



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.1.23.0.0

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## Purpose

The aim of this document is to summarise the changes applied to the Data Exchange Standard covering all 4 forms for version 1.23.0.0 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.

The document is split into five sections, one for common changes across more than one form and one for each of the specific forms affected by the DES changes:

- Common changes across more than one form.
- MAA Human.
- MAA Vet.
- Renewal.
- Variation.

To enable cross reference to the release notes for 1.23.0.0, this document will reference the corresponding Change Request/defect reference number associated with the DES change.

## Change Requests

1. SD-159756
2. SD-145156
3. SD-140624
4. SD-170597

## Defects

5. SD-165173



## 1. eAF dictionary XSD changes:

### a) OMS additional field introduced for all four forms (SD-170597):

For all OMS Address fields there is now an additional field used to capture the date the organisation was last modified. This new field shall not be displayed in the eAF and is a change in the XML schema only.

#### Original eaf\_Dictionary xsd schema definition:

```
<xs:complexType name="contact-details-type">
  <xs:sequence>
    <xs:element name="personal-title" type="rdm:string10" minOccurs="0"/>
    <xs:element name="given-name" type="rdm:string100"/>
    <xs:element name="family-name" type="rdm:string100"/>
    <xs:element name="company-name" type="rdm:string100"/>
    <xs:element name="address1" type="rdm:string100"/>
    <xs:element name="address2" type="rdm:string100"/>
    <xs:element name="address3" type="rdm:string100"/>
    <xs:element name="address4" type="rdm:string100"/>
    <xs:element name="city" type="rdm:string100"/>
    <xs:element name="state" type="rdm:string100" minOccurs="0"/>
    <xs:element name="county" type="rdm:string100"/>
    <xs:element name="post-code" type="rdm:string10"/>
    <xs:element name="country" type="rdm:control-term"/>
    <xs:element name="orgID" type="rdm:string50"/>
    <xs:element name="locID" type="rdm:string50"/>
    <xs:element name="loc-modifiedDate" type="xs:date"/>
    <xs:element name="language" type="rdm:string10"/>
    <xs:element name="phone" type="rdm:string50"/>
    <xs:element name="fax" type="rdm:string30" minOccurs="0"/>
    <xs:element name="email" type="rdm:string100" minOccurs="0"/>
    <xs:element name="qualification" type="xs:string" minOccurs="0"/>
    <xs:element name="residesInEEA" type="rdm:yes-no" minOccurs="0"/>
    <xs:element name="attach" type="rdm:yes-no"/>
    <xs:element name="qualifiedPerson" type="rdm:yes-no" minOccurs="0"/>
    <xs:element name="member-states" type="rdm:member-states"/>
    <xs:element name="admin-manu-address" type="rdm:yes-no"/>
    <xs:element name="admin-office" type="rdm:admin-office"/>
    <xs:element name="manu-facility" type="rdm:manu-facility" maxOccurs="unbounded"/>
  </xs:sequence>
</xs:complexType>
```

#### Updated eaf\_Dictionary xsd schema definition:

```
<xs:complexType name="contact-details-type">
  <xs:sequence>
    <xs:element name="personal-title" type="rdm:string10" minOccurs="0"/>
    <xs:element name="given-name" type="rdm:string100"/>
    <xs:element name="family-name" type="rdm:string100"/>
    <xs:element name="company-name" type="rdm:string100"/>
    <xs:element name="address1" type="rdm:string100"/>
    <xs:element name="address2" type="rdm:string100"/>
    <xs:element name="address3" type="rdm:string100"/>
    <xs:element name="address4" type="rdm:string100"/>
    <xs:element name="city" type="rdm:string100"/>
    <xs:element name="state" type="rdm:string100" minOccurs="0"/>
    <xs:element name="county" type="rdm:string100"/>
    <xs:element name="post-code" type="rdm:string10"/>
    <xs:element name="country" type="rdm:control-term"/>
    <xs:element name="orgID" type="rdm:string50"/>
    <xs:element name="locID" type="rdm:string50"/>
    <xs:element name="loc-modifiedDate" type="xs:date"/>
    <xs:element name="org-modifiedDate" type="xs:date"/>
    <xs:element name="language" type="rdm:string10"/>
    <xs:element name="phone" type="rdm:string50"/>
    <xs:element name="fax" type="rdm:string30" minOccurs="0"/>
    <xs:element name="email" type="rdm:string100" minOccurs="0"/>
    <xs:element name="qualification" type="xs:string" minOccurs="0"/>
    <xs:element name="residesInEEA" type="rdm:yes-no" minOccurs="0"/>
    <xs:element name="attach" type="rdm:yes-no"/>
    <xs:element name="qualifiedPerson" type="rdm:yes-no" minOccurs="0"/>
    <xs:element name="member-states" type="rdm:member-states"/>
    <xs:element name="admin-manu-address" type="rdm:yes-no"/>
    <xs:element name="admin-office" type="rdm:admin-office"/>
    <xs:element name="manu-facility" type="rdm:manu-facility" maxOccurs="unbounded"/>
  </xs:sequence>
</xs:complexType>
```



