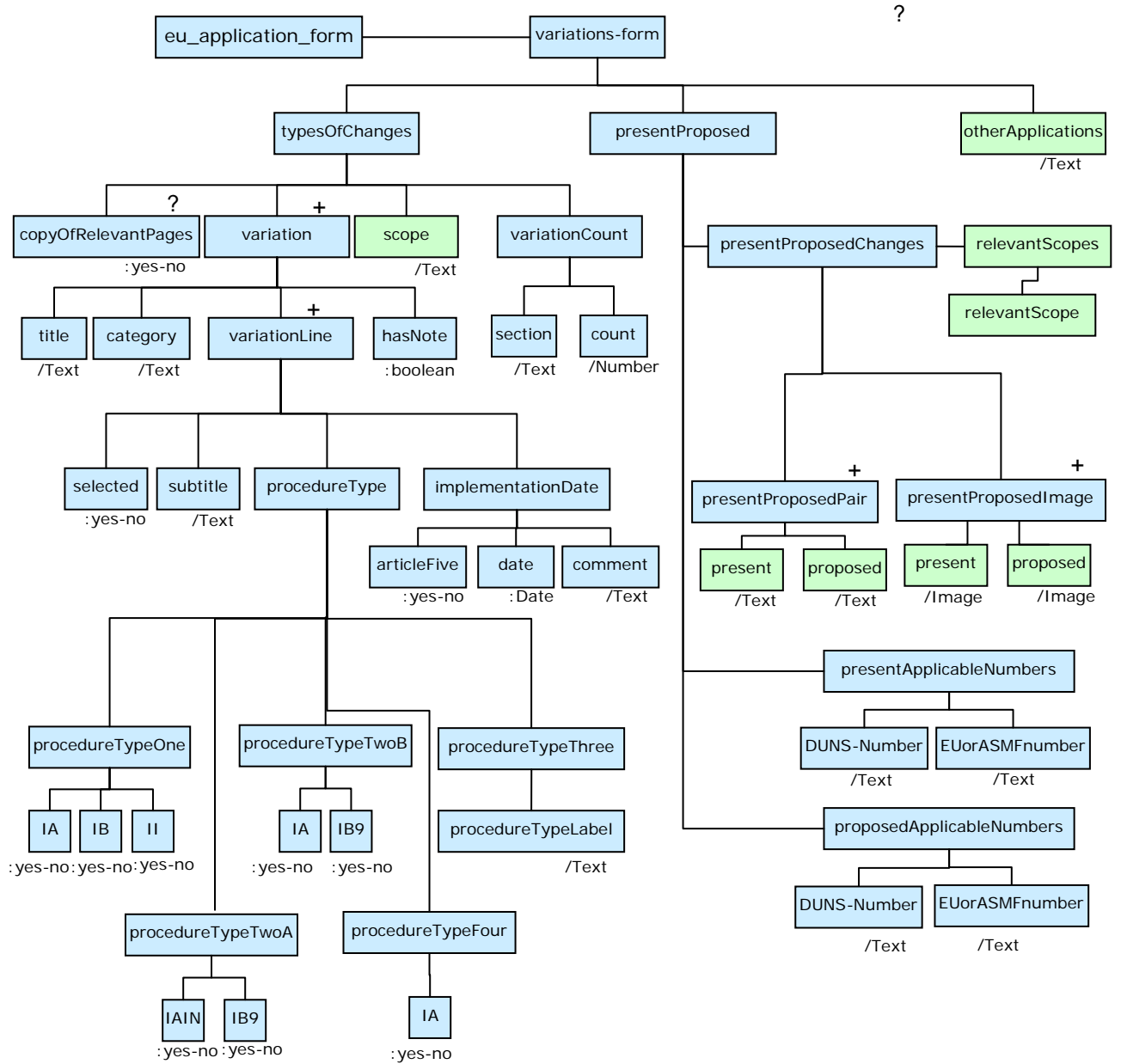|	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:variations-form/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E23-1	Copy of the relevant page(s) from the Guideline for this/these change(s) is attached and the relevant boxes for conditions and documentations (both for Type IA and Type IB) are ticked.	maa:typesofChanges/ maa:copyOfRelevantPages		
E23-2	Variation	maa:typesofChanges/maa:variationCount/ maa:section		
E23-3	Selected	maa:typesofChanges/maa:variationCount/ maa:count		
E23-4	Category (No label present)	maa:typesofChanges/maa:variation/ maa:category		
E23-5	Title (No label present)	maa:typesofChanges/maa:variation/maa:title		
E23-6	Selected (No label present)	maa:typesofChanges/ maa:variation/maa:variationLine/rdm:selected		
E23-7	Subtitle (No label present)	maa:typesofChanges/ maa:variation/maa:variationLine/rdm:subtitle		
E23-8	Procedure type			
E23-9	IA	maa:typesofChanges/ maa:variation/maa:variationLine/rdm:procedure Type/rdm:procedureTypeOne/rdm:IA		
E23-10	IB	maa:typesofChanges/ maa:variation/maa:variationLine/rdm:procedure Type/rdm:procedureTypeOne/rdm:IB		
E23-11	II	maa:typesofChanges/ maa:variation/maa:variationLine/rdm:procedure Type/rdm:procedureTypeOne/rdm:II		
E23-12	IA$_{IN}$	maa:typesofChanges/ maa:variation/maa:variationLine/rdm:procedure Type/rdm:procedureTypeTwoA/rdm:IAIN		
E23-13	IB^9	maa:typesofChanges/ maa:variation/maa:variationLine/rdm:procedure Type/rdm:procedureTypeTwoA/rdm:IB9		
E23-14	IA	maa:typesofChanges/ maa:variation/maa:variationLine/rdm:procedure Type/rdm:procedureTypeTwoB/rdm:IA		
E23-15	IB^9	maa:typesofChanges/ maa:variation/maa:variationLine/rdm:procedure Type/rdm:procedureTypeTwoB/rdm:IB9		
E23-16	Type Three Procedure (No label present)	maa:typesofChanges/ maa:variation/maa:variationLine/rdm:procedure Type/rdm:procedureTypeThree/rdm: procedureTypeLabel		
E23-17	IA	maa:typesofChanges/ maa:variation/maa:variationLine/rdm:procedure Type/rdm:procedureTypeFour/rdm:IA		
E23-18	Subtitle (No label present)	maa:typesofChanges/ maa:variation/maa:variationLine/rdm:subtitle		
E23-19	Art. 5	maa:typesofChanges/ maa:variation/maa:variationLine/rdm:implemen tationDate/rdm:articleFive		
E23-20	Implement. Date	maa:typesofChanges/ maa:variation/maa:variationLine/rdm:implemen tationDate/rdm:date		
E23-21	Comment	maa:typesofChanges/ maa:variation/maa:variationLine/rdm:implemen tationDate/rdm:comment		
E23-22	PRECISE SCOPE AND BACKGROUND FOR CHANGE, AND JUSTIFICATION FOR GROUPING, WORKSHARING AND CLASSIFICATION OF UNFORESEEN CHANGES (if applicable) (include a description and background of all the proposed changes. In case of grouping and worksharing a justification should be provided in a separate paragraph. If a variation concerns	maa:typesofChanges/maa:scope	scope, background	

