

MAA-Veterinary Form DES Changes

Note: Text highlighted in **green** represents additions, text highlighted in **red** represents deletions, and text highlighted in **orange** represents modifications.

MAA Veterinary schema XSD (maa_veterinary.xsd)

From:

```
<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="1.26.0.1">
```

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="1.28.0.0">
```

From:

```
<xs:element name="ms">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="cbArticle42_2_a_i" type="rdm:yes-no"/>
      <xs:element name="cbArticle42_2_a_ii" type="rdm:yes-no"/>
      <xs:element name="cbArticle42_2_a_iii" type="rdm:yes-no"/>
      <xs:element name="cbArticle42_2_b" type="rdm:yes-no"/>
      <xs:element name="cbArticle42_2_c" type="rdm:yes-no"/>
      <xs:element name="cbArticle42_2_d" type="rdm:yes-no"/>
      <xs:element name="cbArticle42_2_e" type="rdm:yes-no"/>
    </xs:sequence>
  </xs:complexType>
</xs:element>
```

To:

```
<xs:element name="ms">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="cbArticle42_2_a_i" type="rdm:yes-no"/>
      <xs:element name="cbArticle42_2_a_ii" type="rdm:yes-no"/>
      <xs:element name="cbArticle42_2_a_iii" type="rdm:yes-no"/>
      <xs:element name="cbArticle42_2_b" type="rdm:yes-no"/>
      <xs:element name="cbArticle42_2_c" type="rdm:yes-no"/>
      <xs:element name="cbArticle42_2_d" type="rdm:yes-no"/>
      <xs:element name="cbArticle42_2_e" type="rdm:yes-no"/>
      <xs:element name="acceptance_cvmp"/>
      <xs:element name="ema-procedure-number" type="xs:string"/>
      <xs:element name="rapporteur-selected" type="rdm:yes-no"/>
      <xs:element name="rapporteur" type="rdm:contact-details-type"/>
      <xs:element name="co-rapporteur-selected" type="rdm:yes-no"/>
      <xs:element name="co-rapporteur" type="rdm:contact-details-type"/>
    </xs:sequence>
  </xs:complexType>
</xs:element>
```

From:

```
<xs:element name="os">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="cbArticle42_4" type="rdm:yes-no"/>
```

```

        <xs:element name="acceptance_cvmp"/>
        <xs:element name="ema-procedure-number" type="xs:string"/>
    </xs:sequence>
</xs:complexType>
</xs:element>
</xs:sequence>
To:
<xs:element name="os">
    <xs:complexType>
        <xs:sequence>
            <xs:element name="cbArticle42_4" type="rdm:yes-no"/>
            <xs:element name="acceptance_cvmp"/>
            <xs:element name="ema-procedure-number" type="xs:string"/>
            <xs:element name="rapporteur-selected" type="rdm:yes-no"/>
            <xs:element name="rapporteur" type="rdm:contact-details-type"/>
            <xs:element name="co-rapporteur-selected" type="rdm:yes-no"/>
            <xs:element name="co-rapporteur" type="rdm:contact-details-type"/>
        </xs:sequence>
    </xs:complexType>
</xs:element>

```

From:

```

<xs:element name="mutual-procedure" type="rdm:yes-no"/>
<xs:element name="mutual-recognition-procedure" type="rdm:mutual-recognition-procedure" minOccurs="0"/>

```

To:

```

<xs:element name="mutual-procedure" type="rdm:yes-no"/>
<xs:element name="mutual-recognition-procedure">
    <xs:complexType>
        <xs:sequence>
            <xs:element name="reference-member-state" type="xs:string"/>
            <xs:element name="date-of-authorisation" type="xs:date"/>
            <xs:element name="market-authorisation-number" type="rdm:string100"/>
            <xs:element name="procedure-number" type="rdm:string100"/>
            <xs:element name="member_state" maxOccurs="unbounded">
                <xs:complexType>
                    <xs:sequence>
                        <xs:element name="member_state" type="xs:string"/>
                    </xs:sequence>
                </xs:complexType>
            </xs:element>
        </xs:sequence>
    </xs:complexType>
</xs:element>
<!-- 1.1.4 SRP -->
<xs:element name="subsequent-procedure" type="rdm:yes-no"/>
<xs:element name="subsequent-recognition-procedure">
    <xs:complexType>
        <xs:sequence>
            <xs:element name="reference-member-state" type="xs:string"/>
            <xs:element name="date-of-authorisation" type="xs:date"/>
            <xs:element name="market-authorisation-number" type="rdm:string100"/>
            <xs:element name="procedure-number" type="rdm:string100"/>
            <xs:element name="member_state" maxOccurs="unbounded">
                <xs:complexType>
                    <xs:sequence>
                        <xs:element name="member_state" type="xs:string"/>
                    </xs:sequence>
                </xs:complexType>
            </xs:element>

            <xs:element name="member-state-original" maxOccurs="unbounded">
                <xs:complexType>

```

```

                <xs:sequence>
                    <xs:element name="member_state" maxOccurs="unbounded">
                        <xs:complexType>
                            <xs:sequence>
                                <xs:element name="member_state" type="xs:string"/>
                            </xs:sequence>
                        </xs:complexType>
                    </xs:element>
                </xs:sequence>
            </xs:complexType>
        </xs:element>

```

Form:

```

<xs:element name="section1-3-1">
    <xs:complexType>
        <xs:sequence>
            <xs:element name="article8" 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>

```

To:

```

<xs:element name="section1-3-1">
    <xs:complexType>
        <xs:sequence>
            <xs:element name="article8" 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:sequence>
    </xs:complexType>
</xs:element>

```

From:

```

<xs:element name="second-rmp">
    <xs:complexType>
        <xs:sequence>
            <xs:element name="reference-medicinal-product" type="rdm:reference-medicinal-product-type"
maxOccurs="unbounded"/>
            <xs:element name="member_state" type="xs:string"/>
            <xs:element name="change-active-substance" type="rdm:yes-no"/>
            <xs:element name="change-therapeutic-indication" type="rdm:yes-no"/>
            <xs:element name="change-strength" type="rdm:yes-no"/>
            <xs:element name="change-addition" type="rdm:yes-no"/>
            <xs:element name="route-admin" type="rdm:yes-no"/>
            <xs:element name="bioequivalence" type="rdm:yes-no"/>
            <xs:element name="raw-materials" type="rdm:yes-no"/>
            <xs:element name="manufacturing-process" type="rdm:yes-no"/>
            <xs:element name="other" type="rdm:yes-no"/>
        </xs:sequence>
    </xs:complexType>
</xs:element>

```

To :

```

<xs:element name="second-rmp">
    <xs:complexType>
        <xs:sequence>

```

```

maxOccurs="unbounded"/>
    <xs:element name="reference-medicinal-product" type="rdm:reference-medicinal-product-type"
    <xs:element name="member_state" type="xs:string"/>
    <xs:element name="change-active-substance" type="rdm:yes-no"/>
    <xs:element name="change-therapeutic-indication" type="rdm:yes-no"/>
    <xs:element name="change-strength" type="rdm:yes-no"/>
    <xs:element name="change-addition" type="rdm:yes-no"/>
    <xs:element name="route-admin" type="rdm:yes-no"/>
    <xs:element name="bioequivalence" type="rdm:yes-no"/>
    <xs:element name="raw-materials" type="rdm:yes-no"/>
    <xs:element name="manufacturing-process" type="rdm:yes-no"/>
    <xs:element name="change-withdrawal-period" type="rdm:yes-no"/>
    <xs:element name="change-target-species" type="rdm:yes-no"/>
    <xs:element name="third-country" type="rdm:yes-no"/>
    <xs:element name="other" type="rdm:yes-no"/>
    <xs:element name="txtOther" type="rdm:string100"/>
  </xs:sequence>
</xs:complexType>
</xs:element>

```

From :

```

<xs:element name="section1-3-7">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="article23" type="rdm:yes-no"/>
      <xs:element name="acceptance-date" type="xs:date"/>
    </xs:sequence>
  </xs:complexType>
</xs:element>

```

To :

