Electronic Application Form Data Exchange Standard 3.0
Supplementary Specification Annex 1 "Initial Human Application 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 maa_human.xsd file contains the XML schema file that provides a description of the structure of all the concepts used for this annex. This will enable you to construct a data extraction/generation script to populate the relevant information to/from your systems. This schema file can be found on the esubmissions website under the eAF page at the following link: http://esubmission.ema.europa.eu/eaf/index.html

The "Chapters" refer to the paragraph number of the paper application form. The "Sections" refer to the paragraph numbering of this document. Some diagrams are too large to describe the whole hierarchy on only one page. Therefore, the diagrams are split in sub sections that might not be in line with the paper document chapters.

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

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

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

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

**The Elements Mapping Table**

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

The table consists in 4 columns:

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

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

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

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

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

**Colours**

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

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

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

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

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

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

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

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

**Rule**: Description of the condition to be evaluated.

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

The Element Tree Diagram (ETD)

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

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

The model is called “Element Tree Diagram” (ETD)

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

The "initial-application-form-human" is the highest level of the form specific model that represents the paper form. All sections are fully mapped to the Reference Data Model core concepts and common application form concepts.

<table>
<thead>
<tr>
<th>Common DES 3.0 Context</th>
<th>Common RDM Entry point</th>
</tr>
</thead>
<tbody>
<tr>
<td>maa:eu_application_form/maa:initial-application-form-human/</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Elem Id</th>
<th>Label</th>
<th>DES 3.0 Mapping</th>
<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>E2.1</td>
<td>APPLICATION FORM : ADMINISTRATIVE DATA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E2.2</td>
<td>DECLARATION AND SIGNATURE</td>
<td>maa:declaration</td>
<td>Application</td>
<td>See Section 2.1</td>
</tr>
<tr>
<td>E2.3</td>
<td>1. TYPE OF APPLICATION</td>
<td>maa:chapter-1</td>
<td>MP Procedure</td>
<td>See section 2.2</td>
</tr>
<tr>
<td>E2.4</td>
<td>2. MARKETING AUTHORISATION APPLICATION PARTICULARS</td>
<td>maa:chapter-2</td>
<td></td>
<td>See Section 2.3</td>
</tr>
<tr>
<td>E2.5</td>
<td>3. SCIENTIFIC ADVICE</td>
<td>maa:scientific-advice</td>
<td>App Scientific Advice</td>
<td>See Section 2.4</td>
</tr>
<tr>
<td>E2.6</td>
<td>4. OTHER MARKETING AUTHORISATION APPLICATIONS</td>
<td>maa:section-4</td>
<td></td>
<td>See Section 2.5</td>
</tr>
<tr>
<td>E2.7</td>
<td>5. ANNEXED DOCUMENTS (WHERE APPROPRIATE)</td>
<td>maa:section-5</td>
<td></td>
<td>See Section 2.6</td>
</tr>
</tbody>
</table>

**Element Tree Diagram**
## 2.1. DECLARATION AND SIGNATURE

<table>
<thead>
<tr>
<th>Common DES 3.0 Context</th>
<th>Common RDM Entry point</th>
</tr>
</thead>
<tbody>
<tr>
<td>maa:eu_application_form/maa:initial-application-form-human/maa:declaration/</td>
<td>Application &gt;</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Elem Id</th>
<th>Label</th>
<th>DES 3.0 Mapping</th>
<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>E21-1</td>
<td>Product (invented) name</td>
<td>rdm:medicinal-product/rdm:invented-name</td>
<td>Medicinal Product &gt; Medicinal Product Group &gt; invented name</td>
<td></td>
</tr>
<tr>
<td>E21-6</td>
<td>Applicant details</td>
<td>maa:applicant/rdm:company-name</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E21-7</td>
<td>Address</td>
<td>maa:applicant/rdm:contact-details</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E21-14</td>
<td>Signature(s)</td>
<td>maa:dec-signature</td>
<td>Not mapped</td>
<td></td>
</tr>
<tr>
<td>E21-15</td>
<td>Title</td>
<td>maa:signature/rdm:personal-title</td>
<td>Role &gt; Party &gt; Person &gt; Personal title</td>
<td></td>
</tr>
<tr>
<td>E21-16</td>
<td>First name</td>
<td>maa:signature/rdm:given-name</td>
<td>Role &gt; Party &gt; Person &gt; given name</td>
<td></td>
</tr>
<tr>
<td>E21-17</td>
<td>Surname</td>
<td>maa:signature/rdm:family-name</td>
<td>Role &gt; Party &gt; Person &gt; family name</td>
<td></td>
</tr>
<tr>
<td>E21-18</td>
<td>Function</td>
<td>maa:function</td>
<td>Manufacturer MP&gt; functions performed</td>
<td></td>
</tr>
<tr>
<td>E21-19</td>
<td>Address</td>
<td>maa:place</td>
<td>signature place</td>
<td></td>
</tr>
<tr>
<td>E21-20</td>
<td>Date</td>
<td>maa:date</td>
<td>signature date</td>
<td></td>
</tr>
<tr>
<td>E21-21</td>
<td>Note: please attach letter of authorisation for communication/signing on behalf of the applicant in annex 5.4</td>
<td>maa:annex5-4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E21-22</td>
<td>Note: if fees have been paid, attach proof of payment in Annex5.1 - see information on fee payments in the Notice to Applicants, Volume2A, chapter 7.</td>
<td>maa:annex5-1</td>
<td></td>
<td></td>
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</tbody>
</table>
## 2.2. TYPE OF APPLICATION

<table>
<thead>
<tr>
<th>Common DES 3.0 Context</th>
<th>Common RDM Entry point</th>
</tr>
</thead>
<tbody>
<tr>
<td>maa:eu_application_form/maa:initial-application-form-human/maa:chapter-1/</td>
<td>Application &gt;</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Elem Id</th>
<th>Label</th>
<th>DES 3.0 Mapping</th>
<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>E22-1</td>
<td>1.1 THIS APPLICATION CONCERNS</td>
<td>maa:procedure-type</td>
<td></td>
<td>See section 2.2.1</td>
</tr>
<tr>
<td>E22-2</td>
<td>1.2 ORPHAN MEDICINAL PRODUCT INFORMATION</td>
<td>maa:orphan-designation</td>
<td></td>
<td>See section 2.2.2</td>
</tr>
<tr>
<td>E22-3</td>
<td>1.3 APPLICATION FOR A CHANGE TO EXISTING MARKETING AUTHORIZATION LEADING TO AN EXTENSION AS REFERRED TO IN ANNEX I OF REGULATIONS (EC) NO 1234/2008 OR ANY NATIONAL LEGISLATION, WHERE APPLICABLE?</td>
<td>maa:change-market-authorization</td>
<td></td>
<td>See section 2.2.3</td>
</tr>
<tr>
<td>E22-4</td>
<td>1.4 THIS APPLICATION IS SUBMITTED IN ACCORDANCE WITH THE FOLLOWING ARTICLE IN DIRECTIVE 2001/83/EC</td>
<td>maa:directive-2001-83-ec</td>
<td></td>
<td>See section 2.2.4</td>
</tr>
<tr>
<td>E22-5</td>
<td>1.5 CONSIDERATION OF THIS APPLICATION ALSO REQUESTED UNDER THE FOLLOWING ARTICLE IN DIRECTIVE 2001/83/EC OR REGULATION (EC) No 726/2004</td>
<td>maa:section1-5</td>
<td></td>
<td>See section 2.2.5</td>
</tr>
<tr>
<td>E22-6</td>
<td>REQUIREMENTS ACCORDING TO REGULATION (EC) No 1901/2006 ('PAEDIATRIC REGULATION')</td>
<td>maa:section1-6</td>
<td></td>
<td>See section 2.2.6</td>
</tr>
</tbody>
</table>

### Element Tree Diagram

![Element Tree Diagram](image-url)

Section 2.2.1 ••• Section 2.2.2 ••• Section 2.2.3 ••• Section 2.2.4 ••• Section 2.2.5 ••• Section 2.2.6 •••
2.2. 1 THIS APPLICATION CONCERNS

<table>
<thead>
<tr>
<th>Common DES 3.0 Context</th>
<th>Common RDM Entry point</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Elem Id</th>
<th>Label</th>
<th>DES 3.0 Mapping</th>
<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>E221-1</td>
<td>1.1.1 A CENTRALISED PROCEDURE</td>
<td>maa:centralised-procedure/rdm:selected</td>
<td>Procedure Type CTL (Value=&quot;centralised&quot;)</td>
<td>B221-1, See section 2.2.1.1</td>
</tr>
<tr>
<td>E221-2</td>
<td>1.1.2 A MUTUAL RECOGNITION PROCEDURE</td>
<td>maa:mutual-recognition-procedure/rdm:selected</td>
<td>Procedure Type CTL (Value=&quot;mutual-recognition&quot;)</td>
<td>B221-1, See section 2.2.1.2</td>
</tr>
<tr>
<td>E221-3</td>
<td>1.1.3 A DECENTRALISED PROCEDURE</td>
<td>maa:decentralised-procedure/rdm:selected</td>
<td>Procedure Type CTL (Value=&quot;decentralised&quot;)</td>
<td>B221-1, See section 2.2.1.3</td>
</tr>
<tr>
<td>E221-4</td>
<td>1.1.4 A NATIONAL PROCEDURE</td>
<td>maa:national-procedure/rdm:selected</td>
<td>Procedure Type CTL (Value=&quot;national&quot;)</td>
<td>B221-1, See section 2.2.1.4</td>
</tr>
</tbody>
</table>

Element Tree Diagram

```plaintext
eu_application_form
  \- initial-application-form-human
    \- chapter-1
      \- centralised-procedure
      \- mutual-recognition-procedure
      \- decentralised-procedure
      \- national-procedure
```

Business Rules

<table>
<thead>
<tr>
<th>Rule ID</th>
<th>Element id(s)</th>
<th>Default BR</th>
<th>Rule</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>B221-1</td>
<td>E221-1 to E221-4</td>
<td>Mandatory.</td>
<td>The specific element ids are mutually exclusive.</td>
<td>Only one of these can be selected.</td>
</tr>
</tbody>
</table>
### 2.2.1.1. A Centralised Procedure

<table>
<thead>
<tr>
<th>Common DES 3.0 Context</th>
<th>Common RDM Entry point</th>
</tr>
</thead>
</table>

#### Elem Id | Label | DES 3.0 Mapping | RDM 3.0 Mapping | Remarks |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>E2211-2</td>
<td>« Mandatory scope » (Article 3(1))</td>
<td>rdm:selected_scope (Value=1)</td>
<td>Basis for Eligibility CTL</td>
<td>B2211-1</td>
</tr>
<tr>
<td>E2211-3</td>
<td>Annex (1) (Biotech medicinal product)</td>
<td>rdm:mandatory/rdm:annex (Value=1)</td>
<td>Basis for Eligibility CTL</td>
<td>B2211-2</td>
</tr>
<tr>
<td>E2211-4</td>
<td>Annex (1a) (Advanced Therapy Medicinal Product)</td>
<td>rdm:mandatory/rdm:advanced-therapy-medicinal-product/</td>
<td>Basis for Eligibility CTL</td>
<td></td>
</tr>
<tr>
<td>E2211-5</td>
<td>Gene therapy medicinal product</td>
<td>rdm:mandatory/rdm:advanced-therapy-medicinal-product/rdm:atmp-type (Value = 1)</td>
<td>Basis for Eligibility CTL</td>
<td></td>
</tr>
<tr>
<td>E2211-6</td>
<td>Somatic cell therapy medicinal product</td>
<td>rdm:mandatory/rdm:advanced-therapy-medicinal-product/rdm:atmp-type (Value = 2)</td>
<td>Basis for Eligibility CTL</td>
<td></td>
</tr>
<tr>
<td>E2211-7</td>
<td>Tissue engineered product</td>
<td>rdm:mandatory/rdm:advanced-therapy-medicinal-product/rdm:atmp-type (Value = 3)</td>
<td>Basis for Eligibility CTL</td>
<td></td>
</tr>
<tr>
<td>E2211-8</td>
<td>Combined Advanced Therapy Medicinal Product</td>
<td>rdm:mandatory/rdm:advanced-therapy-medicinal-product/rdm:atmp-type-is-also (Value = 1)</td>
<td>Basis for Eligibility CTL</td>
<td></td>
</tr>
<tr>
<td>E2211-9</td>
<td>Annex (3) (New active substance for mandatory indications)</td>
<td>rdm:mandatory/rdm:annex (Value=2)</td>
<td>Basis for Eligibility CTL</td>
<td>B2211-2</td>
</tr>
<tr>
<td>E2211-10</td>
<td>Annex (4) (Orphan designated medicinal product)</td>
<td>rdm:mandatory/rdm:annex (Value=3)</td>
<td>Basis for Eligibility CTL</td>
<td>B2211-2</td>
</tr>
<tr>
<td>E2211-11</td>
<td>« Optional scope » (Article 3(2))</td>
<td>rdm:selected_scope (Value=2)</td>
<td>Basis for Eligibility CTL</td>
<td>B2211-1</td>
</tr>
<tr>
<td>E2211-12</td>
<td>Annex 3(2)(a) (New active substance)</td>
<td>rdm:optional-scope/rdm:annex (Value=1)</td>
<td>Basis for Eligibility CTL</td>
<td>B2211-3</td>
</tr>
<tr>
<td>E2211-13</td>
<td>Annex 3(2)(b) (Significant innovation or interest of patients at community level)</td>
<td>rdm:optional-scope/rdm:annex (Value=2)</td>
<td>Basis for Eligibility CTL</td>
<td>B2211-3</td>
</tr>
<tr>
<td>E2211-14</td>
<td>« Generic of a Centrally Authorised Medicinal Product » (Article 3(3))</td>
<td>rdm:selected_scope (Value=3)</td>
<td>Basis for Eligibility CTL</td>
<td>B2211-1</td>
</tr>
<tr>
<td>E2211-15</td>
<td>« Marketing Authorisation including paediatric indication » (Article 28 of Regulation (EC) No 1901/2006)</td>
<td>rdm:selected_scope (Value=4)</td>
<td>Basis for Eligibility CTL</td>
<td>B2211-1</td>
</tr>
<tr>
<td>E2211-16</td>
<td>« Article 29 application » (Article 29 of Regulation (EC) No 1901/2006)</td>
<td>rdm:selected_scope (Value=5)</td>
<td>Basis for Eligibility CTL</td>
<td>B2211-1</td>
</tr>
<tr>
<td>E2211-17</td>
<td>« Paediatric Use Marketing Authorisation (PUMA) » (Article 31 of Regulation (EC) No 1901/2006)</td>
<td>rdm:selected_scope (Value=6)</td>
<td>Basis for Eligibility CTL</td>
<td>B2211-1</td>
</tr>
<tr>
<td>E2211-18</td>
<td>Date of acceptance/confirmation by CHMP:</td>
<td>rdm:article31/rdm:date-of-acceptance</td>
<td>chmp acceptance date</td>
<td></td>
</tr>
<tr>
<td>E2211-19</td>
<td>CHMP Rapporteur</td>
<td>rdm:non-atmp/rdm:chmp-rapporteur_selected</td>
<td>Role &gt; Party &gt; Party Type CTL (Value=&quot;Person&quot;)</td>
<td>B2211-4</td>
</tr>
<tr>
<td>E2211-59</td>
<td>EMA Product Number</td>
<td>rdm:article31/rdm:ema-product-number</td>
<td>Role &gt; Party &gt; Personal Title</td>
<td>B2211-14</td>
</tr>
<tr>
<td>E2211-20</td>
<td>Title</td>
<td>rdm:non-atmp/rdm:chmp-rapporteur/rdm:personal-title</td>
<td>Role &gt; Party &gt; Person &gt; Personal Title</td>
<td>B2211-4</td>
</tr>
<tr>
<td>E2211-21</td>
<td>First name</td>
<td>rdm:non-atmp/rdm:chmp-rapporteur/rdm:given-name</td>
<td>Role &gt; Party &gt; Person &gt; Given Name</td>
<td>B2211-4</td>
</tr>
<tr>
<td>E2211-22</td>
<td>Surname</td>
<td>rdm:non-atmp/rdm:chmp-rapporteur/rdm:family-name</td>
<td>Role &gt; Party &gt; Person &gt; Family Name</td>
<td>B2211-4</td>
</tr>
<tr>
<td>E2211-23</td>
<td>CHMP Co-Rapporteur:</td>
<td>rdm:non-atmp/rdm:chmp-co-rapporteur_selected</td>
<td>Role &gt; Party &gt; Party Type CTL (Value=&quot;Person&quot;)</td>
<td>B2211-5</td>
</tr>
<tr>
<td>E2211-25</td>
<td>First name</td>
<td>rdm:non-atmp/rdm:chmp-co-rapporteur/rdm:given-name</td>
<td>Role &gt; Party &gt; Person &gt; Given Name</td>
<td>B2211-5</td>
</tr>
<tr>
<td>E2211-26</td>
<td>Surname</td>
<td>rdm:non-atmp/rdm:chmp-co-rapporteur/rdm:family-name</td>
<td>Role &gt; Party &gt; Person &gt; Family Name</td>
<td>B2211-5</td>
</tr>
<tr>
<td>E2211-27</td>
<td>PRAC Rapporteur</td>
<td>rdm:non-atmp/rdm:prac-rapporteur_selected</td>
<td>Role &gt; Party &gt; Party Type CTL (Value=&quot;Person&quot;)</td>
<td>B2211-6</td>
</tr>
<tr>
<td>E2211-28</td>
<td>Title</td>
<td>rdm:non-atmp/rdm:prac-rapporteur/rdm:personal-title</td>
<td>Role &gt; Party &gt; Person &gt; Personal Title</td>
<td>B2211-6</td>
</tr>
<tr>
<td>E2211-29</td>
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<td>Role &gt; Party &gt; Person &gt; Given Name</td>
<td>B2211-6</td>
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<td>E2211-30</td>
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<td>rdm:non-atmp/rdm:prac-rapporteur/rdm:family-name</td>
<td>Role &gt; Party &gt; Person &gt; Family Name</td>
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<td>Role &gt; Party &gt; Person &gt; Personal Title</td>
<td>B2211-7</td>
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<td>First name</td>
<td>rdm:non-atmp/rdm:prac-co-rapporteur/rdm:given-name</td>
<td>Role &gt; Party &gt; Person &gt; Given Name</td>
<td>B2211-7</td>
</tr>
<tr>
<td>E2211-34</td>
<td>Surname</td>
<td>rdm:non-atmp/rdm:prac-co-rapporteur/rdm:family-name</td>
<td>Role &gt; Party &gt; Person &gt; Family Name</td>
<td>B2211-7</td>
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<tr>
<td>E2211-35</td>
<td>CAT Rapporteur</td>
<td>rdm:atmp/rdm:cat-rapporteur_selected</td>
<td>Role &gt; Party &gt; Party Type CTL (Value=&quot;Person&quot;)</td>
<td>B2211-8</td>
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<tr>
<td>E2211-36</td>
<td>Title</td>
<td>rdm:atmp/rdm:cat-rapporteur/rdm:personal-title</td>
<td>Role &gt; Party &gt; Person &gt; Personal Title</td>
<td>B2211-8</td>
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<td>E2211-37</td>
<td>First name</td>
<td>rdm:atmp/rdm:cat-rapporteur/rdm:given-name</td>
<td>Role &gt; Party &gt; Person &gt; Given Name</td>
<td>B2211-8</td>
</tr>
<tr>
<td>E2211-38</td>
<td>Surname</td>
<td>rdm:atmp/rdm:cat-rapporteur/rdm:family-name</td>
<td>Role &gt; Party &gt; Person &gt; Family Name</td>
<td>B2211-8</td>
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<td>E2211-40</td>
<td>Title</td>
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<td>Role &gt; Party &gt; Person &gt; Personal Title</td>
<td>B2211-9</td>
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<tr>
<td>E2211-41</td>
<td>First name</td>
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<td>Role &gt; Party &gt; Person &gt; Given Name</td>
<td>B2211-9</td>
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<tr>
<td>E2211-42</td>
<td>Surname</td>
<td>rdm:atmp/rdm:cat-co-rapporteur/rdm:family-name</td>
<td>Role &gt; Party &gt; Person &gt; Family Name</td>
<td>B2211-9</td>
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<tr>
<td>E2211-43</td>
<td>CHMP Coordinator</td>
<td>rdm:atmp / rdm:chmp-coordinator_selected</td>
<td>Role &gt; Party &gt; Party Type CTL (Value=&quot;Person&quot;)</td>
<td>B2211-10</td>
</tr>
<tr>
<td>E2211-44</td>
<td>Title</td>
<td>rdm:atmp/rdm:chmp-coordinator/rdm:personal-title</td>
<td>Role &gt; Party &gt; Person &gt; Personal Title</td>
<td>B2211-10</td>
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<tr>
<td>E2211-45</td>
<td>First name</td>
<td>rdm:atmp/rdm:chmp-coordinator/rdm:given-name</td>
<td>Role &gt; Party &gt; Person &gt; Given Name</td>
<td>B2211-10</td>
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<tr>
<td>E2211-46</td>
<td>Surname</td>
<td>rdm:atmp/rdm:chmp-coordinator/rdm:family-name</td>
<td>Role &gt; Party &gt; Person &gt; Family Name</td>
<td>B2211-10</td>
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<td>E2211-47</td>
<td>CHMP Co-Coordinator</td>
<td>rdm:atmp / rdm:chmp-co-coordinator_selected</td>
<td>Role &gt; Party &gt; Party Type CTL (Value=&quot;Person&quot;)</td>
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<td>Title</td>
<td>rdm:atmp/rdm:chmp-co-coordinator/rdm:personal-title</td>
<td>Role &gt; Party &gt; Person &gt; Personal Title</td>
<td>B2211-11</td>
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<tr>
<td>E2211-49</td>
<td>First name</td>
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<td>Role &gt; Party &gt; Person &gt; Given Name</td>
<td>B2211-11</td>
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<tr>
<td>E2211-50</td>
<td>Surname</td>
<td>rdm:atmp/rdm:chmp-co-coordinator/rdm:family-name</td>
<td>Role &gt; Party &gt; Person &gt; Family Name</td>
<td>B2211-11</td>
</tr>
<tr>
<td>E2211-51</td>
<td>PRAC Rapporteur</td>
<td>rdm:atmp/rdm:prac-rapporteur_selected</td>
<td>Role &gt; Party &gt; Party Type CTL (Value=&quot;Person&quot;)</td>
<td>B2211-12</td>
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<td>Role &gt; Party &gt; Person &gt; Personal Title</td>
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<td>E2211-53</td>
<td>First name</td>
<td>rdm:atmp/rdm:prac-rapporteur/rdm:given-name</td>
<td>Role &gt; Party &gt; Person &gt; Given Name</td>
<td>B2211-12</td>
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<td>E2211-54</td>
<td>Surname</td>
<td>rdm:atmp/rdm:prac-rapporteur/rdm:family-name</td>
<td>Role &gt; Party &gt; Person &gt; Family Name</td>
<td>B2211-12</td>
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<td>E2211-55</td>
<td>PRAC Co-Rapporteur</td>
<td>rdm:atmp/rdm:prac-co-rapporteur_selected</td>
<td>Role &gt; Party &gt; Party Type CTL (Value=&quot;Person&quot;)</td>
<td>B2211-13</td>
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<td>E2211-56</td>
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<td>rdm:atmp/rdm:prac-co-rapporteur/rdm:personal-title</td>
<td>Role &gt; Party &gt; Person &gt; Personal Title</td>
<td>B2211-13</td>
</tr>
<tr>
<td>E2211-57</td>
<td>First name</td>
<td>rdm:atmp/rdm:prac-co-rapporteur/rdm:given-name</td>
<td>Role &gt; Party &gt; Person &gt; Given Name</td>
<td>B2211-13</td>
</tr>
<tr>
<td>E2211-58</td>
<td>Surname</td>
<td>rdm:atmp/rdm:prac-co-rapporteur/rdm:family-name</td>
<td>Role &gt; Party &gt; Person &gt; Family Name</td>
<td>B2211-13</td>
</tr>
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<td>Default BR</td>
<td>Rule</td>
<td>Effect(s)</td>
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<td>------------</td>
<td>------</td>
<td>-----------</td>
</tr>
<tr>
<td>B2211-1</td>
<td>E2211-2, E2211-11, E2211-14 to E2211-17</td>
<td>Mandatory.</td>
<td>Fields are mutually exclusive.</td>
<td>Can only have one of them active at a time.</td>
</tr>
<tr>
<td>B2211-2</td>
<td>E2211-3 to E2211-10</td>
<td>Mandatory if E2211-2 is selected.</td>
<td>Fields are mutually exclusive.</td>
<td>Can only have one of them active at a time.</td>
</tr>
<tr>
<td>B2211-3</td>
<td>E2211-12, E2211-13</td>
<td>Mandatory if E2211-11 is selected.</td>
<td>Fields are mutually exclusive.</td>
<td>Can only have one of them active at a time.</td>
</tr>
<tr>
<td>B2211-4</td>
<td>E2211-19, E2211-20 to E2211-22</td>
<td>E2211-19 is mandatory.</td>
<td>If E2211-19, then E2211-20 to E2211-22 are mandatory.</td>
<td></td>
</tr>
<tr>
<td>B2211-5</td>
<td>E2211-23, E2211-24 to E2211-26</td>
<td>E2211-23 is mandatory, rest are optional.</td>
<td>If E2211-23, then E2211-24 to E2211-26 are mandatory.</td>
<td></td>
</tr>
<tr>
<td>B2211-6</td>
<td>E2211-27, E2211-28 to E2211-30</td>
<td>E2211-27 is mandatory.</td>
<td>If E2211-27, then E2211-28 to E2211-30 are mandatory.</td>
<td></td>
</tr>
<tr>
<td>B2211-7</td>
<td>E2211-31, E2211-32 to E2211-34</td>
<td>All are optional.</td>
<td>If E2211-31, then E2211-32 to E2211-34 are mandatory.</td>
<td></td>
</tr>
<tr>
<td>B2211-8</td>
<td>E2211-35, E2211-36 to E2211-38</td>
<td>E2211-35 is mandatory.</td>
<td>If E2211-35, then E2211-36 to E2211-38 are mandatory.</td>
<td></td>
</tr>
<tr>
<td>B2211-9</td>
<td>E2211-39, E2211-40 to E2211-42</td>
<td>E2211-39 is mandatory, rest are optional.</td>
<td>If E2211-39, then E2211-40 to E2211-42 are mandatory.</td>
<td></td>
</tr>
<tr>
<td>B2211-10</td>
<td>E2211-43, E2211-44 to E2211-46</td>
<td>E2211-43 is mandatory.</td>
<td>If E2211-43, then E2211-44 to E2211-46 are mandatory.</td>
<td></td>
</tr>
<tr>
<td>B2211-11</td>
<td>E2211-47, E2211-48 to E2211-50</td>
<td>E2211-47 is mandatory, rest are optional.</td>
<td>If E2211-47, then E2211-48 to E2211-50 are mandatory.</td>
<td></td>
</tr>
<tr>
<td>B2211-12</td>
<td>E2211-51, E2211-52 to E2211-54</td>
<td>E2211-51 is mandatory.</td>
<td>If E2211-51, then E2211-52 to E2211-54 are mandatory.</td>
<td></td>
</tr>
<tr>
<td>B2211-13</td>
<td>E2211-55, E2211-56 to E2211-58</td>
<td>All are optional.</td>
<td>If E2211-55, then E2211-56 to E2211-58 are mandatory.</td>
<td></td>
</tr>
<tr>
<td>B2211-14</td>
<td>E2211-59</td>
<td>Optional</td>
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</table>
## 2.2.1.2. A MUTUAL RECOGNITION PROCEDURE

<table>
<thead>
<tr>
<th>Elem Id</th>
<th>Label</th>
<th>DES 3.0 Mapping</th>
<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>E2212-1</td>
<td>1.1.2 A MUTUAL RECOGNITION PROCEDURE</td>
<td>rdm: selected</td>
<td>Procedure Type CTL (Value=&quot; mutual-recognition &quot;)</td>
<td></td>
</tr>
<tr>
<td>E2212-2</td>
<td>Reference Member State</td>
<td>rdm:reference-member-state</td>
<td>Role &gt; CountryCTL</td>
<td></td>
</tr>
<tr>
<td>E2212-3</td>
<td>Date of authorisation</td>
<td>rdm:date-of-authorisation</td>
<td>previous auth date</td>
<td></td>
</tr>
<tr>
<td>E2212-4</td>
<td>Marketing authorisation number</td>
<td>rdm: market-authorisation-number</td>
<td>previous auth number</td>
<td></td>
</tr>
<tr>
<td>E2212-5</td>
<td>Procedure number:</td>
<td>rdm:procedure-number</td>
<td>procedure number</td>
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</tr>
<tr>
<td>E2212-6</td>
<td>First use</td>
<td>rdm:first-use (Value=1)</td>
<td>Procedure Use CTL</td>
<td></td>
</tr>
<tr>
<td>E2212-7</td>
<td>Repeat use (Please also complete section 4.2)</td>
<td>rdm:first-use (Value=2)</td>
<td>Procedure Use CTL</td>
<td></td>
</tr>
<tr>
<td>E2212-8</td>
<td>Wave</td>
<td>rdm:member-renewals/rdm:member-renewal</td>
<td>Procedure Use &gt; waive id</td>
<td></td>
</tr>
<tr>
<td>E2212-10</td>
<td>Proposed/Agreed common renewal date</td>
<td>rdm:member-renewals/rdm:member-renewal/rdm:proposed-agreed-renewal-date</td>
<td>Procedure Use &gt; Proposed / agreed common renewal date</td>
<td></td>
</tr>
</tbody>
</table>