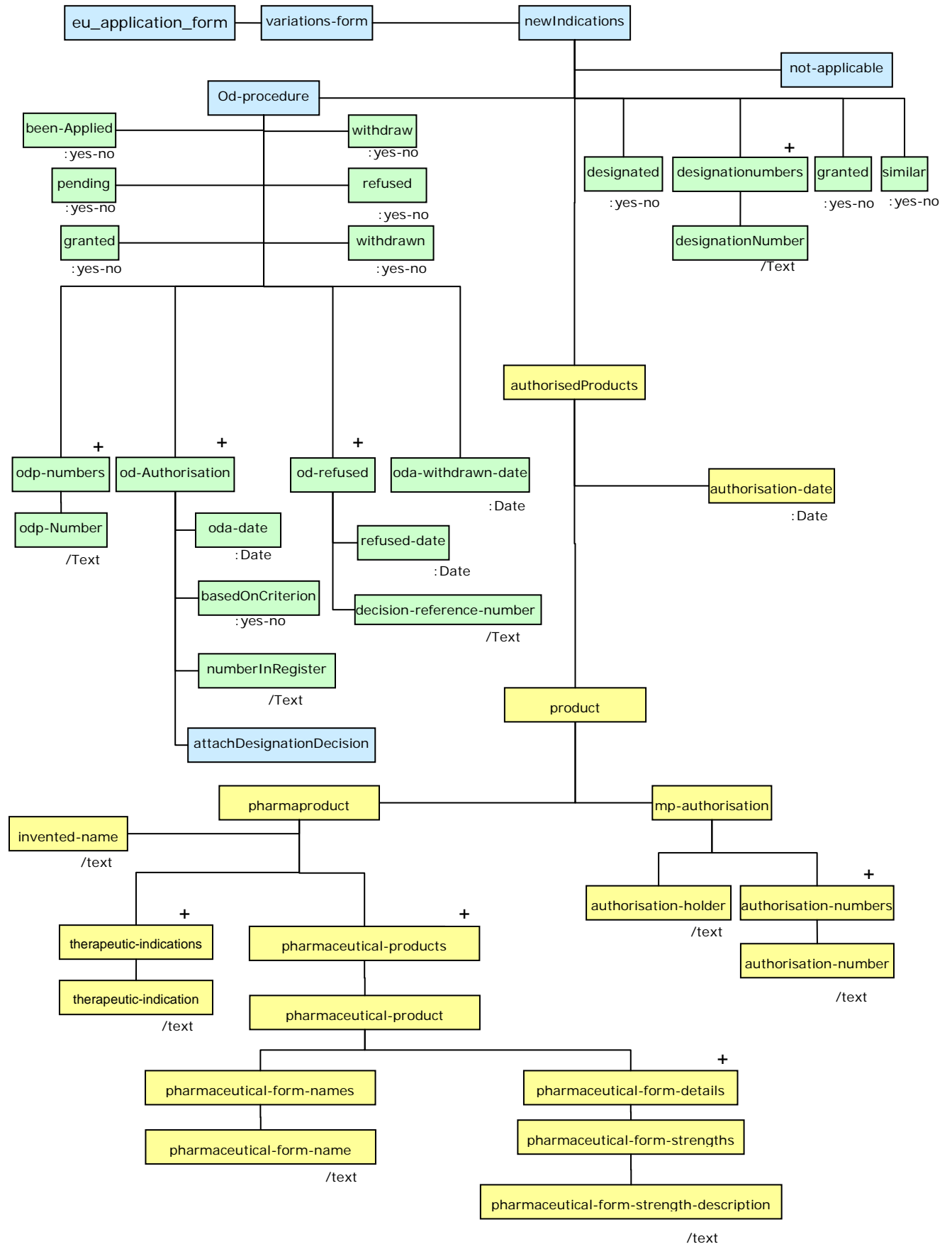|				
	an unforeseen change, include a justification for its proposed classification).			
E23-23	RelevantScope	maa:presentProposed/maa:presentproposedChanges/maa:relevantScopes/maa:relevantScope		
E23-24	PRESENT	maa:presentProposed/maa:presentproposedChanges/maa:presentProposedPair/maa:present	Application Proposal > present product info	
E23-25	PRESENT- IMAGE	maa:presentProposed/maa:presentproposedChanges/maa:presentProposedImage/maa:present		
E23-26	D-U-N-S number	maa:presentProposed/maa:presentApplicableNumbers/maa: DUNS-number		
E23-27	EU or National ASMF number	maa:presentProposed/maa: presentApplicableNumbers/maa: EUorASMFnumber		
E23-28	PROPOSED	maa:presentProposed/maa:presentProposedPair/maa:proposed	Application Proposal > present product info	
E23-29	PROPOSED- IMAGE	maa:presentProposed/maa:presentProposedImage/maa:proposed		
E23-30	D-U-N-S number	maa:presentProposed/maa: proposedApplicableNumbers/maa:DUNS-number		
E23-31	EU or National ASMF number	maa:presentProposed/maa: proposedApplicableNumbers/maa:EUorASMFnumber		
E23-32	OTHER APPLICATIONS	maa:otherApplications	Application > other application	