```

<xs:element name="section1-3-7">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="article23" type="rdm:yes-no"/>
      <xs:element name="acceptance-date" type="xs:date"/>
      <xs:element name="new-active-substance" type="rdm:yes-no"/>
      <xs:element name="known-active-substance" type="rdm:yes-no"/>
    </xs:sequence>
  </xs:complexType>
</xs:element>

```

From:

```

<xs:element name="section1-3-8">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="exceptional" type="rdm:yes-no"/>
      <xs:element name="acceptance-date" type="xs:date"/>
    </xs:sequence>
  </xs:complexType>
</xs:element>

```

To:

```

<xs:element name="section1-3-8">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="exceptional" 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="acceptance-date" type="xs:date"/>
    </xs:sequence>

```

```
        </xs:complexType>
    </xs:element>
```

From:

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

To:

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

```
<!-- Excipients -->
<xs:element name="excipients">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="commission_regulation" maxOccurs="unbounded">
        <xs:complexType>
          <xs:sequence>
            <xs:element name="active-substances">
              <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="mrl_details" minOccurs="1" maxOccurs="unbounded">
              <xs:complexType>
                <xs:sequence>
                  <xs:element name="marker_residue" type="rdm:string50"/>
                  <xs:element name="multi_animal_species" maxOccurs="unbounded">
                    <xs:complexType>
                      <xs:sequence>
                        <xs:element name="animal_species" type="rdm:control-term"/>
                      </xs:sequence>
                    </xs:complexType>
                  </xs:element>
                  <xs:element name="mrl_target_tissues" minOccurs="0" maxOccurs="unbounded">
                    <xs:complexType>
                      <xs:sequence>
                        <xs:element name="mrl" type="rdm:string50"/>
                        <xs:element name="target_tissue" type="rdm:control-term"/>
                      </xs:sequence>
                    </xs:complexType>
                  </xs:element>
                  <xs:element name="other_provisions" minOccurs="0" maxOccurs="unbounded">
                    <xs:complexType>
                      <xs:sequence>
                        <xs:element name="other_previsions" type="rdm:control-term"/>
                      </xs:sequence>
                    </xs:complexType>
                  </xs:element>
                  <xs:element name="therapeutic_classification" type="rdm:string50"/>
                  <xs:element name="date_of_publication" type="xs:date"/>
                </xs:sequence>
              </xs:complexType>
            </xs:element>
          </xs:sequence>
        </xs:complexType>
      </xs:element>
      <xs:element name="substances" type="xs:string"/>
    </xs:sequence>
  </xs:complexType>
</xs:element>
```

From:

```
<xs:element name="section2-1-3">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="atc" type="rdm:atc"/>
      <xs:element name="target_species" maxOccurs="unbounded">
        <xs:complexType>
          <xs:sequence>
            <xs:element name="species" type="rdm:control-term"/>
          </xs:sequence>
        </xs:complexType>
      </xs:element>
    </xs:sequence>
  </xs:complexType>
</xs:element>
```

```
<xs:element name="section2-1-4">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="withdrawal-period-check" type="rdm:yes-no"/>
      <xs:element name="withdrawal-period" maxOccurs="unbounded">
        <xs:complexType>
          <xs:sequence>
            <xs:element name="route-of-administration" maxOccurs="unbounded">
              <xs:complexType>
                <xs:sequence>
                  <xs:element name="name" type="rdm:control-term"/>
                  <xs:element name="code" type="rdm:control-term"/>
                </xs:sequence>
              </xs:complexType>
            </xs:element>
            <xs:element name="target-species" type="rdm:control-term"/>
            <xs:element name="target-tissue" type="rdm:control-term"/>
            <xs:element name="period" type="rdm:string30"/>
            <xs:element name="units" type="xs:string"/>
            <xs:element name="note" type="xs:string"/>
          </xs:sequence>
        </xs:complexType>
      </xs:element>
    </xs:sequence>
  </xs:complexType>
</xs:element>
```

To:

```
<xs:element name="section2-1-3">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="atc" type="rdm:atc"/>
      <xs:element name="target_species" maxOccurs="unbounded">
        <xs:complexType>
          <xs:sequence>
            <xs:element name="species" type="rdm:control-term"/>
          </xs:sequence>
        </xs:complexType>
      </xs:element>
    </xs:sequence>
  </xs:complexType>
</xs:element>
```

From:

```
<xs:element name="medicinal-product" type="rdm:medicinal-product"/>
```

```
<xs:element name="annex5-17" type="rdm:yes-no"/>
```

To:

```
<!-- Section 2.2 Begin -->
```

```
<xs:element name="medicinal-product" type="rdm:medicinal-product" maxOccurs="unbounded"/>
```

```
<xs:element name="annex5-17" type="rdm:yes-no"/>
```

```
<!-- Section 2.2 End -->
```

From:

```
<xs:element name="contact-pharmaco-vigilance" maxOccurs="unbounded">
```

```
  <xs:complexType>
```

```
    <xs:sequence>
```

```
      <xs:element name="contact-details" type="rdm:contact-details-type"/>
```

```
      <xs:element name="reference-number" type="rdm:string30"/>
```

```
      <xs:element name="pharma-system-address" type="rdm:contact-details-type"/>
```

```
    </xs:sequence>
```

```
  </xs:complexType>
```

```
</xs:element>
```

To:

```
<xs:element name="contact-pharmaco-vigilance" maxOccurs="unbounded">
```

```
  <xs:complexType>
```

```
    <xs:sequence>
```

```
      <xs:element name="contact-details" type="rdm:contact-details-type"/>
```

```
      <xs:element name="reference-number" type="rdm:string500"/>
```

```
      <xs:element name="pharma-system-address" type="rdm:contact-details-type"/>
```

```
    </xs:sequence>
```

```
  </xs:complexType>
```

```
</xs:element>
```

From:

```
<xs:element name="compositions">
```

```
  <xs:complexType>
```

```
    <xs:sequence>
```

```
      <xs:element name="medicinal-product" type="rdm:medicinal-product"/>
```

```
    </xs:sequence>
```

```
  </xs:complexType>
```

```
</xs:element>
```

To:

```
<xs:element name="compositions">
```

```
  <xs:complexType>
```

```
    <xs:sequence>
```

```
      <xs:element name="medicinal-product" type="rdm:medicinal-product" maxOccurs="unbounded"/>
```

```
    </xs:sequence>
```

```
  </xs:complexType>
```

```
</xs:element>
```

From:

```
<xs:element name="application" maxOccurs="unbounded">
```

```
  <xs:complexType>
```

```
    <xs:sequence>
```

```
      <xs:element name="product-name"/>
```

```
      <xs:element name="date-application"/>
```

```
      <xs:element name="applicant"/>
```

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

```
      <xs:element name="procedure-number" type="xs:string"/>
```

```
    </xs:sequence>
```

```
  </xs:complexType>
```

```
</xs:element>
```

To:

```
<xs:element name="application" maxOccurs="unbounded">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="product-name"/>
      <xs:element name="date-application"/>
      <xs:element name="applicant"/>
      <xs:element name="procedure-number" type="xs:string"/>
    </xs:sequence>
  </xs:complexType>
</xs:element>
```

Dictionary schema XSD (dictionary.xsd)

From:

```
<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="1.26.0.1">
```

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="1.28.0.0">
```

From:

```
<xs:element name="target_species" maxOccurs="unbounded">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="species" type="rdm:control-term"/>
    </xs:sequence>
  </xs:complexType>
</xs:element>
```

To:

```
<xs:element name="target_species" maxOccurs="unbounded">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="species" type="rdm:control-term"/>
      <xs:element name="withdrawal-period-check" type="rdm:yes-no"/>
      <xs:element name="withdrawal-period" maxOccurs="unbounded">
        <xs:complexType>
          <xs:sequence>
            <xs:element name="target-tissue" type="rdm:control-term"/>
            <xs:element name="period" type="rdm:string30"/>
            <xs:element name="units" type="xs:string"/>
            <xs:element name="note" type="xs:string"/>
          </xs:sequence>
        </xs:complexType>
      </xs:element>
    </xs:sequence>
  </xs:complexType>
</xs:element>
```

