



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.1.22.0.0



Purpose

The aim of this document is to summarise the changes applied to the Data Exchange Standard covering all forms for version 1.22.0.0 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 five sections, one for each of the forms affected by the DES changes including OMS integration in all forms:

- OMS integration for all four forms
- MAA Human
- MAA Vet
- Renewal
- Variation

To enabled cross reference to the release notes for 1.22.0.0, this document will reference the corresponding Change Request/defect reference number associated with the DES change.

Change Requests

1. SD-105001
2. SD-105185
3. SD-105187
4. SD-105670
5. SD-106023
6. SD-124640
7. SD-81544
8. SD-65517

Defects

9. SD-124981



Summary of OMS integration change (SD-65517):

Address fields in the below sections has been amended to in line with OMS data in each form.

Human Form

Declaration Section
Declaration Section (on behalf of Applicant)
Section 2.2.4.1
Section 2.4.1 Address
Section 2.4.1 - Proof of payment
Section 2.4.2
Section 2.4.3
Section 2.4.4
Section 2.4.4 (Pharmacovigilance)
Section 2.4.5
Section 2.5.1.a Admin & Manufacturer
Section 2.5.1.b
Section 2.5.1.1
Section 2.5.1.2
Section 2.5.2 Admin & Manufacturer
Section 2.5.3 Admin & Manufacturer
Section 2.5.4

Veterinary Form

Declaration Section
Declaration Section (on behalf of Applicant)
Section 2.4.1
Section 2.4.1 - Proof of payment
Section 2.4.2
Section 2.4.3
Section 2.4.4
Section 2.4.4 (Pharmacovigilance)
Section 2.4.5
Section 2.5.1.a Admin & Manufacturer
Section 2.5.1.b
Section 2.5.1.1
Section 2.5.1.2
Section 2.5.2 Admin & Manufacturer
Section 2.5.3 Admin & Manufacturer
Section 2.5.4

Renewal Form

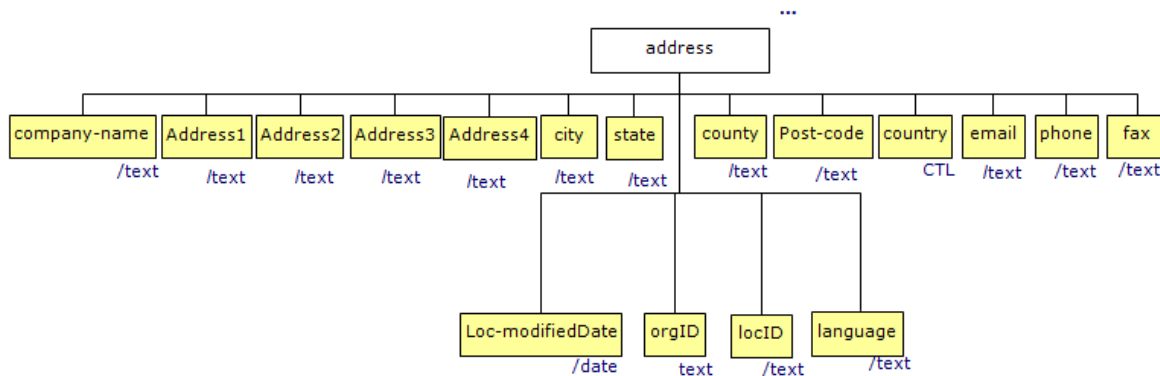
Declaration Section
Section 1 – Address of MA holder
Section 1 – Name of contact Person
Section 2 – Batch Control Testing Admin & Manufacturer
Section 2 – Medicinal Product Admin & Manufacturer
Section 2 – Active Substance Section 2 – Batch Release
Section 2 – Batch Release Admin & Manufacturer
Section 2 – For blood Products Admin & Manufacturer

Variation form

Section 1 – Name of contact Person
Section 1 – Address of MA holder
Signature section - Payment - Address