Element Tree Diagram

```
eu_application_form ── variations-form                              ?
                              │
        ┌─────────────────────┼──────────────────────────────────┐
   typesOfChanges        presentProposed                    otherApplications
        │                      │                                 /Text
   ┌────┼──────┬────────┐      │
   ?           +                      │
copyOfRelevantPages  variation  scope    variationCount    presentProposedChanges ── relevantScopes
   :yes-no              │      /Text         │                    │                      │
                  ┌─────┼──────┬─────┐   ┌───┴───┐               │                  relevantScope
                  +                     section  count           │
               title  category  variationLine  hasNote  /Text  /Number
               /Text   /Text        │         :boolean          │
                          ┌─────┬────┴─────┬──────────┐     ┌────┴──────┐
                                                            +            +
                     selected  subtitle  procedureType  implementationDate   presentProposedPair   presentProposedImage
                     :yes-no   /Text        │              │                    │                     │
                                            │         ┌────┼─────┐         ┌────┴────┐         ┌───────┴───────┐
                                            │     articleFive date comment present proposed   present      proposed
                                            │      :yes-no  :Date /Text    /Text   /Text      /Image       /Image
        ┌───────────────────┬──────────────┤
   procedureTypeOne   procedureTypeTwoB   procedureTypeThree
        │                   │                │                         presentApplicableNumbers
   ┌────┼────┐          ┌───┴───┐      procedureTypeLabel               ┌──────────┴──────────┐
   IA   IB   II         IA     IB9          /Text                   DUNS-Number      EUorASMFnumber
 :yes-no :yes-no :yes-no :yes-no :yes-no                              /Text             /Text
              │                                                      proposedApplicableNumbers
       procedureTypeTwoA   procedureTypeFour                          ┌──────────┴──────────┐
          ┌───┴───┐            │                                  DUNS-Number      EUorASMFnumber
        IAIN     IB9           IA                                    /Text             /Text
       :yes-no :yes-no       :yes-no
```

2.4. Type II Variations – new Indications – orphan medicinal product information

Elem Id	Label	DES 3.0 Mapping	RDM 3.0 Mapping	Remarks
		Common DES 3.0 Context	**Common RDM Entry point**	
		maa:eu_application_form/maa:variations-form/maa:newIndications/	Application >	
E24-1	Select flag if not applicable; section will not be displayed.	maa:not-applicable		B24-7
E24-2	Has orphan designation been applied for, for this new indication?			
E24-3	Yes	maa:been-applied (Value=1)	Orphan Designation > has od applied	B24-2, B24-8
E24-4	No	maa:been-applied (Value=0)	Orphan Designation > has od applied	B24-2
E24-5	Orphan designation procedure number	maa:od-procedure/maa:odp-numbers/maa:odp-number	Orphan Designation > od procedure number	B24-8
E24-6	Pending	maa:od-procedure/maa:pending	Orphan Designation > Authorisation Status CTL	B24-3
E24-7	Orphan designation granted	maa:od-procedure/maa:granted	Orphan Designation > Authorisation Status CTL	B24-3, B24-9
E24-8	Date	maa:od-procedure/maa:od-authorisation/oda-date	Orphan Designation > od status date	B24-9
E24-9	Based on criterion of "significant benefit"			B24-9
E24-10	Yes	maa:od-procedure/maa:od-authorisation/maa: basedOnCriterion (Value=1)	Orphan Designation > is based significant benefit	B24-10, B24-9
E24-11	No	maa:od-procedure/maa:od-authorisation/maa: basedOnCriterion (Value=0)	Orphan Designation > is based significant benefit	B24-10, B24-9
E24-12	Number in the EU Register of Orphan Medicinal Products	maa:od-procedure/maa:od-authorisation /maa:numberInRegister	Orphan Designation > od community reg number	B24-9
E24-13	Attach copy of the Designation Decision	maa:od-procedure/maa:od-authorisation /maa: attachDesignationDecision	od decision ref number	B24-9
E24-14	Orphan Designated Refused	maa:od-procedure /maa:refused	Orphan Designation > Authorisation Status CTL	B24-3, B24-13
E24-15	Date	maa:od-procedure/maa:od-refused/maa:oda-refused-date	Orphan Designation > od status date	B24-13
E24-16	Commission Decision Reference number	maa:od-procedure/maa:od-refused/oda-decision-reference-number	Orphan Designation > od decision ref number	B24-13
E24-17	Orphan Designation Withdrawn	maa:od-procedure/maa:withdrawn	Orphan Designation > Authorisation Status CTL	B24-3, B24-14
E24-18	Date	maa:od-procedure/maa:oda-withdrawn-date	Orphan Designation > od status date	B24-14
E24-19	Information relating to orphan market exclusivity			
E24-20	Has any medicinal product been designated as an Orphan medicinal product for a condition relating to the new indication proposed in this variation application?			
E24-21	Yes	maa:designated (Value=1)	Orphan Designation > has mp designated orphan	B24-4, B24-11
E24-22	No	maa:designated (Value=0)	Orphan Designation > has mp designated orphan	B24-11
E24-23	Please specify the EU Orphan Designation Number(s):	maa:designationNumbers/ maa:designationNumber	OD Number > eu od number	B24-4, B24-11
E24-24	Has any of the designated Orphan medicinal product(s) been granted a marketing authorisation in the EU?			B24-11
E24-25	Yes	maa:granted (Value=1)	Orphan Designation > has mp granted ma	B24-5, B24-11, B24-12
E24-26	No	maa:granted (Value=0)	Orphan Designation > has mp granted ma	B24-5, B24-11, B24-12
E24-27	Please specify for authorised product:			B24-12
E24-28	Product (invented) name	maa:authorisedProducts/maa:product/ rdm:pharmaproduct/rdm:invented-name	Medicinal Product > medicinal product name	B24-12
E24-29	Pharmaceutical form(s)	maa:authorisedProducts/maa:product/ rdm:pharmaproduct/rdm:pharmaceutical-products/rdm:pharmaceutical-	Medicinal Product > Pharmaceutical Dose Form CTL, Pharmaceutical	B24-12