**Element Tree Diagram**

eu_application_form -> initial-application-form-human -> chapter-1

- procedure-type
  - mutual-recognition-procedure
    - selected :yes-no
    - reference-member-state
    - date-of-authorisation :Date
    - market-authorisation-number /text
    - procedure-number /text
    - first-use :CTL
      - member-renewals
        - member-renewal
          - member-states
            - ref-member-state :text
          - name /text
        - proposed-agreed-renewal-date :text
2.2.1.3. A DECENTRALISED PROCEDURE

<table>
<thead>
<tr>
<th>Elem Id</th>
<th>Label</th>
<th>DES 3.0 Mapping</th>
<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
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<tbody>
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<td>1.1.3  A DECENTRALISED PROCEDURE</td>
<td>rdm:selected</td>
<td>Procedure Type CTL (Value=&quot;decentralised&quot;)</td>
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</tr>
<tr>
<td>E2213-2</td>
<td>(according to Article 28(3) of Directives 2001/83/EC)</td>
<td>rdm:reference-member-state</td>
<td>Procedure Use &gt; Role &gt; Country CTL</td>
<td></td>
</tr>
<tr>
<td>E2213-3</td>
<td>Reference Member State</td>
<td>rdm:procedure-number</td>
<td>Procedure number</td>
<td></td>
</tr>
<tr>
<td>E2213-4</td>
<td>Procedure number:</td>
<td>rdm:member-states/rdm:ref-member-state/rdm:name</td>
<td>Procedure Use &gt; Role &gt; Country CTL</td>
<td></td>
</tr>
<tr>
<td>E2213-5</td>
<td>Concerned Member State (specify)</td>
<td>rdm:proposed-agreed-renewal-date</td>
<td></td>
<td></td>
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<tr>
<td>E213-6</td>
<td>Proposed/Agreed common Reewal Date</td>
<td>rdm:proposed-agreed-renewal-date</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Element Tree Diagram

```
  eu_application_form
     | initial-application-form-human
     | chapter-1
        | procedure-type
        | decentralised-procedure
        | selected :yes-no
        | reference-member-state
        | date-of-authorisation :Date
        | procedure-number /text
        | member-states
        | Proposed-agreed-renewal date
        | ref-member-state
        | name /text
```


2.2.1.4. A NATIONAL PROCEDURE

<table>
<thead>
<tr>
<th>Elem Id</th>
<th>Label</th>
<th>DES 3.0 Mapping</th>
<th>Common RDM Entry point</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
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<td>E2214-1</td>
<td>1.1.4  A NATIONAL PROCEDURE</td>
<td>rdm:selected</td>
<td>Application &gt; MP Procedure &gt;</td>
<td></td>
</tr>
<tr>
<td>E2214-2</td>
<td>Member State</td>
<td>rdm:ref-member-state</td>
<td>Procedure Type CTL (Value=&quot;national&quot;)</td>
<td></td>
</tr>
<tr>
<td>E2214-3</td>
<td>Application number (if available)</td>
<td>rdm:application-number</td>
<td>Role &gt; Country CTL</td>
<td></td>
</tr>
</tbody>
</table>

Element Tree Diagram

```
  eu_application_form
     | initial-application-form-human
     |     chapter-1
        | procedure-type
        | national-procedure
            | selected /text
            | ref-member-state /text
            | application-number /text
```
### 2.2.2 ORPHAN MEDICINAL PRODUCT INFORMATION

<table>
<thead>
<tr>
<th>Common DES 3.0 Context</th>
<th>Common RDM Entry point</th>
</tr>
</thead>
</table>

**Element Tree Diagram**

```
  eu_application_form --> initial-application-form-human --> chapter-1
    |                |                        |
    |                |                         |
    |                |   orphan-designation    |
    |                |   od-medicinal-product  |
    |                |   od-market-exclusivity |
```

### 2.2.2.1 HAS ORPHAN DESIGNATION BEEN APPLIED FOR THIS MEDICINAL PRODUCT?

<table>
<thead>
<tr>
<th>Common DES 3.0 Context</th>
<th>Common RDM Entry point</th>
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</thead>
</table>

**Element Tree Diagram**

```
  eu_application_form --> initial-application-form-human --> chapter-1
    |                |                        |
    |                |                         |
    |                |   orphan-designation    |
    |                |   od-medicinal-product  |
    |                |   od-market-exclusivity |
```

**Has any medicinal product been designated as an Orphan medicinal product for a condition relating to the indication proposed in this application?**

**Has Orphan Designation been applied for this medicinal product?**

**Does the medicinal product have significant benefit?**

**Orphan Designation Granted/Refused Decision (Annex 5.18)**

**Authorisation Status**

**Orphan Designation/Withdrawn Date**
**Business Rules**

<table>
<thead>
<tr>
<th>Rule ID</th>
<th>Element id(s)</th>
<th>Default BR</th>
<th>Rule</th>
<th>Effect(s)</th>
</tr>
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<tbody>
<tr>
<td>B2221-1</td>
<td>E2221-1, E2221-2</td>
<td>Mandatory</td>
<td>Mutually exclusive.</td>
<td></td>
</tr>
<tr>
<td>B2221-2</td>
<td>E2221-1, E2221-3 to E2221-5, E2221-12, E2221-15</td>
<td>E2221-1 is mandatory, rest are optional.</td>
<td>If E2221-1 is selected, then the rest is mandatory, else they are optional.</td>
<td></td>
</tr>
<tr>
<td>B2221-3</td>
<td>E2221-4, E2221-5, E2221-12, E2221-15</td>
<td>Optional</td>
<td>Mutually exclusive.</td>
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<tr>
<td>B2221-4</td>
<td>E2221-5, E2221-6 to E2221-11</td>
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<td>If E2221-5 is selected, the rest are mandatory.</td>
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<td>B2221-5</td>
<td>E2221-7, E2221-8</td>
<td>Optional</td>
<td>Mutually Exlusive.</td>
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<tr>
<td>B2221-6</td>
<td>E2221-12 to E2221-14</td>
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<td>If E2221-12 is selected, the rest is mandatory.</td>
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<tr>
<td>B2221-7</td>
<td>E2221-15, E2221-16</td>
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<td>If E2221-15, then E2221-16 is mandatory.</td>
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## 2.2.2.2 INFORMATION RELATING TO ORPHAN MARKET EXCLUSIVITY

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<th>Common RDM Entry point</th>
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</thead>
</table>

<table>
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<th>Label</th>
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<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>E2222-1</td>
<td>Yes</td>
<td>rdm:isorphan (Value=1)</td>
<td>has mp designated orphan</td>
<td>B2222-1, B2222-2</td>
</tr>
<tr>
<td>E2222-2</td>
<td>No</td>
<td>rdm:isorphan (Value=0)</td>
<td>has mp designated orphan</td>
<td>B2222-1</td>
</tr>
<tr>
<td>E2222-3</td>
<td>Please specify the EU Orphan Designation Number:</td>
<td>rdm:od-procedure-numbers/rdm:od-procedure-number</td>
<td>OD Number</td>
<td>B2222-2</td>
</tr>
<tr>
<td>E2222-4</td>
<td>Has any of the designated orphan medicinal product(s) been granted a marketing authorisation in the EU?</td>
<td>rdm:granted-market-auth (Value=1)</td>
<td>has od mp granted ma</td>
<td>B2222-2, B2222-3, B2222-4</td>
</tr>
<tr>
<td>E2222-5</td>
<td>No</td>
<td>rdm:granted-market-auth (Value=0)</td>
<td>has od mp granted ma</td>
<td>B2222-2, B2222-3</td>
</tr>
<tr>
<td>E2222-6</td>
<td>Please specify:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E2222-7</td>
<td>Therapeutic indication(s)</td>
<td>rdm:products/rdm:product/rdm:pharmaprocess/rdm:therapeutic-indications/rdm:therapeutic-indication</td>
<td></td>
<td>B2222-4</td>
</tr>
<tr>
<td>E2222-14</td>
<td>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)</td>
<td>rdm:module171-172 (Value=1)</td>
<td>is mp similar to authorised</td>
<td>B2222-4</td>
</tr>
<tr>
<td>E2222-15</td>
<td>Yes(modules 1.7.1 and 1.7.2 to be completed)</td>
<td>rdm:module171-172 (Value=1)</td>
<td>is mp similar to authorised</td>
<td>B2222-4, B2222-5</td>
</tr>
</tbody>
</table>
## Element Tree Diagram

```
eu_application_form  initial-application-form-human  chapter-1  orphan-designation
     |                              |                                |
     |                              |                                |
     | is mp similar to authorised  |
     |                              |
     |                              |
     | od-market-exclusivity        |
     |                              |
     |                              |
     | isolated                    |
     | :yes-no                     |
     | granted-market-authority    |
     | :yes-no                     |
     | module171-172               |
     | :yes-no                     |
     | od-procedure-numbers        |
     | :yes-no                     |
     | od-procedure-number         |
     | /text                       |
     |                              |
     | pharma-product              |
     |                              |
     |                              |
     | pharmaceutical-products     |
     |                              |
     | pharmaceutical-product      |
     |                              |
     |                              |
     | pharmaceutical-form-names   |
     |                              |
     | pharmaceutical-form-details |
     |                              |
     | pharmaceutical-form-name    |
     | /text                       |
     |                              |
     | pharmaceutical-form-strength |
     | /text                       |
     |                              |
     | mp-authorization            |
     |                              |
     |                              |
     | authorisation-numbers       |
     | /text                       |
     |                              |
     | authorisation-holder        |
     | /text                       |
     |                              |
     | authorisation-date          |
     | :Date                       |
```

## Business Rules

<table>
<thead>
<tr>
<th>Rule ID</th>
<th>Element id(s)</th>
<th>Default BR</th>
<th>Rule</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>B2222-1</td>
<td>E2222-1, E2222-2</td>
<td>Mandatory</td>
<td>Mutually exclusive.</td>
<td></td>
</tr>
<tr>
<td>B2222-2</td>
<td>E2222-1, E2222-3 to E2222-6</td>
<td>Mandatory for E2222-1, optional for the rest.</td>
<td>If E2222-1 is selected, the rest is mandatory.</td>
<td></td>
</tr>
<tr>
<td>B2222-3</td>
<td>E2222-5, E2222-6</td>
<td>Optional</td>
<td>Mutually exclusive.</td>
<td></td>
</tr>
<tr>
<td>B2222-4</td>
<td>E2222-5, E2222-8 to E2222-17</td>
<td>Optional</td>
<td>If E2222-5 is selected, the rest is mandatory.</td>
<td></td>
</tr>
<tr>
<td>B2222-5</td>
<td>E2222-15, E2222-17</td>
<td>Optional</td>
<td>Mutually exclusive.</td>
<td></td>
</tr>
</tbody>
</table>
### 2.2. 3 APPLICATION FOR A CHANGE TO EXISTING MARKETING AUTHORISATION LEADING TO AN EXTENSION AS REFERRED TO IN ANNEX I OF REGULATIONS (EC) NO 1234/2008, OR ANY NATIONAL LEGISLATION, WHERE APPLICABLE?

<table>
<thead>
<tr>
<th>Common DES 3.0 Context</th>
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</tr>
</thead>
</table>

<table>
<thead>
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<th>Label</th>
<th>DES 3.0 Mapping</th>
<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>E223-1</td>
<td>Yes (complete sections below and also complete 1.4 + 1.6)</td>
<td>maa:yes (Value=1)</td>
<td>change in existing ma</td>
<td>B223-1, B223-2</td>
</tr>
<tr>
<td>E223-2</td>
<td>No (complete section 1.4 + 1.6)</td>
<td>maa:yes (Value=0)</td>
<td>change in existing ma</td>
<td>B223-1</td>
</tr>
<tr>
<td>E223-3</td>
<td>Please specify:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E223-4</td>
<td>Qualitative change in declared active substance NOT DEFINED AS A NEW ACTIVE SUBSTANCE</td>
<td>maa:qualitative-change</td>
<td>Difference CTL</td>
<td>B223-2, B223-3</td>
</tr>
<tr>
<td>E223-5</td>
<td>Replacement by a different salt/ester, complex/derivative (same therapeutic moiety)</td>
<td>maa:qualitative-change-detail (Value=1)</td>
<td>Difference CTL</td>
<td>B223-3, B223-4</td>
</tr>
<tr>
<td>E223-6</td>
<td>Replacement by a different isomer, mixture of isomers, of a mixture by an isolated isomer</td>
<td>maa:qualitative-change-detail (Value=2)</td>
<td>Difference CTL</td>
<td>B223-3, B223-4</td>
</tr>
<tr>
<td>E223-7</td>
<td>Replacement of a biological substance or product of biotechnology</td>
<td>maa:qualitative-change-detail (Value=3)</td>
<td>Difference CTL</td>
<td>B223-3, B223-4</td>
</tr>
<tr>
<td>E223-8</td>
<td>New ligand or coupling mechanism for a radiopharmaceutical</td>
<td>maa:qualitative-change-detail (Value=4)</td>
<td>Difference CTL</td>
<td>B223-3, B223-4</td>
</tr>
<tr>
<td>E223-9</td>
<td>Change to the extraction solvent or the radio of herbal drug to herbal drug preparation</td>
<td>maa:qualitative-change-detail (Value=5)</td>
<td>Difference CTL</td>
<td>B223-3, B223-4</td>
</tr>
<tr>
<td>E223-10</td>
<td>Change of bioavailability</td>
<td>maa:bioavailability</td>
<td>Difference CTL</td>
<td>B223-2</td>
</tr>
<tr>
<td>E223-11</td>
<td>Change of pharmacokinetics</td>
<td>maa:pharmacokinetics</td>
<td>Difference CTL</td>
<td>B223-2</td>
</tr>
<tr>
<td>E223-12</td>
<td>Change or addition of a new strength/potency</td>
<td>maa:strength-potency</td>
<td>Difference CTL</td>
<td>B223-2</td>
</tr>
<tr>
<td>E223-13</td>
<td>Change or addition of a new pharmaceutical form</td>
<td>maa:pharma-form</td>
<td>Difference CTL</td>
<td>B223-2</td>
</tr>
<tr>
<td>E223-14</td>
<td>Change or addition of a new route of administration</td>
<td>maa:route-of-admin</td>
<td>Difference CTL</td>
<td>B223-2</td>
</tr>
<tr>
<td>E223-15</td>
<td>Note: - the applicant of the present application must be the same as the marketing authorisation holder of the existing marketing authorisation - this section should be completed without prejudice to the provisions of Articles 8(3), 10, 10a, 10b, 10c, and Directive 2001/83/EC</td>
<td></td>
<td></td>
<td>B223-2</td>
</tr>
<tr>
<td>E223-17</td>
<td>Authorization of a new pharmaceutical form</td>
<td>maa:authorisation-new-pharma-form</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Element Tree Diagram

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<eu_application_form>
  <initial-application-form-human>
    <chapter-1>
      <change-market-authorization>
        <yes/>
        <qualitative-change/>
        <qualitative-change-detail/>
        <Article-29/>
        <bioavailability/>
        <pharmacokinetics/>
        <strength-potency/>
        <specific-yes/>
        <route-of-admin/>
        <pharma-form/>
        <product/>
        <Authorisation-new-pharm/>
        <Authorisation-new-route-of-admin/>
        <pharmaproduct>
          <pharmaceutical-products/>
          <pharmaceutical-product/>
          <pharmaceutical-form-names/>
          <pharmaceutical-form-details/>
          <pharmaceutical-form-name/>
          <pharmaceutical-form-strengths/>
          <pharmaceutical-form-strength-description/>
          <mp-authorisation/>
          <authorisation-holder/>
          <authorisation-numbers/>
        </pharmaproduct>
      </change-market-authorization>
    </chapter-1>
  </initial-application-form-human>
</eu_application_form>
```
### Business Rules

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<tr>
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<th>Default BR</th>
<th>Rule</th>
<th>Effect(s)</th>
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</thead>
<tbody>
<tr>
<td>B223-1</td>
<td>E223-1, E223-2</td>
<td>Mandatory.</td>
<td></td>
<td>Mutually Exclusive.</td>
</tr>
<tr>
<td>B223-2</td>
<td>E223-1, E223-4, E223-10 to E223-23</td>
<td>E223-1 is Mandatory, rest are optional.</td>
<td>If E223-1 is selected, the rest are mandatory.</td>
<td></td>
</tr>
<tr>
<td>B223-3</td>
<td>E223-4, E223-5 to E223-9</td>
<td>Optional.</td>
<td>If E223-4 is selected, the rest is mandatory.</td>
<td></td>
</tr>
<tr>
<td>B223-4</td>
<td>E223-5 to E223-9</td>
<td>Optional.</td>
<td></td>
<td>Mutually Exclusive.</td>
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</table>
2.2. 4 APPLICATION SUBMITTED IN ACCORDANCE WITH THE FOLLOWING ARTICLE IN DIRECTIVE 2001/83/EC

<table>
<thead>
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<th>Common RDM Entry point</th>
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</table>

<table>
<thead>
<tr>
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<th>Label</th>
<th>DES 3.0 Mapping</th>
<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>E224-1</td>
<td>Note: Section to be completed for any application, including applications referred to in section 1.3. For further details, refer to Notice of Applicants, Volume 2A, Chapter 1.</td>
<td>maa:section1-4-1/maa:article-8-3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E224-2</td>
<td>Article 8(3) application, (i.e dossier with administrative, quality, pre-clinical and clinical data)*</td>
<td>maa:generic-application/maa:article-10-1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E224-3</td>
<td>Article 10(1) generic application</td>
<td>maa:hybrid-application/maa:reference-medicinal-products/maa:article10-3</td>
<td>Application Category CTL</td>
<td>B224-1, B224-2, B224-3</td>
</tr>
<tr>
<td>E224-4</td>
<td>Article 10(3) hybrid application</td>
<td>maa:section1-4-1/maa:article-8-3</td>
<td>Application Category CTL</td>
<td>B224-1, B224-2, B224-3</td>
</tr>
<tr>
<td>E224-5</td>
<td>Article 10(4) similar biological application</td>
<td>maa:section1-4-1/maa:article-8-3</td>
<td>Application Category CTL</td>
<td>B224-1, B224-4, B224-3</td>
</tr>
<tr>
<td>E224-6</td>
<td>Article 10a well-established use application</td>
<td>maa:section1-4-1/maa:article-8-3</td>
<td>Application Category CTL</td>
<td>B224-1</td>
</tr>
<tr>
<td>E224-7</td>
<td>Article 10b fixed combination application</td>
<td>maa:section1-4-1/maa:article-8-3</td>
<td>Application Category CTL</td>
<td>B224-1</td>
</tr>
<tr>
<td>E224-8</td>
<td>Article 10c informed consent application</td>
<td>maa:section1-4-1/maa:article-8-3</td>
<td>Application Category CTL</td>
<td>B224-1, B224-5</td>
</tr>
<tr>
<td>E224-9</td>
<td>Article 16a Traditional use registration for herbal medicinal product</td>
<td>maa:section1-4-1/maa:article-8-3</td>
<td>Application Category CTL</td>
<td>B224-1</td>
</tr>
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</table>

Element Tree Diagram

Business Rules

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<th>Rule ID</th>
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<th>Rule</th>
<th>Effect(s)</th>
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</thead>
<tbody>
<tr>
<td>B224-1</td>
<td>E224-2 to E224-9</td>
<td>Mandatory.</td>
<td>Considering that E224-3 and E224-4 is a single element, E224-2 to E224-9 are mutually exclusive.</td>
<td></td>
</tr>
<tr>
<td>B224-2</td>
<td>E224-3, E224-4</td>
<td>Mandatory.</td>
<td>They are not mutually exclusive.</td>
<td></td>
</tr>
</tbody>
</table>
2.2.4.1 Article 8(3) application, (i.e. dossier with administrative, quality, pre-clinical and clinical data*)

<table>
<thead>
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<th>Common DES 3.0 Context</th>
<th>Common RDM Entry point</th>
</tr>
</thead>
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<table>
<thead>
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<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
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</thead>
<tbody>
<tr>
<td>E2241-1</td>
<td>New active substance</td>
<td>maa:new-active-substance/maa:attach-letter</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E2241-2</td>
<td>please provide evidence and justification to support the claim of new active substance status in annex 5.23</td>
<td>maa:attach-letter</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Element Tree Diagram

```
eu_application_form     initial-application-form-human     chapter-1     directive-2001-83-ec
                        |                        |              |
                        |                        |              | section1-4-1
                        |                        |              | new-active-substance
                        |                        |              | :yes-no
                        |                        |              | attach-letter
                        |                        |              | :yes-no
```
### 2.2.4.2 Article 10(1) generic application

**Common DES 3.0 Context**

```
```

**Common RDM Entry point**

```
Application >
```

<table>
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<tr>
<th>Elem Id</th>
<th>Label</th>
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<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>E2242-1</td>
<td>Note: . application for a generic medicinal product as defined in Article 10(2)(b) referring to a so-called reference medicinal product with a marketing authorisation granted in a Member State or in the Community. . complete administrative and quality data, appropriate pre-clinical and clinical data when applicable. . refer to Notice to Applicants, Volume 2A, Chapter 1.</td>
<td>maa:generic-application</td>
<td>Reference Medicinal Product&gt; RMP Usage CTL</td>
<td>B2242-1, See Section 2.2.4.2.1</td>
</tr>
<tr>
<td>E2242-2</td>
<td>Reference medicinal product:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E2242-3</td>
<td>Note: The chosen reference medicinal product must be a medicinal product authorised in the Union on the basis of a complete dossier in accordance with the provisions of the Article 8 of Directive 2001/83/EC.</td>
<td>maa:reference-medicinal-product</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E2242-4</td>
<td>Medicinal product which is or has been authorised in accordance with Union provisions in force for not less than 6/8/10 years in the EEA:</td>
<td>maa:first-rmps/maa:reference-medicinal-product/</td>
<td>Reference Medicinal Product&gt; RMP Usage CTL</td>
<td>B2242-1, See Section 2.2.4.2.2</td>
</tr>
<tr>
<td>E2242-5</td>
<td>Medicinal product authorised in the Union/Member State where the application is made or European reference medicinal product:</td>
<td>maa:second-rmp/maa:reference-medicinal-product/</td>
<td>Reference Medicinal Product&gt; RMP Usage CTL</td>
<td></td>
</tr>
<tr>
<td>E2242-6</td>
<td>Medicinal product which is or has been authorised in accordance with Community provisions in force and to which bioequivalence has been demonstrated by appropriate bioavailability studies:</td>
<td>maa:third-rmp/maa:bio-reference-medicinal-product/</td>
<td>Reference Medicinal Product&gt; RMP Usage CTL</td>
<td>See Section 2.2.4.2.3</td>
</tr>
</tbody>
</table>

**Element Tree Diagram**

```
 eu_application_form  initial-application-form-human  chapter-1  directive-2001-83-ec
       |                                           |                                                  |                              |
       v                                           v                                                  v                              |
  maa:generic-application                        reference-medicinal-products                      |
          |                                           |                                                  |                              |
          v                                           v                                                  v                              |
      first-rmps                                   second-rmp                                       third-rmp                      |
          |                                           |                                                  |                              |
          v                                           v                                                  v                              |
          |                                           |                                                  |                              |
          v                                           v                                                  v                              |
  2.2.4.2.1       2.2.4.2.2         2.2.4.2.3
```

**Business Rules**

<table>
<thead>
<tr>
<th>Rule ID</th>
<th>Element id(s)</th>
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<th>Rule</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>B2242-1</td>
<td>E224-3, E2242-4, E2242-5</td>
<td>E224-3 is mandatory. rest are optional.</td>
<td>When E224-3 is selected, then the rest are mandatory</td>
<td></td>
</tr>
</tbody>
</table>
### 2.2.4.2.1 Medicinal product which is or has been authorised in accordance with Union provisions in force for not less than 6/8/10 years in the EEA

<table>
<thead>
<tr>
<th>Common DES 3.0 Context</th>
<th>Common RDM Entry point</th>
</tr>
</thead>
</table>

<table>
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<tr>
<th>Elem Id</th>
<th>Label</th>
<th>DES 3.0 Mapping</th>
<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>E22421-1</td>
<td>Product (Invented) name</td>
<td>rdm:pharmaproduct/rdm:invented-name</td>
<td>Reference Medicinal Product &gt; Medicinal Product Name</td>
<td></td>
</tr>
<tr>
<td>E22421-8</td>
<td>Union</td>
<td>rdm:community</td>
<td>MP Authorisation &gt; Country CTL</td>
<td>B22421-1</td>
</tr>
<tr>
<td>E22421-9</td>
<td>Member State(EEA)</td>
<td>rdm:mem-selected</td>
<td>MP Authorisation &gt; Country CTL</td>
<td>B22421-1, B22421-2</td>
</tr>
<tr>
<td>E22421-10</td>
<td>Member State(EEA)</td>
<td>rdm:member-state</td>
<td>MP Authorisation &gt; Country CTL</td>
<td>B22421-2</td>
</tr>
<tr>
<td>E22421-11</td>
<td>Note: This section defines the reference medicinal product chosen for the purposes of establishing the expiry of the data protection period.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Element Tree Diagram

Business Rules

<table>
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<tr>
<th>Rule ID</th>
<th>Element Id(s)</th>
<th>Default BR</th>
<th>Rule</th>
<th>Effect(s)</th>
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</thead>
<tbody>
<tr>
<td>B22421-1</td>
<td>E22421-8 to 9</td>
<td>Optional</td>
<td>Mutually Exclusive</td>
<td></td>
</tr>
<tr>
<td>B22421-2</td>
<td>E22421-9 to 10</td>
<td>Optional</td>
<td>If E22421-9 is selected, then E22421-10 is required</td>
<td></td>
</tr>
<tr>
<td>B22421-3</td>
<td>E22421-12</td>
<td>Optional</td>
<td></td>
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</table>
### 2.2.4.2.2 Medicinal product authorised in the Union/Member State where the application is made or European reference medicinal product:

<table>
<thead>
<tr>
<th>Common DES 3.0 Context</th>
<th>Common RDM Entry point</th>
</tr>
</thead>
</table>

<table>
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<tbody>
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<td>E22422-1</td>
<td>Product (Invented) name</td>
<td>rdm:pharmaproduct/rdm:invented-name</td>
<td>Reference Medicinal Product &gt; Medicinal Product Name</td>
<td></td>
</tr>
<tr>
<td>E22422-6</td>
<td>Marketing authorisation granted by</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E22422-7</td>
<td>Union</td>
<td>rdm:community</td>
<td>MP Authorisation &gt; Country CTL</td>
<td>B22422-2</td>
</tr>
<tr>
<td>E22422-8</td>
<td>Member State(EEA)</td>
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<td></td>
<td>B22422-2, B22422-3</td>
</tr>
<tr>
<td>E22422-9</td>
<td>Member State(EEA)</td>
<td>rdm:member-state</td>
<td>MP Authorisation &gt; Country CTL</td>
<td>B22422-3</td>
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Element Tree Diagram

Business Rules

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<td>invented-name</td>
<td>in /text</td>
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<tr>
<td>B22422-3</td>
<td>E22422-8 to 9</td>
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<td>If E22422-8 is selected, then E22422-9 is required</td>
<td></td>
</tr>
<tr>
<td>B22422-4</td>
<td>E22422-10</td>
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### 2.2.4.2.3 Medicinal product which is or has been authorised in accordance with Union provisions in force and to which bioequivalence has been demonstrated by appropriate bioavailability studies:

<table>
<thead>
<tr>
<th>Common DES 3.0 Context</th>
<th>Common RDM Entry point</th>
</tr>
</thead>
</table>

<table>
<thead>
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<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>E22423-1</td>
<td>Note: Should be in accordance with the notion of global marketing authorisation, if different from the medicinal product identified above.</td>
<td>rdm:pharmaproduct/rdm:invented-name</td>
<td>Reference Medicinal Product &gt; Medicinal Product Name</td>
<td></td>
</tr>
<tr>
<td>E22423-8</td>
<td>Member State of source</td>
<td>rdm:member-state-source</td>
<td>Reference Medicinal Product &gt; Country CTL</td>
<td></td>
</tr>
<tr>
<td>E22423-9</td>
<td>Bioavailability study(ies) reference number(s)/EudraCT numbers(s):</td>
<td>rdm:bio-sty-ref-eudract/rdm:number</td>
<td>Reference Medicinal Product &gt; study ref number</td>
<td></td>
</tr>
<tr>
<td>E22423-10</td>
<td>Marketing authorisation granted by</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E22423-11</td>
<td>Union</td>
<td>rdm:community</td>
<td>MP Authorisation &gt; Country CTL</td>
<td>B22423-1</td>
</tr>
<tr>
<td>E22423-12</td>
<td>Member State(EEA)</td>
<td>rdm:mem-selected</td>
<td>B22423-1</td>
<td></td>
</tr>
<tr>
<td>E22423-13</td>
<td>Member State(EEA)</td>
<td>rdm:member-state</td>
<td>MP Authorisation &gt; Country CTL</td>
<td>B22423-2</td>
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Element Tree Diagram

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<td>B22423-1</td>
<td>E22423-11 to 12</td>
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<td></td>
</tr>
<tr>
<td>B22423-2</td>
<td>E22423-12 to 13</td>
<td>Optional</td>
<td>If E22423-12 is selected, then E22423-13 is required</td>
<td></td>
</tr>
<tr>
<td>B22423-3</td>
<td>E22423-14</td>
<td>Optional</td>
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### 2.2.4.3 Article 10(3) hybrid application

<table>
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<th>Remarks</th>
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</thead>
<tbody>
<tr>
<td>E2243-1</td>
<td>Note: Application for a medicinal product referring to a so-called reference medicinal product with a Marketing Authorisation in a Member State or in the Union (e.g. different pharmaceutical form, different therapeutic use .......) Complete administrative and quality data, appropriate preclinical and clinical data. Refer to Notice to Applicants, Volume 2A, Chapter 1.</td>
<td></td>
<td>B2243-1</td>
<td></td>
</tr>
<tr>
<td>E2243-2</td>
<td>Reference medicinal product</td>
<td></td>
<td>B2243-1</td>
<td></td>
</tr>
<tr>
<td>E2243-3</td>
<td>Note: The chosen reference medicinal product must be a medicinal product authorised in the Union on the basis of a complete dossier in accordance with the provisions of the Article 8 of Directive 2001/83/EC.</td>
<td></td>
<td>B2243-1</td>
<td></td>
</tr>
<tr>
<td>E2243-4</td>
<td>Medicinal product which is or has been authorised in accordance with Union provisions in force for not less than 6/10 years in the EEA</td>
<td>maa:hyb-first-rmp/reference-medicinal-product/</td>
<td>RMP Usage CTL</td>
<td>B2243-1, See Section 2.2.4.3.1</td>
</tr>
<tr>
<td>E2243-5</td>
<td>Medicinal product authorised in the Union/Member State where the application is made or European reference medicinal product</td>
<td>maa:second-rmp/</td>
<td>RMP Usage CTL</td>
<td>B2243-1, See Section 2.2.4.3.2</td>
</tr>
<tr>
<td>E2243-6</td>
<td>Medicinal product which is or has been authorised in accordance with Union provisions in force used for the demonstration of bioequivalence (if applicable) and/or in other studies</td>
<td>maa:third-rmp/maa:bio-reference-medicinal-product</td>
<td>RMP Usage CTL</td>
<td>B2243-1, See Section 2.2.4.3.3</td>
</tr>
</tbody>
</table>

#### Element Tree Diagram

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 eu_application_form ---- initial-application-form-human ---- chapter-1 ---- directive-2001-83-ec

              └── hybrid-application
                    └── reference-medicinal-products
                           └── hyb-first-rmp
                           └── second-rmp
                           └── third-rmp
                               └── 2.2.4.3.2
                                                 +
                                               2.2.4.3.1

                           └── reference-medicinal-product
                                                   +
                                                               2.2.4.3.3
```