**b) Removal of Fax number from all OMS Addresses across all forms (SD-145156) – NTA change:****Original eaf\_Dictionary xsd schema definition:**

```

<xs:complexType name="contact-details-type">
  <xs:sequence>
    <xs:element name="personal-title" type="rdm:string10" minOccurs="0"/>
    <xs:element name="given-name" type="rdm:string100"/>
    <xs:element name="family-name" type="rdm:string100"/>
    <xs:element name="company-name" type="rdm:string100"/>
    <xs:element name="address1" type="rdm:string100"/>
    <xs:element name="address2" type="rdm:string100"/>
    <xs:element name="address3" type="rdm:string100"/>
    <xs:element name="address4" type="rdm:string100"/>
    <xs:element name="city" type="rdm:string100"/>
    <xs:element name="state" type="rdm:string100" minOccurs="0"/>
    <xs:element name="county" type="rdm:string100"/>
    <xs:element name="post-code" type="rdm:string10"/>
    <xs:element name="country" type="rdm:control-term"/>
    <xs:element name="orgID" type="rdm:string50"/>
    <xs:element name="locID" type="rdm:string50"/>
    <xs:element name="loc-modifiedDate" type="xs:date"/>
    <xs:element name="language" type="rdm:string10"/>
    <xs:element name="phone" type="rdm:string50"/>
    <xs:element name="fax" type="rdm:string30" minOccurs="0"/>
    <xs:element name="email" type="rdm:string100" minOccurs="0"/>
    <xs:element name="qualification" type="xs:string" minOccurs="0"/>
    <xs:element name="residesInEEA" type="rdm:yes-no" minOccurs="0"/>
    <xs:element name="attach" type="rdm:yes-no"/>
    <xs:element name="qualifiedPerson" type="rdm:yes-no" minOccurs="0"/>
    <xs:element name="member-states" type="rdm:member-states"/>
    <xs:element name="admin-manu-address" type="rdm:yes-no"/>
    <xs:element name="admin-office" type="rdm:admin-office"/>
    <xs:element name="manu-facility" type="rdm:manu-facility" maxOccurs="unbounded"/>
  </xs:sequence>
</xs:complexType>

