



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Information Technology

Electronic Application Form Data Exchange Standard 3.0

Supplementary Specification Annex 2 "Variations Form" v.1.23.0.0



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1. Introduction

1.1. How to read this document

In association with this document the **variations.xsd** file contains the XML schema file that provides a description of the structure of all the concepts used for this annex. This will enable you to construct a data extraction/generation script to populate the relevant information to/from your systems. This schema file can be found on the esubmissions website under the eAF page at the following link:

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

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

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

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

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

Description and definition of the DES 3.0 Concepts used in this document can be found in the DES 3.0 supplementary specifications document. This again can be found on the esubmissions website under the eAF page.

1.2. Sections Components

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

1.2.1. The Elements Mapping Table

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

The table consists in 4 columns:

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

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

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

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

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

Colours

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

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

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

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

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

1.2.2. The Business Rules Table

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

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

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

Rule: Description of the condition to be evaluated.

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

1.2.3. The Element Tree Diagram (ETD)

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

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

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

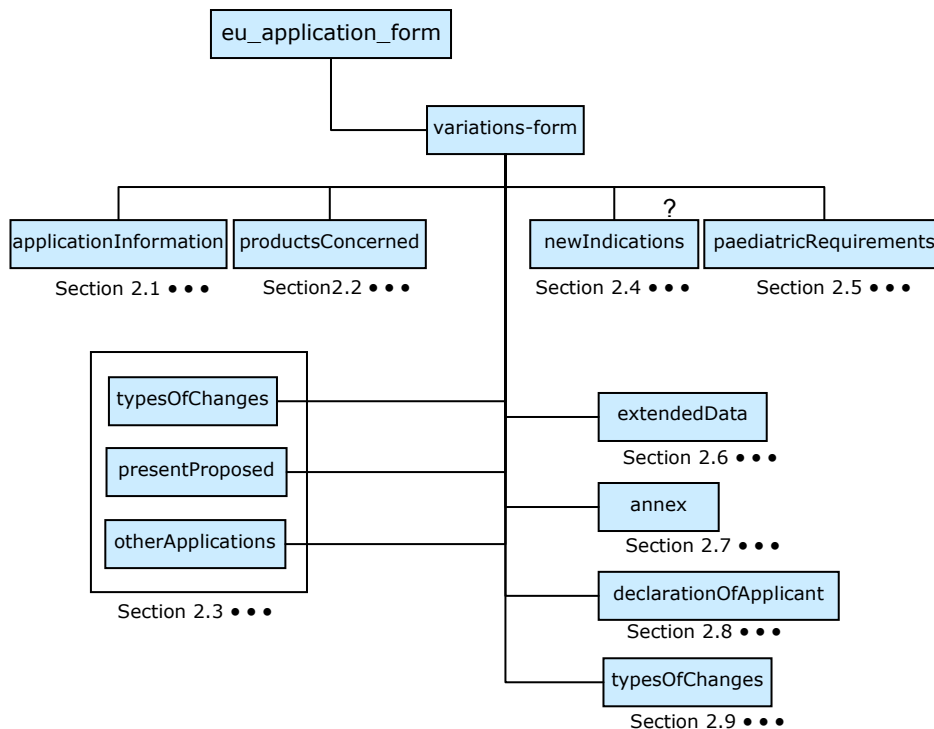
The diagrams of this version reflect the DES 3.0 standard described in the DES 3.0 Supplementary Specifications document. The ETD shows which are the concepts involved in the mapping of all the application form fields in the Element Mapping Table and the hierarchical constraints between them.

