13th July 2018
Information Technology
EMA/396650/2016

eAF DES Change Summary

Summary of DES changes applied to v.1.23.0.0

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:

```xml
<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:

```xml
<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:

```xml
<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:

```xml
<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:

```xml
<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>
```
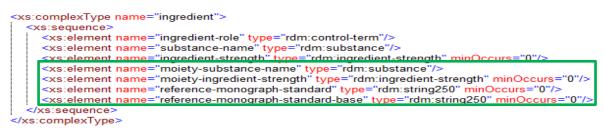
Updated eaf_Dictionary xsd schema definition:

```xml
<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:

```xml
</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:

```xml
</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:

```xml
<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:

```xml
<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:element name="reference-monograph-standard-base" type="rdm:string250" minOccurs="0"/>
    </xs:sequence>
</xs:complexType>
```

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>
```

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>
```

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:

```xml
<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>
```

Updated eaf_Dictionary xsd schema definition:

```xml
<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>
```

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>
```

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>
```

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"/>
```

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 maa_vet xsd schema definition:

```xml
<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 maa_vet xsd schema definition:

```xml
<xs:element name="section2-1-2">
  <xs:complexType>
    <xs:sequence>
      <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: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 maa_vet xsd schema definition:

```xml
<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>
```

Updated maa_vet xsd schema definition:

```xml
<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:

```xml
<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:

```xml
<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:

```xml
<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:

```xml
<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>
```

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom

Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
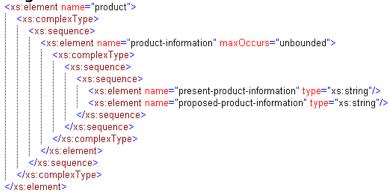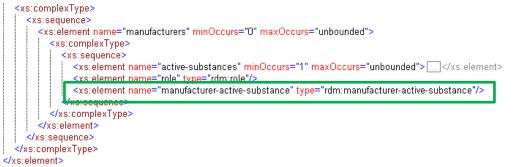**Send a question via our website** www.ema.europa.eu/contact

An agency of the European Union

© European Medicines Agency, 2018. Reproduction is authorised provided the source is acknowledged.

12 of **13**

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:

```xml
<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:

```xml
    </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>
```