```

**Updated eaf\_Dictionary xsd schema definition:**

```

<xs:complexType name="contact-details-type">
  <xs:sequence>
    <xs:element name="personal-title" type="rdm:string10" minOccurs="0"/>
    <xs:element name="given-name" type="rdm:string100"/>
    <xs:element name="family-name" type="rdm:string100"/>
    <xs:element name="company-name" type="rdm:string100"/>
    <xs:element name="address1" type="rdm:string100"/>
    <xs:element name="address2" type="rdm:string100"/>
    <xs:element name="address3" type="rdm:string100"/>
    <xs:element name="address4" type="rdm:string100"/>
    <xs:element name="city" type="rdm:string100"/>
    <xs:element name="state" type="rdm:string100" minOccurs="0"/>
    <xs:element name="county" type="rdm:string100"/>
    <xs:element name="post-code" type="rdm:string10"/>
    <xs:element name="country" type="rdm:control-term"/>
    <xs:element name="orgID" type="rdm:string50"/>
    <xs:element name="locID" type="rdm:string50"/>
    <xs:element name="loc-modifiedDate" type="xs:date"/>
    <xs:element name="org-modifiedDate" type="xs:date"/>
    <xs:element name="language" type="rdm:string10"/>
    <xs:element name="phone" type="rdm:string50"/>
    <xs:element name="email" type="rdm:string100" minOccurs="0"/>
    <xs:element name="qualification" type="xs:string" minOccurs="0"/>
    <xs:element name="residesInEEA" type="rdm:yes-no" minOccurs="0"/>
    <xs:element name="attach" type="rdm:yes-no"/>
    <xs:element name="qualifiedPerson" type="rdm:yes-no" minOccurs="0"/>
    <xs:element name="member-states" type="rdm:member-states"/>
    <xs:element name="admin-manu-address" type="rdm:yes-no"/>
    <xs:element name="admin-office" type="rdm:admin-office"/>
    <xs:element name="manu-facility" type="rdm:manu-facility" maxOccurs="unbounded"/>
  </xs:sequence>
</xs:complexType>

```

**c) Addition of EMA Product Number in Human form (SD-145156) – NTA change:**

Addition of a new EMA Product Number field in the Human Form

**Original eaf\_Dictionary xsd schema definition:**

```

<xs:element name="article31">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="selected" type="rdm:yes-no"/>
      <xs:element name="date-of-acceptance" type="xs:date"/>
    </xs:sequence>
  </xs:complexType>
</xs:element>

```



**Updated eaf\_Dictionary xsd schema definition:**

```

<xs:element name="article31">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="selected" type="rdm:yes-no"/>
      <xs:element name="date-of-acceptance" type="xs:date"/>
      <xs:element name="ema-product-number" type="xs:string"/>
    </xs:sequence>
  </xs:complexType>
</xs:element>

```

**d) Addition of Procedure Number for Human & Vet MAA forms (SD-145156) – NTA change:**

Addition of a Procedure Number field if MRP\DCP in the Human & Vet Forms

**Original eaf\_Dictionary xsd schema definition:**

```

</xs:element>
<xs:element name="mrp-variation-number" type="xs:string"/>
<xs:element name="authorisation-holder" type="rdm:string30"/>
<xs:element name="authorisation-date" type="xs:date"/>
<xs:element name="country" type="xs:string"/>
<xs:element name="authorisation-status" type="xs:string"/>
<xs:element name="expiry-date" type="xs:date"/>

```

**Updated eaf\_Dictionary xsd schema definition:**

```

</xs:element>
<xs:element name="mrp-variation-number" type="xs:string"/>
<xs:element name="authorisation-holder" type="rdm:string30"/>
<xs:element name="authorisation-date" type="xs:date"/>
<xs:element name="country" type="xs:string"/>
<xs:element name="authorisation-status" type="xs:string"/>
<xs:element name="expiry-date" type="xs:date"/>
<xs:element name="mrp-dcp-procedure-number" type="xs:string"/>

```

**e) Addition of Base/active moiety of active substance(s) Human & Vet MAA forms (SD-145156) – NTA change:**

Addition of a Base/active moiety of the active substance(s) field in the Human & Vet Forms in section 2.1.2 and 2.6.1

**Original eaf\_Dictionary xsd schema definition:**

```

<xs:complexType name="ingredient">
  <xs:sequence>
    <xs:element name="ingredient-role" type="rdm:control-term"/>
    <xs:element name="substance-name" type="rdm:substance"/>
    <xs:element name="ingredient-strength" type="rdm:ingredient-strength" minOccurs="0"/>
    <xs:element name="reference-monograph-standard" type="rdm:string250" minOccurs="0"/>
  </xs:sequence>

```

**Updated eaf\_Dictionary xsd schema definition:**

```

<xs:complexType name="ingredient">
  <xs:sequence>
    <xs:element name="ingredient-role" type="rdm:control-term"/>
    <xs:element name="substance-name" type="rdm:substance"/>
    <xs:element name="ingredient-strength" type="rdm:ingredient-strength" minOccurs="0"/>
    <xs:element name="moiety-substance-name" type="rdm:substance"/>
    <xs:element name="moiety-ingredient-strength" type="rdm:ingredient-strength" minOccurs="0"/>
    <xs:element name="reference-monograph-standard" type="rdm:string250" minOccurs="0"/>
  </xs:sequence>