From:

```
<xs:simpleType name="string250">
  <xs:restriction base="xs:string">
```

```

        <xs:maxLength value="250"/>
    </xs:restriction>
</xs:simpleType>
To:
<xs:simpleType name="string250">
    <xs:restriction base="xs:string">
        <xs:maxLength value="250"/>
    </xs:restriction>
</xs:simpleType>
<xs:simpleType name="string500">
    <xs:restriction base="xs:string">
        <xs:maxLength value="500"/>
    </xs:restriction>
</xs:simpleType>

```

From:

```

<xs:complexType name="contact-batch-testing-site">
  <xs:complexContent>
    <xs:extension base="rdm:contact-details-type">
      <xs:sequence>
        <xs:element name="control-tests" minOccurs="1" maxOccurs="unbounded">
          <xs:complexType>
            <xs:sequence>
              <xs:element name="control-test" type="rdm:control-term"/>
            </xs:sequence>
          </xs:complexType>
        </xs:element>
        <xs:element name="function-description" type="xs:string"/>
        <xs:element name="attach-GMP-compliance" type="rdm:yes-no"/>
        <xs:element name="eudraGMP-auth-reference" type="xs:string"/>
        <xs:element name="attach-gmp-certificate" type="rdm:yes-no"/>
        <xs:element name="gmpc" type="rdm:gmpc"/>
      </xs:sequence>
    </xs:extension>
  </xs:complexContent>
</xs:complexType>

```

To :

```

<xs:complexType name="contact-batch-testing-site">
  <xs:complexContent>
    <xs:extension base="rdm:contact-details-type">
      <xs:sequence>
        <xs:element name="medicinal-product" maxOccurs="unbounded">
          <xs:complexType>
            <xs:sequence>
              <xs:element name="medicinal-product-id" type="rdm:string250"/>
            </xs:sequence>
          </xs:complexType>
        </xs:element>
        <xs:element name="control-tests" minOccurs="1" maxOccurs="unbounded">
          <xs:complexType>
            <xs:sequence>
              <xs:element name="control-test" type="rdm:control-term"/>
            </xs:sequence>
          </xs:complexType>
        </xs:element>
        <xs:element name="function-description" type="xs:string"/>
        <xs:element name="attach-GMP-compliance" type="rdm:yes-no"/>
        <xs:element name="eudraGMP-auth-reference" type="xs:string"/>
        <xs:element name="attach-gmp-certificate" type="rdm:yes-no"/>
        <xs:element name="gmpc" type="rdm:gmpc"/>
      </xs:sequence>
    </xs:extension>
  </xs:complexContent>
</xs:complexType>

```

```
</xs:extension>
</xs:complexContent>
</xs:complexType>
```

From :

```
<xs:complexType name="contact-blood-vaccine">
  <xs:complexContent>
    <xs:extension base="rdm:contact-details-type">
      <xs:sequence>
        <xs:element name="laboratory-name" type="xs:string"/>
      </xs:sequence>
    </xs:extension>
  </xs:complexContent>
</xs:complexType>
```

To :

```
<xs:complexType name="contact-blood-vaccine">
  <xs:complexContent>
    <xs:extension base="rdm:contact-details-type">
      <xs:sequence>
        <xs:element name="medicinal-product" maxOccurs="unbounded">
          <xs:complexType>
            <xs:sequence>
              <xs:element name="medicinal-product-id" type="rdm:string250"/>
            </xs:sequence>
          </xs:complexType>
        </xs:element>
        <xs:element name="laboratory-name" type="xs:string"/>
      </xs:sequence>
    </xs:extension>
  </xs:complexContent>
</xs:complexType>
```