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

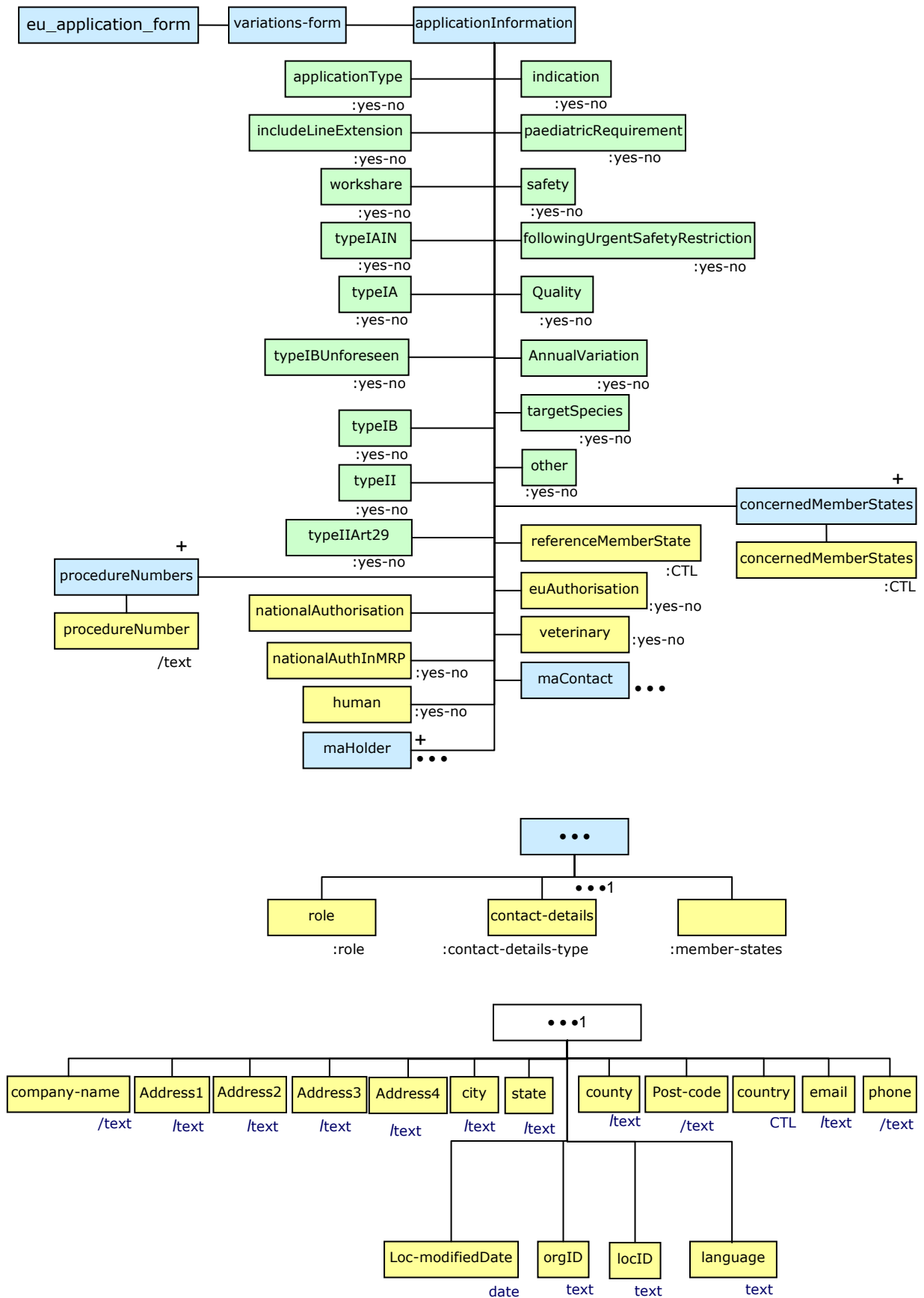


2.1. APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION

| Common DES 3.0 Context | | Common RDM Entry point | | |
|------------------------|---|--|--|----------------------------|
| | maa:eu_application_form/maa:variations-form/maa:applicationInformation/ | | Application > | |
| Elem Id | Label | DES 3.0 Mapping | RDM 3.0 Mapping | Remarks |
| 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 _{TN} | 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 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:address1 | Application > Role > Party > Contact Details > Address | |
| | | maa:maHolder/maa:contact-details/rdm:address2 | | |
| | | maa:maHolder/maa:contact-details/rdm:address3 | | |
| | | maa:maHolder/maa:contact-details/rdm:address4 | | |
| E21-32 | city | maa:maHolder/maa:contact-details /rdm:city | Application > Role > Party > Contact Details > City | |
| E21-32a | state | maa:maHolder/maa:contact-details/rdm:state | | |
| E21-32b | county | maa:maHolder/maa:contact-details/rdm:county | | |
| 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 | |
| E21-34a | orgID | maa:maHolder/maa:contact-details/rdm:orgID | | |
| E21-34b | locID | maa:maHolder/maa:contact-details/rdm:locID | | |
| E21-34c | loc-modifiedDate | maa:maHolder/maa:contact-details/rdm:loc-modifiedDate | | |
| E21-34d | Language | maa:maHolder/maa:contact-details/rdm:language | | |
| 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:address1 | Role>Party>Contact Details > Address | |
| | | maa:maContact/maa:contact-details/rdm:address2 | | |
| | | maa:maContact/maa:contact-details/rdm:address3 | | |
| | | maa:maContact/maa:contact-details/rdm:address4 | | |
| E21-41 | city | maa:maContact/maa:contact-details/rdm:city | Role>Party>Contact Details > City | |
| E21-41a | state | maa:maContact/maa:contact-details/rdm:state | | |
| E21-41b | county | maa:maContact/maa:contact-details/rdm:county | | |
| 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 | |
| E21-43a | orgID | maa:maContact/maa:contact-details/rdm:locID | | |
| E21-43b | locID | maa:maContact/maa:contact-details/rdm:locID | | |
| E21-43c | Loc-modifiedDate | maa:maContact/maa:contact-details/rdm:loc-modifiedDate | | |
| E21-43d | Language | maa:maContact/maa:contact-details/rdm:language | | |
| E21-44 | Telephone | maa:maContact/maa:contact-details/rdm:phone | 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

