



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Information Technology
EMA/396650/2016

eAF DES Change Summary

Summary of DES changes applied to v.1.27.0.0



Purpose

The aim of this document is to summarise the changes applied to the Data Exchange Standard covering human variation form for version 1.27.0.0 of the Electronic Application Forms.

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

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

To enable cross reference to the release notes for 1.27.0.0, this document will reference the corresponding Change Request/defect reference number associated with the DES change.

Change Request 1) US-216232

eAF DES Change Summary

Version 1.27.0.0

Maa-human XSD

1) From: (Version Changed)

```
<xs:schema xmlns:xs="http://www.w3.org/2001/XMLSchema" xmlns:thisfile="me"
xmlns:rdm="http://www.ema.eaf/dictionary/" xmlns:maa="http://www.ema.eaf/maa/"
targetNamespace="http://www.ema.eaf/maa/" elementFormDefault="qualified"
version="1.26.0.0">
```

To:

```
<xs:schema xmlns:xs="http://www.w3.org/2001/XMLSchema" xmlns:thisfile="me"
xmlns:rdm="http://www.ema.eaf/dictionary/" xmlns:maa="http://www.ema.eaf/maa/"
targetNamespace="http://www.ema.eaf/maa/" elementFormDefault="qualified"
version="1.27.0.0">
```

2) From: (Element added)

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

To:

```
<xs:element name="workshare" type="rdm:yes-no"/>
<xs:element name="superGrouping" type="rdm:yes-no"/>
<xs:element name="indication" type="rdm:yes-no"/>
```

3) From: (Elements added)

```
<!-- extra sections for vet -->
<xs:element name="concern-other-Member-State" type="rdm:yes-no"/>
<xs:element name="specify-yes" maxOccurs="unbounded">
<xs:complexType>
  <xs:sequence>
    <xs:element name="country" type="rdm:control-term"/>
    <xs:element name="invented-name" type="xs:string"/>
    <xs:element name="submission-date" type="xs:date" minOccurs="0"/>
    <xs:element name="procedure-number" type="xs:string"/>
    <xs:element name="rbVariationStatus" type="rdm:radiobutton"/>
    <xs:element name="granting-date" type="xs:date" minOccurs="0"/>
    <xs:element name="refusal-date" type="xs:date" minOccurs="0"/>
    <xs:element name="withdrawal-date" type="xs:date" minOccurs="0"/>
  </xs:sequence>
</xs:complexType>
```

To:

```
<!-- extra sections for vet used also for human after us216232-->
<xs:element name="concern-other-Member-State" type="rdm:yes-no"/>
<xs:element name="applicant-confirmation" type="rdm:yes-no"/>
<xs:element name="note" type="xs:string"/>
<xs:element name="specify-yes" maxOccurs="unbounded">
<xs:complexType>
  <xs:sequence>
    <xs:element name="country" type="rdm:control-term"/>
    <xs:element name="invented-name" type="xs:string"/>
    <xs:element name="submission-date" type="xs:date" minOccurs="0"/>
    <xs:element name="procedure-number" type="xs:string"/>
    <xs:element name="rbVariationStatus" type="rdm:radiobutton"/>
    <xs:element name="granting-date" type="xs:date" minOccurs="0"/>
    <xs:element name="refusal-date" type="xs:date" minOccurs="0"/>
    <xs:element name="withdrawal-date" type="xs:date" minOccurs="0"/>
  </xs:sequence>
</xs:complexType>
```

eAF DES Change Summary

dictionary XSD

1) From (version changed)

```
<xs:schema xmlns:xs="http://www.w3.org/2001/XMLSchema"
xmlns:rdm="http://www.ema.eaf/dictionary/"
targetNamespace="http://www.ema.eaf/dictionary/" elementFormDefault="qualified"
attributeFormDefault="unqualified" version="1.26.0.0">
```

To:

```
<xs:schema xmlns:xs="http://www.w3.org/2001/XMLSchema"
xmlns:rdm="http://www.ema.eaf/dictionary/"
targetNamespace="http://www.ema.eaf/dictionary/" elementFormDefault="qualified"
attributeFormDefault="unqualified" version="1.27.0.0">
```