#### Business Rules

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<th>Effect(s)</th>
</tr>
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<tr>
<td>B2243-1</td>
<td>E224-4, E2243-4 to E2243-5</td>
<td>E224-4 is mandatory. rest are optional.</td>
<td>When E224-4 is selected, then the rest are mandatory.</td>
<td></td>
</tr>
</tbody>
</table>
### 2.2.4.3.1 Medicinal product which is or has been authorised in accordance with Union provisions in force for not less than 6/8/10 years in the EEA

<table>
<thead>
<tr>
<th>Common DES 3.0 Context</th>
<th>Common RDM Entry point</th>
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<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
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<tbody>
<tr>
<td>E22431-1</td>
<td>Note: This section defines the reference medicinal product chosen for the purposes of establishing the expiry of the data protection period.</td>
<td>rdm:pharmaproduct/rdm:invented-name</td>
<td>Reference Medicinal Product &gt; Medicinal Product Name</td>
<td></td>
</tr>
<tr>
<td>E22431-8</td>
<td>Marketing authorisation granted by</td>
<td>rdm:community</td>
<td>MP Authorisation &gt; Country CTL</td>
<td>B22431-1</td>
</tr>
<tr>
<td>E22431-9</td>
<td>Union</td>
<td>rdm:mem-selected</td>
<td>MP Authorisation &gt; Country CTL</td>
<td>B22431-1, B22431-2</td>
</tr>
<tr>
<td>E22431-10</td>
<td>Member State(EEA)</td>
<td>rdm:member-state</td>
<td>MP Authorisation &gt; Country CTL</td>
<td>B22431-2</td>
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### Business Rules

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<th>Effect(s)</th>
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<tbody>
<tr>
<td>B22431-1</td>
<td>E22431-9 to 10</td>
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<td>Mutually Exclusive</td>
<td></td>
</tr>
<tr>
<td>B22431-2</td>
<td>E22431-10 to 11</td>
<td>Optional</td>
<td>IF E22431-10 is selected, then E22431-11 is required</td>
<td></td>
</tr>
<tr>
<td>B22431-3</td>
<td>E22431-12</td>
<td>Optional</td>
<td></td>
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</table>
### 2.2.4.3.2 Medicinal product authorised in the Community/Member State where the application is made or European reference medicinal product

<table>
<thead>
<tr>
<th>Common DES 3.0 Context</th>
<th>Common RDM Entry point</th>
</tr>
</thead>
</table>

<table>
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<th>DES 3.0 Mapping</th>
<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
</tr>
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<tbody>
<tr>
<td>E22432-1</td>
<td>Product (Invented) name</td>
<td>maa:reference-medicinal-product/rdm:pharmaproduct/</td>
<td>Reference Medicinal Product &gt; Medicinal Product Name</td>
<td></td>
</tr>
<tr>
<td>E22432-6</td>
<td>Marketing authorisation granted by</td>
<td>maa:reference-medicinal-product/rdm:community</td>
<td>MP Authorisation &gt; Country CTL</td>
<td></td>
</tr>
<tr>
<td>E22432-7</td>
<td>Union</td>
<td>maa:reference-medicinal-product/rdm:community</td>
<td>B22423-1</td>
<td></td>
</tr>
<tr>
<td>E22432-8</td>
<td>Member State(EEA)</td>
<td>maa:reference-medicinal-product/rdm:mem-selected</td>
<td>B22423-1, B22423-2</td>
<td></td>
</tr>
<tr>
<td>E22432-10</td>
<td>Difference(s) compared to this reference medicinal product:</td>
<td>maa:change-active-substance</td>
<td>Difference CTL</td>
<td></td>
</tr>
<tr>
<td>E22432-11</td>
<td>changes in the active substance(s)</td>
<td>maa:change-active-substance</td>
<td>Difference CTL</td>
<td></td>
</tr>
<tr>
<td>E22432-12</td>
<td>change in therapeutic indications</td>
<td>maa:change-therapeutic-indication</td>
<td>Difference CTL</td>
<td></td>
</tr>
<tr>
<td>E22432-13</td>
<td>change in pharmaceutical form</td>
<td>maa:change-addition</td>
<td>Difference CTL</td>
<td></td>
</tr>
<tr>
<td>E22432-14</td>
<td>change in strength(quantitative change to the active substance(s))</td>
<td>maa:change-strength</td>
<td>Difference CTL</td>
<td></td>
</tr>
<tr>
<td>E22432-15</td>
<td>change in route of administration</td>
<td>maa:route-admin</td>
<td>Difference CTL</td>
<td></td>
</tr>
<tr>
<td>E22432-16</td>
<td>bioequivalence cannot be demonstrated through bioavailability</td>
<td>maa:bioavailability</td>
<td>Difference CTL</td>
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**Element Tree Diagram**

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| hybrid-application  | reference-medicinal-products  | second-rmp |
| change-addition     | change-strength               | change-therapeutic-indication | change-active-substance | route-admin | bioavailability |
| reference-medicinal-product |                  |
| member-state       | union                         | mem-selected | pharmacaproduct |                  |
| :CTL               | :yes-no                       | :yes-no    |
| +                  |                              |
| pharmaceutical-products |                  |
| +                  |                              |
| invented-name      |                              |
| /text              |                              |
| +                  |                              |
| pharmaceutical-form-names |          |
| +                  |                              |
| pharmaceutical-form-details |          |
| +                  |                              |
| pharmaceutical-form-name |          |
| /text              |                              |
| +                  |                              |
| pharmaceutical-form-strength-description |          |
| +                  |                              |
| Mrp-dcp-procedure-number |            |
| +                  |                              |
| authorisation-number |                  |
| +                  |                              |
| authorisation-number |                  |
| /text              |                              |

**Business Rules**

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<th>Rule</th>
<th>Effect(s)</th>
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<td>E22423-7 to 8</td>
<td>Optional</td>
<td>Mutually Exclusive</td>
<td></td>
</tr>
<tr>
<td>B22423-2</td>
<td>E22423-8 to 9</td>
<td>Optional</td>
<td>If E22423-8 is selected, then E22423-9 is required</td>
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<tr>
<td>B22423-3</td>
<td>E22433-11 to 16</td>
<td>Mandatory</td>
<td>Mutually Exclusive</td>
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<tr>
<td>B22423-4</td>
<td>E22423-17, E22423-17,</td>
<td>E22423-17, is not visible.</td>
<td>When E221-2 or E221-3 is selected, then E22422-10 is visible and mandatory</td>
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<tr>
<td>B22423-5</td>
<td>E22423-18</td>
<td>Optional</td>
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2.2.4.3.3 Medicinal product which is or has been authorised in accordance with Union provisions in force used for the demonstration of bioequivalence (if applicable) and/or in other studies

<table>
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<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
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<tbody>
<tr>
<td>E22433-1</td>
<td>Study reference number/EudraCT number</td>
<td>rdm:bio-sty-ref-eudract/rdm:number</td>
<td>Reference Medicinal Product &gt; study ref number</td>
<td></td>
</tr>
<tr>
<td>E22433-2</td>
<td>Product (Invented) name</td>
<td>rdm:pharmaproduct/rdm:invented-name</td>
<td>Reference Medicinal Product &gt; Medicinal Product Name</td>
<td></td>
</tr>
<tr>
<td>E22433-7</td>
<td>Marketing authorisation granted by</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E22433-8</td>
<td>Union</td>
<td>rdm:community</td>
<td>MP Authorisation &gt; Country CTL</td>
<td>B22433-1</td>
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<tr>
<td>E22433-9</td>
<td>Member State(EEA)</td>
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<td>E22433-10</td>
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<td>rdm:member-state</td>
<td>MP Authorisation &gt; Country CTL</td>
<td>B22433-1, B22433-2</td>
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<tr>
<td>E22433-11</td>
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<td>rdm:member-state-source</td>
<td>Reference Medicinal Product &gt; Country CTL</td>
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Element Tree Diagram

Business Rules

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<th>Rule</th>
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<tbody>
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<td>B22433-1</td>
<td>E22433-8 to 9</td>
<td>Optional</td>
<td>Mutually Exclusive</td>
<td></td>
</tr>
<tr>
<td>B22433-2</td>
<td>E22433-9 to 10</td>
<td>Optional</td>
<td>If E22433-9 is selected, then E22433-10 is required</td>
<td></td>
</tr>
<tr>
<td>B22433-3</td>
<td>E22433-12</td>
<td>Optional</td>
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### 2.2.4.4 Article 10(4) similar biological application

<table>
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<table>
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<th>DES 3.0 Mapping</th>
<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>E2244-1</td>
<td>Note: Application for a product referring to a reference biological product: administrative and quality data, appropriate pre-clinical and clinical data. Refer to Notice of Applicants, Volume 2A, Chapter 1.</td>
<td></td>
<td></td>
<td>B2244-1</td>
</tr>
<tr>
<td>E2244-2</td>
<td>Reference medicinal product:</td>
<td></td>
<td></td>
<td>B2244-1</td>
</tr>
<tr>
<td>E2244-3</td>
<td>Note: The chosen reference medicinal product must be a medicinal product authorised in the Community on the basis of a complete dossier in accordance with the provisions of Article 8 of Directive 2001/83/EC.</td>
<td></td>
<td></td>
<td>B2244-1</td>
</tr>
<tr>
<td>E2244-4</td>
<td>Medicinal product which is or has been authorised in accordance with Union provisions in force for not less than 6/10 years in the EEA</td>
<td>maa:first-rmp/maa:reference-medical-product</td>
<td>RMP Usage CTL</td>
<td>B2244-1, See Section 2.2.4.4.1</td>
</tr>
<tr>
<td>E2244-5</td>
<td>Medicinal product authorised in the Union/Member State where the application is made or European reference medicinal product</td>
<td>maa:second-rmp</td>
<td>RMP Usage CTL</td>
<td>B2244-1, See Section 2.2.4.4.2</td>
</tr>
<tr>
<td>E2244-6</td>
<td>Medicinal product which is or has been authorised in accordance with Union provisions in force and to which comparability tests and studies have been conducted</td>
<td>maa:third-rmp</td>
<td>RMP Usage CTL</td>
<td>B2244-1, See Section 2.2.4.4.3</td>
</tr>
</tbody>
</table>

**Element Tree Diagram**

```
  eu_application_form
   \- initial-application-form-human
      \- chapter-1
         \- directive-2001-83-ec
            \- similar-application
               \- reference-medical-products
                  \- first-rmp
                  \- second-rmp
                  \- third-rmp
```

**Business Rules**

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<th>Default BR</th>
<th>Rule</th>
<th>Effect(s)</th>
</tr>
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<tbody>
<tr>
<td>B2244-1</td>
<td>E224-5, E2244-1 to E2243-6</td>
<td>E224-5 is mandatory. Rest is optional.</td>
<td>When E224-5 is selected, then the rest is mandatory.</td>
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### 2.2.4.4.1 Medicinal product which is or has been authorised in accordance with Community provisions in force for not less than 6/8/10 years in the EEA

#### Common DES 3.0 Context

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<td>rdm:pharmaproduct/rdm:invented-name</td>
<td>Reference Medicinal Product &gt; Medicinal Product Name</td>
</tr>
<tr>
<td>E22441-7</td>
<td>Marketing authorisation granted by</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E22441-8</td>
<td>Union</td>
<td>rdm:community</td>
<td>MP Authorisation &gt; Country CTL</td>
</tr>
<tr>
<td>E22441-9</td>
<td>Member State (EEA)</td>
<td>rdm:mem-selected</td>
<td>B22441-1</td>
</tr>
<tr>
<td>E22441-10</td>
<td>Member State (EEA)</td>
<td>rdm:member-state</td>
<td>B22441-1, B22441-2</td>
</tr>
<tr>
<td>E22441-11</td>
<td>Note: This section defines the reference medicinal product chosen for the purposes of establishing the expiry of the data protection period.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Element Tree Diagram

Business Rules

<table>
<thead>
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<th>Default BR</th>
<th>Rule</th>
<th>Effect(s)</th>
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<tbody>
<tr>
<td>B22441-1</td>
<td>E22441-8 to 9</td>
<td>Optional</td>
<td>Mutually Exclusive</td>
<td></td>
</tr>
<tr>
<td>B22441-2</td>
<td>E22441-9 to 10</td>
<td>Optional</td>
<td>If E22441-9, then E22441-10 is required</td>
<td></td>
</tr>
<tr>
<td>B22441-3</td>
<td>E22441-12</td>
<td>Optional</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### 2.2.4.4.2 Medicinal product authorised in the Union/Member State where the application is made or European reference medicinal product

<table>
<thead>
<tr>
<th>Common DES 3.0 Context</th>
<th>Common RDM Entry point</th>
</tr>
</thead>
</table>

<table>
<thead>
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<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>E22442-1</td>
<td>Product (Invented) name</td>
<td>maa:reference-medicinal-product/rdm:pharmaproduct/rdm:invented-name</td>
<td>Reference Medicinal Product &gt; Medicinal Product Name</td>
<td></td>
</tr>
<tr>
<td>E22442-6</td>
<td>Marketing authorisation granted by</td>
<td>maa:reference-medicinal-product/rdm:community</td>
<td>MP Authorisation &gt; Country CTL</td>
<td></td>
</tr>
<tr>
<td>E22442-7</td>
<td>Union</td>
<td>maa:reference-medicinal-product/rdm:community</td>
<td>B22442-1</td>
<td></td>
</tr>
<tr>
<td>E22442-10</td>
<td>Difference(s) compared to this reference medicinal product:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E22442-11</td>
<td>change(s) in the raw material(s)</td>
<td>maa:change-raw-substance</td>
<td>Difference CTL</td>
<td></td>
</tr>
<tr>
<td>E22442-12</td>
<td>change(s) in the manufacturing process(es)</td>
<td>maa:manufacturing</td>
<td>Difference CTL</td>
<td></td>
</tr>
<tr>
<td>E22442-13</td>
<td>change in therapeutic indication(s)</td>
<td>maa:change-therapeutic-indication</td>
<td>Difference CTL</td>
<td></td>
</tr>
<tr>
<td>E22442-14</td>
<td>change in pharmaceutical form(s)</td>
<td>maa:change-addition</td>
<td>Difference CTL</td>
<td></td>
</tr>
<tr>
<td>E22442-15</td>
<td>change in strength (quantitative)</td>
<td>maa:change-strength</td>
<td>Difference CTL</td>
<td></td>
</tr>
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</table>

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### Business Rules

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<th>Effect(s)</th>
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<tbody>
<tr>
<td>B22442-1</td>
<td>E22442-7 to 8</td>
<td>Optional</td>
<td>Mutually Exclusive</td>
<td></td>
</tr>
<tr>
<td>B22442-2</td>
<td>E22442-8 to 9</td>
<td>Optional</td>
<td>If E22442-8, then E22442-9 is required</td>
<td></td>
</tr>
<tr>
<td>B22442-3</td>
<td>E22442-11 to 17</td>
<td>Mandatory</td>
<td>Mutually Exclusive</td>
<td></td>
</tr>
<tr>
<td>B22442-4</td>
<td>E22442-18</td>
<td>Optional</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### 2.2.4.4.3 Medicinal product which is or has been authorised in accordance with Union provisions in force and to which comparability tests and studies have been conducted

<table>
<thead>
<tr>
<th>Common DES 3.0 Context</th>
<th>Common RDM Entry point</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>E22443-1</th>
<th>Note: This chosen reference medicinal product must be a medicinal product authorised in the Community and should be used throughout the comparability programme for quality, safety and efficacy studies.</th>
</tr>
</thead>
<tbody>
<tr>
<td>E22443-2</td>
<td>Product (Invented) name</td>
</tr>
<tr>
<td>E22443-8</td>
<td>Marketing authorisation granted by</td>
</tr>
<tr>
<td>E22443-9</td>
<td>Union</td>
</tr>
<tr>
<td>E22443-10</td>
<td>Member State(EEA)</td>
</tr>
<tr>
<td>E22443-11</td>
<td>Member State(EEA)</td>
</tr>
</tbody>
</table>

**Remarks**

- Reference Medicinal Product > Medicinal Product Name
- Reference Medicinal Product > Pharmaceutical Dose Form CTL
- Ingredient
- Role > Party > Organisation > Name

**MP Authorisation**

- MP Authorisation > authorisation number
- MP Authorisation > authorisation date

| E22443-1 | | B22443-1 |
| E22443-9 | | B22443-1, B22443-2 |
| E22443-10 | | B22443-2 |
| E22443-11 | | B22443-2 |
### Business Rules

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<th>Effect(s)</th>
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</thead>
<tbody>
<tr>
<td>B22443-1</td>
<td>E22443-9 to 10</td>
<td>Optional</td>
<td>Mutually Exclusive</td>
<td></td>
</tr>
<tr>
<td>B22443-2</td>
<td>E22443-10 to 11</td>
<td>Optional</td>
<td>IF E22443-10, then E22443-11 is required</td>
<td></td>
</tr>
<tr>
<td>B22443-3</td>
<td>E22443-12</td>
<td>Optional</td>
<td></td>
<td></td>
</tr>
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</table>
### 2.2.4.5 Article 10c informed consent application

<table>
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<tr>
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<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
</tr>
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<tbody>
<tr>
<td>E2245-1</td>
<td>Note: - Application for a medicinal product possessing the same qualitative and quantitative composition in terms of active substances and the same pharmaceutical form of an authorised product where consent has been given by the existing marketing authorisation holder to use their data in support of this application - Complete administrative data should be provided with consent to pharmaceutical, preclinical and clinical data - The authorised product and the informed consent application can have the same or different MAH.</td>
<td></td>
<td></td>
<td>B2245-1</td>
</tr>
<tr>
<td>E2245-2</td>
<td>Authorised product in the Union/Member State where the application is made:</td>
<td></td>
<td></td>
<td>B2245-1</td>
</tr>
<tr>
<td>E2245-3</td>
<td>Product (Invented) name</td>
<td>rdm:products/rdm:product/rdm:pharmaproduct/rdm:invented-name</td>
<td></td>
<td>B2245-1</td>
</tr>
<tr>
<td>E2245-8</td>
<td>Attach letter of consent from marketing authorisation holder of the authorised product (Annex 5.2)</td>
<td>maa:attach-letter</td>
<td></td>
<td>B2245-1</td>
</tr>
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</table>
### Business Rules

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<th>Rule</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>B2245-1</td>
<td>E224-8, E2245-1 to E2245-8</td>
<td>E224-5 is mandatory. Rest are optional.</td>
<td>When E224-5 is selected, then the rest are mandatory.</td>
<td></td>
</tr>
</tbody>
</table>
2.2.5 CONSIDERATION OF THIS APPLICATION IS ALSO REQUESTED UNDER THE FOLLOWING ARTICLE IN DIRECTIVE 2001/83/EC OR REGULATION (EC) No 726/2004

<table>
<thead>
<tr>
<th>Common DES 3.0 Context</th>
<th>Common RDM Entry point</th>
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</thead>
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<table>
<thead>
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<th>DES 3.0 Mapping</th>
<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>E225-1</td>
<td>Conditional Approval</td>
<td>maa:section1-5-1</td>
<td>Consideration CTL</td>
<td>B225-1</td>
</tr>
<tr>
<td>E225-2</td>
<td>Note: centralised procedure only according to Article 14(7) of Regulation (EC) No 726/2004</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E225-3</td>
<td>Exceptional Circumstances</td>
<td>maa:section1-5-2</td>
<td>Consideration CTL</td>
<td>B225-1</td>
</tr>
<tr>
<td>E225-6</td>
<td>Date of acceptance by CHMP</td>
<td>maa:section1-5-3/maa:chmp</td>
<td>MP Procedure &gt; chmp accepte date</td>
<td>B225-2</td>
</tr>
<tr>
<td>E225-7a</td>
<td>Free text field</td>
<td>maa:section1-5-3/maa:chmp-details</td>
<td>MP Procedure &gt; chmp accepte date</td>
<td>B225-2</td>
</tr>
<tr>
<td>E225-9</td>
<td>(one year of market exclusivity for a new indication)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E225-10</td>
<td>Article 10(5) of Directive 2001/83/EC (one year of data exclusivity for a new indication)</td>
<td>maa:section1-5-5</td>
<td>Consideration CTL</td>
<td>B225-1</td>
</tr>
<tr>
<td>E225-11</td>
<td>Article 74(a) of Directive 2001/83/EC (one year of data exclusivity for a change in classification)</td>
<td>maa:section1-5-6</td>
<td>Consideration CTL</td>
<td>B225-1</td>
</tr>
</tbody>
</table>

Element Tree Diagram

![Element Tree Diagram](image-url)

Business Rules

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<tr>
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<th>Default BR</th>
<th>Rule</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>B225-1</td>
<td>E225-5 to E225-7</td>
<td>optional.</td>
<td>When E224-5 is selected, then When E224-7 is mandatory.</td>
<td>E225-5 to E225-7</td>
</tr>
</tbody>
</table>
2.2. 6 REQUIREMENTS ACCORDING TO REGULATION (EC) No 1901/2006 ('PAEDIATRIC REGULATION')

<table>
<thead>
<tr>
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<th>Label</th>
<th>DES 3.0 Mapping</th>
<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>E226-1</td>
<td>Sections 1.6.1, 1.6.2 and 1.6.3 not applicable for well-established use, generic, hybrid and bio-similar applications and traditional herbal medicinal products</td>
<td>maa:section-decision</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E226-2</td>
<td>Does the same applicant hold other marketing authorisation(s) for a medicinal product(s) containing the same active substance(s) in the EEA?</td>
<td>maa:section-same-active-substance</td>
<td></td>
<td>See Section 2.2.6.1</td>
</tr>
<tr>
<td>E226-3</td>
<td>ARTICLE 7 OF PAEDIATRIC REGULATION APPLIES TO THIS APPLICATION, SINCE:</td>
<td>maa:section-new-indication</td>
<td></td>
<td>See Section 2.2.6.2</td>
</tr>
<tr>
<td>E226-4</td>
<td>ARTICLE 8 OF PAEDIATRIC REGULATION APPLIES TO THIS APPLICATION, SINCE:</td>
<td>maa:section-application-process</td>
<td>Paed Regulation App CTL</td>
<td>See Section 2.2.6.3</td>
</tr>
<tr>
<td>E226-5</td>
<td>ARTICLE 30 (PUMA) OF THE PAEDIATRIC REGULATION APPLIES TO THIS APPLICATION:</td>
<td>maa:section-puma</td>
<td></td>
<td>See Section 2.2.6.4</td>
</tr>
<tr>
<td>E226-6</td>
<td>HAS THIS APPLICATION BEEN SUBJECT TO PIP COMPLIANCE VERIFICATION?</td>
<td>maa:section-compliance-verification</td>
<td></td>
<td>See Section 2.2.6.5</td>
</tr>
</tbody>
</table>

Element Tree Diagram

```
  eu_application_form
   | initial-application-form-human
    | chapter-1
     | section1-6
      \          |      \       |        \       |        \       |        \       |        \       |
       | Section-same-active-substance | section-new-indication | section-application-process | section-puma | section-compliance-verification | section-decision
```
### 2.2.6.1 Does the same³ applicant hold other marketing authorisation(s) for a medicinal product(s) containing the same active substance(s) in the EEA?

<table>
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<th>Common RDM Entry point</th>
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<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>E2261-1</td>
<td>Yes</td>
<td>maa:yes-no (Value = 1)</td>
<td>Paediatric Designation &gt; has same active substance</td>
<td></td>
</tr>
<tr>
<td>E2261-2</td>
<td>No (Complete section 1.6.3)</td>
<td>maa:yes-no (Value = 0)</td>
<td>Paediatric Designation &gt; has same active substance</td>
<td></td>
</tr>
<tr>
<td>E2261-3</td>
<td>Active substance</td>
<td>maa:products/maa:medproduct:/maa:active-substances/maa:active-substance-name</td>
<td>Medicinal Product &gt; Pharmaceutical Product &gt; Ingredient &gt; Substance CTL &gt; term Id</td>
<td></td>
</tr>
<tr>
<td>E2261-10</td>
<td>Date(s) of marketing authorisation(s)</td>
<td>maa:products/maa:medproduct:/maa:product/rdm:mp-authorisation/rdm:authorisation-date</td>
<td>MP Authorisation &gt; authorisation date</td>
<td></td>
</tr>
<tr>
<td>E2261-13</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

³ "Same" applicant/marketing authorisation holder: as per the Commission Communication (98/C 299/03) (i.e. belonging to the same mother company or group of companies or which are "licensees")
Element Tree Diagram

![Element Tree Diagram](image)

**Business Rules**

<table>
<thead>
<tr>
<th>Rule ID</th>
<th>Element id(s)</th>
<th>Default BR</th>
<th>Rule</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>B2261-1</td>
<td>E2261-1, E2261-2</td>
<td>Mandatory.</td>
<td>Mutually exclusive.</td>
<td></td>
</tr>
<tr>
<td>B2261-2</td>
<td>E2261-1, E2261-3 to E2261-13</td>
<td></td>
<td>If E2261-1 is selected, then the other fields are mandatory.</td>
<td></td>
</tr>
</tbody>
</table>
2.2.6.2 Does this application relate to a new indication, new pharmaceutical form or new route of administration?