Extract from Human DES:



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="address" type="rdm:string100"/>
    <xs:element name="city" type="rdm:string100"/>
    <xs:element name="state" type="rdm:string100" minOccurs="0"/>
    <xs:element name="phone" type="rdm:string50" minOccurs="0"/>
    <xs:element name="fax" type="rdm:string30" minOccurs="0"/>
    <xs:element name="email" type="rdm:string100" minOccurs="0"/>
    <xs:element name="post-code" type="rdm:string10"/>
    <xs:element name="qualification" type="xs:string" minOccurs="0"/>
    <xs:element name="country" type="rdm:control-term"/>
    <xs:element name="company-name" type="rdm:string100"/>
  </xs:sequence>
</xs:complexType>
```

Updated/Amended 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:sequence>
</xs:complexType>
```

The new nodes have been added in contact-details-type.

Address1, address2, address3, address4, state, county, orgId, locID, loc-modifiedDate, language

```
<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="state" type="rdm:string100" minOccurs="0"/>
<xs:element name="county" type="rdm:string100"/>
<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="xs:date"/>
```



MAA-Human

There was two changes applied to the human form

Schema File Affected: maa_human.xsd

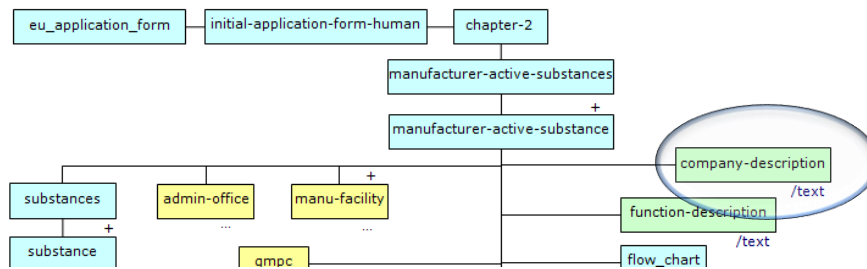
Change Request Reference: SD-81544

1.Summary of Human change (SD-81544):

New free text field has been added in section 2-5-3

Extract from Human DES:

Element Tree Diagram



Original eaf_Dictionary xsd Schema definition:

```

496 <xs:complexType name="manufacturer-active-substance">
497   <xs:sequence>
498     <xs:element name="active-substances" minOccurs="1" maxOccurs="unbounded">
499       <xs:complexType>
500         <xs:sequence>
501           <xs:element name="active-substance" type="rdm:ingredient" minOccurs="1" maxOccurs="unbounded"/>
502         </xs:sequence>
503       </xs:complexType>
504     </xs:element>
505     <xs:element name="contact-details" type="rdm:contact-details-type"/>
  
```

Updated/Amended eaf_Dictionary xsd Schema Definition:

```

496 <xs:complexType name="manufacturer-active-substance">
497   <xs:sequence>
498     <xs:element name="active-substances" minOccurs="1" maxOccurs="unbounded">
499       <xs:complexType>
500         <xs:sequence>
501           <xs:element name="active-substance" type="rdm:ingredient" minOccurs="1" maxOccurs="unbounded"/>
502         </xs:sequence>
503       </xs:complexType>
504     </xs:element>
505     <xs:element name="company-description" type="xs:string"/>
  
```

The new node in section-2-5-3

```
<xs:element name="company-description" type="xs:string"/>
```

2.Summary of Human change (SD-124981)

Section 1.1.2 - "Proposed/Agreed common renewal date" field type has been changed to String

Original eaf_Dictionary xsd Schema definition:

```
<xs:element name="proposed-agreed-renewal-date" type="xs:date"/>
```

Updated/Amended eaf_Dictionary xsd schema definition:

```
<xs:element name="proposed-agreed-renewal-date" type="xs:string"/>
```