```



### **d) Addition of address section in 2.5.3 under ASMF in Human form (SD-145156) – NTA change:**

Addition of address fields in 2.5.3 section under ASMF in the Human Form

#### **Original eaf\_Dictionary xsd schema definition:**

```
<xs:complexType name="manufacturer-active-substance">
  <xs:sequence>
    <xs:element name="active-substances" minOccurs="1" maxOccurs="unbounded">...</xs:element>
    <xs:element name="company-description" type="xs:string"/>
    <xs:element name="contact-details" type="rdm:contact-details-type"/>
    <xs:element name="manu-facility" type="rdm:manu-facility" maxOccurs="unbounded"/>
    <xs:element name="function-description" type="xs:string"/>
    <xs:element name="manu-steps" minOccurs="1" maxOccurs="unbounded">...</xs:element>
    <xs:element name="flow_chart" type="rdm:yes-no"/>
    <xs:element name="qualified-person-declaration" type="rdm:yes-no"/>
    <xs:element name="inspected_gmp_compliance" type="rdm:yes-no"/>
    <xs:element name="competent-authority" type="rdm:yes-no"/>
    <xs:element name="gmp_cert" type="rdm:yes-no"/>
    <xs:element name="gmpc" type="rdm:gmpc"/>
    <xs:element name="gmp-compliance-other" type="rdm:yes-no"/>
    <xs:element name="summary-information" type="rdm:yes-no"/>
    <xs:element name="ph-eur-cert-suitability" type="rdm:yes-no"/>
    <xs:element name="provide-copy" type="rdm:yes-no"/>
    <xs:element name="qualification" type="xs:string" minOccurs="0"/>
    <xs:element name="attach" type="rdm:yes-no" minOccurs="0"/>
    <xs:element name="residesInEEA" type="rdm:yes-no" minOccurs="0"/>
    <xs:element name="personal-title" type="rdm:string30" minOccurs="0"/>
    <xs:element name="mia" type="rdm:mia"/>
    <xs:element name="active-substance-master-file" type="rdm:yes-no"/>
    <xs:element name="access-community-member-state" type="rdm:yes-no"/>
    <xs:element name="written-confirmation" type="rdm:yes-no"/>
    <xs:element name="asmf" minOccurs="1" maxOccurs="unbounded">
      <xs:complexType>
        <xs:sequence>
          <xs:element name="substance-certificate" type="rdm:substance-certificate"/>
        </xs:sequence>
      </xs:complexType>
    </xs:element>
  </xs:sequence>
</xs:complexType>
```

#### **Updated eaf\_Dictionary xsd schema definition:**

```
<xs:complexType name="manufacturer-active-substance">
  <xs:sequence>
    <xs:element name="active-substances" minOccurs="1" maxOccurs="unbounded">...</xs:element>
    <xs:element name="company-description" type="xs:string"/>
    <xs:element name="contact-details" type="rdm:contact-details-type"/>
    <xs:element name="manu-facility" type="rdm:manu-facility" maxOccurs="unbounded"/>
    <xs:element name="function-description" type="xs:string"/>
    <xs:element name="manu-steps" minOccurs="1" maxOccurs="unbounded">...</xs:element>
    <xs:element name="flow_chart" type="rdm:yes-no"/>
    <xs:element name="qualified-person-declaration" type="rdm:yes-no"/>
    <xs:element name="inspected_gmp_compliance" type="rdm:yes-no"/>
    <xs:element name="competent-authority" type="rdm:yes-no"/>
    <xs:element name="gmp_cert" type="rdm:yes-no"/>
    <xs:element name="gmpc" type="rdm:gmpc"/>
    <xs:element name="gmp-compliance-other" type="rdm:yes-no"/>
    <xs:element name="summary-information" type="rdm:yes-no"/>
    <xs:element name="ph-eur-cert-suitability" type="rdm:yes-no"/>
    <xs:element name="provide-copy" type="rdm:yes-no"/>
    <xs:element name="qualification" type="xs:string" minOccurs="0"/>
    <xs:element name="attach" type="rdm:yes-no" minOccurs="0"/>
    <xs:element name="residesInEEA" type="rdm:yes-no" minOccurs="0"/>
    <xs:element name="personal-title" type="rdm:string30" minOccurs="0"/>
    <xs:element name="mia" type="rdm:mia"/>
    <xs:element name="active-substance-master-file" type="rdm:yes-no"/>
    <xs:element name="access-community-member-state" type="rdm:yes-no"/>
    <xs:element name="written-confirmation" type="rdm:yes-no"/>
    <xs:element name="asmf" minOccurs="1" maxOccurs="unbounded">
      <xs:complexType>
        <xs:sequence>
          <xs:element name="substance-certificate" type="rdm:substance-certificate"/>
          <xs:element name="contact-details" type="rdm:contact-details-type"/>
        </xs:sequence>
      </xs:complexType>
    </xs:element>
  </xs:sequence>
</xs:complexType>
```