<table>
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<tr>
<th>Common DES 3.0 Context</th>
<th>Common RDM Entry point</th>
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</thead>
</table>

<table>
<thead>
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<th>DES 3.0 Mapping</th>
<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>E2262-1</td>
<td>Yes/ (Complete section-application-process)</td>
<td>maa:new-indication (Value = 1)</td>
<td>Pediatric Designation &gt; has same active substance</td>
<td>B2262-1,</td>
</tr>
<tr>
<td>E2262-2</td>
<td>No</td>
<td>maa:new-indication (Value = 0)</td>
<td>Pediatric Designation &gt; has same active substance</td>
<td>B2262-1,</td>
</tr>
</tbody>
</table>

Element Tree Diagram

eu_application_form → initial-application-form-human → chapter-1 → section1-6 → section-new-indication → new-indication :yes-no

Business Rules

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<th>Default BR</th>
<th>Rule</th>
<th>Effect(s)</th>
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<tbody>
<tr>
<td>B2262-1</td>
<td>E2261-1, E2262-2</td>
<td>E2262-1 is optional.</td>
<td>If E2262-1 is yes, then section-application-process needs to be visible and mandatory.</td>
<td>2.2.3.3</td>
</tr>
</tbody>
</table>
### 2.2.6.3 This Application Includes

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<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>E2263-1</td>
<td>THIS APPLICATION INCLUDES:</td>
<td>maa:decision/rdm:decision-number/rdm:decision-number</td>
<td>Paediatric Designation &gt; art 8 pip decision number</td>
<td>B2263-1</td>
</tr>
<tr>
<td>E2263-2</td>
<td>PIP Decision Number(s)</td>
<td>maa:decision/rdm:decision-numbers/rdm:decision-number/rdm:decision-number</td>
<td>Paediatric Designation &gt; art 8 product waiver number</td>
<td>B2263-1</td>
</tr>
<tr>
<td>E2263-3</td>
<td>cbCheckBox</td>
<td>maa:decision/rdm:product-specific-decisions/rdm:product-specific-decision</td>
<td>Paediatric Designation &gt; art 8 class waiver number</td>
<td>B2263-1</td>
</tr>
<tr>
<td>E2263-4</td>
<td>Product-Specific Waiver Decision Number(s)</td>
<td>maa:decision/rdm:product-specific-decisions/rdm:product-specific-decision</td>
<td>Paediatric Designation &gt; art 8 product waiver number</td>
<td>B2263-1</td>
</tr>
<tr>
<td>E2263-5</td>
<td>cbCheckBox</td>
<td>maa:decision/rdm:product-specific-decisions/rdm:selected</td>
<td>Paediatric Designation &gt; art 8 class waiver number</td>
<td>B2263-1</td>
</tr>
<tr>
<td>E2263-6</td>
<td>Class Waiver Decision Number(s)</td>
<td>maa:decision/rdm:class-waiver/rdm:class-waiver-number</td>
<td>Paediatric Designation &gt; art 8 class waiver number</td>
<td>B2263-1</td>
</tr>
</tbody>
</table>

(If E2261-1 is selected, then E2263-1 to E2263-6 fields are hidden if E2263-1 is selected, then E2263-1 to E2263-6 fields are visible.)

#### Element Tree Diagram

![Element Tree Diagram](image)

#### Business Rules

<table>
<thead>
<tr>
<th>Rule ID</th>
<th>Element id(s)</th>
<th>Default BR</th>
<th>Rule</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>B2263-1</td>
<td>E2261-1, E2263-1 to E2263-6</td>
<td>E2263-1 to E2263-6 are hidden</td>
<td>If E2261-1 is selected, then E2263-1 to E2263-6 fields are visible.</td>
<td></td>
</tr>
</tbody>
</table>
2.2.6.4 **ARTICLE 30 (PUMA) OF THE PAEDIATRIC REGULATION APPLIES TO THIS APPLICATION:**

<table>
<thead>
<tr>
<th>Common DES 3.0 Context</th>
<th>Common RDM Entry point</th>
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<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
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</thead>
<tbody>
<tr>
<td>E2264-1</td>
<td>ARTICLE 30 (PUMA) OF THE PAEDIATRIC REGULATION APPLIES TO THIS APPLICATION:</td>
<td>maa:article-30</td>
<td></td>
<td>B2264-1</td>
</tr>
<tr>
<td>E2264-2</td>
<td>(Note: Also applies to Extension applications of PUMA)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E2264-3</td>
<td>The application relates to a medicinal product, which is not protected by either a Supplementary Protection Certificate under Regulation (EEC) No 469/2009, or by a patent which qualifies for the granting of the Supplementary Protection Certificate</td>
<td>maa:not-protected-by-supplementary</td>
<td>Paediatric Designation &gt; relates to non-protected product</td>
<td>B2264-1</td>
</tr>
<tr>
<td>E2264-4</td>
<td>PIP Decision Number:</td>
<td>maa:pip-decision-nms/maa:decision-number/maa:number</td>
<td>Paediatric Designation &gt; art 30 pip decision number</td>
<td>B2264-1</td>
</tr>
<tr>
<td>E2264-5</td>
<td>(Note: a copy of the PIP/Waiver decision is to be included in Module 1.10)</td>
<td></td>
<td></td>
<td>B2264-1</td>
</tr>
</tbody>
</table>

**Element Tree Diagram**

```
  eu_application_form
    | initial-application-form-human
    | chapter-1
    |     section1-6
    | Section-puma
    |     pip-decision-nms
    |     | article-30
    |     | not-protected-by-supplementary
    |     + decision-number
    |     | number/text
```

**Business Rules**

<table>
<thead>
<tr>
<th>Rule ID</th>
<th>Element id(s)</th>
<th>Default BR</th>
<th>Rule</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>B2264-1</td>
<td>E2264-1, E2264-3 to E2264-5</td>
<td>E2264-1 is mandatory, rest are optional.</td>
<td>If E2264-1 is selected, the other fields become visible and mandatory.</td>
<td></td>
</tr>
</tbody>
</table>
### 2.2.6.5 Has this application been subject to PIP Compliance Verification?

#### Common DES 3.0 Context

```plaintext
```

#### Common RDM Entry point

```
Application >
```

<table>
<thead>
<tr>
<th>Elem Id</th>
<th>Label</th>
<th>DES 3.0 Mapping</th>
<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>E2265-1</td>
<td>Yes</td>
<td>maa:yes (Value=1)</td>
<td>Paediatric Designation &gt; subject to pip compliance</td>
<td>B2265-1</td>
</tr>
<tr>
<td>E2265-2</td>
<td>No</td>
<td>maa:yes (Value=0)</td>
<td>Paediatric Designation &gt; subject to pip compliance</td>
<td></td>
</tr>
<tr>
<td>E2265-2a</td>
<td>Not applicable</td>
<td>maa:yes (Value=2)</td>
<td>Paediatric Designation &gt; subject to pip compliance</td>
<td></td>
</tr>
<tr>
<td>E2265-3</td>
<td>If, yes, please specify</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E2265-4</td>
<td>Compliance document reference(s)</td>
<td>maa:compliance-document-references/maa:reference</td>
<td>Paediatric Designation &gt; pdco opinion number</td>
<td>B2265-1</td>
</tr>
<tr>
<td>E2265-5</td>
<td>(Note: if available a copy of the PDCO compliance report with, where applicable, the PSCO opinion or the document issued by the national competent authority is to be included in Module 1.10)</td>
<td></td>
<td>B2265-1</td>
<td></td>
</tr>
<tr>
<td>E2265-6</td>
<td>Please identify any parallel, ongoing or previous variation(s) or extension(s) containing paediatric data relevant for the full PIP compliance verification, if applicable</td>
<td></td>
<td>B2265-1</td>
<td></td>
</tr>
<tr>
<td>E2265-7</td>
<td>Procedure-number</td>
<td>maa:procedure-numps/maa:proc-num/maa:number</td>
<td>Paediatric Procedure &gt; paed procedure number</td>
<td>B2265-1</td>
</tr>
</tbody>
</table>

#### Element Tree Diagram

```
  eu_application_form       initial-application-form-human     chapter-1
                         /              \                        /\                      /
                   section1-6      section1-6-3               Procedure-numps
                        \                 \                     yes
                           /                 /                    compliance-document-references
                          /                 /                      :yes-no-not applicable
                         /                 /                        reference
                        /                 /                         /text
                       /                 /                        number
                      /                 /                         /text
```

#### Business Rules

<table>
<thead>
<tr>
<th>Rule ID</th>
<th>Element id(s)</th>
<th>Default BR</th>
<th>Rule</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>B2265-1</td>
<td>E2265-1, E2265-4 to E2265-7</td>
<td>E2265-1 is mandatory, rest are optional.</td>
<td>If E2265-1 is selected, the other fields are visible and mandatory.</td>
<td></td>
</tr>
</tbody>
</table>
## 2.3. MARKETING AUTHORISATION APPLICATION PARTICULARS

<table>
<thead>
<tr>
<th>Elem Id</th>
<th>Label</th>
<th>DES 3.0 Mapping</th>
<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>E23-1</td>
<td>NAME(S) and ATC CODE</td>
<td></td>
<td></td>
<td>See Section 2.3.1</td>
</tr>
<tr>
<td>E23-2</td>
<td>STRENGTH, PHARMACEUTICAL FORM, ROUTE OF ADMINISTRATION, CONTAINER AND PACK SIZES</td>
<td></td>
<td></td>
<td>See Section 2.3.2</td>
</tr>
<tr>
<td>E23-3</td>
<td>LEGAL STATUS</td>
<td></td>
<td></td>
<td>See Section 2.3.3</td>
</tr>
<tr>
<td>E23-4</td>
<td>MARKETING AUTHORISATION HOLDER/CONTACT PERSONS/COMPANY</td>
<td></td>
<td></td>
<td>See Section 2.3.4</td>
</tr>
<tr>
<td>E23-5</td>
<td>Manufacturers Note: ALL manufacturing and control sites mentioned throughout the whole dossier MUST be consistent regarding their names, detailed addresses and activities.</td>
<td></td>
<td></td>
<td>See Section 2.3.5</td>
</tr>
<tr>
<td>E23-6</td>
<td>Qualitative and Quantitative composition</td>
<td></td>
<td></td>
<td>See Section 2.3.6</td>
</tr>
</tbody>
</table>
### 2.3.1 NAME(S) and ATC CODE

<table>
<thead>
<tr>
<th>Elem Id</th>
<th>Label</th>
<th>DES 3.0 Mapping</th>
<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>E231-1</td>
<td>Proposed (invented) name of the medicinal product in the Community/Member State/ Iceland/ Liechtenstein/Norway:</td>
<td>rdm:medicinal-product/rdm:invented-name</td>
<td>Medicinal Product Group &gt; invented name</td>
<td></td>
</tr>
<tr>
<td>E231-2</td>
<td>If different (invented) names in different Member States are proposed in a mutual recognition or decentralised procedure, these should be listed in Annex 5.19</td>
<td>maa:annex5-19</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E231-3</td>
<td>Full name of the Active substance(s), if applicable including salt or hydrate*.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E231-4</td>
<td>Note: &quot;active substance should be indicated here as full substance. If the substance is included in the product as a salt or hydrate, the corresponding base/active moiety should be indicated in the additional field; Name should be based on the following order of priority: INN*, Ph.Eur., National Pharmacopeia, common name, scientific name;*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E231-5</td>
<td>Active substance</td>
<td>maa:active-substances/maa:active-substance/maa:substance-name</td>
<td>Medicinal Product &gt; Pharmaceutical Product &gt; Ingredient &gt; Substance &gt; Role CTL &gt; term id</td>
<td></td>
</tr>
<tr>
<td>E231-10</td>
<td>Base/active moiety of the active substance(s)</td>
<td>maa:active-substances/maa:active-substance/maa:moiety-substance-name</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E231-11</td>
<td>Substance type (e.g. chemical substance, recombinant biological substance)</td>
<td>maa:substanceType</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E231-12</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E231-13</td>
<td>Claim for new active substance(s)</td>
<td>maa:new-active-substance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E231-14</td>
<td>known active substance(s)</td>
<td>maa:known-active-substance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E231-15</td>
<td>Attach letter</td>
<td>maa:attach-letter</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E231-6</td>
<td>Pharmacotherapeutic group (Please use current ATC code)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E231-9</td>
<td>If no ATC code has been assigned, please indicate if an application for ATC code has been made</td>
<td>rdm:medicinal-product/rdm:atc/rdm:atc-status</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Element Tree Diagram

```
<eu_application_form>
  <initial-application-form-human>
    <chapter-2>
      <annex5-19>
        <substances>
          <New-active-substances>
            <Known-active-substances>
              <medicinal-product>
                <attach-letter>
                  <atc>
                    <invented-name/>
                    <atc-code/>
                    <atc-name/>
                    <atc-status/>
                    <code/>
                  </atc>
                </attach-letter>
              </Known-active-substances>
              <New-active-substances/>
            </substances>
            <substance/>
          </New-active-substances>
          <substance-name/>
          <Moieties-substance-name/>
        </substances>
        <substance/>
      </annex5-19>
    </chapter-2>
  </initial-application-form-human>
</eu_application_form>
```
### 2.3. STRENGTH, PHARMACEUTICAL FORM, ROUTE OF ADMINISTRATION, CONTAINER AND PACK SIZES

<table>
<thead>
<tr>
<th>Elem Id</th>
<th>Label</th>
<th>DES 3.0 Mapping</th>
<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>E232-6</td>
<td>Route(s) of administration (use current list of standard terms - European Pharmacopoeia)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E232-8</td>
<td>Container, closure and administration device(s), including description of material from which it is constructed. (use current list of standard terms - European Pharmacopoeia)</td>
<td>rdm:medicinal-product/maa:packages/rdm:package/rdm:package-description</td>
<td>Package &gt; Package Description</td>
<td></td>
</tr>
<tr>
<td>E232-9</td>
<td>For each type of pack give:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E232-11</td>
<td>Note: For mutual recognition and decentralised procedures, all package sizes authorised in the Reference Member State should be listed</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E232-22</td>
<td>Attach a list of Mock-ups or Samples/specimens sent with the application, as appropriate (see Annex 5.17)</td>
<td>maa:annex5-17</td>
<td></td>
<td>B232-1</td>
</tr>
</tbody>
</table>
Element Tree Diagram

Business Rules

<table>
<thead>
<tr>
<th>Rule ID</th>
<th>Element id(s)</th>
<th>Default BR</th>
<th>Rule</th>
<th>Effect(s)</th>
</tr>
</thead>
</table>
### 2.3.2.1 THE MEDICINAL PRODUCT INCORPORATES, AS AN INTEGRAL PART, ONE OR MORE MEDICAL DEVICES WITHIN THE MEANING OF Article 1(2)(a) of Directive 93/42/EEC OR ONE OR MORE ACTIVE IMPLANTABLE MEDICAL DEVICES WITHIN THE MEANING OF ARTICLE 1(2)(C) OF DIRECTIVE 90/385/EEC

<table>
<thead>
<tr>
<th>Elem Id</th>
<th>Label</th>
<th>DES 3.0 Mapping</th>
<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>E2321-0</td>
<td>Yes</td>
<td>maa:eu_application_form/maa:initial-application-form-human/maa:chapter-2/Manufacturer-device</td>
<td>Application &gt; Medicinal Product &gt;</td>
<td></td>
</tr>
<tr>
<td>E2321-1</td>
<td>Manufacturer of the device (for manufactures outside the EEA, please add the authorized representative):</td>
<td>maa:manu-device-checkbox</td>
<td>Role &gt; Party &gt; Person &gt; Personal title</td>
<td>B2321-1</td>
</tr>
<tr>
<td>E2321-2</td>
<td>Name of the contact person</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E2321-3</td>
<td>Title</td>
<td>maa:Manufacture-contact-details/rdm:personal-title</td>
<td>Role &gt; Party &gt; Person &gt; given name</td>
<td>B2321-1</td>
</tr>
<tr>
<td>E2321-4</td>
<td>First name</td>
<td>maa:Manufacture-contact-details/rdm:given-name</td>
<td>Role &gt; Party &gt; Person &gt; family name</td>
<td>B2321-1</td>
</tr>
<tr>
<td>E2321-5</td>
<td>Surname</td>
<td>maa:Manufacture-contact-details/rdm:family-name</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E2321-6</td>
<td>Address</td>
<td>maa:Manufacture-contact-details/rdm:address1</td>
<td>Role&gt;Party&gt;Contact Details &gt; Address</td>
<td>B2321-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>maa:Manufacture-contact-details/rdm:address2</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>maa:Manufacture-contact-details/rdm:address3</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>maa:Manufacture-contact-details/rdm:address4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E2321-6a</td>
<td>City</td>
<td>maa:Manufacture-contact-details/rdm:city</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E2321-6b</td>
<td>State</td>
<td>maa:Manufacture-contact-details/rdm:state</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E2321-6c</td>
<td>County</td>
<td>maa:Manufacture-contact-details/rdm:county</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E2321-7</td>
<td>Postcode</td>
<td>maa:Manufacture-contact-details/rdm:post-code</td>
<td>Role&gt;Party&lt;Contact Details &gt; Address&gt; post code</td>
<td>B2321-1</td>
</tr>
<tr>
<td>E2321-8</td>
<td>Country</td>
<td>maa:Manufacture-contact-details/rdm:country</td>
<td>Role&gt;Party&lt;Contact Details &gt; Address &gt; Country CTL</td>
<td>B2321-1</td>
</tr>
<tr>
<td>E2321-8a</td>
<td>orgID</td>
<td>maa:Manufacture-contact-details/rdm:orgID</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E2321-8b</td>
<td>locID</td>
<td>maa:Manufacture-contact-details/rdm:locID</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E2321-8c</td>
<td>Loc-modifiedDate</td>
<td>maa:Manufacture-contact-details/rdm:loc-modifiedDate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E2321-8d</td>
<td>Org-modifiedDate</td>
<td>maa:Manufacture-contact-details/rdm:org-modifiedDate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E2321-8e</td>
<td>Language</td>
<td>maa:Manufacture-contact-details/rdm:language</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E2321-9</td>
<td>Telephone</td>
<td>maa:Manufacture-contact-details/rdm:phone</td>
<td>Role&gt;Party&lt;Contact Details&gt; Electronic Contact &gt; electronic contact</td>
<td>B2321-1</td>
</tr>
<tr>
<td>E2321-11</td>
<td>E-mail</td>
<td>maa:Manufacture-contact-details/rdm:email</td>
<td>Role&gt;Party&lt;Contact Details&gt; Electronic Contact &gt; electronic contact</td>
<td>B2321-1</td>
</tr>
<tr>
<td>Medical Device</td>
<td>Maa:manu-device-yes-no</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does this application include one or more medical devices within the meaning of Article 1(2)(a) of Directive 93/42/EEC or one or more active implantable medical devices within the meaning of Article 1(2)(c) of Directive 90/385/EEC intended to administer a medicinal product</td>
<td>Yes or No</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>If yes, does the medical device and the medicinal product form a single integral product, which is intended exclusively for use in the given combination and which is not reusable?</td>
<td>Yes or No</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: If no, CE marking of the device is mandatory. If yes, CE marking of the device is optional. Further details must be provided in sections 2.2.4.3 and 2.2.4.4.

---

**E2321-12** Device(s) identification:

**E2321-13** Name of the device(s)

**E2321-38** Brief description of the device

**E2321-14** Serial numbers or other indications necessary to delimit precisely the device(s) incorporated

**E2321-15** CE mark:

**E2321-16** Does the device(s) have a CE mark?

**E2321-17** Yes

**E2321-18** No

**E2321-19** If yes, please add the manufacturers declaration of conformity in module 3.2 R of the EU-CTD

**E2321-20** Notified Body

**E2321-21** Is the device(s) covered by certificates issued by a Notified Body?

**E2321-22** Yes

**E2321-23** No

**E2321-24** If yes, please add the certificate(s) in module 3.2 R of the EU-CTD.

**E2321-25** Please indicate for each notified Body involved: (For combined ATMPs, identify a Notified Body in any case)

**E2321-26** Name of the Notified Body

**E2321-27** Name of the Notified Number

**E2321-28** Name of the contact person:

**E2321-29** Title

**E2321-30** First Name

**E2321-31** Surname

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

<table>
<thead>
<tr>
<th>Rule ID</th>
<th>Element id(s)</th>
<th>Default BR</th>
<th>Rule</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>B2321-1</td>
<td>E2321-3 to E2321-11, E2321-13, E2321-14, E2321-17, E2321-18, E2321-22, E2321-23, E2321-26, E2321-37,</td>
<td>Optional.</td>
<td>These fields are optional.</td>
<td></td>
</tr>
</tbody>
</table>
### 2.3. 3 LEGAL STATUS

<table>
<thead>
<tr>
<th>Common DES 3.0 Context</th>
<th>Common RDM Entry point</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Elem Id</th>
<th>Label</th>
<th>DES 3.0 Mapping</th>
<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>E233-1</td>
<td>Proposed dispensing/classification</td>
<td>maa:subject_to_prescription</td>
<td>Procedure Use &gt; Role &gt; Country CTL</td>
<td>B233-1</td>
</tr>
<tr>
<td>E233-3</td>
<td>Subject to medical prescription (Complete 2.3.2)</td>
<td>maa:subject_to_prescription_details/maa:subject-member-states/rdm:ref-member-state/rdm:name</td>
<td>Procedure Use &gt; Role &gt; Country CTL</td>
<td>B233-2</td>
</tr>
<tr>
<td>E233-4</td>
<td>txtPackageSize</td>
<td>maa:subject_to_prescription_details</td>
<td>B233-2</td>
<td></td>
</tr>
<tr>
<td>E233-6</td>
<td>Not subject to medical prescription (Complete 2.3.3 &amp; 2.3.4)</td>
<td>maa:subject_to_prescription</td>
<td>B233-2</td>
<td></td>
</tr>
</tbody>
</table>

#### Element Tree Diagram

```
  eu_application_form
     | initial-application-form-human
        | chapter-2
        | legal-status
        
        subject-medical-prescription
          | :yes-no
          +
          
          subject-member-states
          +
          
          txtSubject
          |
          /Text
          
        non-subject-medical-prescription
          | :yes-no
          +
          
          non-subject-member-states
          +
          
          member-states
          +
          
          ref-member-state
          |
          name
          |
          /text

        member-states
        |
        txtNonSubject
        |
        /Text

Business Rules

<table>
<thead>
<tr>
<th>Rule ID</th>
<th>Element id(s)</th>
<th>Default BR</th>
<th>Rule</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>B233-1</td>
<td>E233-5</td>
<td>optional</td>
<td>If E233-3 is selected, E233-5 and E233-6 are visible and E233-5 is mandatory</td>
<td></td>
</tr>
<tr>
<td>B233-2</td>
<td>E233-8</td>
<td>optional</td>
<td>If E233-6 is selected, E233-7 and E233-8 are visible and E233-8 is mandatory</td>
<td></td>
</tr>
</tbody>
</table>
### 2.3.3.1 For products subject to medicinal prescription

<table>
<thead>
<tr>
<th>Common DES 3.0 Context</th>
<th>Common RDM Entry point</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Elem Id</th>
<th>Label</th>
<th>DES 3.0 Mapping</th>
<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>E2331-1</td>
<td>Product on prescription which may be renewed (if applicable)</td>
<td>maa:renewed</td>
<td>Supply CTL</td>
<td></td>
</tr>
<tr>
<td>E2331-2</td>
<td>Product on prescription which may not be renewed (if applicable)</td>
<td>maa:not-renewed</td>
<td>Supply CTL</td>
<td></td>
</tr>
<tr>
<td>E2331-3</td>
<td>Product on special prescription*</td>
<td>maa:special</td>
<td>Supply CTL</td>
<td></td>
</tr>
<tr>
<td>E2331-4</td>
<td>Product on restricted prescription*</td>
<td>maa:restricted</td>
<td>Supply CTL</td>
<td></td>
</tr>
<tr>
<td>E2331-5</td>
<td>(Not all the listed options are available in each member state. Applicants are invited to indicate which categories they are requesting, however, the Member States reserve the right to apply only those categories provided for in their national legislation) Note: *For further information, please refer to Article 71 of Directive 2001/83/EC</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E2331-6</td>
<td>Member-states</td>
<td>maa:renewed-member-states/rdm:ref-member-state/rdm:name</td>
<td>Procedure Use &gt; Role &gt; Country CTL</td>
<td>B2331-1</td>
</tr>
<tr>
<td>E2331-7</td>
<td>Member-states</td>
<td>maa:not-renewed-member-states/rdm:ref-member-state/rdm:name</td>
<td>Procedure Use &gt; Role &gt; Country CTL</td>
<td>B2331-2</td>
</tr>
<tr>
<td>E2331-8</td>
<td>Member-states</td>
<td>maa:special-member-states/rdm:ref-member-state/rdm:name</td>
<td>Procedure Use &gt; Role &gt; Country CTL</td>
<td>B2331-3</td>
</tr>
<tr>
<td>E2331-9</td>
<td>Member-states</td>
<td>maa:restricted-member-states/rdm:ref-member-state/rdm:name</td>
<td>Procedure Use &gt; Role &gt; Country CTL</td>
<td>B2331-4</td>
</tr>
</tbody>
</table>

#### Element Tree Diagram

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<table>
<thead>
<tr>
<th>eu_application_form</th>
<th>initial-application-form-human</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>chapter-2</td>
</tr>
<tr>
<td></td>
<td>legal-status</td>
</tr>
<tr>
<td></td>
<td>subject-medical-prescription</td>
</tr>
<tr>
<td>renewed</td>
<td></td>
</tr>
<tr>
<td>:yes-no</td>
<td>+</td>
</tr>
<tr>
<td>member-states</td>
<td></td>
</tr>
<tr>
<td>ref-member-state</td>
<td>/text</td>
</tr>
<tr>
<td>not-renewed</td>
<td></td>
</tr>
<tr>
<td>:yes-no</td>
<td>+</td>
</tr>
<tr>
<td>member-states</td>
<td></td>
</tr>
<tr>
<td>ref-member-state</td>
<td>/text</td>
</tr>
<tr>
<td>special</td>
<td></td>
</tr>
<tr>
<td>:yes-no</td>
<td>+</td>
</tr>
<tr>
<td>member-states</td>
<td></td>
</tr>
<tr>
<td>ref-member-state</td>
<td>/text</td>
</tr>
<tr>
<td>restricted</td>
<td></td>
</tr>
<tr>
<td>:yes-no</td>
<td>+</td>
</tr>
<tr>
<td>member-states</td>
<td></td>
</tr>
<tr>
<td>ref-member-state</td>
<td>/text</td>
</tr>
</tbody>
</table>
```

#### Business Rules

<table>
<thead>
<tr>
<th>Rule ID</th>
<th>Element Id(s)</th>
<th>Default BR</th>
<th>Rule</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>B2331-1</td>
<td>E2331-6</td>
<td>Optional.</td>
<td>If E2331-1 is selected then E2331-6 is mandatory</td>
<td></td>
</tr>
<tr>
<td>B2331-2</td>
<td>E2331-7</td>
<td>Optional.</td>
<td>If E2331-2 is selected then E2331-7 is mandatory</td>
<td></td>
</tr>
<tr>
<td>B2331-3</td>
<td>E2331-8</td>
<td>Optional.</td>
<td>If E2331-3 is selected then E2331-8 is mandatory</td>
<td></td>
</tr>
<tr>
<td>B2331-4</td>
<td>E2331-9</td>
<td>Optional.</td>
<td>If E2331-4 is selected then E2331-9 is mandatory</td>
<td></td>
</tr>
</tbody>
</table>
2.3.3.2 Supply for products not subject to medical prescription

<table>
<thead>
<tr>
<th>Common DES 3.0 Context</th>
<th>Common RDM Entry point</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Elem Id</th>
<th>Label</th>
<th>DES 3.0 Mapping</th>
<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>E2332-1</td>
<td>Supply through pharmacy only</td>
<td>maa:pharmacy</td>
<td>Legal Status for the Supply CTL</td>
<td>B2332-1</td>
</tr>
<tr>
<td>E2332-2</td>
<td>Member-states</td>
<td>maa:pharmacy-member-states/rdm:ref-member-state/rdm:name</td>
<td>Procedure Use &gt; Role &gt; Country CTL</td>
<td>B2332-1</td>
</tr>
<tr>
<td>E2332-3</td>
<td>Supply through non-pharmacy outlets and pharmacies (if applicable)</td>
<td>maa:non-pharmacy</td>
<td>Legal Status for the Supply CTL</td>
<td>B2332-2</td>
</tr>
<tr>
<td>E2332-4</td>
<td>Member-states</td>
<td>maa:non-pharmacy-member-states/rdm:ref-member-state/rdm:name</td>
<td>Procedure Use &gt; Role &gt; Country CTL</td>
<td>B2332-2</td>
</tr>
</tbody>
</table>

**Business Rules**

<table>
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<th>Rule</th>
<th>Effect(s)</th>
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<tbody>
<tr>
<td>B2332-1</td>
<td>E2332-2</td>
<td>Optional.</td>
<td>If E2332-1 is selected then E2332-2 is visible and mandatory</td>
<td></td>
</tr>
<tr>
<td>B2332-2</td>
<td>E2332-4</td>
<td>Optional.</td>
<td>If E2332-3 is selected then E2332-4 is visible and mandatory</td>
<td></td>
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### Promotion for products not subject to medical prescription

<table>
<thead>
<tr>
<th>Elem Id</th>
<th>Label</th>
<th>DES 3.0 Mapping</th>
<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>E2333-1</td>
<td>Promotion to health care professionals only</td>
<td>maa:health-care-Professional</td>
<td>Legal Status for the Supply CTL</td>
<td>B2332-1</td>
</tr>
<tr>
<td>E2333-2</td>
<td>Member-states</td>
<td>maa:health-care-member-states/rdm:ref-member-state/rdm:name</td>
<td>Procedure Use &gt; Role &gt; Country CTL</td>
<td>B2332-1</td>
</tr>
<tr>
<td>E2333-3</td>
<td>Promotion to general public and health care professionals</td>
<td>maa:public-health-care-Professional</td>
<td>Legal Status for the Supply CTL</td>
<td>B2332-2</td>
</tr>
<tr>
<td>E2333-4</td>
<td>Member-states</td>
<td>maa:public-member-states/rdm:ref-member-state/rdm:name</td>
<td>Procedure Use &gt; Role &gt; Country CTL</td>
<td>B2332-2</td>
</tr>
</tbody>
</table>