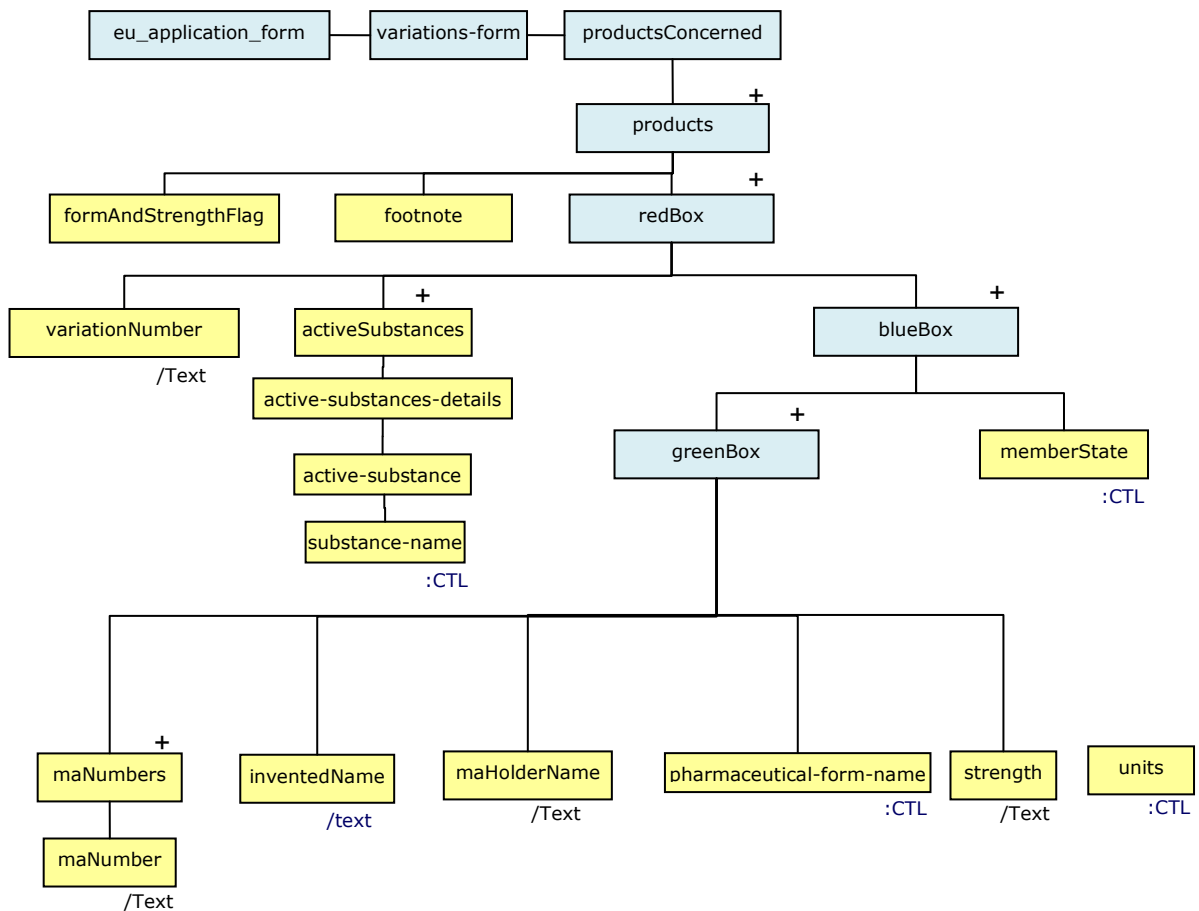


| Business Rules | | | | |
|----------------|--|---|---|-----------|
| Rule ID | Element id(s) | Default BR | Rule | Effect(s) |
| B21-1 | E21-1, E21-2 | Mandatory | Mutually Exclusive | |
| B21-2 | E21-10, E21-11 | Mandatory | Mutually Exclusive | |
| B21-3 | E21-11, E21-12 | E21-11 is mandatory , E21-12 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