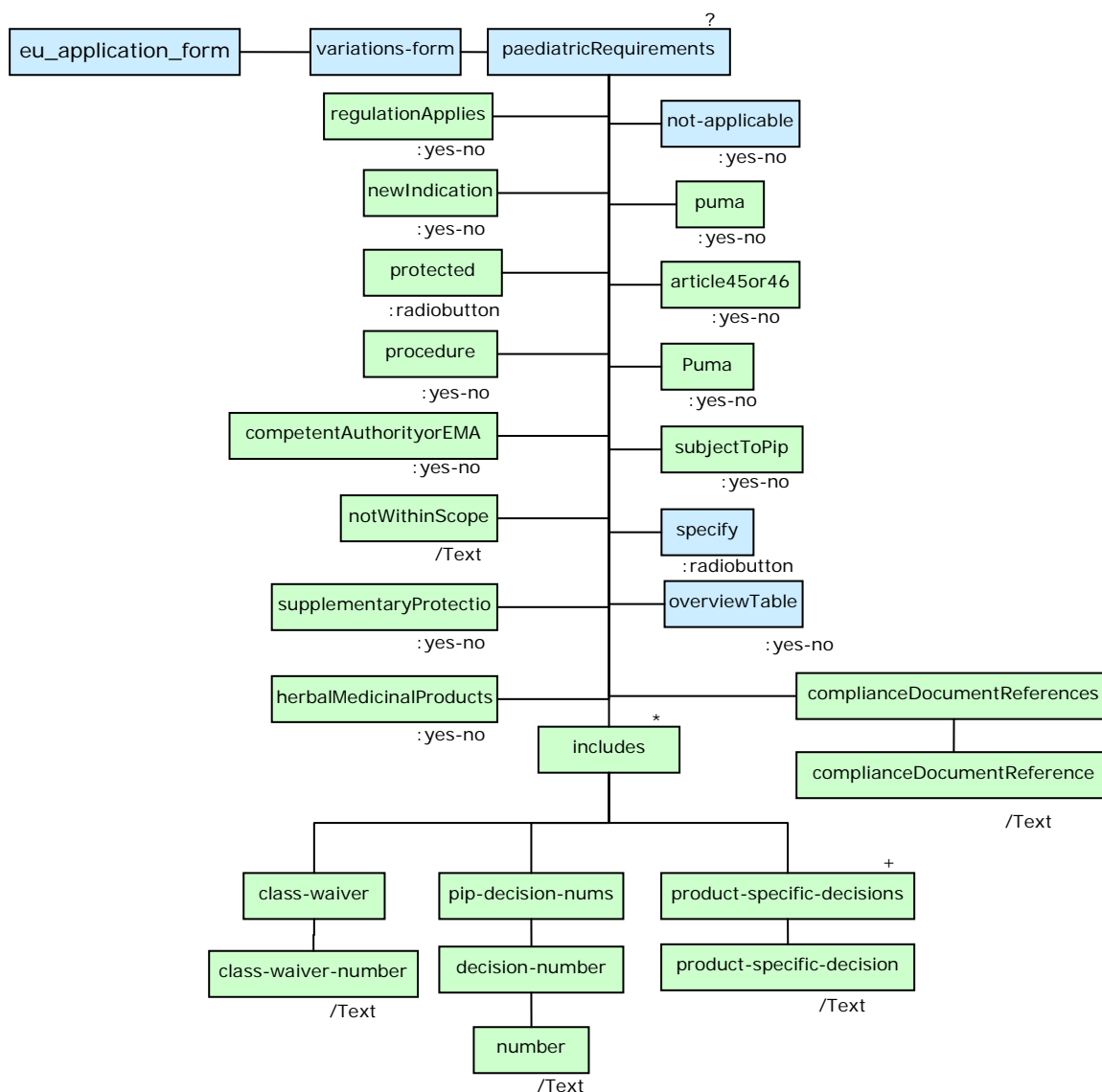|		product/rdm:pharmaceutical-form-names/rdm: pharmaceutical-form-name	Product > Pharmaceutical Dose Form CTL	
E24-30	Strength(s)	maa:authorisedProducts/maa:product/rdm:pharmaproduct/rdm:pharmaceutical-products/rdm:pharmaceutical-product/rdm:pharmaceutical-form-details/rdm:pharmaceutical-form-stengths/rdm:pharmaceutical-form-strength-description	Ingredient	B24-12
E24-31	Marketing authorization holder	maa:authorisedProducts/maa:product/rdm:mp-authorisation/rdm:authorisation-holder	Role>Party>Person> given name	B24-12
E24-32	Marketing authorisation number	maa:authorisedProducts/maa:product/rdm:mp-authorisation/rdm:authorisation-numbers/rdm:authorisation-number	MP Authorisation > authorisation number	B24-12
E24-33	Date of authorization	maa:authorisedProducts/maa:authDate	MP Procedure > procedure number	B24-12
E24-34	Therapeutic indication	maa:authorisedProducts/rdm:product/rdm:pharmaproduct/rdm:therapeutic-indications/rdm:therapeutic-indication		B24-12
E24-35	Is the medicinal product, subject of this application, considered as "similar" to any of the authorised Orphan medicinal product(s)? *(as defined in Article 3 of Commission Regulation (EC) No 847/2000)*			
E24-36	No (module 1.7.1 to be completed)	maa:similar (Value=0)	Orphan Designation > is mp similar to authorised	B24-6
E24-37	Yes (modules 1.7.1 and 1.7.2 to be completed)	maa:similar (Value=1)	Orphan Designation > is mp similar to authorised	B24-6