#### Element Tree Diagram

```
  eu_application_form
     | initial-application-form-human
        | chapter-2
        | legal-status
        | not-subject-medical-prescription
            | health-care-Professional
                | Yes-no
                | +
                | Member-states
                    | :CTL
                    | ref-member-state
                        | name
                            | /text
            | health-care-Professional
                | Yes-no
                | +
                | Member-states
                    | :CTL
                    | ref-member-state
                        | name
                            | /text
```

#### Business Rules

<table>
<thead>
<tr>
<th>Rule ID</th>
<th>Element id(s)</th>
<th>Default BR</th>
<th>Rule</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>B2333-1</td>
<td>E2333-2</td>
<td>Optional</td>
<td>If E2333-1 is selected then E2333-2 is visible and mandatory</td>
<td></td>
</tr>
<tr>
<td>B2333-2</td>
<td>E2333-4</td>
<td>Optional</td>
<td>If E2333-3 is selected then E2333-4 is visible and mandatory</td>
<td></td>
</tr>
</tbody>
</table>
### 2.3.4 MARKETING AUTHORISATION HOLDER/CONTACT PERSONS/COMPANY

<table>
<thead>
<tr>
<th>Common DES 3.0 Context</th>
<th>Common RDM Entry point</th>
</tr>
</thead>
</table>

#### Element Id | Label | DES 3.0 Mapping | RDM 3.0 Mapping | Remarks |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>E234-1</td>
<td>Proposed marketing authorisation holder/person legally responsible for placing the product on the market in the European Union/each Member State</td>
<td>maa:marketing-authorisation-holders/maa:marketing-authorisation-holder</td>
<td></td>
<td>See Section 2.3.4.1</td>
</tr>
<tr>
<td>E234-2</td>
<td>Person/company authorised for communication on behalf of the applicant during the procedure in the European Union/each Member State</td>
<td>maa:contact-during-procedures/maa:contact-during-procedure/</td>
<td></td>
<td>See Section 2.3.4.2</td>
</tr>
<tr>
<td>E234-3</td>
<td>Person/company authorised for communication between the marketing authorisation holder and the competent authorities after authorisation if different from 2.4.2 in European Union/each Member State</td>
<td>maa:contact-after-procedures/maa:contact-after-procedure/</td>
<td></td>
<td>See Section 2.3.4.3</td>
</tr>
<tr>
<td>E234-4</td>
<td>Qualified person in the EEA for Pharmacovigilance</td>
<td>maa:contact-pharmaco-vigilances/maa:contact-pharmaco-vigilance/</td>
<td></td>
<td>See Section 2.3.4.4</td>
</tr>
<tr>
<td>E234-5</td>
<td>For the purposes of this application form, a Qualified Person Responsible for Pharmacovigilance &quot;resides&quot; in the place where he/she makes his/her home, where he/she lives, can be traced, located, identified for all legal and contractual obligations, whether or not it is owned by him/her or he/she is permanently dwelling there.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E234-6</td>
<td>Scientific service of the MAH in the EEA as referred to in Article 98 of Directive 2001/83/EC (for DCP, MRP and national applications, the contact person in the country where the application is made)</td>
<td>maa:contact-scientific-advises/maa:contact-scientific-advice/</td>
<td></td>
<td>See Section 2.3.4.5</td>
</tr>
</tbody>
</table>

#### Element Tree Diagram

```
  eu_application_form
     | initial-application-form-human
        | chapter-2

  marketing-authorisation-holders + contact-during-procedures + contact-after-procedures + contact-pharmaco-vigilances + contact-scientific-advises
     + marketing-authorisation-holder + contact-during-procedure + contact-after-procedure + contact-pharmaco-vigilance + contact-scientific

   2.3.4.1 • • •  2.3.4.2 • • •  2.3.4.3 • • •  2.3.4.4 • • •  2.3.4.5 • • •
```
### 2.3.4.1 Proposed marketing authorisation holder/person legally responsible for placing the product on the market in the European Union/each MS

<table>
<thead>
<tr>
<th>Common DES 3.0 Context</th>
<th>Common RDM Entry point</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Elem Id</th>
<th>Label</th>
<th>DES 3.0 Mapping</th>
<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>E2341-1</td>
<td>National procedure</td>
<td>maa:centralised-nationalprocedure(value=1)</td>
<td>Procedure Type CTL (Value=&quot;national&quot;)</td>
<td>B2341-3, B2342-1, B2343-2, B2344-1</td>
</tr>
<tr>
<td>E2341-2</td>
<td>Centralized procedure</td>
<td>maa:centralised-nationalprocedure(value=2)</td>
<td>Procedure Type CTL (Value=&quot;centralised&quot;)</td>
<td>B2341-3, B2342-1, B2343-2, B2344-1</td>
</tr>
<tr>
<td>E2341-3</td>
<td>Member states</td>
<td>maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:member-states/rdm:ref-member-state/rdm:name</td>
<td>Procedure Use &gt; Role &gt; Country CTL</td>
<td>B2341-3,</td>
</tr>
<tr>
<td>E2341-4</td>
<td>Company name</td>
<td>maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:company-name</td>
<td>MAH for Placing Product&gt;Role&gt;Party&gt;Organisation&gt;Name</td>
<td></td>
</tr>
<tr>
<td>E2341-5</td>
<td>Address1</td>
<td>maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:address1</td>
<td>MAH for Placing Product&gt;Role&gt;Party&gt; Contact Details &gt; Address</td>
<td></td>
</tr>
<tr>
<td>E2341-6</td>
<td>city</td>
<td>maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:city</td>
<td>MAH for Placing Product&gt;Role&gt;Party&gt; Contact Details &gt; city</td>
<td></td>
</tr>
<tr>
<td>E2341-6a</td>
<td>state</td>
<td>maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:state</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E2341-6b</td>
<td>county</td>
<td>maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:country</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E2341-7</td>
<td>Postcode</td>
<td>maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:postcode</td>
<td>MAH for Placing Product&gt;Role&gt;Party&gt; Contact Details &gt; Address&gt;post code</td>
<td></td>
</tr>
<tr>
<td>E2341-8</td>
<td>Country</td>
<td>maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:country</td>
<td>MAH for Placing Product&gt;Role&gt;Party&gt; Contact Details &gt; Address &gt; Country CTL</td>
<td></td>
</tr>
<tr>
<td>E2341-8a</td>
<td>orgID</td>
<td>maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:orgID</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E2341-8b</td>
<td>locID</td>
<td>maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:locID</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E2341-8c</td>
<td>Loc-modifiedDate</td>
<td>maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:loc-modifiedDate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E2341-8d</td>
<td>Org-modifiedDate</td>
<td>maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:org-modifiedDate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E2341-8d</td>
<td>languae</td>
<td>maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:language</td>
<td>MAH for Placing Product&gt;Role&gt;Party&gt; Contact Details &gt; Electronic Contact &gt; electronic contact</td>
<td></td>
</tr>
<tr>
<td>E2341-9</td>
<td>Telephone</td>
<td>maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:telephone</td>
<td>MAH for Placing Product&gt;Role&gt;Party&gt; Contact Details &gt; Electronic Contact &gt; electronic contact</td>
<td></td>
</tr>
<tr>
<td>E2341-11</td>
<td>E-mail</td>
<td>maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:email</td>
<td>MAH for Placing Product&gt;Role&gt;Party&gt; Contact Details &gt; Electronic Contact &gt; electronic contact</td>
<td></td>
</tr>
<tr>
<td>E2341-12</td>
<td>Contact person at this address</td>
<td></td>
<td>B2341-4</td>
<td></td>
</tr>
<tr>
<td>E2341-13</td>
<td>Title</td>
<td>maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:personal-title</td>
<td>MAH for Placing Product&gt;Role&gt;Party&gt;Personal Title</td>
<td>B2341-4</td>
</tr>
<tr>
<td>E2341-14</td>
<td>First name</td>
<td>maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:given-name</td>
<td>MAH for Placing Product&gt;Role&gt;Party&gt;Person&gt; given name</td>
<td>B2341-4</td>
</tr>
<tr>
<td>E2341-15</td>
<td>Surname</td>
<td>maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:family-name</td>
<td>MAH for Placing Product&gt;Role&gt;Party&gt;Person&gt;family name</td>
<td>B2341-4</td>
</tr>
<tr>
<td>---------</td>
<td>--------</td>
<td>---------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------</td>
<td>------</td>
</tr>
<tr>
<td>E2341-16</td>
<td>Attach proof of establishment of the applicant in the EEA (Annex 5.3)</td>
<td>maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:family-name</td>
<td>MAH for Placing Product&gt;has SME assigned to emea</td>
<td>B2341-1, B2341-2</td>
</tr>
<tr>
<td>E2341-17</td>
<td>Has SME status been assigned by the EMA?</td>
<td>maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:sme-status/rdm:annex5-3</td>
<td>MAH for Placing Product&gt;has sme assigned to emea</td>
<td>B2341-1</td>
</tr>
<tr>
<td>E2341-18</td>
<td>Yes</td>
<td>maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:sme-status/rdm:assigned</td>
<td>MAH for Placing Product&gt;has sme assigned to emea</td>
<td>B2341-1</td>
</tr>
<tr>
<td>E2341-19</td>
<td>No</td>
<td>maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:sme-status/rdm:assigned</td>
<td>MAH for Placing Product&gt;has sme assigned to emea</td>
<td>B2341-1</td>
</tr>
<tr>
<td>----------</td>
<td>------</td>
<td>---------------------------------------------------------------------------------</td>
<td>------------------------------------------</td>
<td>---------</td>
</tr>
<tr>
<td>E2341-34b</td>
<td>locID</td>
<td>maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:locID</td>
<td>MAH for Placing Product&gt;Role&gt;Party&gt;Address</td>
<td>B2341-5</td>
</tr>
<tr>
<td>E2341-34c</td>
<td>Loc-modifiedDate</td>
<td>maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:loc-modifiedDate</td>
<td>MAH for Placing Product&gt;Role&gt;Party&gt;Address</td>
<td>B2341-5</td>
</tr>
<tr>
<td>E2341-34d</td>
<td>Org-modifiedDate</td>
<td>maa:marketing-authorisation-holders/maa:marketing-authorisation-holder/rdm:org-modifiedDate</td>
<td>MAH for Placing Product&gt;Role&gt;Party&gt;Address</td>
<td>B2341-5</td>
</tr>
</tbody>
</table>
**Element tree diagram**

```
+ eu_application_form
  - initial-application-form-human
  + chapter-2
  + marketing-authorisation-holders
    + Centralised-naitonalprocedure
      :yes-no
    - marketing-authorisation-holder
      + sme-status
        + member-states
          - personal-title
          - given-name
          - family-name
          - ref-member-state
            - name
              CTL
        + member-states
          - ref-member-state
            - name
              CTL
      + member-states
        + ref-member-state
          - name
            CTL
          + member-states
            + ref-member-state
              - name
                CTL
      + member-states
        + ref-member-state
          - name
            CTL
      + ref-member-state
        - name
          CTL
    + Address
      ......1
    + Proof-of-payment
      + payment
        + Fees-paid
          :yes-no
      + Billing address
    + Purchase-order-number
      /text
    + org-modifiedDate
      date
    + Loc-modifiedDate
      date
    + orgID
      text
    + locID
      text
    + language
      text
```

**Business Rules**

<table>
<thead>
<tr>
<th>Rule ID</th>
<th>Element id(s)</th>
<th>Default BR</th>
<th>Rule</th>
<th>Effect(s)</th>
</tr>
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<tbody>
<tr>
<td>B2341-2</td>
<td>E2341-18, E2341-20 to E2341-22</td>
<td>Mandatory.</td>
<td>If E2341-18 is selected, then the rest are mandatory, else they are hidden.</td>
<td></td>
</tr>
<tr>
<td>B2341-3</td>
<td>E2341-1, E2341-2, E2341-3</td>
<td>hidden</td>
<td>If E2341-2 is selected then E2341-3 is visible if E2341-1 is selected then E2341-3 is invisible</td>
<td></td>
</tr>
<tr>
<td>B2341-4</td>
<td>E2341-1, E2341-2, E2341-12, E2341-15, E2341-16, E2341-17</td>
<td>hidden</td>
<td>If E2341-2 is selected then E2341-12, E2341-15 is visible if E2341-1 is selected then E2341-12, E2341-15 is invisible</td>
<td></td>
</tr>
<tr>
<td>B2341-5</td>
<td>E2341-25 to E2341-38</td>
<td>hidden</td>
<td>If E2341-25 is selected, then E2341-27 is visible and E2341-28 to E2341-38 are hidden if E2341-26 is selected, then E2341-28 to E2341-38 are visible and E2341-27 is hidden</td>
<td></td>
</tr>
</tbody>
</table>
2.3.4.2 Person/company authorised for communication on behalf of the applicant during the procedure in the European Union/each MS

<table>
<thead>
<tr>
<th>Common DES 3.0 Context</th>
<th>Common RDM Entry point</th>
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</table>

<table>
<thead>
<tr>
<th>Elem Id</th>
<th>Label</th>
<th>DES 3.0 Mapping</th>
<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
</tr>
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<tbody>
<tr>
<td>E2342-1</td>
<td>Member states</td>
<td>rdm:member-states/rdm:ref-member-state/rdm:name</td>
<td>Procedure Use &gt; Role &gt; Country CTL</td>
<td>B2342-1</td>
</tr>
<tr>
<td>E2342-2</td>
<td>Title</td>
<td>rdm:contact-details/rdm:personal-title</td>
<td>Role&gt;Party&gt;Person&gt; Personal Title</td>
<td></td>
</tr>
<tr>
<td>E2342-3</td>
<td>First name</td>
<td>rdm:contact-details/rdm:given-name</td>
<td>Role&gt;Party&gt;Person&gt; given name</td>
<td></td>
</tr>
<tr>
<td>E2342-4</td>
<td>Surname</td>
<td>rdm:contact-details/rdm:family-name</td>
<td>Role&gt;Party&gt;Person&gt; family name</td>
<td></td>
</tr>
<tr>
<td>E2342-5</td>
<td>Company name</td>
<td>rdm:contact-details/rdm:company-name</td>
<td>Role&gt;Party&gt;Organisation&gt;Name</td>
<td></td>
</tr>
<tr>
<td>E2342-6</td>
<td>Address1</td>
<td>rdm:contact-details/rdm:address1</td>
<td>Role&gt;Party&gt;Contact Details &gt; Address</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>rdm:contact-details/rdm:address2</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>rdm:contact-details/rdm:address3</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>rdm:contact-details/rdm:address4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E2342-7</td>
<td>City</td>
<td>rdm:contact-details/rdm:city</td>
<td>Role&gt;Party&gt;Contact Details &gt; city</td>
<td></td>
</tr>
<tr>
<td>E2342-7a</td>
<td>State</td>
<td>rdm:contact-details/rdm:state</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E2342-7b</td>
<td>County</td>
<td>rdm:contact-details/rdm:county</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E2342-8</td>
<td>Postcode</td>
<td>rdm:contact-details/rdm:post-code</td>
<td>Role&gt;Party&gt;Contact Details &gt; postcode</td>
<td></td>
</tr>
<tr>
<td>E2342-9</td>
<td>Country</td>
<td>rdm:contact-details/rdm:country</td>
<td>Role&gt;Party&gt;Contact Details &gt; Address &gt; Country CTL</td>
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</tr>
<tr>
<td>E2342-9a</td>
<td>orgID</td>
<td>rdm:contact-details/rdm:orgID</td>
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</tr>
<tr>
<td>E2342-9b</td>
<td>locID</td>
<td>rdm:contact-details/rdm:locID</td>
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<td></td>
</tr>
<tr>
<td>E2342-9c</td>
<td>Loc-modifiedDate</td>
<td>rdm:contact-details/rdm:loc-modifiedDate</td>
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</tr>
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<td>E2342-9d</td>
<td>Org-modifiedDate</td>
<td>rdm:contact-details/rdm:org-modifiedDate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E2342-9e</td>
<td>language</td>
<td>rdm:contact-details/rdm:language</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E2342-10</td>
<td>Telephone</td>
<td>rdm:contact-details/rdm:phone</td>
<td>Role&gt;Party&gt;Contact Details &gt; Electronic Contact &gt; electronic contact</td>
<td></td>
</tr>
<tr>
<td>E2342-12</td>
<td>E-mail</td>
<td>rdm:contact-details/rdm:email</td>
<td>Role&gt;Party&gt;Contact Details &gt; Electronic Contact &gt; electronic contact</td>
<td></td>
</tr>
<tr>
<td>E2342-13</td>
<td>If different to 2.4.1 above, Attach letter of authorisation (Annex 5.4)</td>
<td>rdm:contact-details/rdm:attach</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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Element Tree Diagram

Business Rules

<table>
<thead>
<tr>
<th>Rule ID</th>
<th>Element id(s)</th>
<th>Default BR</th>
<th>Rule</th>
<th>Effect(s)</th>
</tr>
</thead>
</table>
| B2342-1 | E2341-1       | hidden     | If E2341-2 is selected then is visible  
If E2341-1 is selected then is invisible | E2342-1 |

2.3.4.3 Person/company authorised for communication between the marketing authorisation holder and the competent authorities after authorisation if different from 2.4.2 in the European Union/each MS

<table>
<thead>
<tr>
<th>Common DES 3.0 Context</th>
<th>Common RDM Entry point</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Elem Id</th>
<th>Label</th>
<th>DES 3.0 Mapping</th>
<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>E2343-1</td>
<td>Member states</td>
<td>rdm:member-states/rdm:ref-member-state/rdm:name</td>
<td>Procedure Use &gt; Role &gt; Country CTL</td>
<td>B2343-2</td>
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<tr>
<td>E2343-2</td>
<td>Title</td>
<td>rdm:contact-details/rdm:personal-title</td>
<td>Role&gt;Party&gt;Person&gt; Personal Title</td>
<td>B2343-1</td>
</tr>
<tr>
<td>E2343-3</td>
<td>First name</td>
<td>rdm:contact-details/rdm:given-name</td>
<td>Role&gt;Party&gt;Person&gt; given name</td>
<td>B2343-1</td>
</tr>
<tr>
<td>E2343-4</td>
<td>Surname</td>
<td>rdm:contact-details/rdm:family-name</td>
<td>Role&gt;Party&gt;Person&gt; family name</td>
<td>B2343-1</td>
</tr>
<tr>
<td>E2343-5</td>
<td>Company name</td>
<td>rdm:contact-details/rdm:company-name</td>
<td>Role&gt;Party&gt;Organisation&gt;Name</td>
<td>B2343-1</td>
</tr>
<tr>
<td>E2343-6</td>
<td>Address1</td>
<td>rdm:contact-details/rdm:address1</td>
<td>Role&gt;Party&gt;Contact Details &gt; Address</td>
<td>B2343-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>rdm:contact-details/rdm:address2</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>rdm:contact-details/rdm:address3</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>rdm:contact-details/rdm:address4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E2343-7</td>
<td>city</td>
<td>rdm:contact-details/rdm:city</td>
<td>Role&gt;Party&gt;Contact Details &gt; city</td>
<td>B2343-1</td>
</tr>
</tbody>
</table>
Element Tree Diagram

```
+------------------+
| eu_application_form | initial-application-form-human | chapter-2 | contact-after-procedures |
+------------------+
    | contact-after-procedures+ |
    | contact-details + | attach? |
    | name | personal-title | given-name | family-name | company-name | Address1 | Address2 | Address3 |
    | CTL | /text | /text | /text | /text | /text | /text | /text |
    | Address4 | City | State | county | post-code | country | orgID | locID | Loc-modifiedDate | org-modifiedDate | language | email | phone |
```

Business Rules

<table>
<thead>
<tr>
<th>Rule ID</th>
<th>Element id(s)</th>
<th>Default BR</th>
<th>Rule</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>B2343-1</td>
<td>E2343-1 to E2343-12</td>
<td>Optional.</td>
<td>Elements should be optional.</td>
<td></td>
</tr>
<tr>
<td>B2343-2</td>
<td>E2343-1</td>
<td>hidden</td>
<td>If E2341-2 is selected then E2343-1 is visible. If E2341-1 is selected then E2343-1 is invisible.</td>
<td></td>
</tr>
</tbody>
</table>
### 2.3.4.4 Summary of the applicant pharmacovigilance system

<table>
<thead>
<tr>
<th>Elem Id</th>
<th>Label</th>
<th>maa DES 3.0 Context</th>
<th>Common RDM Entry point</th>
<th>Remarks</th>
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</thead>
<tbody>
<tr>
<td>E2344-1</td>
<td>Member states</td>
<td>maa:contact-pharmaco-vigilance/rdm:member-states</td>
<td>Procedure Use &gt; Role &gt; Country CTL</td>
<td>B2344-1</td>
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<tr>
<td>E2344-2</td>
<td>Title</td>
<td>maa:contact-pharmaco-vigilance/rdm:personal-title</td>
<td>Role&gt;Party&gt;Person&gt;Personal Title</td>
<td></td>
</tr>
<tr>
<td>E2344-3</td>
<td>First name</td>
<td>maa:contact-pharmaco-vigilance/rdm:given-name</td>
<td>Role&gt;Party&gt;Person&gt;given name</td>
<td></td>
</tr>
<tr>
<td>E2344-4</td>
<td>Surname</td>
<td>maa:contact-pharmaco-vigilance/rdm:family-name</td>
<td>Role&gt;Party&gt;Person&gt;family name</td>
<td></td>
</tr>
<tr>
<td>E2344-5</td>
<td>Company name</td>
<td>maa:contact-pharmaco-vigilance/rdm:company-name</td>
<td>Role&gt;Party&gt;Organisation&gt;name</td>
<td></td>
</tr>
<tr>
<td>E2344-6</td>
<td>Address1</td>
<td>maa:contact-pharmaco-vigilance/rdm:address1</td>
<td>Role&gt;Party&gt;Contact Details &gt; Address</td>
<td></td>
</tr>
<tr>
<td>E2344-7</td>
<td>city</td>
<td>maa:contact-pharmaco-vigilance/rdm:city</td>
<td>Role&gt;Party&gt;Contact Details &gt; city</td>
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<tr>
<td>E2344-8</td>
<td>Postcode</td>
<td>maa:contact-pharmaco-vigilance/rdm:post-code</td>
<td>Role&gt;Party&gt;Contact Details &gt; Address &gt; post code</td>
<td></td>
</tr>
<tr>
<td>E2344-9</td>
<td>Country</td>
<td>maa:contact-pharmaco-vigilance/rdm:country</td>
<td>Role&gt;Party&gt;Contact Details &gt; Address &gt; Country CTL</td>
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</tr>
<tr>
<td>E2344-9a</td>
<td>state</td>
<td>maa:contact-pharmaco-vigilance/rdm:state</td>
<td>Role&gt;Party&gt;Contact Details &gt; Address &gt; Country CTL</td>
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</tr>
<tr>
<td>E2344-9b</td>
<td>county</td>
<td>maa:contact-pharmaco-vigilance/rdm:county</td>
<td>Role&gt;Party&gt;Contact Details &gt; Address &gt; Country CTL</td>
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<tr>
<td>E2344-10</td>
<td>24H Telephone</td>
<td>maa:contact-pharmaco-vigilance/rdm:phone</td>
<td>Role&gt;Party&gt;Contact Details &gt; Electronic Contact &gt; electronic contact</td>
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</tr>
<tr>
<td>E2344-11a</td>
<td>orgID</td>
<td>maa:contact-pharmaco-vigilance/rdm:orgID</td>
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<td></td>
</tr>
<tr>
<td>E2344-11b</td>
<td>locID</td>
<td>maa:contact-pharmaco-vigilance/rdm:locID</td>
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</tr>
<tr>
<td>E2344-11c</td>
<td>Loc-modifiedDate</td>
<td>maa:contact-pharmaco-vigilance/rdm:loc-modifiedDate</td>
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<td>E2344-11d</td>
<td>Org-modifiedDate</td>
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<td>E2344-11e</td>
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<td>E-mail</td>
<td>maa:contact-pharmaco-vigilance/rdm:email</td>
<td>Role&gt;Party&gt;Contact Details&gt; Electronic Contact &gt; electronic contact</td>
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<tr>
<td>E2344-13</td>
<td>The above-mentioned qualified person resides in the EEA</td>
<td>maa:contact-pharmaco-vigilance/rdm:residesInEEA</td>
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</tr>
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<td>E2344-14</td>
<td>Pharmacovigilance system master file</td>
<td>maa:details-pharmaco-vigilance/maa:file</td>
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<td></td>
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</tr>
<tr>
<td>E2344-16a</td>
<td>city</td>
<td>maa:details-pharmaco-vigilance/rdm:city</td>
<td>Role&gt;Party&gt;Contact Details &gt; Address</td>
<td></td>
</tr>
<tr>
<td>E2344-16b</td>
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<td>maa:details-pharmaco-vigilance/rdm:post-code</td>
<td>Role&gt;Party&gt;Contact Details &gt; Address &gt; post code</td>
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<tr>
<td>E2344-16c</td>
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<td>maa:details-pharmaco-vigilance/rdm:country</td>
<td>Role&gt;Party&gt;Contact Details &gt; Address &gt; post code</td>
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<tr>
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<td>Role&gt;Party&gt;Contact Details &gt; Address &gt; post code</td>
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<td>Role&gt;Party&gt;Contact Details &gt; Address &gt; post code</td>
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</tr>
</tbody>
</table>
Element Tree Diagram

![Element Tree Diagram](image-url)

Business Rules

<table>
<thead>
<tr>
<th>Rule ID</th>
<th>Element id(s)</th>
<th>Default BR</th>
<th>Rule</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>B2344-1</td>
<td>E2343-1</td>
<td>hidden</td>
<td>If E2341-2 is selected then E2344-1 is visible If E2341-1 is selected then E2344-1 is hidden</td>
<td></td>
</tr>
</tbody>
</table>
### Scientific service of the MAH in the EEA as referred to in Article 98 of Directive 2001/83/EC (for DCP, MRP and national applications, the contact person in the country where the application is made)

<table>
<thead>
<tr>
<th>Elem Id</th>
<th>Label</th>
<th>DES 3.0 Mapping</th>
<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
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<tbody>
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<td>Name of the contact person</td>
<td>maa:eu_application_form/maa:initial-application-form-human/maa:chapter-2/maa:contact-scientific-advices/maa:contact-scientific-advice/</td>
<td>Application &gt;</td>
<td></td>
</tr>
<tr>
<td>E2345-2</td>
<td>Title</td>
<td>rdm:personal-title</td>
<td>Role&gt;Party&gt;Person&gt; Personal Title</td>
<td></td>
</tr>
<tr>
<td>E2345-3</td>
<td>First name</td>
<td>rdm:given-name</td>
<td>Role&gt;Party&gt;Person&gt; given name</td>
<td></td>
</tr>
<tr>
<td>E2345-4</td>
<td>Surname</td>
<td>rdm:family-name</td>
<td>Role&gt;Party&gt;Person&gt; family name</td>
<td></td>
</tr>
<tr>
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<td>rdm:company-name</td>
<td>Role&gt;Party&gt;Organisation&gt; Name</td>
<td></td>
</tr>
<tr>
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<td>Role&gt;Party&gt;Contact Details &gt; city</td>
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<tr>
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<td>rdm:state</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E2345-7b</td>
<td>county</td>
<td>rdm:county</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E2345-8</td>
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<tr>
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</tr>
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<tr>
<td>E2345-9b</td>
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<td>rdm:locID</td>
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<td></td>
</tr>
<tr>
<td>E2345-9c</td>
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<td>rdm:loc-modifiedDate</td>
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<td></td>
</tr>
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<td>E2345-9d</td>
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<td>rdm:org-modifiedDate</td>
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</tr>
<tr>
<td>E2345-9e</td>
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<td>rdm:language</td>
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<tr>
<td>E2345-10</td>
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<td>rdm:phone</td>
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<tr>
<td>E2345-13</td>
<td>Member-states</td>
<td>rdm:member-states/rdm:ref-member-state/rdm:name</td>
<td>Procedure Use &gt; Role &gt; Country CTL</td>
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2.3. 5 MANUFACTURERS

