



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Information Technology  
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## eAF DES Change Summary

Summary of DES changes applied to v.1.21.0.0



**Purpose**

The aim of this document is to summarise the changes applied to the Data Exchange Standard covering all forms for version 1.21.0.0 of the Electronic Application Form.

It should be noted this document in no way replaces the current DES documents for each of the forms.

In all instances, and to facilitate understanding, an extract of the original schema definition is supplied, along with the updated version.

The document is split into four sections, one for each of the forms affected by the DES changes:

- MAA Human
- MAA Vet

To enabled cross reference to the release notes for 1.21.0.0, this document will reference the corresponding Change Request reference number associated with the DES change.

**MAA-Human**

There was two changes applied to the human form

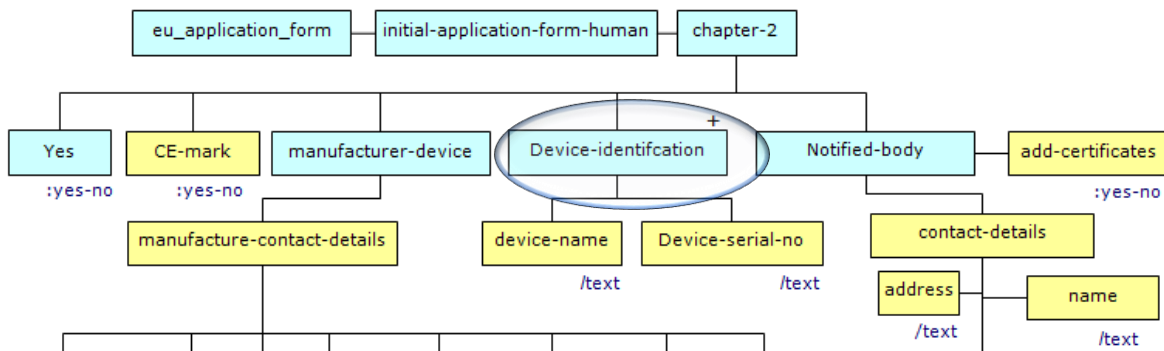
**Schema File Affected:** maa\_human.xsd

**Change Request Reference:** SD-27699

**Summary of Human change (SD-27699):**

To allow multiple device-idenfication records to be captured.

**Extract from Human DES:**



**Original Human xsd Schema definition:**

```

372 | <xs:element name="Mann-device-checkbox" type="rdm:yes-no"/>
373 | <xs:element name="Manufacture-contact-details" type="rdm:contact-details-type" minOccurs="1" maxOccurs="unbounded"/>
374 | <xs:element name="CE-mark" type="rdm:yes-no"/>
375 | <xs:element name="Device-identification">
376 |   <xs:complexType>
377 |     <xs:sequence>
378 |       <xs:element name="Device-name" type="xs:string"/>
379 |       <xs:element name="Device-serial-no" type="xs:string"/>
380 |     </xs:sequence>
381 |   </xs:complexType>
382 | </xs:element>
    
```



**Updated/Amended Human xsd Schema Definition:**

```

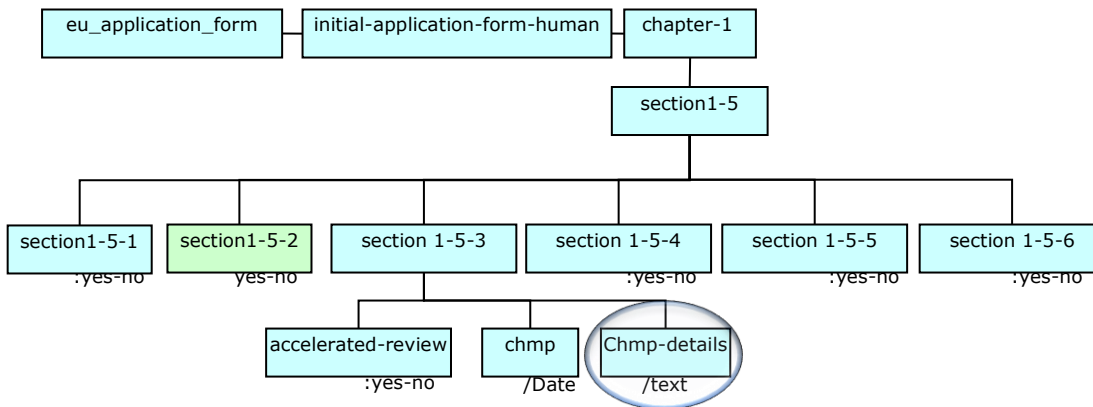
373 <xs:element name="Mann-device-checkbox" type="rdm:yes-no"/>
374 <xs:element name="Manufacture-contact-details" type="rdm:contact-details-type" minOccurs="1" maxOccurs="unbounded"/>
375 <xs:element name="CE-mark" type="rdm:yes-no"/>
376 <xs:element name="Device-identification" minOccurs="0" maxOccurs="unbounded">
377 <xs:complexType>
378 <xs:sequence>
379 <xs:element name="Device-name" type="xs:string"/>
380 <xs:element name="Device-serial-no" type="xs:string"/>
381 </xs:sequence>
382 </xs:complexType>
383 </xs:element>
    
```

In this instance the addition of a minOccurs = "0" and maxOccurs = "unbounded" has been added to the device-identification entry.