Element Tree Diagram

eu_application_form — variations-form — newIndications

newIndications — not-applicable

Od-procedure

been-Applied — withdraw
:yes-no — :yes-no

pending — refused
:yes-no — :yes-no

granted — withdrawn
:yes-no — :yes-no

designated — designationumbers — granted — similar
:yes-no — + — :yes-no — :yes-no

designationNumber
/Text

authorisedProducts

+
odp-numbers — od-Authorisation

+
od-refused — oda-withdrawn-date
:Date

authorisation-date
:Date

odp-Number
/Text

oda-date
:Date

refused-date
:Date

basedOnCriterion
:yes-no

decision-reference-number
/Text

numberInRegister
/Text

attachDesignationDecision

product

pharmaproduct — mp-authorisation

invented-name
/text

authorisation-holder
/text

authorisation-numbers
+

+
therapeutic-indications — pharmaceutical-products
+

authorisation-number
/text

therapeutic-indication
/text

pharmaceutical-product

pharmaceutical-form-names — pharmaceutical-form-details
+

pharmaceutical-form-name
/text

pharmaceutical-form-strengths

pharmaceutical-form-strength-description
/text

Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B24-1	E21-18, E21-19, E21-21, E21-22	This section is optional	If E21-18 or E21-19 are selected, and E21-21or E21-22 is selected, then this section(2.4) is available	
B24-2	E24-3, E24-4	Mandatory	Mutually Exclusive	
B24-3	E24-6, E24-7, E24-14, E24-17	Mandatory	Mutually Exclusive	
B24-4	E24-21, E24-22	Mandatory	Mutually Exclusive	
B24-5	E24-20, E24-21	Mandatory	Mutually Exclusive	
B24-6	E24-36, E24-37	Mandatory	Mutually Exclusive	
B24-7	E24-1	Mandatory	If selected, this section (2.4) is not available	
B24-8	E24-3, E24-5	E24-3 is Mandatory, E24-5 is Optional	If E24-3 is selected, then E24-5 is required	
B24-9	E24-7, E24-8 to E24-13	E24-7 is Mandatory, E24-8 is Optional	If E24-7 is selected, then E24-8 to E24-11 are required.	
B24-10	E24-10, E24-11	Mandatory	Mutually Exclusive	
B24-11	E24-21, E24-23 to E24-21	E24-21 is Mandatory, E24-23 to E24-26 are Optional	If E24-21 is selected, then E24-23 to E24-26 are required	
B24-12	E24-25, E24-26, E24-27 to E24-34	E24-25, E24-26 is Mandatory, E24-27 to E24-34 are Optional	If E24-25 is selected, then the rest are required.	
B24-13	E24-14, E24-15 and E24-16	E24-14 is Mandatory, E24-15 and E24-16 is Optional	If E24-14 is selected, then E24-15 and E24-16 are required.	
B24-14	E24-17, E24-18	E24-17 is Mandatory, E24-18 is Optional	If E24-17 is selected, then E24-18 is required.	