<table>
<thead>
<tr>
<th>Common DES 3.0 Context</th>
<th>Common RDM Entry point</th>
<th>DES 3.0 Mapping</th>
<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
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<tbody>
<tr>
<td>elem Id</td>
<td>Label</td>
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<tr>
<td>E235-1</td>
<td>Authorised manufacturer(s) (or importer(s)) responsible for batch release in the EEA in accordance with Article 40 and Article 51 of Directive 2001/83/EC (as shown in the package leaflet and where applicable in the labeling of Annex II of the Commission Decision):</td>
<td>maa:manufacturer-batch-releases/maa:manufacturer-batch-release/</td>
<td>See Section 2.3.5.1</td>
<td></td>
</tr>
<tr>
<td>E235-2</td>
<td>Official batch release for Blood products and Vaccines Details of the Official Medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official batch release (in accordance with Articles 111(1), 113, 114(1)-(2) and 115 of Directive 2001/83/EC as amended)</td>
<td>maa:contact-blood-vaccines/maa:contact-blood-vaccine/</td>
<td>See Section 2.3.5.2</td>
<td></td>
</tr>
<tr>
<td>E235-3</td>
<td>Contact person in the EEA for product defects and recalls</td>
<td>maa:contact-product-defects/maa:contact-product-defect</td>
<td>See Section 2.3.5.3</td>
<td></td>
</tr>
<tr>
<td>E235-4</td>
<td>Batch control Testing arrangements Site(s) in the EEA or in countries where an MRA or other Community arrangements apply, where batch control testing takes place as required by Article 51 of Directive 2001/83/EC:</td>
<td>maa:manufacturer-batch-testing-sites/maa:manufacturer-batch-testing-site/</td>
<td>See Section 2.3.5.4</td>
<td></td>
</tr>
<tr>
<td>E235-5</td>
<td>Manufacturer(s) of the medicinal product and site(s) of manufacture: (Note: including manufacturing sites of any diluent/solvent presented in a separate container but forming part of the medicinal product, quality control/ in-process testing sites, and importer(s))</td>
<td>maa:manufacturer-pharmaceutical-products/maa:manufacturer-pharmaceutical-product/</td>
<td>See Section 2.3.5.5</td>
<td></td>
</tr>
<tr>
<td>E235-6</td>
<td>Manufacturer(s) of the active substance(s) and site(s) of manufacture Note: All manufacturing sites involved the manufacturing process of each source of active substance, including quality control/ in-process testing sites, should be listed. Broker or supplier details alone are not acceptable. For biotech products include all sites of storage of master and working cell bank and preparation of working cell banks.</td>
<td>maa:manufacturer-active-substances/maa:manufacturer-active-substance</td>
<td>See Section 2.3.5.6</td>
<td></td>
</tr>
<tr>
<td>E235-7</td>
<td>Contract companies used for clinical trial(s) on bioavailability or bioequivalence or used for the validation of blood product manufacturing processes. For each contract company, state where analytical tests are performed and where clinical data are collected and give:</td>
<td>maa:contract-companies/maa:contract-study</td>
<td>See Section 2.3.5.7</td>
<td></td>
</tr>
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Element Tree Diagram

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<table>
<thead>
<tr>
<th>eu_application_form</th>
<th>initial-application-form-human</th>
<th>chapter-2</th>
<th></th>
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<td>manufacturer-batch-releases</td>
<td>contact-blood-vaccines</td>
<td>contact-product-defects</td>
<td>manufacturer-batch-testing-sites</td>
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<tr>
<td>manufacturer-batch-release</td>
<td>contact-blood-vaccine</td>
<td>contact-product-defect</td>
<td>manufacturer-batch-testing-site</td>
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</tr>
<tr>
<td>manufacturer-batch-releases</td>
<td>contact-blood-vaccine</td>
<td>contact-product-defect</td>
<td>manufacturer-batch-testing-site</td>
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<tr>
<td>manufacturer-batch-release</td>
<td>contact-blood-vaccine</td>
<td>contact-product-defect</td>
<td>manufacturer-batch-testing-site</td>
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<tr>
<td>manufacturer-pharmaceutical-products</td>
<td>manufacturer-active-substances</td>
<td>contract-companies</td>
<td></td>
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<tr>
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<td>+</td>
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<tr>
<td>manufacturer-pharmaceutical-product</td>
<td>manufacturer-active-substance</td>
<td>contract-company</td>
<td></td>
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See Section 2.3.5.1
See Section 2.3.5.2
See Section 2.3.5.3
See Section 2.3.5.4
See Section 2.3.5.5
See Section 2.3.5.6
See Section 2.3.5.7
### 2.3.5.1 Authorised manufacturer(s) (or importer(s)) responsible for batch release in the EEA in accordance with Article 40 and Article 51 of Directive 2001/83/EC (as shown in the package leaflet and where applicable in the labeling of Annex II of the Commission Decision):

<table>
<thead>
<tr>
<th>Elem Id</th>
<th>Label</th>
<th>DES 3.0 Mapping</th>
<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
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</thead>
<tbody>
<tr>
<td>E2351-1</td>
<td>Do you have admin address and manufacturer address</td>
<td>maa:contact-details/rdm:admin-manu-address</td>
<td>rdm:contact-details/rdm:admin-office/rdm:company-name</td>
<td>B2351-5</td>
</tr>
<tr>
<td>E2351-3</td>
<td>Admin Office Address 1</td>
<td>rdm:contact-details/rdm:admin-office/rdm:address1</td>
<td>rdm:contact-details/rdm:admin-office/rdm:address2</td>
<td>Role&gt;Party&gt;Address &gt; Address</td>
</tr>
<tr>
<td>E2351-4</td>
<td>city</td>
<td>rdm:contact-details/rdm:admin-office/rdm:city</td>
<td>Role&gt;Party&gt;Address &gt; City</td>
<td>B2351-5</td>
</tr>
<tr>
<td>E2351-4a</td>
<td>state</td>
<td>rdm:contact-details/rdm:admin-office/rdm:state</td>
<td>Role&gt;Party&gt;Address</td>
<td>B2351-5</td>
</tr>
<tr>
<td>E2351-4b</td>
<td>county</td>
<td>rdm:contact-details/rdm:admin-office/rdm:county</td>
<td>Role&gt;Party&gt;Address</td>
<td>B2351-5</td>
</tr>
<tr>
<td>E2351-5</td>
<td>Postcode</td>
<td>rdm:contact-details/rdm:post-code</td>
<td>Role&gt;Party&gt;Address &gt; post code</td>
<td>B2351-5</td>
</tr>
<tr>
<td>E2351-6a</td>
<td>orgID</td>
<td>rdm:contact-details/rdm:admin-office/rdm:country</td>
<td>Role&gt;Party&gt;Address</td>
<td>B2351-5</td>
</tr>
<tr>
<td>E2351-6b</td>
<td>locID</td>
<td>rdm:contact-details/rdm:admin-office/rdm:country</td>
<td>Role&gt;Party&gt;Address</td>
<td>B2351-5</td>
</tr>
<tr>
<td>E2351-6c</td>
<td>Loc-modifiedDate</td>
<td>rdm:contact-details/rdm:admin-office/rdm:loc-modifiedDate</td>
<td>Role&gt;Party&gt;Address</td>
<td>B2351-5</td>
</tr>
<tr>
<td>E2351-6d</td>
<td>Org-modifiedDate</td>
<td>rdm:contact-details/rdm:admin-office/rdm:org-modifiedDate</td>
<td>Role&gt;Party&gt;Address</td>
<td>B2351-5</td>
</tr>
<tr>
<td>E2351-6e</td>
<td>language</td>
<td>rdm:contact-details/rdm:admin-office/rdm:language</td>
<td>Role&gt;Party&gt;Address</td>
<td>B2351-5</td>
</tr>
<tr>
<td>E2351-7</td>
<td>Admin Office Telephone</td>
<td>rdm:contact-details/rdm:admin-office/rdm:phone</td>
<td>Role&gt;Party&gt;Address &gt; emergency contact</td>
<td>B2351-5</td>
</tr>
<tr>
<td>E2351-9</td>
<td>Admin Office E-mail</td>
<td>rdm:contact-details/rdm:admin-office/rdm:email</td>
<td>Role&gt;Party&gt;Address</td>
<td>B2351-5</td>
</tr>
<tr>
<td>E2351-10</td>
<td>Company name</td>
<td>rdm:contact-details/rdm:manu-facility/rdm:company-name</td>
<td>Role&gt;Party&gt;Organisation&gt;Name</td>
<td>B2351-5</td>
</tr>
<tr>
<td>E2351-11</td>
<td>Manufacturing Facility Address 1</td>
<td>rdm:contact-details/rdm:manu-facility/rdm:address1</td>
<td>rdm:contact-details/rdm:manu-facility/rdm:address2</td>
<td>Role&gt;Party&gt;Address &gt; address</td>
</tr>
</tbody>
</table>

Electronic Application Form Data Exchange Standard 3.0  
Page 84/120
| E2351-12 | City | rdm:/contact-details/rdm:manu-facility/rdm:city | Role>Party>Details > city | B2351-5 |
| E2351-12a | Post code | rdm:/contact-details/rdm:manu-facility/rdm:postcode | | |
| E2351-12b | Manufacturing Facility Country | rdm:/contact-details/rdm:manu-facility/rdm:country | Role>Party>Details > country | B2351-5 |
| E2351-13 | state | rdm:/contact-details/rdm:manu-facility/rdm:state | Role>Party>Details > state | B2351-5 |
| E2351-14 | county | rdm:/contact-details/rdm:manu-facility/rdm:county | Role>Party>Details > country CTL | B2351-5 |
| E2351-14a | orgID | rdm:/contact-details/rdm:manu-facility/rdm:orgID | | |
| E2351-14b | locID | rdm:/contact-details/rdm:manu-facility/rdm:locID | | |
| E2351-14c | Loc-modifiedDate | rdm:/contact-details/rdm:manu-facility/rdm:loc-modifiedDate | | |
| E2351-14d | Org-modifiedDate | rdm:/contact-details/rdm:manu-facility/rdm:org-modifiedDate | | |
| E2351-14e | language | rdm:/contact-details/rdm:manu-facility/rdm:language | | |
| E2351-17 | Manufacturing Facility E-mail | rdm:/contact-details/rdm:manu-facility/rdm:email | Role>Party>Details > Electronic Contact > electronic contact | B2351-5 |
| E2351-18 | Manufacturing Authorisation number | rdm:manufacturing-auth-number | | |
| E2351-19 | Attach copy of manufacturing authorisation(s) (Annex 5.6) | rdm:attach-annex5-6 | Manufacturing auth number | B2351-1 |
| E2351-22 | Attach latest GMP certificate (Annex 5.9) | rdm:attach-gmp-certificate | | B2351-2 |
| E2351-23 | Enter EudraGMDP document reference number | rdm:selected-eudraGMP-certificate-reference | | B2351-2, B2351-4 |
| E2351-24 | Enter EudraGMDP document reference number | rdm:eudraGMDP-certificate-reference | Eudragmp certificate ref no | B2351-4 |
Element Tree Diagram

Business Rules

<table>
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<tr>
<th>Rule ID</th>
<th>Element id(s)</th>
<th>Default BR</th>
<th>Rule</th>
<th>Effect(s)</th>
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<td>E2351-22, E2351-23</td>
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<td>Mutually Exclusive.</td>
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<td>E2351-20, E2351-21</td>
<td>Mandatory, Optional.</td>
<td>If E2351-20 is selected, E2351-21 is mandatory.</td>
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</tr>
<tr>
<td>B2351-4</td>
<td>E2351-23, E2351-24</td>
<td>Mandatory, Optional.</td>
<td>If E2351-23 is selected, E2351-24 is mandatory.</td>
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<td>E2351-1 to E2351-17</td>
<td>mandatory and visible</td>
<td>E2351-1 is yes then E2351-3 to E2351-17 are visible else E2351-10 to E2351-17 are visible</td>
<td></td>
</tr>
</tbody>
</table>
### 2.3.5.1.1 Official batch release for Blood products and Vaccines Details of the Official Medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official batch release (in accordance with Articles 111(1), 113, 114(1)-(2) and 115 of Directive 2001/83/EC as amended)

<table>
<thead>
<tr>
<th>Common DES 3.0 Context</th>
<th>Common RDM Entry point</th>
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</table>

<table>
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<th>Label</th>
<th>DES 3.0 Mapping</th>
<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
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<tr>
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<td>Role&gt;Party&gt;Contact Details &gt; Address&gt; post code</td>
<td>B2352-1</td>
</tr>
<tr>
<td>E2352-5</td>
<td>Country</td>
<td>rdm:country</td>
<td>Role&gt;Party&lt;Contact Details &gt; Address &gt; Country CTL</td>
<td>B2352-1</td>
</tr>
<tr>
<td>E2352-6</td>
<td>Telephone</td>
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<td>Role&gt;Party&gt;Contact Details &gt; Electronic Contact &gt; electronic contact</td>
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<td>Role&gt;Party&lt;Contact Details&gt; Electronic Contact &gt; electronic contact</td>
<td>B2352-1</td>
</tr>
<tr>
<td>E2352-2</td>
<td>Admin Office Address 1</td>
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<td>Role&gt;Party&lt;Contact Details &gt; Address</td>
<td>B2352-1</td>
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</tr>
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<td>E2352-5</td>
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<td>rdm:county</td>
<td></td>
<td></td>
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<tr>
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<td>Role&gt;Party&lt;Contact Details &gt; Electronic Contact &gt; electronic contact</td>
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<td>rdm:email</td>
<td>Role&gt;Party&lt;Contact Details &gt; Electronic Contact &gt; electronic contact</td>
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</table>
Element Tree Diagram

Business Rules

<table>
<thead>
<tr>
<th>Rule ID</th>
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<th>Default BR</th>
<th>Rule</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
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<td>E2352-1 to E2352-13</td>
<td>Optional</td>
<td>Elements should be optional</td>
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### 2.3.5.2 Contact person in the EEA for product defects and recalls

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<th>Elem Id</th>
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<th>DES 3.0 Mapping</th>
<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
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<td>Role&gt;Party&gt;Organisation&gt; Name</td>
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<tr>
<td>E2353-2</td>
<td>Title</td>
<td>rdm:personal-title</td>
<td>Role&gt;Party&gt;Person&gt; Personal Title</td>
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<tr>
<td>E2353-3</td>
<td>First name</td>
<td>rdm:given-name</td>
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<td>Surname</td>
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<tr>
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<td></td>
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</tr>
<tr>
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<td>rdm:post-code</td>
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<tr>
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<td>E2353-9</td>
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#### Business Rules

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<th>Effect(s)</th>
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<td>Optional</td>
<td>Elements should be optional</td>
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2.3.5.2.1 Batch control Testing arrangements Site(s) in the EEA or in countries where an MRA or other European Union arrangements apply, where batch control testing takes place as required by Article 51 of Directive 2001/83/EC:

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<td>rdm:address1</td>
<td>Role&gt;Party&gt; Contact Details &gt; Address</td>
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<tr>
<td></td>
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<td>rdm:address2</td>
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<td>rdm:address3</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>rdm:address4</td>
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<td></td>
</tr>
<tr>
<td>E2354-3</td>
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<td>rdm:city</td>
<td>Role&gt;Party&gt; Contact Details &gt; city</td>
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<tr>
<td>E2354-4</td>
<td>state</td>
<td>rdm:state</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E2354-4a</td>
<td>County</td>
<td>rdm:county</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E2354-4b</td>
<td>postcode</td>
<td>rdm:post-code</td>
<td></td>
<td></td>
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<tr>
<td>E2354-5</td>
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<td>rdm:country</td>
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<td></td>
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<tr>
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<td>Role&gt;Party&gt; Contact Details &gt; Electronic Contact &gt; electronic contact</td>
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<tr>
<td>E2354-9</td>
<td>control-test</td>
<td>rdm:control-tests/rdm:control-test</td>
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<tr>
<td>E2354-11</td>
<td>Attach copy of manufacturing authorisation(s) or other proof of GMP compliance (Annex 5.6)</td>
<td>rdm:attach-auth-gmp</td>
<td></td>
<td>B2354-1</td>
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<tr>
<td>E2354-12</td>
<td>Enter EudraGMDP document reference number</td>
<td>rdm:selectedeudragmp</td>
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<td>B2354-1, B2354-2</td>
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Element Tree Diagram

Business Rules

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<th>Rule</th>
<th>Effect(s)</th>
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<td>Elements are mutually exclusive.</td>
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<td>B2354-2</td>
<td>E2352-11, E2352-12</td>
<td>E2352-11 is Mandatory, E2352-12 is Optional.</td>
<td>If E2352-11 is selected then E2352-12 is mandatory.</td>
<td></td>
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2.3.5.3 Manufacturer(s) of the medicinal product and site(s) of manufacture: (Note: including manufacturing sites of any diluent/solvent presented in a separate container but forming part of the medicinal product, quality control/ in-process testing sites, and importer(s). For each site provide the relevant information.)

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<thead>
<tr>
<th>Elem Id</th>
<th>Label</th>
<th>Common DES 3.0 Context</th>
<th>Common RDM Entry point</th>
<th>Remarks</th>
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<td>maa:contact-details/rdm:admin-manu-address</td>
<td>Role&gt;Party&gt;Electronic Contact &gt; Electronic Contact</td>
<td>B2355-12</td>
</tr>
<tr>
<td>E2355-2</td>
<td>Admin Office Address</td>
<td>rdm:/contact-details/rdm:admin-office/rdm:address1</td>
<td>Role&gt;Party&gt;Electronic Contact &gt; Address</td>
<td>B2355-12</td>
</tr>
<tr>
<td></td>
<td></td>
<td>rdm:/contact-details/rdm:admin-office/rdm:address2</td>
<td>Role&gt;Party&gt;Electronic Contact &gt; Address</td>
<td>B2355-12</td>
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<tr>
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<td></td>
<td>rdm:/contact-details/rdm:admin-office/rdm:address3</td>
<td>Role&gt;Party&gt;Electronic Contact &gt; Address</td>
<td>B2355-12</td>
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<tr>
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<td></td>
<td>rdm:/contact-details/rdm:admin-office/rdm:address4</td>
<td>Role&gt;Party&gt;Electronic Contact &gt; Address</td>
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</tr>
<tr>
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<td>Role&gt;Party&gt;Electronic Contact &gt; Address &gt; City</td>
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<td>Role&gt;Party&gt;Electronic Contact &gt; Address &gt; Org</td>
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<td>Role&gt;Party&gt;Electronic Contact &gt; Address &gt; Org</td>
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<td>E2355-4e</td>
<td>languagae</td>
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<td>Role&gt;Party&gt;Electronic Contact &gt; Address &gt; Org</td>
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<td>E2355-5</td>
<td>Admin Office Telephone</td>
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<td>Role&gt;Party&gt;Electronic Contact &gt; Address &gt; Org</td>
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<td>E2355-7</td>
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<td>E2355-8</td>
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<td>Role&gt;Party&gt;Electronic Contact &gt; Address</td>
<td>B2355-12</td>
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<td>Description</td>
<td>xpath</td>
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<td>E2355-8a</td>
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<td>Role&gt;Party&gt;Details &gt; Entity Contact Details &gt; City</td>
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<td>E2355-8c</td>
<td>Manufacturing Facility Country</td>
<td>rdm:/contact-details/rdm:manu-facility/rdm:country</td>
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<td>E2355-9a</td>
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<td>E2355-12</td>
<td>Manufacturing Facility E-mail</td>
<td>rdm:/contact-details/rdm:manu-facility/rdm:email</td>
<td>Role&gt;Party&gt;Details &gt; Email</td>
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<td>E2355-13</td>
<td>Brief description of functions performed. (note: please see the 'Compilation of Union Procedures on Inspections and Exchange of Information' document, (see pages 127-128) Interpretation of the Union Format for Manufacturer/Importer Authorisation):</td>
<td>rdm:desc</td>
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<td>Manufacturer functions</td>
<td>rdm:manu-functions/rdm:manu-function</td>
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<td>Site is in the EEA:</td>
<td>rdm:site-in-EEA</td>
<td>is site in eea</td>
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<tr>
<td>E2355-15</td>
<td>Site is outside the EEA:</td>
<td>rdm:site-in-EEA</td>
<td>is site in eea</td>
<td></td>
</tr>
<tr>
<td>E2355-16</td>
<td>Manufacturing authorisation number</td>
<td>rdm:inside/rdm:manufacturing-auth-number</td>
<td>manufacturing auth number</td>
<td></td>
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<td>E2355-17</td>
<td>Attach copy of manufacturing authorisation(s) (Annex 5.6)</td>
<td>rdm:inside/rdm:attach-annex-5-6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E2355-18</td>
<td>Enter EudraGMP document reference number</td>
<td>rdm:inside/rdm:manufacturing-auth-reference</td>
<td>eudragmp auth ref</td>
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</tr>
<tr>
<td>E2355-19</td>
<td>Name of qualified person</td>
<td>rdm:inside/rdm:qualified-person</td>
<td>Role&gt;Party&gt;Person&gt; given name</td>
<td>B2355-4</td>
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<td>---</td>
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<td>---</td>
</tr>
<tr>
<td>E2355-20</td>
<td>Attach document equivalent of manufacturing authorisation in accordance with Article 8(k) of Directive 2001/83/EC (Annex 5.6)</td>
<td>rdm:outside/rdm:attach-directive-annex-5-6</td>
<td></td>
<td>B2355-4</td>
</tr>
<tr>
<td>E2355-21</td>
<td>Has the site been inspected for GMP compliance by an EEA authority or by an authority of countries where MRA or other Community arrangements apply within the terms of the agreement?</td>
<td></td>
<td></td>
<td>B2355-4</td>
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<td>E2355-23</td>
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<td>Inspected by eea authority</td>
<td>B2355-4, B2355-5, B2355-6, B2355-7</td>
</tr>
<tr>
<td>E2355-24</td>
<td>No</td>
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<td>Inspected by eea authority</td>
<td>B2355-4, B2355-5, B2355-6, B2355-9</td>
</tr>
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<td>E2355-25</td>
<td>Attach latest GMP certificate or other proof of GMP compliance</td>
<td>rdm:outside/rdm:attach-GMP-certificate</td>
<td></td>
<td>B2355-4, B2355-7, B2355-8, B2355-9</td>
</tr>
<tr>
<td>E2355-27</td>
<td>Has the site been inspected for GMP compliance by any other authority (including those of countries where MRA or other European Union arrangements apply but not within their respective territory)?</td>
<td></td>
<td></td>
<td>B2355-4,</td>
</tr>
<tr>
<td>E2355-28</td>
<td>Yes</td>
<td>rdm:outside/rdm:gmp-compliance-other</td>
<td>Inspected by other authority</td>
<td>B2355-4, B2355-5, B2355-9, B2355-10</td>
</tr>
<tr>
<td>E2355-29</td>
<td>No</td>
<td>rdm:outside/rdm:gmp-compliance-other</td>
<td>Inspected by other authority</td>
<td>B2355-4, B2355-5, B2355-9</td>
</tr>
<tr>
<td>E2355-30</td>
<td>Please provide summary information in Annex 5.9 (and, if available a GMP certificate or a statement from the competent authority which carried out the inspection)</td>
<td>rdm:outside/rdm:attach-annex-5-9</td>
<td></td>
<td>B2355-4, B2355-10</td>
</tr>
<tr>
<td>E2355-31</td>
<td>Attach flow chart indicating the sequence and activities of the different sites involved in the manufacturing process, including testing sites (Annex 5.8)</td>
<td>rdm:attach-annex-5-8</td>
<td></td>
<td></td>
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</table>
Element Tree Diagram

**Business Rules**

<table>
<thead>
<tr>
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<th>Element id(s)</th>
<th>Default BR</th>
<th>Rule</th>
<th>Effect(s)</th>
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<td>Mutually Exclusive.</td>
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<td>E2355-14, E2355-16 to E2355-18</td>
<td>Mandatory</td>
<td>If E2355-14 is selected, then the other fields are required.</td>
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<td>Optional</td>
<td>Mutually Exclusive.</td>
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<td>invisible</td>
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<td>E2355-15, E2355-23 to E2355-24, E2355-28 to E2355-29</td>
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<td>If E2355-15 is selected, then the other fields are mandatory.</td>
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<td>E2355-23, E2355-24</td>
<td>Mandatory</td>
<td>Mutually Exclusive.</td>
<td></td>
</tr>
<tr>
<td>B2355-7</td>
<td>E2355-23, E2355-25 to E2355-26</td>
<td>Optional</td>
<td>If E2355-23 is selected, then the rest are required.</td>
<td></td>
</tr>
<tr>
<td>B2355-8</td>
<td>E2355-25, E2355-26</td>
<td>Optional</td>
<td>Mutually Exclusive.</td>
<td></td>
</tr>
<tr>
<td>B2355-9</td>
<td>E2355-24, E2355-25 to E2355-26</td>
<td>Invisible</td>
<td>If E2355-24 is selected, then the rest of the fields are invisible</td>
<td></td>
</tr>
<tr>
<td>B2355-10</td>
<td>E2355-28, E2355-30</td>
<td>Optional</td>
<td>If E2355-28 is selected, then E2355-30 is mandatory</td>
<td></td>
</tr>
<tr>
<td>B2355-11</td>
<td>E2355-28, E2355-30</td>
<td>Invisible</td>
<td>If E2355-29 is selected, then E2355-30 is visible.</td>
<td></td>
</tr>
<tr>
<td>B2355-12</td>
<td>E2355-1 to E2355-12</td>
<td>mandatory and visible</td>
<td>E2355-1 is yes then E2355-1a to E2355-12 are visible else E2355-1a to E2355-7 are hidden</td>
<td></td>
</tr>
</tbody>
</table>
### 2.3.5.4 Manufacturer(s) of the active substance(s) and site(s) of manufacture

Note: All manufacturing sites involved the manufacturing process of each source of active substance, including quality control/ in-process testing sites, should be listed. Broker or supplier details alone are not acceptable. For biotech products include all sites of storage of master and working cell bank and preparation of working cell banks.

<table>
<thead>
<tr>
<th>Common DES 3.0 Context</th>
<th>Common RDM Entry point</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Elem Id</th>
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<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
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<tr>
<td>E2356-0</td>
<td>Description of the company</td>
<td>maa: company-description</td>
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<tr>
<td>E2356-1</td>
<td>Active Substance</td>
<td>rdm:active-substances/rdm:active-substance/rdm:substance-name</td>
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<td></td>
</tr>
<tr>
<td>E2356-2</td>
<td>Do you have admin address and manufacturer address</td>
<td>maa:role/maa:contact-details/rdm:admin-manu-address</td>
<td></td>
<td>B2356-12</td>
</tr>
<tr>
<td>E2356-2a</td>
<td>Company Name</td>
<td>rdm:/contact-details/rdm:admin-office/rdm:company-name</td>
<td>Role &gt; Party &gt; Organisation&gt; Name</td>
<td>B2356-12</td>
</tr>
<tr>
<td>E2356-3</td>
<td>Admin Office Address 1</td>
<td>rdm:/contact-details/rdm:admin-office/rdm:address1</td>
<td>Role&gt;Party&gt;Contacts Details &gt; Address</td>
<td>B2356-12</td>
</tr>
<tr>
<td>E2356-3</td>
<td>Admin Office Address 1</td>
<td>rdm:/contact-details/rdm:admin-office/rdm:address2</td>
<td>Role&gt;Party&gt;Contacts Details &gt; Address</td>
<td>B2356-12</td>
</tr>
<tr>
<td>E2356-3</td>
<td>Admin Office Address 1</td>
<td>rdm:/contact-details/rdm:admin-office/rdm:address3</td>
<td>Role&gt;Party&gt;Contacts Details &gt; Address</td>
<td>B2356-12</td>
</tr>
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<td>E2356-3</td>
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<td>rdm:/contact-details/rdm:admin-office/rdm:address4</td>
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<td>E2356-3a</td>
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<td>B2356-12</td>
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<tr>
<td>E2356-3b</td>
<td>State</td>
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<td>Role&gt;Party&gt;Contacts Details &gt; State</td>
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<tr>
<td>E2356-3c</td>
<td>County</td>
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</tr>
<tr>
<td>E2356-4</td>
<td>Admin Office Country</td>
<td>rdm:/contact-details/rdm:admin-office/rdm:country</td>
<td>Role&gt;Party&gt;Contacts Details &gt; Country CTL</td>
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</tr>
<tr>
<td>E2356-4a</td>
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<td>Role&gt;Party&gt;Contacts Details &gt; Electronic Contact</td>
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<td>rdm:/contact-details/rdm:admin-office/rdm:loc-modifiedDate</td>
<td>Role&gt;Party&gt;Contacts Details &gt; Electronic Contact</td>
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</tr>
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<td>E2356-4d</td>
<td>Org-modifiedDate</td>
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<td>Role&gt;Party&gt;Contacts Details &gt; Electronic Contact</td>
<td>B2356-12</td>
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<tr>
<td>E2356-4e</td>
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<td>rdm:/contact-details/rdm:admin-office/rdm:language</td>
<td>Role&gt;Party&gt;Contacts Details &gt; Electronic Contact</td>
<td>B2356-12</td>
</tr>
<tr>
<td>E2356-5</td>
<td>Admin Office Telephone</td>
<td>rdm:/contact-details/rdm:admin-office/rdm:phone</td>
<td>Role&gt;Party&gt;Contacts Details &gt; Electronic Contact</td>
<td>B2356-12</td>
</tr>
<tr>
<td>E2356-7</td>
<td>Admin Office E-mail</td>
<td>rdm:/contact-details/rdm:admin-office/rdm:email</td>
<td>Role&gt;Party&gt;Contacts Details &gt; Electronic Contact</td>
<td>B2356-12</td>
</tr>
<tr>
<td>E2356-7a</td>
<td>Company Name</td>
<td>rdm:/contact-details/rdm:manu-facility/rdm:company-name</td>
<td>Role &gt; Party &gt; Organisation &gt; Name</td>
<td>B2356-12</td>
</tr>
<tr>
<td>E2356-8</td>
<td>Manufacturing Facility Address 1</td>
<td>rdm:/contact-details/rdm:manu-facility/rdm:company-name</td>
<td>Role&gt;Party&gt;Contacts Details &gt; Address</td>
<td>B2356-12</td>
</tr>
<tr>
<td>E2356-8</td>
<td>Manufacturing Facility Address 1</td>
<td>rdm:/contact-details/rdm:manu-facility/rdm:address1</td>
<td>Role&gt;Party&gt;Contacts Details &gt; Address</td>
<td>B2356-12</td>
</tr>
<tr>
<td>E2356-8</td>
<td>Manufacturing Facility Address 1</td>
<td>rdm:/contact-details/rdm:manu-facility/rdm:address2</td>
<td>Role&gt;Party&gt;Contacts Details &gt; Address</td>
<td>B2356-12</td>
</tr>
<tr>
<td>E2356-8</td>
<td>Manufacturing Facility Address 1</td>
<td>rdm:/contact-details/rdm:manu-facility/rdm:address3</td>
<td>Role&gt;Party&gt;Contacts Details &gt; Address</td>
<td>B2356-12</td>
</tr>
<tr>
<td>E2356-8</td>
<td>Manufacturing Facility Address 1</td>
<td>rdm:/contact-details/rdm:manu-facility/rdm:address4</td>
<td>Role&gt;Party&gt;Contacts Details &gt; Address</td>
<td>B2356-12</td>
</tr>
<tr>
<td>E2356-8a</td>
<td>City</td>
<td>rdm:/contact-details/rdm:manu-facility/rdm:city</td>
<td>Role&gt;Party&gt;Contacts Details &gt; City</td>
<td>B2356-12</td>
</tr>
<tr>
<td>E2356-8b</td>
<td>Post code</td>
<td>rdm:/contact-details/rdm:manu-facility/rdm:postcode</td>
<td>Role&gt;Party&gt;Contacts Details &gt; City</td>
<td>B2356-12</td>
</tr>
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**E2356-8c** state  
rdm:/contact-details/rdm:manu-facility/rdm: state