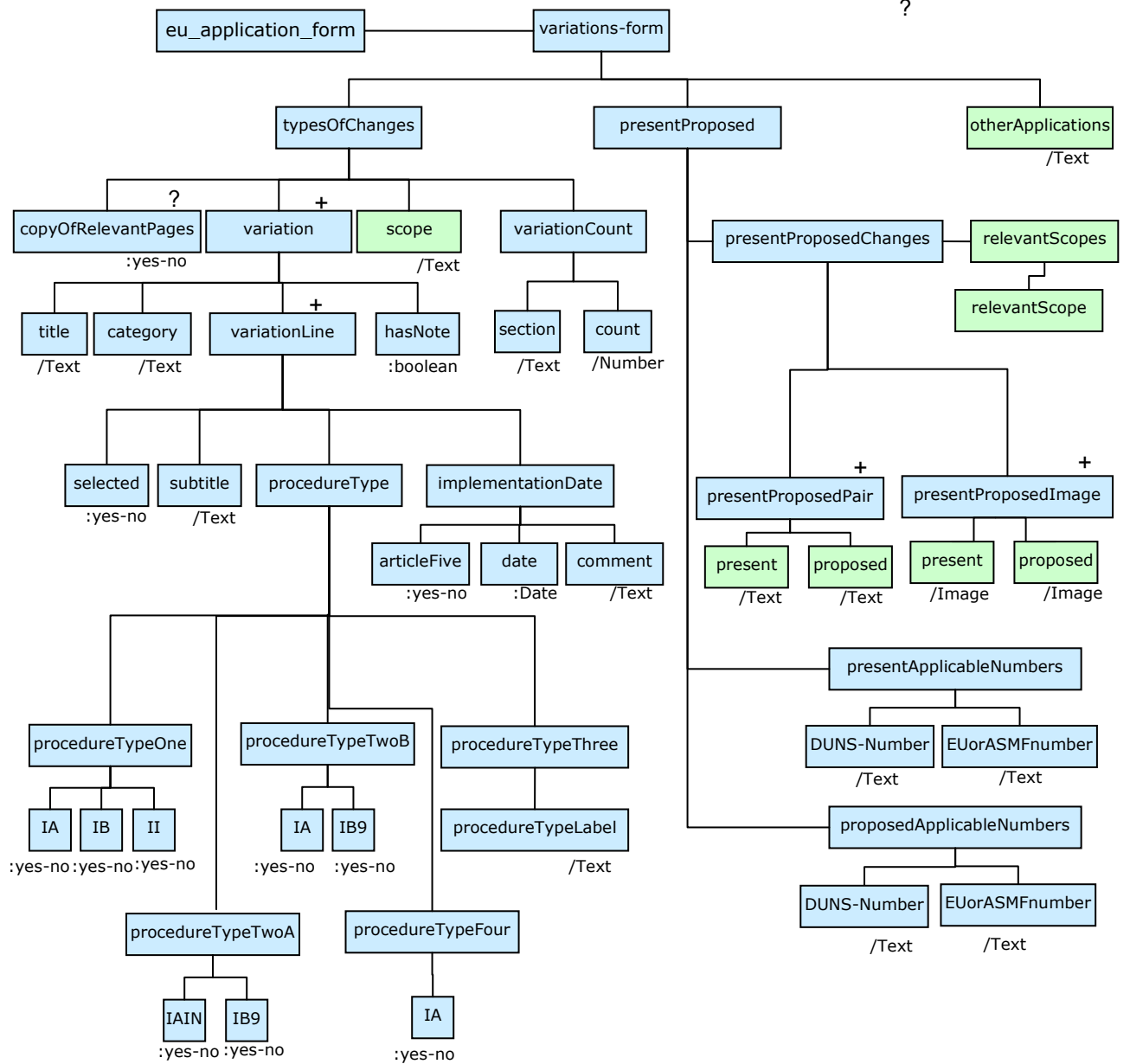


2.3. TYPE OF CHANGE(S)

| 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) <i>(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 an unforeseen change, include a justification for its proposed classification).</i> | maa:typesofChanges/maa:scope | scope, background | |

| | | | | |
|---------|----------------------------|---|---|--|
| 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 | |
| E23-28a | PresentAddress | maa:presentProposed/maa:presentProposedAddress/maa:present | | |
| E23-28a | ProposedAddress | maa:presentProposed/maa:presentProposedAddress/maa:proposed | | |
| 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