2.5. Type II variations - Paediatric requirements

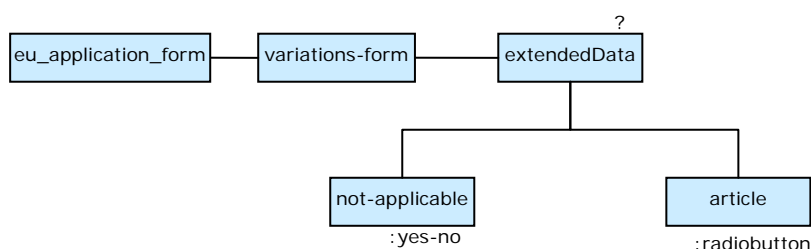|	Common DES 3.0 Context			Common RDM Entry point	
	maa:eu_application_form/maa:variations-form/ maa:paediatricRequirements/			Application >	
Elem Id	**Label**		**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E25-1	Select flag if not applicable; section will not be displayed.		maa:not-applicable		B25-3
E25-2	Article 8 of paediatric regulation applies to this variation application since.		maa:regulationApplies	Paed Regulation App CTL	B25-1,B25-4
E25-3	This application relates to a new indication for an authorised medicinal product which:		maa:newIndication	Paed Regulation App CTL	B25-4, B25-5, B25-6
E25-4	is protected by a supplementary protection certificate under Regulation (EC) No 469/2009.		maa:protected (Value=1)	Paed Regulation App CTL	B25-6, B25-7
E25-5	is protected by a patent which qualifies for the granting of the supplementary protection certificate.		maa:protected (Value=2)	Paed Regulation App CTL	B25-6, B25-7
E25-6	This application relates to a previous/ongoing/parallel procedure which triggered Article 8 requirement.		maa:procedure	Paed Regulation App CTL	B25-4, B25-5
E25-7	Competent authority/EMA procedure number		maa:competentAuthorityor EMA	Paed Regulation App CTL	B25-9
E25-8	Article 8 of the paediatric regulation does not apply to this application, since.		maa:notWithinScope	Paed Regulation App CTL	B25-1, B25-8
E25-9	The authorised medicinal product is not protected by a supplementary protection certificate under Regulation (EC) No 469/2009 or by a patent which qualifies for the granting of the supplementary protection		maa:supplementaryProtec tion	Paed Regulation App CTL	B25-8
E25-10	It relates to a well-established use, generic, hybrid, bio-similar marketing authorisations or traditional herbal medicinal products		maa: herbalMedicinalProducts	Paed Regulation App CTL	B25-8
E25-11	This application relates to a new indication for a paediatric use marketing authorisation (PUMA).		maa:puma	Paed Regulation App CTL	
E25-12	This application relates to paediatric studies submitted according to Article 45 or 46 of the paediatric regulation.		maa:article45or46	Paed Regulation App CTL	
E25-13	This application relates to paediatric studies included in a paediatric investigation plan		maa:articlePIP	Paed Regulation App CTL	B25-1
E25-14	This application includes:				
E25-15	PIP Decision Number		maa:includes/ maa:pip-decision-nums/ maa:decision-number/ maa:number	Paediatric Designation > art 7 pip decision number	
E25-16	Product-Specific Waiver Decision Number		maa:includes/maa:product -specific-decisions/ maa:product-specific-decision	Paediatric Designation > art 7 product waiver number	
E25-17	Class Waiver decision Number		maa:includes/ maa:class-waiver/ maa:class-waiver-number	Paediatric Designation > art 7 class waiver number	
E25-18	Has this application been subject to PIP compliance verification?				
E25-19	Yes		maa:subjectToPip (Value=1)	Paediatric Designation > subject to pip compliance	B25-2
E25-20	No		maa:subjectToPip (Value=2)	Paediatric Designation > subject to pip compliance	
E25-21	Please specify				B25-2
E25-22	The compliance document reference		maa:complianceDocument References/ maa:complianceDocument Reference	Paediatric Designation > nca emea doc reference	B25-2
E25-23	Please provide the overview table of PIP results in Module 1.10		maa:overviewTable		

Element Tree Diagram

Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B25-1	E25-2, E25-8, E25-13	Mandatory	Mutually Exclusive	
B25-2	E25-19, E25-22	Optional	If E25-19 is selected, then E25-22 is required	
B25-3	E25-1	Optional section	If E25-1 is selected, then this section is not displayed	
B25-4	E25-2, E25-3, E25-6	E25-2 is Mandatory, rest are optional	If E25-2 is selected, then the rest are required.	
B25-5	E25-3, E25-6	Optional	Mutually Exclusive	
B25-6	E25-3, E25-4, E25-5	Optional	If E25-3 is selected, then E25-4 and E25-5 are mandatory.	
B25-7	E25-4, E25-5	Optional	Mutually Exclusive	
B25-8	E25-8, E25-9, E25-10	E25-8 is Mandatory, rest are Optional	If E25-8 is selected, then E25-9 and E25-10 are required	
B25-9	E25-6, E25-7	E25-7 is optional	If E25-6 is selected, then E25-7 is required	

2.6. Type II variations – Extended data exclusivity/market protection

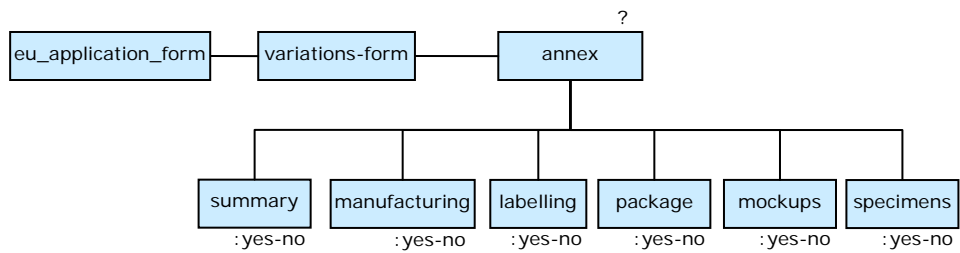|	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_form/maa:variations-form/maa:extendedData/		Application >	
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E26-1	Select flag if not applicable; section will not be displayed.	maa:not-applicable		B26-1
E26-2	Consideration of this application is also requested under the following article in directive 2001/83/EC or regulation (EC) No 726/2004:			
E26-3	Article 10(1) of Directive 2001/83/EC / Article 14(11) of Regulation (EC) No 726/2004 (one year of market protection for a new indication)	maa:article (Value=1)		
E26-4	Article 10(5) of Directive 2001/83/EC (one year of data exclusivity for a new indication)	maa:article (Value=2)		
E26-5	Article 74(a) of Directive 2001/83/EC (one year of data exclusivity for a change in classification)	maa:article (Value=3)		

Element Tree Diagram

Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B26-1	E26-1	Optional section	If E26-1 is selected, then this section is not displayed	
B26-2	E21-18, E21-19	Optional Section	If any of E21-18 and E21-19 are selected, then this section is displayed	