**E2356-8d** County  
rdm:/contact-details/rdm:manu-facility/rdm: county

**E2356-9** Manufacturing Facility Country  
rdm:/contact-details/rdm:manu-facility/rdm:country 
Role>Party>Address > Country CTL  
B2356-12

**E2356-9a** orgID  
rdm:/contact-details/rdm:manu-facility/rdm: orgID

**E2356-9b** locID  
rdm:/contact-details/rdm:manu-facility/rdm: locID

**E2356-9c** Loc-modifiedDate  
rdm:/contact-details/rdm:manu-facility/rdm: loc-modifiedDate  
B2356-12

**E2356-9d** Org-modifiedDate  
rdm:/contact-details/rdm:manu-facility/rdm: org-modifiedDate  
B2356-12

**E2356-9e** language  
rdm:/contact-details/rdm:manu-facility /rdm:language

**E2356-10** Manufacturing Facility Telephone  
rdm:/contact-details/rdm:manu-facility/rdm:phone 
Role>Party>Contact Details > Electronic Contact > electronic contact  
B2356-12

**E2356-12** Manufacturing Facility E-mail  
rdm:/contact-details/rdm:manu-facility/rdm:email 
Role>Party>Contact Details > Electronic Contact > electronic contact  
B2356-12

**E2356-13** Brief description of manufacturing steps performed by manufacturing site:  

rdm:function-description  
Manufacturing steps

**E2356-13a** Manufacturer steps  
rdm:manu-steps/rdm: manu-step

**E2356-14** Attach flow-chart indicating the sequence and activities of the different sites involved in the manufacturing process, including batch control sites (Annex 5.8)  
rdm:flow_chart

**E2356-15** For each active substance, attach a Qualified Person declaration that the active substance is manufactured in compliance with the principles and Guidelines on good manufacturing practice for starting materials (Annex 5.22)  
rdm:qualified-person-declaration

**E2356-16** Has the site been inspected for GMP compliance by an EEA authority or by an authority of countries where MRA or other European Union arrangements apply within the terms of agreement?  
Yes  
rdm:inspected_gmp_compliance (Value=1)  
inspected by eea authority  
B2356-1, B2356-2

No  
rdm:inspected_gmp_compliance (Value=0)  
inspected by eea authority  
B2356-1

**E2356-19**  
E2356-20

**E2356-21** Attach latest GMP certificate in Annex 5.9  
rdm:gmp_cert  
B2356-2, B2356-3

**E2356-22** EudraGMPD document reference number  
rdm:gmpc/rdm:gmpc-number  
Eudragmp certificate ref no  
B2356-2

**E2356-23** Has the site been inspected for GMP compliance by any other authority (including those of countries where MRA or other Community arrangements apply but not within their respective territory)?  
Yes  
rdm:gmp-compliance-other (Value=1)  
inspected by other authority  
B2356-4, B2356-5

No  
rdm:gmp-compliance-other (Value=0)  
inspected by other authority  
B2356-4

**E2356-26** If yes, please provide summary information in Annex 5.9 (and, if available a GMP certificate or a statement from the competent authority  
r.dm:summary-information  
B2356-5
<table>
<thead>
<tr>
<th>E2356-27</th>
<th>Has a Ph.Eur. Certificate of suitability been issued for the active substance(s):</th>
</tr>
</thead>
<tbody>
<tr>
<td>E2356-28</td>
<td>Yes</td>
</tr>
<tr>
<td>E2356-29</td>
<td>Ph Eur Certificate &gt; has certificate issued</td>
</tr>
<tr>
<td>E2356-30</td>
<td>No</td>
</tr>
<tr>
<td>E2356-31</td>
<td>Provide copy in Annex 5.10</td>
</tr>
<tr>
<td>E2356-32</td>
<td>Name of the CEP holder</td>
</tr>
<tr>
<td>E2356-33</td>
<td>Name of the manufacturer</td>
</tr>
<tr>
<td>E2356-34</td>
<td>CEP number</td>
</tr>
<tr>
<td>E2356-35</td>
<td>Date of last update</td>
</tr>
<tr>
<td>E2356-36</td>
<td>Is an Active Substance Master File (European Drug Master File) to be used for the active substance(s) reference/original?</td>
</tr>
<tr>
<td>E2356-37</td>
<td>Yes</td>
</tr>
<tr>
<td>E2356-38</td>
<td>European Drug Master File &gt; used for active substance</td>
</tr>
<tr>
<td>E2356-39</td>
<td>No</td>
</tr>
<tr>
<td>E2356-40</td>
<td>Name of the ASMF holder</td>
</tr>
<tr>
<td>E2356-41</td>
<td>Name of the manufacturer</td>
</tr>
<tr>
<td>E2356-42</td>
<td>Reference number for EMEA/competent authority</td>
</tr>
<tr>
<td>E2356-43</td>
<td>Applicant part version number</td>
</tr>
<tr>
<td>E2356-44</td>
<td>Date of submission</td>
</tr>
<tr>
<td>E2356-45</td>
<td>Date of last update</td>
</tr>
<tr>
<td>E2356-46</td>
<td>Attach letter of access for Community/Member State authorities where the application is made (see &quot;European ASMF procedure for active ingredients&quot;) (Annex 5.10)</td>
</tr>
<tr>
<td>E2356-47</td>
<td>Attach copy of written confirmation from the manufacturer of the active substance to inform the applicant in case of modification of the manufacturing process or specifications according to Annex 1 of Directive 2001/82/EC (Annex 5.11)</td>
</tr>
<tr>
<td>E2356-48</td>
<td>Is an EMEA certificate for a Vaccine Antigen Master File (VAMF) issued or submitted in accordance with Directive 2001/83/EC Annex I, Part III, being used for this MAA?</td>
</tr>
<tr>
<td>E2356-49</td>
<td>Yes</td>
</tr>
<tr>
<td>E2356-50</td>
<td>No</td>
</tr>
<tr>
<td>E2356-51</td>
<td>Active Substance</td>
</tr>
<tr>
<td>E2356-52</td>
<td>Name of the VAMF Certificate Holder/VAMF Applicant</td>
</tr>
<tr>
<td>E2356-53</td>
<td>Reference number of Application/ Certificate</td>
</tr>
<tr>
<td>E2356-54</td>
<td>Date of submission (if pending)</td>
</tr>
<tr>
<td>E2356-55</td>
<td>Date of approval or last update (if approved)</td>
</tr>
<tr>
<td>E2356-56</td>
<td>Provide copy in (Annex 5.20)</td>
</tr>
</tbody>
</table>

**Legend:**
- rdm:ph-eur-cert-suitability
- rdm:active-substance-master-file
- rdm:asmf
- rdm:written-confirmation
- rdm:access-community-member-state
- rdm:attach

**Notes:**
- E2356-28: Ph Eur Certificate > has certificate issued (Value=1)
- E2356-29: Ph Eur Certificate > has certificate issued (Value=0)
- E2356-31: rdm:provide-copy

**Dates:**
- Date of approval or last update (if approved)
- Date of submission
- Date of last update
- Date of last update date
- Date of approval or last update date

**Numbers:**
- Reference number of Application/ Certificate
- Reference number
- Reference number of Application
- Reference number
- Reference number

**Additional Information:**
- Date of approval or last update (if approved)
- Date of submission
- Date of last update
- Date of approval or last update
- Date of submission (if pending)
- Date of approval or last update (if approved)
- Date of submission (if pending)
- Date of approval or last update
- Date of submission
- Date of approval or last update
- Date of submission (if pending)
- Date of approval or last update (if approved)
- Date of submission (if pending)
- Date of approval or last update (if approved)
- Date of submission (if pending)
- Date of approval or last update (if approved)
- Date of submission (if pending)
- Date of approval or last update (if approved)
- Date of submission (if pending)
- Date of approval or last update (if approved)
## Business Rules

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<thead>
<tr>
<th>Rule ID</th>
<th>Element id(s)</th>
<th>Default BR</th>
<th>Rule</th>
<th>Effect(s)</th>
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<td>E2356-17, E2356-18</td>
<td>Mandatory.</td>
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<td></td>
</tr>
<tr>
<td>B2356-2</td>
<td>E2356-17, E2356-20 to E2356-22</td>
<td>E2356-20 to E2356-22 are optional, E2356-17 is mandatory.</td>
<td>IF E2356-17 is selected, then E2356-20 to E2356-22 are required.</td>
<td></td>
</tr>
<tr>
<td>B2356-3</td>
<td>E2356-20, E2356-21</td>
<td>Optional.</td>
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</tr>
<tr>
<td>B2356-5</td>
<td>E2356-24, E2356-26</td>
<td>Mandatory.</td>
<td></td>
<td>IF E2356-24 is selected, then E2356-26 is required.</td>
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<tr>
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<td>E2356-28, E2356-32 to E2356-35</td>
<td>E2356-28 is Mandatory, Rest are optional.</td>
<td>IF E2356-28 is selected, the rest are required.</td>
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<tr>
<td>B2356-9</td>
<td>E2356-38, E2356-40 to E2356-46</td>
<td>E2356-38 is Mandatory, Rest are optional.</td>
<td>IF E2356-38 is selected, the rest are required.</td>
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<tr>
<td>B2356-11</td>
<td>E2356-48, E2356-50 to E2356-56</td>
<td>E2356-48 is Mandatory, Rest are optional.</td>
<td>IF E2356-48 is selected, the rest are required.</td>
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<tr>
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<td>E2356-2 to E2356-12</td>
<td>mandatory and visible</td>
<td>E2356-2 is yes then E2356-3 to E2356-12 are visible else E2356-8 to E2356-12 are hidden</td>
<td></td>
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</tbody>
</table>
### 2.3.5.5 Contract companies used for clinical trial(s) on bioavailability or bioequivalence or used for the validation of blood product manufacturing processes.

For each contract company, state where analytical tests are performed and where clinical data are collected and give:

<table>
<thead>
<tr>
<th>Elem Id</th>
<th>Label</th>
<th>DES 3.0 Mapping</th>
<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
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<td>Role &gt; Party &gt; Organisation &gt; Name</td>
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<td>Role &gt; Party &gt; Contact Details &gt; Address</td>
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<td>City</td>
<td>rdm:contract-company/rdm:city</td>
<td>Role &gt; Party &gt; Contact Details &gt; Address &gt; City</td>
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</tr>
<tr>
<td>E2357-3a</td>
<td>state</td>
<td>rdm:contract-company/rdm:state</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E2357-3b</td>
<td>county</td>
<td>rdm:contract-company/rdm:county</td>
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<tr>
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<td>PostCode</td>
<td>rdm:contract-company/rdm:post-code</td>
<td>Role &gt; Party &gt; Contact Details &gt; Address &gt; post code</td>
<td></td>
</tr>
<tr>
<td>E2357-5</td>
<td>Country</td>
<td>rdm:contract-company/rdm:country</td>
<td>Role &gt; Party &gt; Contact Details &gt; Address &gt; Country CTL</td>
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</tr>
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<td>Telephone</td>
<td>rdm:contract-company/rdm:phone</td>
<td>Role &gt; Party &gt; Contact Details &gt; Electronic Contact &gt; electronic contact</td>
<td></td>
</tr>
<tr>
<td>E2357-7</td>
<td>E-mail</td>
<td>rdm:contract-company/rdm:email</td>
<td>Role &gt; Party &gt; Contact Details &gt; Electronic Contact &gt; electronic contact</td>
<td></td>
</tr>
<tr>
<td>E2357-8</td>
<td>Duty performed according to contract</td>
<td>rdm:contract-company/rdm:contract-duty-performed</td>
<td>Duty performed</td>
<td></td>
</tr>
</tbody>
</table>
### 2.3.6 QUALITATIVE AND QUANTITATIVE COMPOSITION

<table>
<thead>
<tr>
<th>Elem Id</th>
<th>Label</th>
<th>DES 3.0 Mapping</th>
<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>E236-1</td>
<td>Qualitative and Quantitative composition in terms of the active substance(s) and the excipient(s)</td>
<td>maa:compositions/</td>
<td></td>
<td>See Section 2.3.6.1</td>
</tr>
<tr>
<td>E236-2</td>
<td>List of materials of animal and/or human origin contained or used in the manufacturing process of the medicinal product?</td>
<td>maa:materials/</td>
<td></td>
<td>See Section 2.3.6.2</td>
</tr>
<tr>
<td>E236-3</td>
<td>Is an EMA certificate for a Plasma Master File (PMF) issued or submitted in accordance with Directive 2001/83/EC Annex I, Part III, being used for this MAA?</td>
<td>maa:pmfs/</td>
<td></td>
<td>See Section 2.3.6.3</td>
</tr>
<tr>
<td>E236-4</td>
<td>Does the medicinal product contain or consist of Genetically Modified Organisms (GMOs) within the meaning of Directive 2001/18/EC?</td>
<td>maa:gmo/</td>
<td></td>
<td>See Section 2.3.6.4</td>
</tr>
</tbody>
</table>

#### Element Tree Diagram

```
  eu_application_form
       |----------------|
       | initial-application-form-human
       |                   |
       |                     | chapter-2
       |                     |
       | compositions       | materials
       |                 2.3.6.1  | 2.3.6.2
       |                         |
       | pmfs
       | 2.3.6.3
       |
       | gmo
       | 2.3.6.4
```
### 2.3.6.1 Qualitative and Quantitative composition in terms of the active substance(s) and the excipient(s)

<table>
<thead>
<tr>
<th>Common DES 3.0 Context</th>
<th>Common RDM Entry point</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Elem Id</th>
<th>Label</th>
<th>DES 3.0 Mapping</th>
<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>E2361-1</td>
<td>A note should be given as to which quantity the composition refers (e.g. 1 capsule)</td>
<td><code>rdm:pharmaceutical-form-names/rdm:composition-quantity</code></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E2361-2</td>
<td>composition-unit</td>
<td><code>rdm:pharmaceutical-form-names/rdm:Low-strength-numerator-unit</code></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E2361-3</td>
<td>Pharmaceutical Form</td>
<td><code>rdm:pharmaceutical-form-names/rdm:pharmaceutical-form-name/</code></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E2361-4a</td>
<td>Units</td>
<td><code>rdm:pharmaceutical-form-details/rdm:pharmaceutical-form-strengths/rdm:units</code></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E2361-12</td>
<td>Overage</td>
<td><code>rdm:active-substance-overages/rdm:overage</code></td>
<td></td>
<td>Ingredient &gt; Overage</td>
</tr>
</tbody>
</table>
**Element Tree Diagram**

```
+ eu_application_form
  + initial-application-form-human
  + chapter-2
    + compositions

  + medicinal-product
    + pharmaceutical-products
      + pharmaceutical-product

  + pharmaceutical-form-names
    + composition-quantity
      + Text

  + Low-strength-numerator-unit
    + pharmaceutical-form-name
      + Text

  + pharmaceutical-form-details

  + active-substances
    + active-substances-details

  + excipients
    + excipient-details
    + pharmaceutical-form-strengths
      + units
        + Text

  + active-substance
    + substance-name
      + Text
    + ingredient-strength
      + Text
    + reference-monograph-standard
      + Text
    + moiety-ingredient-strength
      + Text
    + reference-monograph-standard-base
      + Text

  + excipient-description
    + Text

  + excipient
    + substance-name
      + Text
    + ingredient-strength
      + Text
    + reference-monograph-standard
      + Text
    + moiety-ingredient-strength
      + Text
    + reference-monograph-standard-base
      + Text

  + ingredient-strength
    + Text

  + quantity-operator
    + Text

+ rdm:excipient-overages
  + rdm:excipient-code

+ Ingredient > Substance

+ Ingredient > Overage
```
2.3.6.2 List of materials of animal and/or human origin contained or used in the manufacturing process of the medicinal product?

<table>
<thead>
<tr>
<th>Common DES 3.0 Context</th>
<th>Common RDM Entry point</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Elem Id</th>
<th>Label</th>
<th>DES 3.0 Mapping</th>
<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>E2362-1</td>
<td>NONE</td>
<td>maa:none</td>
<td>is material used</td>
<td>B2362-1</td>
</tr>
<tr>
<td>E2362-2</td>
<td>Material name</td>
<td>maa:material/maa:substance/rdm:substance-name</td>
<td>material name</td>
<td>B2362-1</td>
</tr>
<tr>
<td>E2362-3</td>
<td>Function*</td>
<td>maa:material/function (Value=1)</td>
<td>Material Function CTL</td>
<td>B2362-1, B2362-2</td>
</tr>
<tr>
<td>E2362-4</td>
<td>AS</td>
<td>maa:material/function (Value=2)</td>
<td>Material Function CTL</td>
<td>B2362-1, B2362-2</td>
</tr>
<tr>
<td>E2362-5</td>
<td>EX</td>
<td>maa:material/function (Value=3)</td>
<td>Material Function CTL</td>
<td>B2362-1, B2362-2</td>
</tr>
<tr>
<td>E2362-6</td>
<td>R</td>
<td>maa:material/animal-origin-tse</td>
<td>Material Origin CTL</td>
<td>B2362-1, B2362-3</td>
</tr>
<tr>
<td>E2362-7</td>
<td>Animal Origin susceptible to TSE**</td>
<td>maa:material/animal-origin-tse</td>
<td>Material Origin CTL</td>
<td>B2362-1, B2362-3</td>
</tr>
<tr>
<td>E2362-8</td>
<td>Other Animal Origin</td>
<td>maa:material/other-animal-origin</td>
<td>Material Origin CTL</td>
<td>B2362-1, B2362-3</td>
</tr>
<tr>
<td>E2362-9</td>
<td>Human Origin</td>
<td>maa:material/human-origin</td>
<td>Material Origin CTL</td>
<td>B2362-1, B2362-3</td>
</tr>
<tr>
<td>E2362-10</td>
<td>Certificate of suitability for TSE</td>
<td>maa:material/certificate-suitable-tse</td>
<td></td>
<td>B2362-1, B2362-4</td>
</tr>
<tr>
<td>E2362-11</td>
<td>TSE number</td>
<td>maa:material/tse-numbers/tse-number</td>
<td>certificate number</td>
<td>B2362-1, B2362-4</td>
</tr>
<tr>
<td>E2362-12</td>
<td>If a Ph. Eur. Certificate of suitability for TSE is available according to the Resolution AP/CSP(99)4 of the Council of Europe attach it in Annex 5.12</td>
<td>maa:annex5-13</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Element Tree Diagram

```
   eu_application_form
   |________________________|
   | initial-application-form-human |
   |________________________|
   | chapter-2 |
   |___________|
   | materials |
   |___________|
   | + |
   |___________|
   | material |
   |___________|
   | /text |
   |___________|
   | annex5-13 |
   |___________|
   | none |
   |___________|
   + |
   |___________|
   | substance |
   |___________|
   | /text |
   |___________|
   + |
   |___________|
   | tse-numbers |
   |___________|
   | /text |
   |___________|
   + |
   |___________|
   | certificate-suitable-tse |
   |___________|
   | /text |
   |___________|
   + |
   |___________|
   | function |
   |___________|
   | /text |
   |___________|
   + |
   |___________|
   | animal-origin-tse |
   |___________|
   | /text |
   |___________|
   + |
   |___________|
   | other-animal-origin |
   |___________|
   | /text |
   |___________|
   + |
   |___________|
   | human-origin |
   |___________|
   | /text |
```

Business Rules

<table>
<thead>
<tr>
<th>Rule ID</th>
<th>Element id(s)</th>
<th>Default BR</th>
<th>Rule</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>B2362-1</td>
<td>E2362-1, E2362-2 to E2362-11</td>
<td>Mandatory.</td>
<td>If E2362-1 is selected then the rest are optional.</td>
<td></td>
</tr>
<tr>
<td>B2362-2</td>
<td>E2362-4 to E2362-6</td>
<td>Optional.</td>
<td>Mutually Exclusive.</td>
<td></td>
</tr>
<tr>
<td>B2362-3</td>
<td>E2362-7 to E2362-9</td>
<td>Optional.</td>
<td>Mutually Exclusive.</td>
<td></td>
</tr>
<tr>
<td>B2362-4</td>
<td>E2362-10, E2362-11</td>
<td>Optional.</td>
<td>If E2362-10 is selected, E2362-11 is required.</td>
<td></td>
</tr>
</tbody>
</table>
2.3.6.3  Is an EMA certificate for a Plasma Master File (PMF) issued or submitted in accordance with Directive 2001/83/EC Annex I, Part III, being used for this MAA?

<table>
<thead>
<tr>
<th>Common DES 3.0 Context</th>
<th>Common RDM Entry point</th>
</tr>
</thead>
</table>

### Element Id | Label | DES 3.0 Mapping | RDM 3.0 Mapping | Remarks |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>E2363-1</td>
<td>Yes</td>
<td>maa:is-certificate-issued (Value=1)</td>
<td>App PMF Certificate &gt; is certificate issued</td>
<td>B2363-1, B2363-2</td>
</tr>
<tr>
<td>E2363-2</td>
<td>No</td>
<td>maa:is-certificate-issued (Value=0)</td>
<td>App PMF Certificate &gt; is certificate issued</td>
<td>B2363-1</td>
</tr>
<tr>
<td>E2363-3</td>
<td>Provide copy in Annex 5.21</td>
<td>maa:annex5-21</td>
<td></td>
<td>B2363-2</td>
</tr>
<tr>
<td>E2363-4</td>
<td>If yes, Enter Substance(s) referring to PMF:</td>
<td></td>
<td></td>
<td>B2363-2</td>
</tr>
<tr>
<td>E2363-6</td>
<td>Function*</td>
<td></td>
<td></td>
<td>B2363-2</td>
</tr>
<tr>
<td>E2363-12</td>
<td>Date of submission (if pending)</td>
<td>maa:pmf/maa:substance-certificate/rdm:date-submission</td>
<td>App PMF certificate &gt; submission date</td>
<td>B2363-2</td>
</tr>
<tr>
<td>E2363-13</td>
<td>Date of approval or last update (if approved)</td>
<td>maa:pmf/maa:substance-certificate/rdm:date-last-update</td>
<td>App PMF certificate &gt; approval or last update date</td>
<td>B2363-2</td>
</tr>
</tbody>
</table>

### Element Tree Diagram

![Element Tree Diagram](image)

### Business Rules

<table>
<thead>
<tr>
<th>Rule ID</th>
<th>Element Id(s)</th>
<th>Default BR</th>
<th>Rule</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>B2363-1</td>
<td>E2363-1, E2363-2</td>
<td>Mandatory</td>
<td>Mutually Exclusive.</td>
<td></td>
</tr>
<tr>
<td>B2363-2</td>
<td>E2363-1, E2363-3 to E2363-13</td>
<td>E2363-1 is Mandatory, rest are optional.</td>
<td>If E2363-1 is selected, then the rest are required.</td>
<td></td>
</tr>
<tr>
<td>B2363-3</td>
<td>E2363-7 to E2363-9</td>
<td>Optional</td>
<td>Mutually Exclusive.</td>
<td></td>
</tr>
</tbody>
</table>
2.3.6.4  **Does the medicinal product contain or consist of Genetically Modified Organisms (GMOs) within the meaning of Directive 2001/18/EC?**

<table>
<thead>
<tr>
<th>Common DES 3.0 Context</th>
<th>Common RDM Entry point</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Elem Id</th>
<th>Label</th>
<th>DES 3.0 Mapping</th>
<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>E2364-1</td>
<td>Yes</td>
<td>maa:is-gmo (Value=1)</td>
<td>App GMO &gt; mp consist of gmo</td>
<td>B2364-1</td>
</tr>
<tr>
<td>E2364-2</td>
<td>No</td>
<td>maa:is-gmo (Value=0)</td>
<td>App GMO &gt; mp consist of gmo</td>
<td>B2364-1</td>
</tr>
<tr>
<td>E2364-3</td>
<td>If yes, does the product comply with Directive 2001/18/EC?</td>
<td>maa:directive</td>
<td>App GMO &gt; comply with directive</td>
<td></td>
</tr>
<tr>
<td>E2364-4</td>
<td>Yes</td>
<td>maa:directive</td>
<td>App GMO &gt; comply with directive</td>
<td></td>
</tr>
<tr>
<td>E2364-5</td>
<td>No</td>
<td>maa:directive</td>
<td>App GMO &gt; comply with directive</td>
<td></td>
</tr>
<tr>
<td>E2364-6</td>
<td>Attach a copy of any written consent(s) of the competent authorities to the deliberate release into the environment of the GMOs for research and development purposes where provided for by Part B of the above-mentioned Directive (Annex 5.13)</td>
<td>maa:annex5-13</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Element Tree Diagram**

```
  eu_application_form
    | initial-application-form-human
    |   chapter-2
    |     gmo
    |       is-gmo
    |       :yes-no
    |       directive
    |       :yes-no
    |       annex5-13
    |       :yes-no
```

**Business Rules**

<table>
<thead>
<tr>
<th>Rule ID</th>
<th>Element id(s)</th>
<th>Default BR</th>
<th>Rule</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>B2364-1</td>
<td>E2364-1, E2364-2</td>
<td>Mandatory.</td>
<td>Mutually Exclusive.</td>
<td></td>
</tr>
<tr>
<td>B2364-2</td>
<td>E2364-1, E2364-3 to E2364-6</td>
<td>E2364-1 is Mandatory, rest are optional.</td>
<td>If E2364-1 is selected, then the rest are required.</td>
<td></td>
</tr>
<tr>
<td>B2364-3</td>
<td>E2364-4, E2364-5</td>
<td>Optional.</td>
<td>Mutually Exclusive.</td>
<td></td>
</tr>
</tbody>
</table>
### 2.4. SCIENTIFIC ADVICE