### **e) Addition of address section in 2.5.3 under ASMF in #VET Form (SD-145156) – NTA change:**

Addition of address fields in 2.5.3 section under ASMF in the Vet Form

#### **Original eaf\_Dictionary xsd schema definition:**

```
<xs:complexType name="manufacturer-active-substance-vet">
  <xs:sequence>
    <xs:element name="active-substances" minOccurs="1" maxOccurs="unbounded">...</xs:element>
    <xs:element name="contact-details" type="rdm:contact-details-type"/>
    <xs:element name="function-description" type="xs:string"/>
    <xs:element name="manu-steps" minOccurs="1" maxOccurs="unbounded">...</xs:element>
    <xs:element name="flow_chart" type="rdm:yes-no"/>
    <xs:element name="qualified-person-declaration" type="rdm:yes-no"/>
    <xs:element name="inspected_gmp_compliance" type="rdm:yes-no"/>
    <xs:element name="competent-authority" type="rdm:yes-no"/>
    <xs:element name="gmp_cert" type="rdm:yes-no"/>
    <xs:element name="gmpc" type="rdm:gmpc"/>
    <xs:element name="gmp-compliance-other" type="rdm:yes-no"/>
    <xs:element name="summary-information" type="rdm:yes-no"/>
    <xs:element name="ph-eur-cert-suitability" type="rdm:yes-no"/>
    <xs:element name="provide-copy" type="rdm:yes-no"/>
    <xs:element name="qualification" type="xs:string" minOccurs="0"/>
    <xs:element name="attach" type="rdm:yes-no" minOccurs="0"/>
    <xs:element name="active-substance-master-file" type="rdm:yes-no"/>
    <xs:element name="access-community-member-state" type="rdm:yes-no"/>
    <xs:element name="written-confirmation" type="rdm:yes-no"/>
    <xs:element name="ph-eur-cert">...</xs:element>
    <xs:element name="asmf">
      <xs:complexType>
        <xs:sequence>
          <xs:element name="substance-certificate" type="rdm:substance-certificate-vet"/>
        </xs:sequence>
      </xs:complexType>
    </xs:element>
  </xs:sequence>
</xs:complexType>
```