**Summary of Human change (SD-27733):**

New free text field has been added in section 1-5-3

**Extract from Human DES:**



**Original Human xsd Schema definition:**

```

234 <xs:element name="section1-5-3">
235 <xs:complexType>
236 <xs:sequence>
237 <xs:element name="accelerated-review" type="rdm:yes-no"/>
238 <xs:element name="chmp" type="xs:date"/>
239 </xs:sequence>
240 </xs:complexType>
241 </xs:element>
    
```

**Updated/Amended Human xsd Schema Definition:**

```

234 <xs:element name="section1-5-3">
235 <xs:complexType>
236 <xs:sequence>
237 <xs:element name="accelerated-review" type="rdm:yes-no"/>
238 <xs:element name="chmp" type="xs:date"/>
239 <xs:element name="chmp-details" type="xs:string"/>
240 </xs:sequence>
241 </xs:complexType>
242 </xs:element>
    
```

The new node in section-1-5-3 id:

```
xs:element name="chmp-details" type="xs:string"/>
```



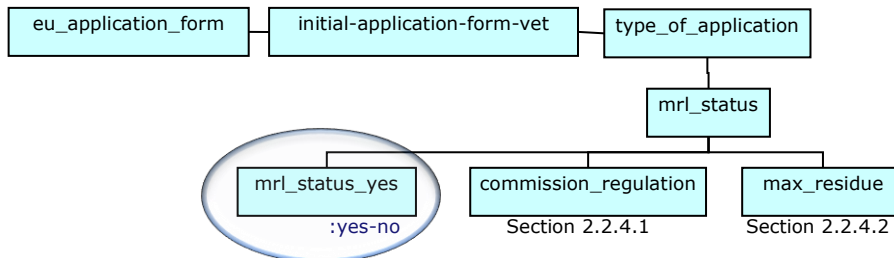
**MAA-VET**

There are three changes applied to the Veterinary form.

**Summary of Human change (SD-27782):**

New check box has been added to hide and visible the 1.4 mrl status section

**Extract from Veterinary DES:**



**Original Human xsd Schema definition:**

```

282 <xs:element name="mrl_status">
283   <xs:complexType>
284     <xs:sequence>
285       <xs:element name="commission_regulation" maxOccurs="unbounded">
286         <xs:complexType>
287           <xs:sequence>
    
```

**Updated/Amended Human xsd Schema Definition:**

```

282 <xs:element name="mrl_status">
283   <xs:complexType>
284     <xs:sequence>
285       <xs:element name="mrl_status_yes" type="rdm:yes-no"/>
286       <xs:element name="commission_regulation" maxOccurs="unbounded">
287         <xs:complexType>
288           <xs:sequence>
    
```

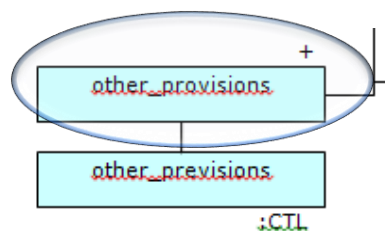
The new node in mrl\_status parent is:

```
<xs:element name="mrl_status_yes" type="rdm:yes-no"/>
```

**Summary of Human change (SD-27717):**

Include a + and - button to allow additional "other provisions".

**Extract from Veterinary DES:**



**Original Human xsd Schema definition:**

```
315 <xs:element name="other_provisions" type="rdm:control-term"/>
```

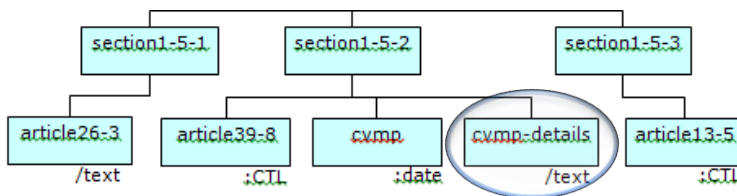
**Updated/Amended Human xsd Schema Definition:**

```
316 <xs:element name="other_provisions" minOccurs="0" maxOccurs="unbounded">
317 <xs:complexType>
318 <xs:sequence>
319 <xs:element name="other_provisions" type="rdm:control-term"/>
320 </xs:sequence>
321 </xs:complexType>
322 </xs:element>
```

**Summary of Human change (SD-27733):**

New free text field has been added in section 1-5-2

**Extract from Veterinary DES:**



**Original Human xsd Schema definition:**

```
361 <xs:element name="section1-5-2">
362 <xs:complexType>
363 <xs:sequence>
364 <xs:element name="article39-8" type="rdm:yes-no"/>
365 <xs:element name="cvmp" type="xs:date"/>
366 </xs:sequence>
367 </xs:complexType>
368 </xs:element>
```

**Updated/Amended Human xsd Schema Definition:**

```
368 <xs:element name="section1-5-2">
369 <xs:complexType>
370 <xs:sequence>
371 <xs:element name="article39-8" type="rdm:yes-no"/>
372 <xs:element name="cvmp" type="xs:date"/>
373 <xs:element name="cvmp-details" type="xs:string"/>
374 </xs:sequence>
375 </xs:complexType>
376 </xs:element>
```

The new node in section-1-5-2 id:

```
<xs:element name="cvmp-details" type="xs:string"/>
```