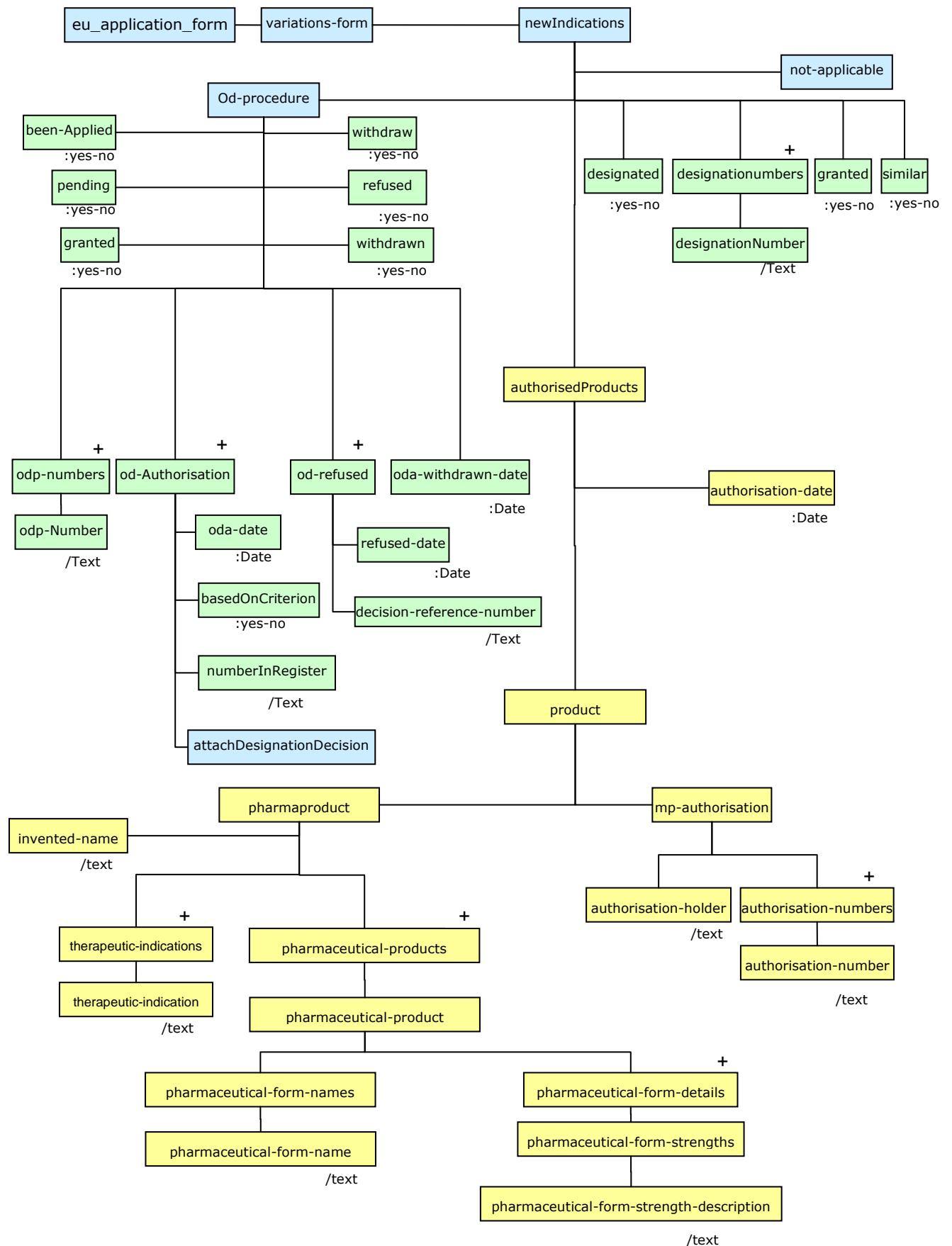


2.4. Type IB & Type II Variations – new Indications – orphan medicinal product information

| | Common DES 3.0 Context | | Common RDM Entry point | |
|---------|---|--|--|-----------------------|
| | maa:eu_application_form/maa:variations-form/maa:newIndications/ | | Application > | |
| Elem Id | Label | DES 3.0 Mapping | RDM 3.0 Mapping | Remarks |
| 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-strengths/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