#### **Updated eaf\_Dictionary xsd schema definition:**

```
<xs:complexType name="manufacturer-active-substance-vet">
  <xs:sequence>
    <xs:element name="active-substances" minOccurs="1" maxOccurs="unbounded">...</xs:element>
    <xs:element name="contact-details" type="rdm:contact-details-type"/>
    <xs:element name="function-description" type="xs:string"/>
    <xs:element name="manu-steps" minOccurs="1" maxOccurs="unbounded">...</xs:element>
    <xs:element name="flow_chart" type="rdm:yes-no"/>
    <xs:element name="qualified-person-declaration" type="rdm:yes-no"/>
    <xs:element name="inspected_gmp_compliance" type="rdm:yes-no"/>
    <xs:element name="competent-authority" type="rdm:yes-no"/>
    <xs:element name="gmp_cert" type="rdm:yes-no"/>
    <xs:element name="gmpc" type="rdm:gmpc"/>
    <xs:element name="gmp-compliance-other" type="rdm:yes-no"/>
    <xs:element name="summary-information" type="rdm:yes-no"/>
    <xs:element name="ph-eur-cert-suitability" type="rdm:yes-no"/>
    <xs:element name="provide-copy" type="rdm:yes-no"/>
    <xs:element name="qualification" type="xs:string" minOccurs="0"/>
    <xs:element name="attach" type="rdm:yes-no" minOccurs="0"/>
    <xs:element name="active-substance-master-file" type="rdm:yes-no"/>
    <xs:element name="access-community-member-state" type="rdm:yes-no"/>
    <xs:element name="written-confirmation" type="rdm:yes-no"/>
    <xs:element name="ph-eur-cert">...</xs:element>
    <xs:element name="asmf">
      <xs:complexType>
        <xs:sequence>
          <xs:element name="substance-certificate" type="rdm:substance-certificate-vet"/>
          <xs:element name="contact-details" type="rdm:contact-details-type"/>
        </xs:sequence>
      </xs:complexType>
    </xs:element>
  </xs:sequence>
</xs:complexType>
```



**f) Check box has been added in section 2.4.4 in Human form (SD-145156) – NTA change:**

Check box has been added in section 2.4.4 in the Human Form

**Original eaf\_Dictionary xsd schema definition:**

```
> <xs:complexType name="pharmaco-vigilance">
>   <xs:complexContent>
>     <xs:extension base="rdm:contact-details-type">
>       <xs:sequence>
-         <xs:element name="number" type="xs:string"/>
-       </xs:sequence>
-     </xs:extension>
-   </xs:complexContent>
- </xs:complexType>
```

**Updated eaf\_Dictionary xsd schema definition:**

```
<xs:complexType name="pharmaco-vigilance">
  <xs:complexContent>
    <xs:extension base="rdm:contact-details-type">
      <xs:sequence>
-       <xs:element name="number" type="xs:string"/>
+       <xs:element name="art57-database-box" type="rdm:yes-no"/>
      </xs:sequence>
    </xs:extension>
  </xs:complexContent>
```





## 2. MAA-Human – Human XSD changes

### a) Addition of Medical Device fields for Human form (SD-145156) – NTA change:

#### Original maa\_human xsd schema definition:

```
<xs:element name="Manufacturer-device">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="Manu-device-checkbox" type="rdm:yes-no"/>
      <xs:element name="Manufacture-contact-details" type="rdm:contact-details-type" minOccurs="1" maxOccurs="unbounded"/>
      <xs:element name="CE-mark" type="rdm:yes-no"/>
      <xs:element name="Device-identification" minOccurs="0" maxOccurs="unbounded">
        <xs:complexType>
          <xs:sequence>
            <xs:element name="Device-name" type="xs:string"/>
            <xs:element name="Device-serial-no" type="xs:string"/>
          </xs:sequence>
        </xs:complexType>
      </xs:element>
    </xs:sequence>
  </xs:complexType>
</xs:element>
```

#### Updated maa\_human xsd schema definition:

```
<xs:element name="Manufacturer-device">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="Manu-device-checkbox" type="rdm:yes-no"/>
      <xs:element name="Manu-device-Yes-No" type="rdm:yes-no"/>
      <xs:element name="Manufacture-contact-details" type="rdm:contact-details-type" minOccurs="1" maxOccurs="unbounded"/>
      <xs:element name="CE-mark" type="rdm:yes-no"/>
      <xs:element name="Device-identification" minOccurs="0" maxOccurs="unbounded">
        <xs:complexType>
          <xs:sequence>
            <xs:element name="Device-name" type="xs:string"/>
            <xs:element name="Device-description" type="xs:string"/>
            <xs:element name="Device-serial-no" type="xs:string"/>
          </xs:sequence>
        </xs:complexType>
      </xs:element>
    </xs:sequence>
  </xs:complexType>
</xs:element>
```

### b) New active substance and known active substance radio buttons moved to 2.1.2 in Human MAA forms (SD-145156) – NTA change

#### b) SubstanceType added in Human MAA forms (SD-145156) – NTA change:

Human form – Claim for new active substance is deleted in section 1.4.1 and added in 2.1.2, Known active substance has been added and SubstanceType field has been added.