2.7. The following amended product information proposals are provided in the relevant sections of the EU-CTD format or NTA volume 6B format, where applicable:

	Common DES 3.0 Context			Common RDM Entry point	
	maa:eu_application_form/maa:variations-form/maa:annex/			Application >	
Elem Id	Label		DES 3.0 Mapping	RDM 3.0 Mapping	Remarks
E27-1	Summary of product characteristics		maa:summary		
E27-2	Manufacturing Authorisation Holder responsible for batch release and conditions of the Marketing Authorisation[15]		maa:manufacturing		
E27-3	Labelling		maa:labelling		
E27-4	Package leaflet		maa:package		
E27-5	Mock-ups[16]		maa:mockups		
E27-6	Specimens[16]		maa:specimens		

Element Tree Diagram

2.8. DECLARATION OF APPLICANT

		Common DES 3.0 Context		Common RDM Entry point	
		maa:eu_application_form/maa:variations-form/maa:declarationOfApplicant/		Application >	
Elem Id	**Label**		**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E28-1	I hereby submit a notification/application for the above Marketing Authorisation(s) to be varied in accordance with the proposals given above. I declare that *(Please tick appropriate declarations)*:				
E28-2	There are no other changes than those identified in this application (except for those addressed in other variations submitted in parallel);		maa:noOtherChanges		
E28-3	Where applicable, all conditions as set for the variation(s) concerned are fulfilled;		maa:conditionsSet		
E28-4	For type IA notifications: the required documents as specified for the changes concerned have been submitted;		maa:requiredDocuments		
E28-5	Where applicable, national fees have been paid;		maa:nationalFees		
E28-6	This notification/application has been submitted simultaneously in RMS and all CMSs *(for products within the Mutual Recognition Procedure and worksharing)* or both to EMA and (Co-)Rapporteur *(for products within the Centralised Procedure) or, in case of worksharing involving the EMA, to the relevant National Competent Authorities and/or RMS/CMS (as applicable) and the EMA;*		maa:submitted		
E28-7	For worksharing or grouped variations affecting more than one MA: the MAs concerned belong to the same MAH.		maa:sharing		
E28-8	Change(s) will be implemented from[17]:				
E28-9	Next production run/next printing		maa:implementedNext	change from next production	B28-1
E28-10	Date		maa:implementedDate		B28-1,B28-2
E28-11	Date		maa:impDate	change from date	B28-2
E28-12	Free Text field		maa:impDateText		B28-2

Element Tree Diagram

Business Rules				
Rule ID	**Element id(s)**	**Default BR**	**Rule**	**Effect(s)**
B28-1	E28-9, E28-10	Optional	To be completed only for Type IB and Type II applications	
B28-2	E28-10, E28-12	E28-10 is mandatory, E28-11 and 12 is optional	If E28-10 is clicked, then E28-11 is required	

2.9. Signatures

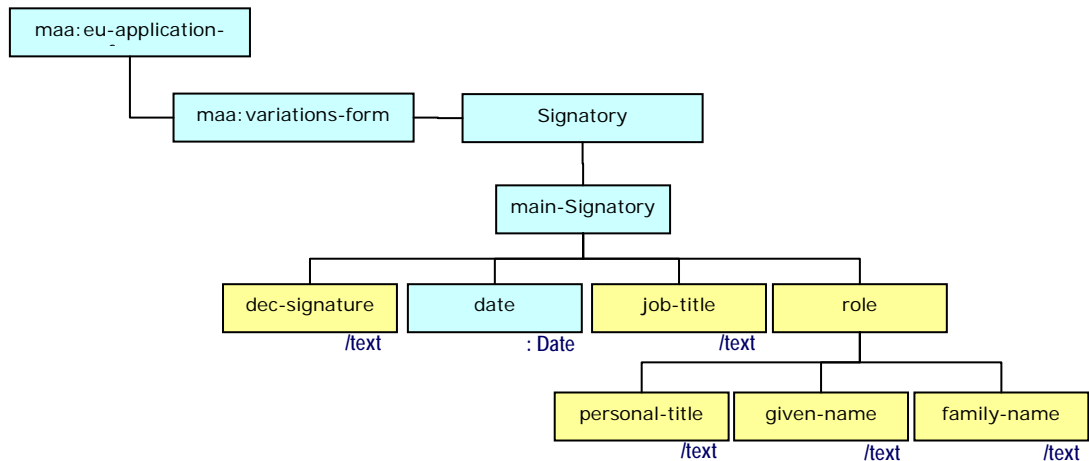| Elem Id	Label	DES 3.0 Mapping	RDM 3.0 Mapping	Remarks
Common DES 3.0 Context			**Common RDM Entry point**	
maa:eu_application_form/maa:variations-form/maa:Signatory/			Application >	
E29-1	Proof of payment (when relevant)			B29-1
E29-2	Have all relevant fees been prepaid to competent authorities?			B29-1,
E29-3	Yes	maa:payment/maa:payment/ maa:fees-paid (1)		B29-1, B29-2, B29-3
E29-4	No	maa:payment/maa:payment/ maa:fees-paid (0)		B29-1, B29-2, B29-3
E29-5	For Member States	maa:payment/maa:fee-category-details/rdm:member-states/rdm:ref-member-state/rdm:name		B29-1, B29-2, B29-3
E29-6	Please specify fee category under National rules	Maa:payment/maa: fee-category-details/maa:category		B29-1, B29-2, B29-3
E29-7	Please specify the reasons according to National requirements (exemption or later payment).	maa:payment/maa:payment/ maa:billingdetails/ maa:reason		B29-1, B29-2, B29-3
E29-8	Billing address (when relevant)			B29-1, B29-2, B29-3
E29-9	For Member States	maa:payment/maa:payment/ maa:billing-details /rdm:member-states/rdm:ref-member-state/rdm:name		B29-1, B29-2, B29-3
E29-10	Company Name	maa:payment/maa:payment/ maa:billing-details/ rdm:contact-details-type/maa:company-name		B29-1, B29-2, B29-3
E29-11	VAT Number	maa:payment/maa:payment/ maa:billing-details/maa:VAT-number		B29-1, B29-2, B29-3
E29-12	Address1	maa:payment/maa:payment/ maa:billing-details/ rdm:contact-details-type/rdm:address	Role>Party>Contact Details > Address	B29-1, B29-2, B29-3
E29-13	Address2	maa:payment/maa:payment/ maa:billing-details/ rdm:contact-details-type/rdm:city	Role>Party>Contact Details > city	B29-1, B29-2, B29-3
E29-14	Postcode	maa:payment/maa:payment/ maa:billing-details/ rdm:contact-details-type/rdm:postcode	Role>Party>Contact Details > postcode	B29-1, B29-2, B29-3
E29-15	Country	maa:payment/maa:payment/ maa:billing-details/ rdm:contact-details-type/rdm:country	Role>Party>Contact Details > Address > Country CTL	B29-1, B29-2, B29-3
E29-16	Telephone	maa:payment/maa:payment/ maa:billing-details/ rdm:contact-details-type/rdm:phone	Role>Party>Contact Details > Electronic Contact > electronic contact	B29-1, B29-2, B29-3
E29-17	Telefax	maa:payment/maa:payment/ maa:billing-details/ rdm:contact-details-type/rdm:fax	Role>Party>Contact Details > Electronic Contact > electronic contact	B29-1, B29-2, B29-3
E29-18	E-mail	maa:payment/maa:payment/ maa:billing-details/ rdm:contact-details-type/rdm:email	Role>Party>Contact Details> Electronic Contact > electronic contact	B29-1, B29-2, B29-3
E29-19	Purchase Order (PO) Number	maa:payment/maa:payment/ maa:billing-details/Purchase-order-number		B29-1, B29-2, B29-3