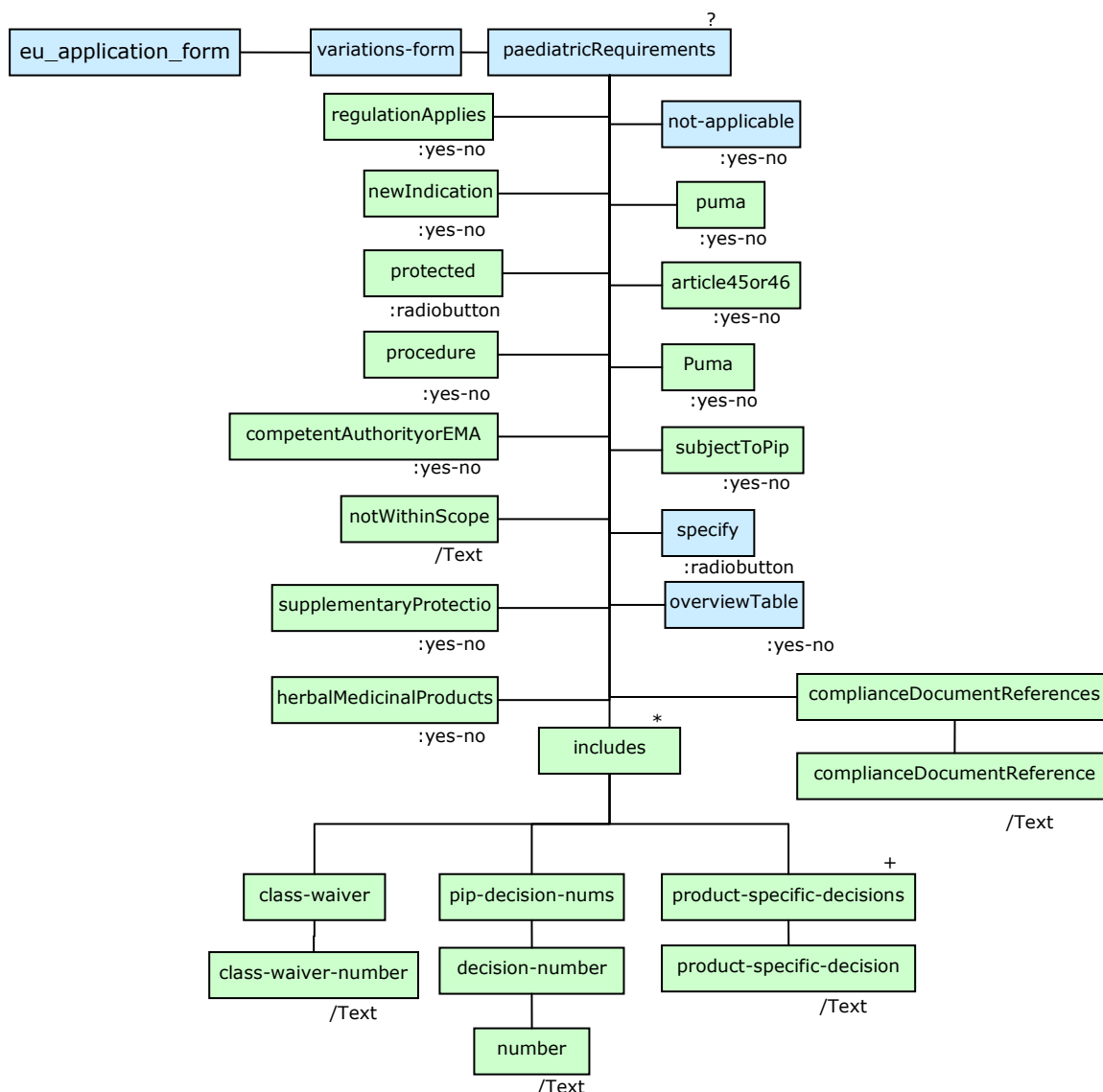


| Business Rules | | | | |
|----------------|----------------------------------|--|---|-----------|
| Rule ID | Element id(s) | Default BR | Rule | Effect(s) |
| B24-1 | E21-18, E21-19, E21-21, E21-22 | This section is optional | If E21-18 or E21-19 are selected, and E21-21 or E21-22 is selected, then 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 IB & 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:supplementaryProtection | 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:complianceDocumentReferences/ maa:complianceDocumentReference | 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

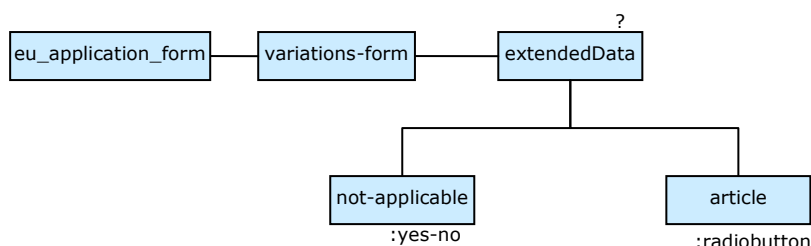


| Business Rules | | | | |
|----------------|----------------------|---------------------------------------|---|-----------|
| Rule ID | Element id(s) | Default BR | Rule | Effect(s) |
| B25-1 | E25-2, E25-8, E25-13 | Mandatory | Mutually Exclusive | |
| B25-2 | E25-19, E25-22 | Optional | If E25-19 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

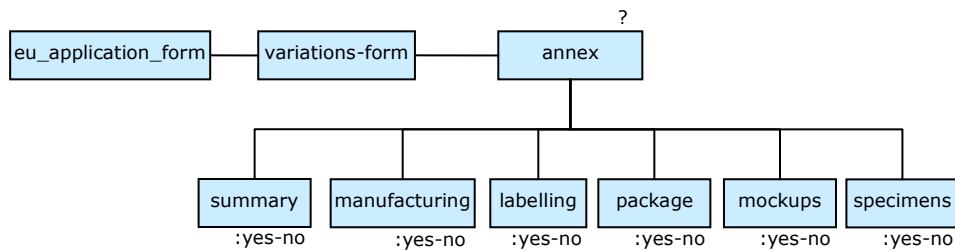


| Business Rules | | | | |
|----------------|----------------|------------------|--|-----------|
| Rule ID | Element id(s) | Default BR | Rule | Effect(s) |
| B26-1 | E26-1 | Optional section | If E26-1 is selected, then this section is not displayed | |
| B26-2 | E21-18, E21-19 | Optional Section |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

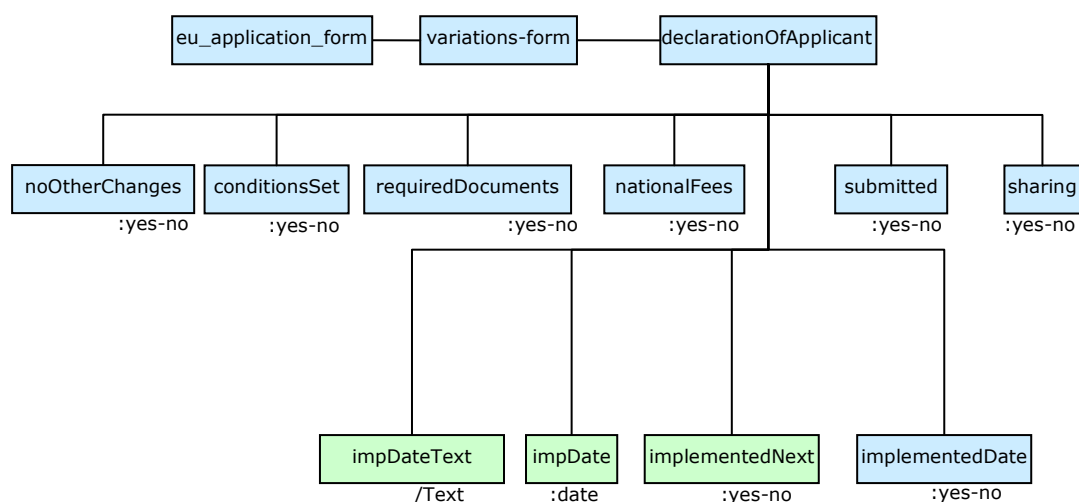
Element Tree Diagram



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 <i>(Please tick appropriate declarations)</i> : | | | |
| 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