#### Original maa\_Human xsd schema definition:

```
<xs:element name="section1-4-1">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="article-8-3" type="rdm:yes-no"/>
      <xs:element name="new-active-substance" type="rdm:yes-no"/>
      <xs:element name="known-active-substance" type="rdm:yes-no"/>
      <xs:element name="attach-letter" type="rdm:yes-no"/>
    </xs:sequence>
  </xs:complexType>
</xs:element>
```



**Updated maa\_human xsd schema definition:**

```
<xs:element name="chapter-2">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="medicinal-product" type="rdm:medicinal-product"/>
      <xs:element name="annex5-19" type="rdm:yes-no"/>
      <xs:element name="active-substances">[...]</xs:element>
      <xs:element name="substanceType" type="rdm:control-term"/>
      <xs:element name="new-active-substance" type="rdm:yes-no"/>
      <xs:element name="known-active-substance" type="rdm:yes-no"/>
      <xs:element name="attach-letter" type="rdm:yes-no"/>
      <xs:element name="annex5-17" type="rdm:yes-no"/>
    </xs:sequence>
  </xs:complexType>
</xs:element>
```



### 3.MAA-VET – VET XSD Changes

#### **a) New active substance and known active substance radio buttons moved to 2.1.2 (SD-145156) – NTA change**

#### **b) SubstanceType added in Vet MAA forms (SD-145156) – NTA change:**

VET form - Claim for new active substance radio button is deleted in section 1.3.1 and added in 2.1.2, Known active substance has been added and substance Type has been added.

#### **Original vet\_Human xsd schema definition:**

```
<xs:element name="section1-3-1">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="article-12-3" type="rdm:yes-no"/>
      <xs:element name="new-active-substance" type="rdm:yes-no"/>
      <xs:element name="known-active-substance" type="rdm:yes-no"/>
      <xs:element name="attach-letter" type="rdm:yes-no"/>
    </xs:sequence>
  </xs:complexType>
</xs:element>
```

#### **Updated vet\_human xsd schema definition:**

```
<xs:element name="chapter-2">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="medicinal-product" type="rdm:medicinal-product"/>
      <xs:element name="annex5-19" type="rdm:yes-no"/>
      <xs:element name="active-substances"><input type="checkbox"/></xs:element>
      <xs:element name="substanceType" type="rdm:control-term"/>
      <xs:element name="new-active-substance" type="rdm:yes-no"/>
      <xs:element name="known-active-substance" type="rdm:yes-no"/>
      <xs:element name="attach-letter" type="rdm:yes-no"/>
      <xs:element name="annex5-17" type="rdm:yes-no"/>
    </xs:sequence>
  </xs:complexType>
</xs:element>
```

#### **b) Addition of EMA Product Number in Vet MAA form (SD-145156) – NTA change:**

Addition of a new EMA Product Number field in the Vet Form

#### **Original vet xsd schema definition:**

```
<xs:element name="os">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="new_active_substance" type="rdm:yes-no"/>
      <xs:element name="significant_innovation" type="rdm:yes-no"/>
      <xs:element name="immunological" type="rdm:yes-no"/>
      <xs:element name="acceptance_cvmp"/>
    </xs:sequence>
  </xs:complexType>
</xs:element>
```

#### **Updated vet xsd schema definition:**

```
<xs:element name="os">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="new_active_substance" type="rdm:yes-no"/>
      <xs:element name="significant_innovation" type="rdm:yes-no"/>
      <xs:element name="immunological" type="rdm:yes-no"/>
      <xs:element name="acceptance_cvmp"/>
      <xs:element name="ema-product-number" type="xs:string"/>
    </xs:sequence>
  </xs:complexType>
</xs:element>
```