Element Tree Diagram

Business Rules					
Rule ID	**Element id(s)**	**Default BR**	**Rule**		**Effect(s)**
B29-1	E29.1, E29.2 - E29.19		If E29.1 is selected (value = 1), then E29.2 – E29.19 are visible.		
B29-2	E29.3, E261.4, E29.19		If E29.3 is selected (value = 1), then E29.5 – E29.6 is visible.		If E29.3 is not selected (value = 0), then E29.7 – E29.19 is invisible, rest are visible
B29-3	E29.3, E29.4, E29.19		If E29.4 is selected (value = 0), then E29.7 - E29.19 is visible		If E29.4 is not selected (value = 1), then E29.5 – E29.6 is invisible, rest are visible

Main Signatory Section

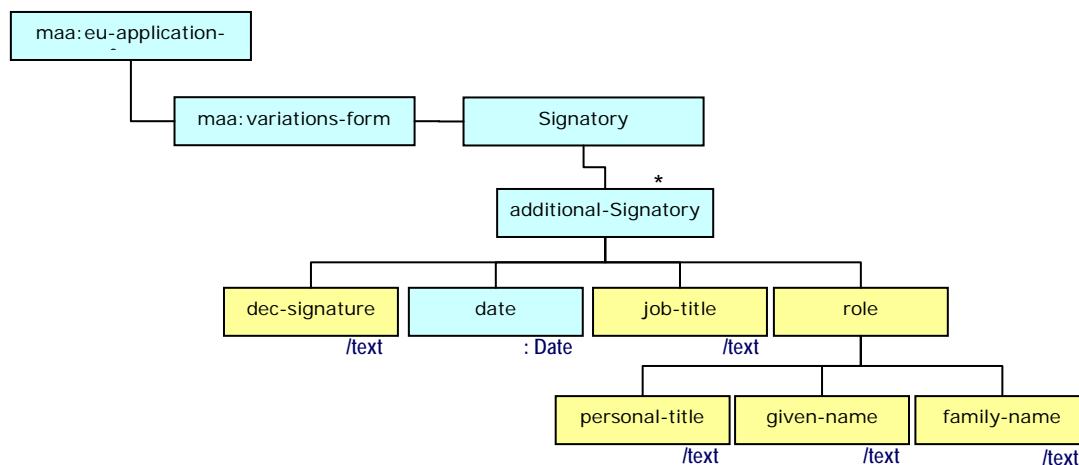|	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_formmaa: variations-form /maa:Signatory/rdm:main-Signatory			
Elem Id	**Label**	**DES 3.0 Mapping**	**RDM 3.0 Mapping**	**Remarks**
E262.1	Main Signatory	rdm: dec-signature	Application>Role>Party>Person>given name	Is this the same 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	For worksharing/grouping for more than one MA: the main signatory confirms authorisation to sign on behalf of the designated contacts as specified in section 2.4.3 in Part IA/Module 1 Application Form for each of the MAs concerned.	rdm:signOnBehalf		
E262.7	Date	rdm:date	Application > signature date	

Element Diagram

Additional Signatories Section

	Common DES 3.0 Context		Common RDM Entry point	
	maa:eu_application_formmaa: variations - 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

ABOUT THIS DOCUMENT

Definitions, Acronyms, and Abbreviations

Acronyms

Name	Definition
cms	concerned member state
DCP	Decentralised Procedure
DTD	Data Type Definition
ETD	Element Tree Diagram
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	eXtensible Markup Language
XSL	XML Stylesheet Language