**Common DES 3.0 Context**  
maa:eu_application_form/maa:initial-application-form-human/maa:scientific-advice/

**Common RDM Entry point**  
Application > App Scientific Advice >

<table>
<thead>
<tr>
<th>Elem Id</th>
<th>Label</th>
<th>DES 3.0 Mapping</th>
<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>E24-1</td>
<td>Was there formal scientific advice(s) given by the CHMP for this medicinal product?</td>
<td>rdm:scientific-advice-chmp/rdm:advice-given</td>
<td>was scientific advice given</td>
<td>B24-1, B24-2</td>
</tr>
<tr>
<td>E24-2</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E24-3</td>
<td>No</td>
<td>rdm:scientific-advice-chmp/rdm:advice-given</td>
<td>was scientific advice given</td>
<td>B24-1</td>
</tr>
<tr>
<td>E24-4</td>
<td>Reference(s) of the scientific advice(s)</td>
<td>rdm:scientific-advice-chmp/rdm:advice-details/rdm:reference</td>
<td>scientific advice ref</td>
<td>B24-2</td>
</tr>
<tr>
<td>E24-5</td>
<td>Date</td>
<td>rdm:scientific-advice-chmp/rdm:advice-details/rdm:date</td>
<td>scientific advice date</td>
<td>B24-2</td>
</tr>
<tr>
<td>E24-6</td>
<td>Was there scientific advice(s) given by Member State(s) for this medicinal product?</td>
<td>rdm:scientific-advice-member-state/rdm:advice-given</td>
<td>scientific Advice Source CTL</td>
<td>B24-3,B24-4</td>
</tr>
<tr>
<td>E24-7</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E24-8</td>
<td>No</td>
<td>rdm:scientific-advice-member-state/rdm:advice-given</td>
<td>scientific Advice Source CTL</td>
<td>B24-3</td>
</tr>
<tr>
<td>E24-9</td>
<td>Member State</td>
<td>rdm:scientific-advice-member-state/rdm:advice-details/rdm:member-state</td>
<td>Country CTL</td>
<td>B24-4</td>
</tr>
<tr>
<td>E24-10</td>
<td>Date</td>
<td>rdm:scientific-advice-member-state/rdm:advice-details/rdm:date</td>
<td>scientific advice date</td>
<td>B24-4</td>
</tr>
<tr>
<td>E24-11</td>
<td>Reference(s) of the scientific advice(s)</td>
<td>rdm:scientific-advice-member-state/rdm:advice-details/rdm:reference</td>
<td>scientific advice ref</td>
<td>B24-4</td>
</tr>
<tr>
<td>E24-12</td>
<td>Attach copy of scientific advice(s) (Annex 5.14)</td>
<td>rdm:scientific-advice-member-state/rdm:attach-copy</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Element Tree Diagram**

```plaintext
eu_application_form → initial-application-form-human → scientific-advice

scientific-advice-chmp + scientific-advice-member-state

<table>
<thead>
<tr>
<th>advice-given</th>
<th>advice-details</th>
</tr>
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<tbody>
<tr>
<td>:yes-no</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>attach-copy</th>
<th>advice-given</th>
<th>advice-details</th>
</tr>
</thead>
<tbody>
<tr>
<td>:yes-no</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>reference</th>
<th>date</th>
</tr>
</thead>
<tbody>
<tr>
<td>/text</td>
<td>/Date</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>member-state</th>
<th>reference</th>
<th>date</th>
</tr>
</thead>
<tbody>
<tr>
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<td>/text</td>
<td>/Date</td>
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**Business Rules**

<table>
<thead>
<tr>
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<th>Element id(s)</th>
<th>Default BR</th>
<th>Rule</th>
<th>Effect(s)</th>
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</thead>
<tbody>
<tr>
<td>B24-1</td>
<td>E24-1, E24-2</td>
<td>Mandatory</td>
<td>Mutually Exclusive</td>
<td></td>
</tr>
<tr>
<td>B24-2</td>
<td>E24-1, E24-4, E24-5</td>
<td>Mandatory</td>
<td>If E24-1 is selected, then the others are required</td>
<td></td>
</tr>
<tr>
<td>B24-3</td>
<td>E24-7, E24-8</td>
<td>Mandatory</td>
<td>Mutually Exclusive</td>
<td></td>
</tr>
<tr>
<td>B24-4</td>
<td>E24-7, E24-9 to E24-11</td>
<td>E24-7 is Mandatory, rest are optional</td>
<td>If E24-7 is selected, then the other fields are required.</td>
<td></td>
</tr>
</tbody>
</table>
### 2.5. OTHER MARKETING AUTHORISATION APPLICATIONS

<table>
<thead>
<tr>
<th>Elem Id</th>
<th>Label</th>
<th>DES 3.0 Mapping</th>
<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
</tr>
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<tbody>
<tr>
<td>E25-1</td>
<td>FOR NATIONAL/MRP/DCP APPLICATIONS, PLEASE COMPLETE THE FOLLOWING IN ACCORDANCE WITH ARTICLE 8(l)-(i) OF DIRECTIVE 2001/83/EC</td>
<td>maa:section4-1-1 and maa:section4-1-2 and maa:section4-1-3</td>
<td>See Section 2.5.1</td>
<td></td>
</tr>
<tr>
<td>E25-2</td>
<td>Marketing authorisation applications for the same product in the EEA (same qualitative and quantitative composition in active substance(s) and having the same pharmaceutical form)</td>
<td>maa:section4-2</td>
<td>See Section 2.5.2</td>
<td></td>
</tr>
<tr>
<td>E25-3</td>
<td>For multiple/duplicate applications of the same medicinal product</td>
<td>maa:section4-3</td>
<td>See Section 2.5.3</td>
<td></td>
</tr>
<tr>
<td>E25-4</td>
<td>Marketing authorisation applications for the same product outside the EEA (i.e. from applicants belonging to the same mother company or group of companies OR which are &quot;licensees&quot;). Same qualitative and quantitative composition in active substance(s) and having the same pharmaceutical form)</td>
<td>maa:section4-4</td>
<td>See Section 2.5.4</td>
<td></td>
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</table>

#### Element Tree Diagram

```
  eu_application_form
     | initial-application-form-human
     | section-4
         | section4-1-1
         | section4-1-2
         | section4-1-3
         | ?
         | section4-2
         | section4-3
         | Section4-4

  2.5.1 •••
  2.5.2 •••
  2.5.3 •••
  2.5.4 •••
```
### 2.5.1 FOR NATIONAL/MRP/DCP APPLICATIONS, PLEASE COMPLETE THE FOLLOWING IN ACCORDANCE WITH ARTICLE 8(j)- (l) OF DIRECTIVE 2001/83/EC

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<td>maa:eu_application_form/maa:initial-application-form-human/maa:section-4/</td>
<td>Application &gt; Other MA Application</td>
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</tbody>
</table>

<table>
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<th>Elem Id</th>
<th>Label</th>
<th>DES 3.0 Mapping</th>
<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>E251-1</td>
<td>Is there another Member State(s) where an application for the same* product is pending**?</td>
<td>maa:section4-1-1 (Value=1)</td>
<td>app pending in other ms</td>
<td>B251-1, B252-1</td>
</tr>
<tr>
<td>E251-2</td>
<td>Yes</td>
<td>maa:section4-1-1 (Value=0)</td>
<td>app pending in other ms</td>
<td>B251-1</td>
</tr>
<tr>
<td>E251-3</td>
<td>No</td>
<td>maa:section4-1-1 (Value=1)</td>
<td>app pending in other ms</td>
<td>B251-1</td>
</tr>
<tr>
<td>E251-3a</td>
<td>Not applicable</td>
<td>maa:section4-1-1 NA (Value=0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E251-4</td>
<td>Is there another Member state(s) where an authorisation is granted for the same* product?</td>
<td>maa:section4-1-2/maa:yes-member (Value=1)</td>
<td>is auth granted in other ms</td>
<td>B251-2, B251-3, B252-1</td>
</tr>
<tr>
<td>E251-5</td>
<td>Yes</td>
<td>maa:section4-1-2/maa:yes-member (Value=0)</td>
<td>is auth granted in other ms</td>
<td>B251-2</td>
</tr>
<tr>
<td>E251-6</td>
<td>No</td>
<td>maa:section4-1-2/maa:yes-member (Value=1)</td>
<td>is auth granted in other ms</td>
<td>B251-2</td>
</tr>
<tr>
<td>E251-7</td>
<td>Are there any differences which have therapeutic implications between this application and the applications/authorisations for the same product in other Member States (for national applications, Article 17 or 18 of Directive 2001/83/EC shall apply).</td>
<td>maa:section4-1-2/maa:member-state (Value=0)</td>
<td>are there differences</td>
<td>B251-3, B251-4, B251-5</td>
</tr>
<tr>
<td>E251-8</td>
<td>Yes</td>
<td>maa:section4-1-2/maa:member-state (Value=0)</td>
<td>are there differences</td>
<td>B251-3, B251-4</td>
</tr>
<tr>
<td>E251-9</td>
<td>No</td>
<td>maa:section4-1-2/maa:member-state (Value=0)</td>
<td>are there differences</td>
<td>B251-3, B251-4</td>
</tr>
<tr>
<td>E251-10</td>
<td>Please elaborate</td>
<td>maa:section4-1-2/maa:elaborate</td>
<td>differences description</td>
<td>B251-3, B251-5</td>
</tr>
<tr>
<td>E251-11</td>
<td>Is there another Member State(s) where an authorisation was refused/suspended/revoked by competent authorities for the same* product?</td>
<td>maa:section4-1-3/maa:yes-member (Value=1)</td>
<td>was auth refused</td>
<td>B251-6, B252-1</td>
</tr>
<tr>
<td>E251-12</td>
<td>Yes</td>
<td>maa:section4-1-3/maa:yes-member (Value=0)</td>
<td>was auth refused</td>
<td>B251-6</td>
</tr>
<tr>
<td>E251-13</td>
<td>No</td>
<td>maa:section4-1-3/maa:yes-member (Value=0)</td>
<td>was auth refused</td>
<td>B251-6</td>
</tr>
<tr>
<td>E251-14</td>
<td>Note: * &quot;same product&quot; means same qualitative and quantitative composition in active substance(s) and having the same pharmaceutical form from applicants belonging to the same mother company or group of companies OR which are &quot;licensees&quot;. ** This is covering applications submitted at an earlier time or in parallel to this application if not already listed under 1.1.2 or 1.1.3</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
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### Business Rules

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<th>Rule</th>
<th>Effect(s)</th>
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<td>Mandatory.</td>
<td>Mutually Exclusive.</td>
<td></td>
</tr>
<tr>
<td>B251-2</td>
<td>E251-5, E251-6</td>
<td>Mandatory.</td>
<td>Mutually Exclusive.</td>
<td></td>
</tr>
<tr>
<td>B251-3</td>
<td>E251-5, E251-7 to E251-10</td>
<td>E251-5 is mandatory, rest are optional.</td>
<td>If E251-5 is selected, then the other fields are required.</td>
<td></td>
</tr>
<tr>
<td>B251-4</td>
<td>E251-8, E251-9</td>
<td>Mandatory.</td>
<td>Mutually Exclusive.</td>
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<tr>
<td>B251-5</td>
<td>E251-8, E251-10</td>
<td>Optional.</td>
<td>If E251-8 is selected, then E251-10 is required.</td>
<td></td>
</tr>
<tr>
<td>B251-6</td>
<td>E251-12, E251-13</td>
<td>Mandatory.</td>
<td>Mutually Exclusive.</td>
<td></td>
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</table>
2.5.2 Marketing authorisation applications for the same product in the EEA (same qualitative and quantitative composition in active substance(s) and having the same pharmaceutical form from applicants belonging to the same mother company or group of companies OR which are "licensees").

<table>
<thead>
<tr>
<th>Common DES 3.0 Context</th>
<th>Common RDM Entry point</th>
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</table>

<table>
<thead>
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<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
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<tr>
<td>E252-1</td>
<td>Authorised</td>
<td>maa:authorised/rdm:selected</td>
<td>Authorisation Status CTL</td>
<td>B252-2</td>
</tr>
<tr>
<td>E252-3</td>
<td>Date of authorisation</td>
<td>maa:authorised/rdm:mark-auth-detail/rdm:date-of-auth</td>
<td>MP Authorisation &gt; authorisation date</td>
<td>B252-2</td>
</tr>
<tr>
<td>E252-5</td>
<td>marketing authorisation number</td>
<td>maa:authorised/rdm:mark-auth-detail/rdm:auth-number</td>
<td>MP Authorisation &gt; authorisation number</td>
<td>B252-2</td>
</tr>
<tr>
<td>E252-6</td>
<td>Procedure number of MRP/DCP</td>
<td>maa:authorised/rdm:mark-auth-detail/ procedure-number</td>
<td>MP Authorisation &gt; MP Procedure &gt; procedure number</td>
<td>B252-2</td>
</tr>
<tr>
<td>E252-8</td>
<td>Submitted</td>
<td>maa:pending/rdm:selected</td>
<td>Authorisation Status CTL</td>
<td>B252-3</td>
</tr>
<tr>
<td>E252-10</td>
<td>Date of submission</td>
<td>maa:pending/rdm:mark-auth-detail/rdm:date-submission</td>
<td>Application &gt; submission date</td>
<td>B252-3</td>
</tr>
<tr>
<td>E252-11</td>
<td>Procedure number of MRP/DCP</td>
<td>maa:pending/rdm:mark-auth-detail/ procedure-number</td>
<td>MP Authorisation &gt; MP Procedure &gt; procedure number</td>
<td>B252-3</td>
</tr>
<tr>
<td>E252-12</td>
<td>Refused</td>
<td>maa:refused/selected</td>
<td>Authorisation Status CTL</td>
<td>B252-7</td>
</tr>
<tr>
<td>E252-14</td>
<td>Date of refusal</td>
<td>maa:refused/rdm:mark-auth-detail/rdm:date-refusal</td>
<td>MP Authorisation &gt; authorisation date</td>
<td>B252-7</td>
</tr>
<tr>
<td>E252-15</td>
<td>Procedure number of MRP/DCP</td>
<td>maa:refused/rdm:mark-auth-detail/ procedure-number</td>
<td>MP Authorisation &gt; MP Procedure &gt; procedure number</td>
<td>B252-7</td>
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<tr>
<td>E252-16</td>
<td>Reason for refusal</td>
<td>maa:refused/rdm:mark-auth-detail/ reason-refusal</td>
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<td>B252-7</td>
</tr>
<tr>
<td>E252-17</td>
<td>Withdrawn (by applicant before authorisation)</td>
<td>maa:withdrawn-before/rdm:selected</td>
<td>Authorisation Status CTL</td>
<td>B252-4</td>
</tr>
<tr>
<td>E252-19</td>
<td>Date of withdrawal</td>
<td>maa:withdrawn-before/rdm:mark-auth-detail/rdm:date-withdrawal</td>
<td>MP Authorisation &gt; authorisation date</td>
<td>B252-4</td>
</tr>
<tr>
<td>E252-20</td>
<td>Invented name</td>
<td>maa:withdrawn-before/rdm:mark-auth-detail/rdm:invented-name</td>
<td>Medicinal Product Group &gt; invented name</td>
<td>B252-4</td>
</tr>
<tr>
<td>E252-22</td>
<td>Procedure number of MRP/DCP</td>
<td>maa:withdrawn-before/rdm:mark-auth-detail/ procedure-number</td>
<td>MP Authorisation &gt; MP Procedure &gt; procedure number</td>
<td>B252-4</td>
</tr>
<tr>
<td>E252-23</td>
<td>Withdrawn (by applicant after authorisation)</td>
<td>maa:withdrawn-after/rdm:selected</td>
<td>Authorisation Status CTL</td>
<td>B252-5</td>
</tr>
<tr>
<td>E252-25</td>
<td>Date of withdrawal</td>
<td>maa:withdrawn-after/rdm:mark-auth-detail/rdm:date-withdrawal</td>
<td>MP Authorisation &gt; authorisation date</td>
<td>B252-5</td>
</tr>
<tr>
<td>E252-26</td>
<td>Authorisation number</td>
<td>maa:withdrawn-after/rdm:mark-auth-detail/rdm:auth-number</td>
<td>MP Authorisation &gt; authorisation number</td>
<td>B252-5</td>
</tr>
<tr>
<td>E252-30</td>
<td>Suspended/revoked (by competent authority)</td>
<td>maa:suspended/rdm:selected</td>
<td>Authorisation Status CTL</td>
<td>B252-6</td>
</tr>
</tbody>
</table>
**Element Tree Diagram**

```
Eu_application_form  ->  Initial-application-form-human  ->  Section-4

authorised  ->  submitted  ->  refused  ->  withdrawn-before  ->  withdrawn-after  ->  suspended

:yes-no  *:mark-auth-detail

auth-number  /text

country  /text  |  :CTL

date-of-auth  /text  |  :Date

invented-name  /text

procedure-number  /text

attach  /text  :yes-no
```

**Business Rules**

<table>
<thead>
<tr>
<th>Rule ID</th>
<th>Element id(s)</th>
<th>Default BR</th>
<th>Rule</th>
<th>Effect(s)</th>
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<tr>
<td>B252-1</td>
<td>E251-1, E251-5, E251-12</td>
<td>Mandatory.</td>
<td>If one of the fields are selected, section 2.5.2 is mandatory.</td>
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<td>B252-2</td>
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<td>E252-1 mandatory, rest are optional.</td>
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<tr>
<td>B252-3</td>
<td>E252-8 to E252-11</td>
<td>E252-8 mandatory, rest are optional.</td>
<td>If E252-8 is selected, then the rest are mandatory.</td>
<td></td>
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<tr>
<td>B252-4</td>
<td>E252-17 to E252-22</td>
<td>E252-17 mandatory, rest are optional.</td>
<td>If E252-17 is selected, then the rest are mandatory.</td>
<td></td>
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<tr>
<td>B252-5</td>
<td>E252-23 to E252-29</td>
<td>E252-23 mandatory, rest are optional.</td>
<td>If E252-23 is selected, then the rest are mandatory.</td>
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<tr>
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<td>E252-30 to E252-35</td>
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<td>E252-12 to E252-16</td>
<td>E252-12 mandatory, rest are optional.</td>
<td>If E252-12 is selected, then the rest are mandatory.</td>
<td></td>
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</tbody>
</table>
2.5.3 For multiple/duplicate applications of the same medicinal product:

<table>
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<th>Label</th>
<th>DES 3.0 Mapping</th>
<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
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<tbody>
<tr>
<td>E253-1</td>
<td>Multiple/duplicate applications (submitted simultaneously or subsequently to the original product) for:</td>
<td>maa:mult-duplicates/mma:application/mma:product-name</td>
<td>Medicinal Product &gt; medicinal product name</td>
<td></td>
</tr>
<tr>
<td>E253-2</td>
<td>Name of other product</td>
<td>maa:mult-duplicates/mma:application/mma:product-name</td>
<td>Medicinal Product &gt; medicinal product name</td>
<td></td>
</tr>
<tr>
<td>E253-3</td>
<td>Date of application(s)</td>
<td>maa:mult-duplicates/mma:application/mma:date-application</td>
<td>Application &gt; Submission date</td>
<td></td>
</tr>
<tr>
<td>E253-4</td>
<td>Applicant</td>
<td>maa:mult-duplicates/mma:application/mma:applicant</td>
<td>Role &gt; Party &gt; Organisation &gt; Name</td>
<td></td>
</tr>
<tr>
<td>E253-5</td>
<td>Procedure number for MRP/DCP (if applicable)</td>
<td>maa:mult-duplicates/mma:application/mma:procedure-number</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E253-6</td>
<td>Attach copy of correspondence with the European Commission, for centralised procedures only (Annex 5.16)</td>
<td>maa:mult-duplicates/mma:application/mma:attach-copy</td>
<td>maa:attach-copy</td>
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</tr>
</tbody>
</table>

Element Tree Diagram

```
  eu_application_form
         | initial-application-form-human
                  | section-4
                      | section4-3
                              | attach-copy :yes-no
                                      | mult-duplicates
                                              | application
                                                      | applicant :yes-no
                                                              | date-application :Date
                                                                  | product-name /text
                                                                      | attach-copy :yes-no
```
2.5.4 Marketing authorisation applications for the same product outside the EEA (i.e. from applicants belonging to the same mother company or group of companies OR which are "licensees". Same qualitative and quantitative composition in active substance(s) and having the same pharmaceutical form).

<table>
<thead>
<tr>
<th>Common DES 3.0 Context</th>
<th>Common RDM Entry point</th>
</tr>
</thead>
</table>

<table>
<thead>
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<th>Elem Id</th>
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<th>RDM 3.0 Mapping</th>
<th>Remarks</th>
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<td>maa:authorised/rdm:selected</td>
<td>Authorisation Status CTL</td>
<td>B254-1</td>
</tr>
<tr>
<td>E254-3</td>
<td>Date of authorisation</td>
<td>maa:authorised/rdm:mark-auth-detail/rdm:country</td>
<td>MP Authorisation &gt; authorisation date</td>
<td>B254-3</td>
</tr>
<tr>
<td>E254-4</td>
<td>Invented name</td>
<td>maa:authorised/rdm:mark-auth-detail/rdm:invented-name</td>
<td>Medicinal Product Group &gt; invented name</td>
<td>B254-4</td>
</tr>
<tr>
<td>E254-6</td>
<td>Pending</td>
<td>maa:pending/rdm:selected</td>
<td>Authorisation Status CTL</td>
<td>B254-5</td>
</tr>
<tr>
<td>E254-8</td>
<td>Date of submission</td>
<td>maa:pending/rdm:mark-auth-detail/rdm:date-submission</td>
<td>Application &gt; submission date</td>
<td>B254-7</td>
</tr>
<tr>
<td>E254-9</td>
<td>Refused</td>
<td>maa:refused/selected</td>
<td>Authorisation Status CTL</td>
<td>B254-8</td>
</tr>
<tr>
<td>E254-11</td>
<td>Date of refusal</td>
<td>maa:refused/rdm:mark-auth-detail/rdm:date-refusal</td>
<td>MP Authorisation &gt; authorisation date</td>
<td>B254-10</td>
</tr>
<tr>
<td>E254-13</td>
<td>Withdrawn (by applicant before authorisation)</td>
<td>maa:withdrawn-before/rdm:selected</td>
<td>Authorisation Status CTL</td>
<td>B254-12</td>
</tr>
<tr>
<td>E254-15</td>
<td>Date of withdrawal</td>
<td>maa:withdrawn-before/rdm:mark-auth-detail/rdm:date-withdrawal</td>
<td>MP Authorisation &gt; authorisation date</td>
<td>B254-14</td>
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<tr>
<td>E254-16</td>
<td>Invented name</td>
<td>maa:withdrawn-before/rdm:mark-auth-detail/rdm:invented-name</td>
<td>Medicinal Product Group &gt; invented name</td>
<td>B254-15</td>
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<tr>
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<td>maa:withdrawn-after/rdm:selected</td>
<td>Authorisation Status CTL</td>
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</tr>
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<td>maa:withdrawn-after/rdm:mark-auth-detail/rdm:date-withdrawal</td>
<td>MP Authorisation &gt; authorisation date</td>
<td>B254-19</td>
</tr>
<tr>
<td>E254-21</td>
<td>Authorisation number</td>
<td>maa:withdrawn-after/rdm:mark-auth-detail/rdm:auth-number</td>
<td>MP Authorisation &gt; authorisation number</td>
<td>B254-20</td>
</tr>
<tr>
<td>E254-22</td>
<td>Invented name</td>
<td>maa:withdrawn-after/rdm:mark-auth-detail/rdm:invented-name</td>
<td>Medicinal Product Group &gt; invented name</td>
<td>B254-21</td>
</tr>
<tr>
<td>E254-24</td>
<td>Suspended/revoked (by competent authority)</td>
<td>maa:suspended/rdm:selected</td>
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<td>B254-23</td>
</tr>
<tr>
<td>E254-26</td>
<td>Date of suspension/revocation</td>
<td>maa:suspended/rdm:mark-auth-detail/rdm:date-suspension</td>
<td>MP Authorisation &gt; authorisation date</td>
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Element Tree Diagram

### Business Rules

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<th>Default BR</th>
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<td>B254-1</td>
<td>E254-1 to E254-4</td>
<td>E254-1 mandatory, rest are Optional.</td>
<td>If E254-1 is selected, then the rest are mandatory.</td>
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<td>B254-2</td>
<td>E254-6 to E254-8</td>
<td>E254-6 mandatory, rest are Optional.</td>
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<td>B254-3</td>
<td>E254-9 to E254-12</td>
<td>E254-9 mandatory, rest are Optional.</td>
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<td>B254-4</td>
<td>E254-13 to E254-17</td>
<td>E254-13 mandatory, rest are Optional.</td>
<td>If E254-13 is selected, then the rest are mandatory.</td>
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<td>B254-5</td>
<td>E254-18 to E254-23</td>
<td>E254-18 mandatory, rest are Optional.</td>
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<td>B254-6</td>
<td>E254-24 to E254-28</td>
<td>E254-24 mandatory, rest are Optional.</td>
<td>If E254-24 is selected, then the rest are mandatory.</td>
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### 2.6. ANNEXED DOCUMENTS (WHERE APPROPRIATE)

<table>
<thead>
<tr>
<th>Elem Id</th>
<th>Label</th>
<th>Common DES 3.0 Context</th>
<th>Common RDM Entry point</th>
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<tbody>
<tr>
<td>E26-2</td>
<td>Informed consent letter of marketing authorisation holder of authorised medicinal product.</td>
<td></td>
<td>maa:section5-2</td>
</tr>
<tr>
<td>E26-3</td>
<td>Proof of establishment of the applicant in the EEA.</td>
<td></td>
<td>maa:section5-3</td>
</tr>
<tr>
<td>E26-4</td>
<td>Letter of authorisation for communication on behalf of the applicant/MAH.</td>
<td></td>
<td>maa:section5-4</td>
</tr>
<tr>
<td>E26-5</td>
<td></td>
<td></td>
<td>maa:section5-5</td>
</tr>
<tr>
<td>E26-6</td>
<td>Manufacturing Authorisation required under Article 40 of Directive 2001/83/EC (or equivalent, outside of the EEA where MRA or other European Union arrangements apply); any proof of authorisation in accordance with Article 8(k) of Directive 2001/83/EC.</td>
<td></td>
<td>maa:sections6</td>
</tr>
<tr>
<td>E26-7</td>
<td>Copy of the “Qualification of SME Status”.</td>
<td></td>
<td>maa:section5-7</td>
</tr>
<tr>
<td>E26-8</td>
<td>Flow-chart indicating all manufacturing and control sites involved in the manufacturing process of the medicinal product and the active substance.</td>
<td></td>
<td>maa:sections8</td>
</tr>
<tr>
<td>E26-9</td>
<td>GMP certificate(s) or other GMP statement(s); Where applicable a summary of other GMP inspections performed.</td>
<td></td>
<td>maa:sections9</td>
</tr>
<tr>
<td>E26-10</td>
<td>Letter(s) of access to Active Substance Master File(s) or copy of ph. Eur. Certificate(s) of Suitability.</td>
<td></td>
<td>maa:section5-10</td>
</tr>
<tr>
<td>E26-11</td>
<td>Copy of written confirmation from the manufacturer of the active substance to inform the applicant in case of modification of the manufacturing process or specifications according to Annex I of Directive 2001/83/EC.</td>
<td></td>
<td>maa:section5-11</td>
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<tr>
<td>E26-12</td>
<td>Ph. Eur. Certificate(s) of suitability for TSE.</td>
<td></td>
<td>maa:section5-12</td>
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<tr>
<td>E26-13</td>
<td>Written consent(s) of the competent authorities regarding GMO release in the environment.</td>
<td></td>
<td>maa:section5-13</td>
</tr>
<tr>
<td>E26-14</td>
<td>Scientific Advice given by CHMP and/or by member state(s).</td>
<td></td>
<td>maa:section5-14</td>
</tr>
<tr>
<td>E26-15</td>
<td>Copy of Marketing Authorization(s) required under Article 8(j)-(L) of Directive 2001/83/EC in the EEA and the equivalent in third countries on request (a photocopy of the pages which give the marketing authorization number, the date of authorisation and the page which has been signed by the authorizing competent authority will suffice).</td>
<td></td>
<td>maa:sections5-15</td>
</tr>
<tr>
<td>E26-16</td>
<td>Letter by Commission services regarding multiple applications.</td>
<td></td>
<td>maa:section5-16</td>
</tr>
<tr>
<td>E26-17</td>
<td>List of Mock-ups or Samples/specimens sent with the application, as appropriate (see EMA/CMDh websites).</td>
<td></td>
<td>maa:section5-17</td>
</tr>
<tr>
<td>E26-18</td>
<td>Copy of the Orphan Designation Decision.</td>
<td></td>
<td>maa:section5-18</td>
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<tr>
<td>E26-19</td>
<td>List of proposed (invented) names and marketing authorisation holders in the concerned member states.</td>
<td></td>
<td>maa:section5-19</td>
</tr>
<tr>
<td>E26-20</td>
<td>Copy of EMA certificate for a Vaccine Antigen Master File(VAMF).</td>
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<td>maa:section5-20</td>
</tr>
<tr>
<td>E26-21</td>
<td>Copy of EMA certificate for a Plasma Master File (PMF).</td>
<td></td>
<td>maa:section5-21</td>
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<tr>
<td>E26-22</td>
<td>For each active substance, attach a declaration(s) from the Qualified Person of the manufacturing authorisation holder in Section 2.5.1 and from the Qualified Person of the manufacturing authorisation holders (i.e located in EEA) listed in Section 2.5.2 where the active substance is used as a starting material that the active substance is manufactured in compliance with the principles and guidelines of good manufacturing practice for starting materials. Alternatively, such declaration may be signed by one Qualified Person on behalf of all QPs involved (provided this is clearly indicated). The declaration should refer to an audit and the date of the audit.</td>
<td></td>
<td>maa:section5-22</td>
</tr>
<tr>
<td>E26-23</td>
<td>Evidence and justification to support the claim of new active substance status in the Union for applications based on Article 8(3) of Directive 2001/83/EC.</td>
<td></td>
<td>maa:section5-23</td>
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</tbody>
</table>
3. About this Document

3.1. Definitions, Acronyms, and Abbreviations

**Acronyms**

<table>
<thead>
<tr>
<th>Name</th>
<th>Definition</th>
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<tbody>
<tr>
<td>cms</td>
<td>concerned member state</td>
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<tr>
<td>DCP</td>
<td>DeCentralised Procedure</td>
</tr>
<tr>
<td>DTD</td>
<td>Data Type Definition</td>
</tr>
<tr>
<td>ETD</td>
<td>Element Tree Diagram</td>
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<tr>
<td>EU</td>
<td>European Community</td>
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<tr>
<td>EudraGMPD</td>
<td>Eudra Good Manufacturing &amp; Distribution Practice</td>
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<tr>
<td>MA</td>
<td>Marketing Authorisation</td>
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<td>MRP</td>
<td>Mutual Recognition Procedure</td>
</tr>
<tr>
<td>NP</td>
<td>National Procedure</td>
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<td>RDM</td>
<td>Reference Data Model</td>
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<tr>
<td>rms</td>
<td>Reference member state</td>
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<td>TSE</td>
<td>Transmissible Spongiform Encephalopathy</td>
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<tr>
<td>XML</td>
<td>extended Markup Language</td>
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<td>XSL</td>
<td>XML Stylesheet Language</td>
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