## 4. RENEWAL – Renewal\_Human\_Vet XSD

### a) New check boxes has been added in Present and proposed section (SD-145156) – NTA change

New check boxes has been added in Renewal Form

#### Original Renewal xsd schema definition:

```
<xs:element name="product">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="product-information" maxOccurs="unbounded">
        <xs:complexType>
          <xs:sequence>
            <xs:sequence>
              <xs:element name="present-product-information" type="xs:string"/>
              <xs:element name="proposed-product-information" type="xs:string"/>
            </xs:sequence>
          </xs:sequence>
        </xs:complexType>
      </xs:element>
    </xs:sequence>
  </xs:complexType>
</xs:element>
```

#### Updated Renewal xsd schema definition:

```
<xs:element name="product">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="product-summary" type="rdm:yes-no"/>
      <xs:element name="product-labelling" type="rdm:yes-no"/>
      <xs:element name="product-packageLeaflet" type="rdm:yes-no"/>
      <xs:element name="product-Mock-ups" type="rdm:yes-no"/>
      <xs:element name="product-specimens" type="rdm:yes-no"/>
      <xs:element name="product-information" maxOccurs="unbounded">
        <xs:complexType>
          <xs:sequence>
            <xs:sequence>
              <xs:element name="present-product-information" type="xs:string"/>
              <xs:element name="proposed-product-information" type="xs:string"/>
            </xs:sequence>
          </xs:sequence>
        </xs:complexType>
      </xs:element>
    </xs:sequence>
  </xs:complexType>
</xs:element>
```



## **b) New Ph.Eur Certificate and ASMF section has been added in Renewal form (SD-145156) – NTA change**

New Ph.Eur Certificate and ASMF section has been added in Renewal form

### **Original Renewal xsd schema definition:**

```
<xs:element name="manufacturers-active-substance" maxOccurs="unbounded">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="manufacturers" minOccurs="0" maxOccurs="unbounded">
        <xs:complexType>
          <xs:sequence>
            <xs:element name="active-substances" minOccurs="1" maxOccurs="unbounded">...</xs:element>
            <xs:element name="role" type="rdm:role"/>
          </xs:sequence>
        </xs:complexType>
      </xs:element>
    </xs:sequence>
  </xs:complexType>
</xs:element>
```

### **Updated Renewal xsd schema definition:**

```
<xs:element name="manufacturers-active-substance" maxOccurs="unbounded">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="manufacturers" minOccurs="0" maxOccurs="unbounded">
        <xs:complexType>
          <xs:sequence>
            <xs:element name="active-substances" minOccurs="1" maxOccurs="unbounded">...</xs:element>
            <xs:element name="role" type="rdm:role"/>
            <xs:element name="manufacturer-active-substance" type="rdm:manufacturer-active-substance"/>
          </xs:sequence>
        </xs:complexType>
      </xs:element>
    </xs:sequence>
  </xs:complexType>
</xs:element>
```



## 5.Variation Form - Variation XSD -Changes

### **a) OMS integration in variation form (SD-140624):**

For the variation form only; the present & proposed sections have been amended to allow for an entry of an OMS organisation; This is aligned with other OMS Address sections.

#### **Original eaf\_Dictionary xsd Schema definition:**

```
<xs:element name="presentProposedImage" maxOccurs="unbounded">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="present" type="xs:string"/>
      <xs:element name="proposed" type="xs:string"/>
    </xs:sequence>
  </xs:complexType>
</xs:element>
```

#### **Updated/Amended eaf\_Dictionary xsd schema definition:**

```
</xs:element>
<xs:element name="presentProposedImage" maxOccurs="unbounded">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="present" type="xs:string"/>
      <xs:element name="proposed" type="xs:string"/>
    </xs:sequence>
  </xs:complexType>
</xs:element>
<xs:element name="presentProposedAddress" maxOccurs="unbounded">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="present" minOccurs="0">
        <xs:complexType>
          <xs:sequence>
            <xs:element name="contact-details" type="rdm:contact-details-type"/>
          </xs:sequence>
        </xs:complexType>
      </xs:element>
      <xs:element name="proposed" minOccurs="0">
        <xs:complexType>
          <xs:sequence>
            <xs:element name="contact-details" type="rdm:contact-details-type"/>
          </xs:sequence>
        </xs:complexType>
      </xs:element>
    </xs:sequence>
  </xs:complexType>
</xs:element>
```