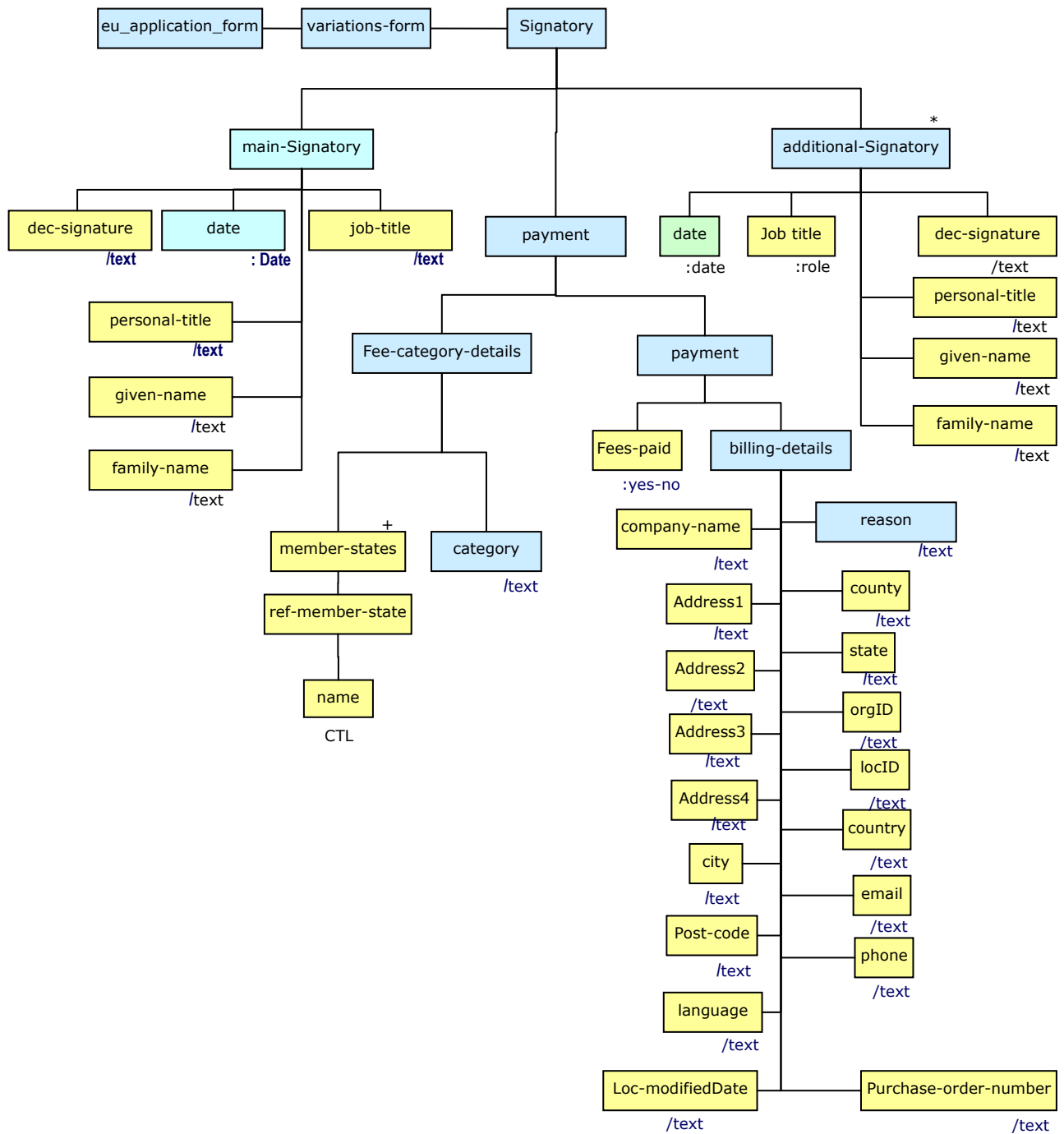
| Business Rules | | | | |
|----------------|----------------|--|---|-----------|
| Rule ID | Element id(s) | Default BR | Rule | Effect(s) |
| B28-1 | E28-9, E28-10 | Optional | To be completed only for Type IB and Type II applications | |
| B28-2 | E28-10, E28-12 | E28-10 is mandatory, E28-11 and 12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