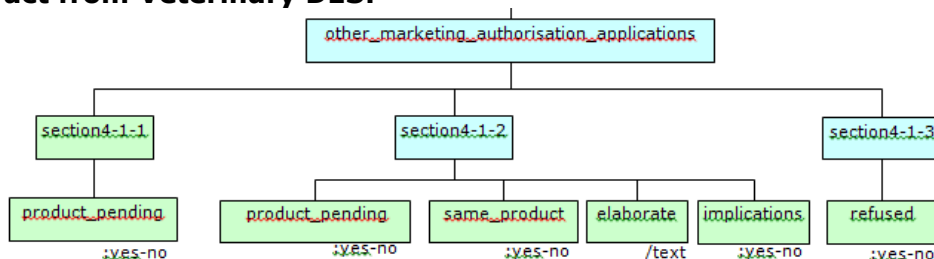


MAA-VET

There are four changes applied to the Veterinary form.

1. Summary of VET change (SD-105001):

Not Applicable check box has been removed from 4.1.1 section

Extract from Veterinary DES:**Original Vet xsd Schema definition:**

```

<xs:element name="other_marketing_authorisation_applications">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="section4-1-1">
        <xs:complexType>
          <xs:sequence>
            <xs:element name="product_pending" type="rdm:yes-no"/>
            <xs:element name="product_pending_NA" type="rdm:yes-no"/>
          </xs:sequence>
        </xs:complexType>
      </xs:element>
    </xs:sequence>
  </xs:complexType>
</xs:element>
  
```

Updated/Amended Vet xsd Schema Definition:

```

<xs:element name="other_marketing_authorisation_applications">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="section4-1-1">
        <xs:complexType>
          <xs:sequence>
            <xs:element name="product_pending" type="rdm:yes-no"/>
          </xs:sequence>
        </xs:complexType>
      </xs:element>
    </xs:sequence>
  </xs:complexType>
</xs:element>
  
```

The product_pending_NA node is removed :

```

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

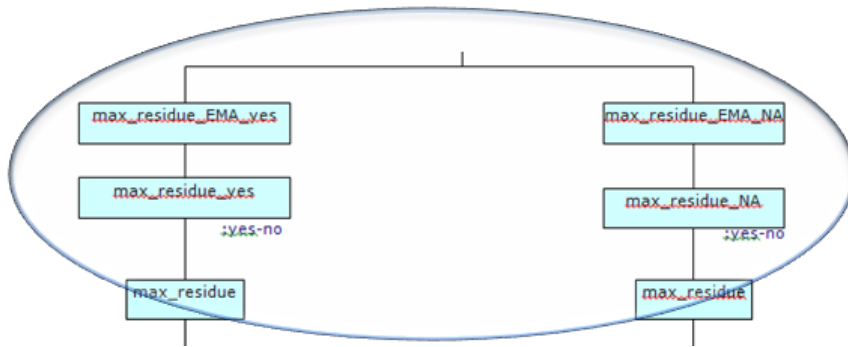
2. Summary of Vet change (SD-106023):

In Application for a Maximum Residue Limit has been made to the EMA - "Yes" and "Not" applicable should be changed from radio boxes into check boxes.

- When "Yes" is selected then **Substance, Date of Submission, Species** and **Remarks** should be displayed below.
- When "Not Applicable" is selected then **Substance, Species** and **Remarks** should be displayed and Date of submission should be hidden.



Extract from Veterinary DES:



Original vet xsd Schema definition:

```

<xs:element name="max_residue_EMA" type="rdm:yes-no"/>
<xs:element name="max_residue" maxOccurs="unbounded">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="active-substances" minOccurs="0">
        <xs:complexType>
          <xs:sequence>
            <xs:element name="active-substance" type="rdm:ingredient" minOccurs="1" maxOccurs="unbounded"/>
          </xs:sequence>
        </xs:complexType>
      </xs:element>
      <xs:element name="temp-substances" type="xs:string"/>
      <xs:element name="date_of_submission" type="xs:date"/>
      <xs:element name="species_set" maxOccurs="unbounded">
        <xs:complexType>
          <xs:sequence>
            <xs:element name="species" type="rdm:control-term"/>
          </xs:sequence>
        </xs:complexType>
      </xs:element>
      <xs:element name="remarks" type="rdm:string50"/>
    </xs:sequence>
  </xs:complexType>
</xs:element>
  
```

Updated/Amended vet xsd Schema Definition:

```

<xs:element name="max_residue_EMA_Yes" maxOccurs="unbounded">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="max_residue_yes" type="rdm:yes-no"/>
      <xs:element name="max_residue" maxOccurs="unbounded">
        <xs:complexType>
          <xs:sequence>
            <xs:element name="active-substances" minOccurs="0">
              <xs:complexType>
                <xs:sequence>
                  <xs:element name="active-substance" type="rdm:ingredient" minOccurs="1" maxOccurs="unbounded"/>
                </xs:sequence>
              </xs:complexType>
            </xs:element>
            <xs:element name="temp-substances" type="xs:string"/>
            <xs:element name="date_of_submission" type="xs:date"/>
            <xs:element name="species_set" maxOccurs="unbounded">
              <xs:complexType>
                <xs:sequence>
                  <xs:element name="species" type="rdm:control-term"/>
                </xs:sequence>
              </xs:complexType>
            </xs:element>
            <xs:element name="remarks" type="rdm:string50"/>
          </xs:sequence>
        </xs:complexType>
      </xs:element>
    </xs:sequence>
  </xs:complexType>
</xs:element>
  
```



```

<xs:element name="max_residue_EMA_NA" maxOccurs="unbounded">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="max_residue_NA" type="rdm:yes-no"/>
      <xs:element name="max_residue" maxOccurs="unbounded">
        <xs:complexType>
          <xs:sequence>
            <xs:element name="active-substances" minOccurs="0">
              <xs:complexType>
                <xs:sequence>
                  <xs:element name="active-substance" type="rdm:ingredient" minOccurs="1" maxOccurs="unbounded"/>
                </xs:sequence>
              </xs:complexType>
            </xs:element>
            <xs:element name="temp-substances" type="xs:string"/>
            <xs:element name="species_set" maxOccurs="unbounded">
              <xs:complexType>
                <xs:sequence>
                  <xs:element name="species" type="rdm:control-term"/>
                </xs:sequence>
              </xs:complexType>
            </xs:element>
            <xs:element name="remarks" type="rdm:string50"/>
          </xs:sequence>
        </xs:complexType>
      </xs:element>
    </xs:sequence>
  </xs:complexType>
</xs:element>

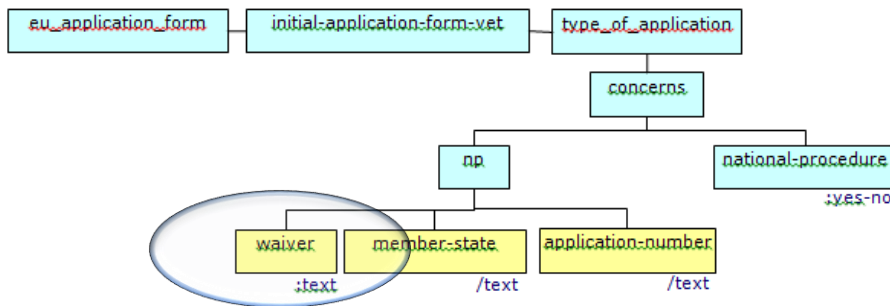
```

3. Summary of Vet change (SD-124640):

This is a NTA change request which has below changes.

a). Section 1.1.4 "If a waiver or amendment of PSUR-cycle is applied for, to harmonise with a substance birth-date, please specify" text field has been implemented.

Extract from Veterinary DES:



Original Vet xsd Schema definition:

```

<xs:element name="np">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="member_state" type="xs:string"/>
      <xs:element name="application_number" type="rdm:string30"/>
      <!-- <xs:element name="waiver" type="xs:string"/> removed in version 7.3 word form -->
      <!-- <xs:element name="date" type="xs:date"/> removed in version 7.3 word form -->
    </xs:sequence>
  </xs:complexType>
</xs:element>

```

Updated/Amended Vet xsd Schema Definition:

```

<xs:element name="np">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="member_state" type="xs:string"/>
      <xs:element name="application_number" type="rdm:string30"/>
      <xs:element name="waiver" type="xs:string"/> <!-- removed in version 7.3 word form and then added again 7.5-->
      <!-- <xs:element name="date" type="xs:date"/> removed in version 7.3 word form -->
    </xs:sequence>
  </xs:complexType>
</xs:element>

```

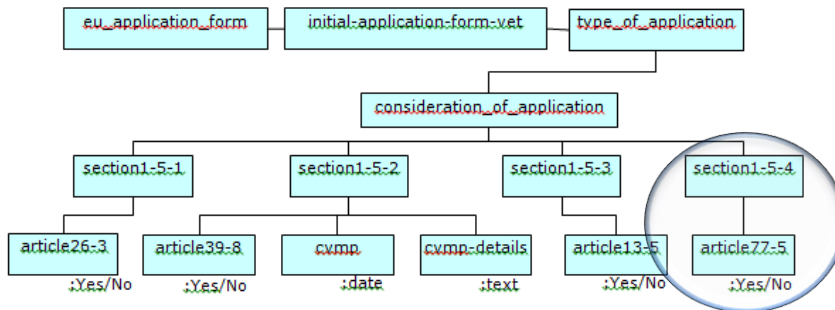
The new node in section-1-1-4 has been added

```
<xs:element name="waiver" type="xs:string"/>
```



b). Section 1.5.4 "Article 77 (5) of Directive 2001/82/EC and Article 49 (3) of Regulation (EC) No 726/2004 (other requirements for the PSUR submission cycle" . The new Check box has been implemented.

Extract from Veterinary DES:



Original Vet xsd Schema definition:

This is a new field no xsd element for this before.

Updated/Amended Vet xsd Schema Definition:

```

<xs:element name="section1-5-4">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="article77-5" type="rdm:yes-no"/>
    </xs:sequence>
  </xs:complexType>
</xs:element>
    
```

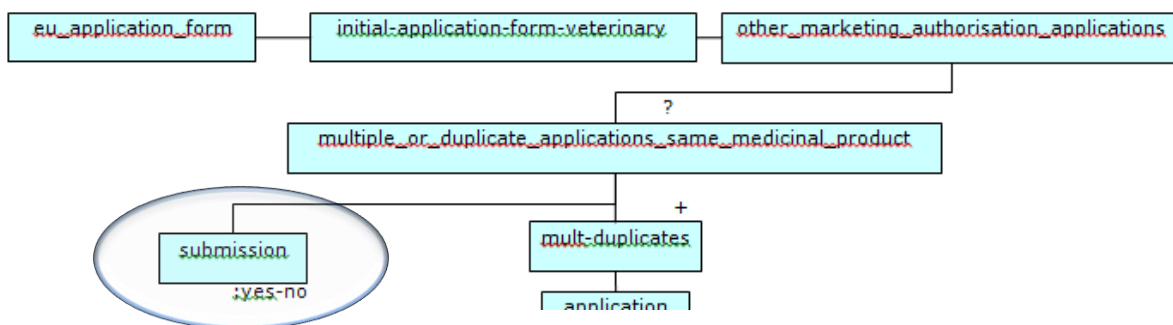
The new node in section-1-5-4 has been added

```

<xs:element name="article77-5" type="rdm:yes-no"/>
    
```

c). Section 4.3 "Multiple applications submitted simultaneously or subsequently to the initial application/MA for" . The new radio button has been implemented.

Extract from Veterinary DES:



Original Vet xsd Schema definition:

```

<xs:element name="multiple_or_duplicate_applications_same_medical_product">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="mult-duplicates">
        <xs:complexType>
          <xs:sequence>
            <xs:element name="application" type="rdm:application"/>
          </xs:sequence>
        </xs:complexType>
      </xs:element>
    </xs:sequence>
  </xs:complexType>
</xs:element>
    
```



Updated/Amended Vet xsd Schema Definition:

```

<xs:element name="multiple_or_duplicate_applications_same_medicinal_product">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="submission" type="rdm:yes-no"/>
      <xs:element name="mult-duplicates">
        <xs:complexType>
          <xs:sequence>

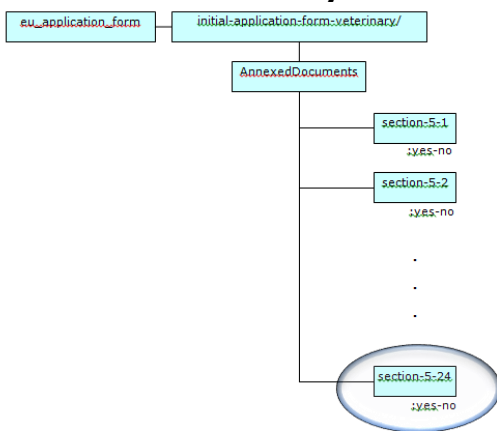
```

The new node in section-1-5-4 has been added

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

d). Section 5.24 "Justification for requesting deviation from the 'standard' PSUR cycle as stated in legislation." . The new annex check box has been implemented.

Extract from Veterinary DES



Original Vet xsd Schema definition:

```

<xs:element name="annex5-22" type="rdm:yes-no"/>
<xs:element name="annex5-23" type="rdm:yes-no"/>
</xs:sequence>

```

Updated/Amended Vet xsd Schema Definition:

```

<xs:element name="annex5-22" type="rdm:yes-no"/>
<xs:element name="annex5-23" type="rdm:yes-no"/>
<xs:element name="annex5-24" type="rdm:yes-no"/>

```

4.Summary of Human change (SD-124981)

Section 1.1.2 - "Proposed/Agreed common renewal date" field type has been changed to String

Original eaf_Dictionary xsd Schema definition:

```
<xs:element name="proposed-agreed-renewal-date" type="xs:date"/>
```

Updated/Amended eaf_Dictionary xsd schema definition:

```
<xs:element name="proposed-agreed-renewal-date" type="xs:string"/>
```



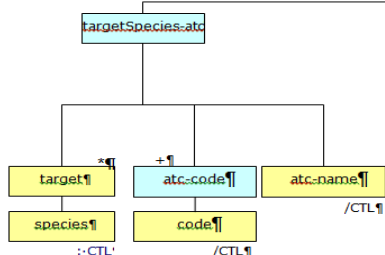
RENEWAL

There are four changes applied to the Veterinary form.

1. Summary of RENEWAL change (SD-105670):

Not Applicable check box has been removed from 4.1.1 section

Extract from Renewal DES: _



The atc-status node is removed :

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

2. Summary of RENEWAL change (SD-105187):

New nameless free text field has been added in section 2 – Batch Control Testing

Updated/Amended Renewal xsd Schema Definition:

```

<xs:complexType name="role">
  <xs:sequence>
    <xs:element name="party-identification" minOccurs="0" maxOccurs="unbounded"/>
    <xs:element name="party-relationship" type="rdm:CTL" minOccurs="0"/>
    <xs:element name="business-category" type="rdm:CTL" minOccurs="0"/>
    <xs:element name="party-type" type="rdm:CTL" minOccurs="0"/>
    <xs:element name="personal-title" type="rdm:string10" minOccurs="0"/>
    <xs:element name="job-title" type="rdm:string50" minOccurs="0"/>
    <xs:element name="given-name" type="rdm:string50"/>
    <xs:element name="middle-name" type="rdm:string50" minOccurs="0"/>
    <xs:element name="family-name" type="rdm:string50"/>
    <xs:element name="initials" type="rdm:string10" minOccurs="0"/>
    <xs:element name="qualifications" type="rdm:CTL" minOccurs="0"/>
    <xs:element name="gender" type="rdm:CTL" minOccurs="0"/>
    <xs:element name="name" type="rdm:string100"/>
    <xs:element name="company-description" type="xs:string"/>
    <xs:element name="contact-details" type="rdm:contact-details-type" minOccurs="0"/>
  
```

The new node in section-2 – Batch Control Testing has been added

```
<xs:element name="company-description" type="xs:string"/>
```

3. Summary of RENEWAL change (SD-105185):

New nameless free text field has been added in section 2 – Manufacturer of Active Substance(s)

Updated/Amended Renewal xsd Schema Definition:

```

<xs:complexType name="role">
  <xs:sequence>
    <xs:element name="party-identification" minOccurs="0" maxOccurs="unbounded"/>
    <xs:element name="party-relationship" type="rdm:CTL" minOccurs="0"/>
    <xs:element name="business-category" type="rdm:CTL" minOccurs="0"/>
    <xs:element name="party-type" type="rdm:CTL" minOccurs="0"/>
    <xs:element name="personal-title" type="rdm:string10" minOccurs="0"/>
    <xs:element name="job-title" type="rdm:string50" minOccurs="0"/>
    <xs:element name="given-name" type="rdm:string50"/>
    <xs:element name="middle-name" type="rdm:string50" minOccurs="0"/>
    <xs:element name="family-name" type="rdm:string50"/>
    <xs:element name="initials" type="rdm:string10" minOccurs="0"/>
    <xs:element name="qualifications" type="rdm:CTL" minOccurs="0"/>
    <xs:element name="gender" type="rdm:CTL" minOccurs="0"/>
    <xs:element name="name" type="rdm:string100"/>
    <xs:element name="company-description" type="xs:string"/>
    <xs:element name="contact-details" type="rdm:contact-details-type" minOccurs="0"/>
  
```



The new node in section-2 – Manufacturer of Active Substance(s) has been added
`<xs:element name="company-description" type="xs:string"/>`

4. Summary of RENEWAL change (SD-125823):

New check box and free text field has been added in section 4 – Documents appended to this application – For Human Medicinal Products only and For Veterinary Medicinal Products only. And when National Authorisation in MRP/DCP and National Applications selected this will be visible.

For Human - Updated/Amended Renewal xsd Schema Definition

```

<xs:element name="annex">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="human-annex">
        <xs:complexType>
          <xs:sequence>
            <xs:element name="simplifiedProcedure" type="rdm:yes-no"/>
            <xs:element name="simplifiedProcedureReason" type="xs:string"/>
            <xs:element name="cover-letter" type="rdm:yes-no"/>
            <xs:element name="table-of-content" type="rdm:yes-no"/>
            <xs:element name="following-annexes" type="rdm:yes-no"/>
          </xs:sequence>
        </xs:complexType>
      </xs:element>
    </xs:sequence>
  </xs:complexType>
</xs:element>

```

For VET - Updated/Amended Renewal xsd Schema Definition

```

<xs:element name="veterinary-annex">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="simplifiedProcedure" type="rdm:yes-no"/>
      <xs:element name="simplifiedProcedureReason" type="xs:string"/>
      <xs:element name="cover-letter" type="rdm:yes-no"/>
      <xs:element name="table-of-content" type="rdm:yes-no"/>
    </xs:sequence>
  </xs:complexType>
</xs:element>

```

The new node in section-4 – Human / Vet Documentation

```

<xs:element name="simplifiedProcedure" type="rdm:yes-no"/>
<xs:element name="simplifiedProcedureReason" type="xs:string"/>

```

Variation form

There was no individual change other than oms integration.