2.9. Signatures

| | Common DES 3.0 Context | | Common RDM Entry point | |
|---------|---|---|--|---------------------|
| | maa:eu_application_form/maa:variations-form/maa:Signatory/ | | Application > | |
| Elem Id | Label | DES 3.0 Mapping | RDM 3.0 Mapping | Remarks |
| 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:address1 | Role>Party>Contact Details > Address | B29-1, B29-2, B29-3 |
| | | maa:payment/maa:payment/maa:billing-details/rdm:contact-details-type/rdm:address2 | | |
| | | maa:payment/maa:payment/maa:billing-details/rdm:contact-details-type/rdm:address3 | | |
| | | maa:payment/maa:payment/maa:billing-details/rdm:contact-details-type/rdm:address4 | | |
| E29-13 | city | maa:payment/maa:payment/maa:billing-details/rdm:contact-details-type/rdm:city | Role>Party>Contact Details > city | B29-1, B29-2, B29-3 |
| E29-13a | state | maa:payment/maa:payment/maa:billing-details/rdm:contact-details-type/rdm:state | | |
| E29-13b | county | maa:payment/maa:payment/maa:billing-details/rdm:contact-details-type/rdm:county | | |
| 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 |
| E29-15a | orgID | maa:payment/maa:payment/maa:billing-details/rdm:contact-details-type/rdm:orgID | | |
| E29-15b | locID | maa:payment/maa:payment/maa:billing-details/rdm:contact-details-type/rdm:locID | | |

| | | | | |
|---------|----------------------------|---|---|-------------------------|
| E29-15c | Loc-modifiedDate | maa:payment/maa:payment/ maa:billing-details/ rdm:contact-details- type/rdm:loc-modifiedDate | | |
| E29-15d | Language | maa:payment/maa:payment/ maa:billing-details/ rdm:contact-details- type/rdm:language | | |
| 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 |
| E29-18 | 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

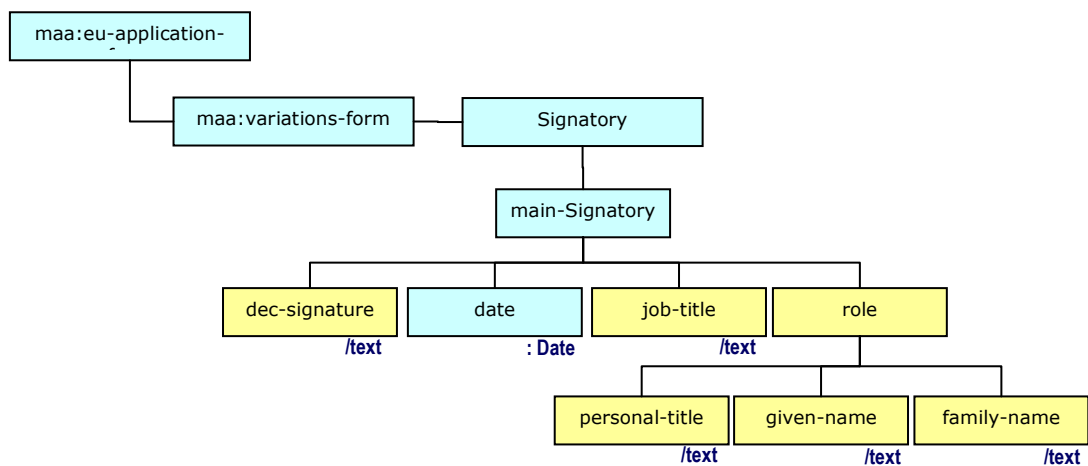


| Business Rules | | | | |
|----------------|-----------------------|------------|--|--|
| Rule ID | Element id(s) | Default BR | Rule | Effect(s) |
| B29-1 | E29.1, E29.2 - E29.19 | | If E29.1 is selected (value = 1), then E29.2 - E29.19 are visible. | |
| B29-2 | E29.3, E261.4, E29.19 | | If E29.3 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 | |

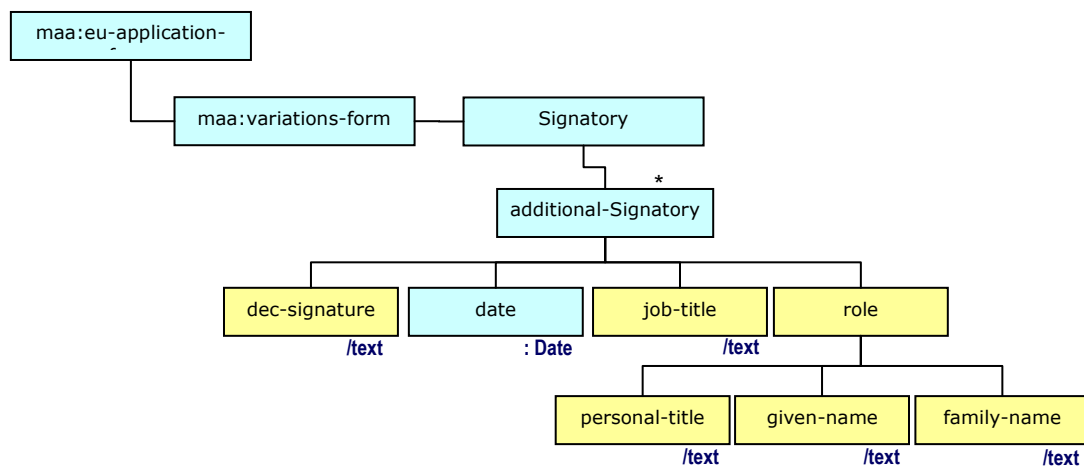
Element Diagram



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 |