From :

```
<xs:element name="lists" minOccurs="1" maxOccurs="1">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="countries" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
      <xs:element name="nonEEACountries" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
      <xs:element name="eeaCountries" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
      <xs:element name="euAndFreeTradeCountries" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
      <xs:element name="eeaCountriesExcludingUkNi" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
      <xs:element name="euAndEftaCountriesExcludingUkNi" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
      <xs:element name="eeaCountriesAndUkGb" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
      <xs:element name="pharmaForms" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
      <xs:element name="routesOfAdmin" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
      <xs:element name="strengthOperators" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
      <xs:element name="strengthUnits" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
      <xs:element name="containers" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
      <xs:element name="adminDevices" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
      <xs:element name="closures" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
      <xs:element name="specPrecaution4Storage" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
      <xs:element name="mrlSpecies" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
      <xs:element name="mrlProvision" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
      <xs:element name="tissueMRL" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
      <xs:element name="targetSpecies" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
      <xs:element name="manufacturerControlTests" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
      <xs:element name="manufacturerFunctions" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
      <xs:element name="manufacturerSteps" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
      <xs:element name="substanceType" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
    </xs:sequence>
  </xs:complexType>
</xs:element>
```

```

    <xs:element name="edibleTissue" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
    <xs:element name="pharmaceuticalForms" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
  </xs:sequence>
</xs:complexType>
</xs:element>
To :
<xs:element name="lists" minOccurs="1" maxOccurs="1">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="countries" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
      <xs:element name="nonEEACountries" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
      <xs:element name="eeaCountries" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
      <xs:element name="euAndFreeTradeCountries" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
      <xs:element name="eeaCountriesExcludingUkNi" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
      <xs:element name="euAndEftaCountriesExcludingUkNi" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
      <xs:element name="eeaCountriesAndUkGb" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
      <xs:element name="pharmaForms" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
      <xs:element name="routesOfAdmin" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
      <xs:element name="strengthOperators" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
      <xs:element name="strengthUnits" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
      <xs:element name="containers" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
      <xs:element name="adminDevices" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
      <xs:element name="closures" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
      <xs:element name="specPrecaution4Storage" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
      <xs:element name="mrlSpecies" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
      <xs:element name="mrlProvision" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
      <xs:element name="tissueMRL" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
      <xs:element name="targetSpecies" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
      <xs:element name="manufacturerControlTests" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
      <xs:element name="manufacturerFunctions" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
      <xs:element name="manufacturerSteps" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
      <xs:element name="substanceType" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
      <xs:element name="edibleTissue" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
      <xs:element name="pharmaceuticalForms" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
      <xs:element name="materials" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
      <xs:element name="pharmaDose" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
      <xs:element name="presentationUnits" type="rdm:eutctListType" minOccurs="1" maxOccurs="1"/>
    </xs:sequence>
  </xs:complexType>
</xs:element>

```

From :

```

<xs:element name="ph-eur-cert">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="substance-certificate" type="rdm:substance-certificate-with-address" maxOccurs="unbounded"/>
    </xs:sequence>
  </xs:complexType>
</xs:element>
To :
<xs:element name="ph-eur-cert">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="substance-certificate" type="rdm:substance-certificate-with-address" maxOccurs="unbounded"/>
    </xs:sequence>
  </xs:complexType>
</xs:element>
.....

```

```

<xs:complexType name="substance-certificate-with-address">
  <xs:complexContent>

```

```

        <xs:extension base="rdm:substance-certificate">
            <xs:sequence>
                <xs:element name="contact-details" type="rdm:contact-details-type"/>
            </xs:sequence>
        </xs:extension>
    </xs:complexContent>
</xs:complexType>

```

From :

```

<xs:complexType name="manufacturer-batch-release">
    <xs:sequence>
        <xs:element name="contact-details" type="rdm:contact-details-type"/>
        <xs:element name="manufacturing-auth-number" type="rdm:string100"/>
        <xs:element name="attach-annex5-6" type="rdm:yes-no"/>
        <xs:element name="eudraGMP-auth-reference" type="rdm:string100"/>
        <xs:element name="selecteudraGMP-auth-reference" minOccurs="0"/>
        <xs:element name="attach-gmp-certificate" type="rdm:yes-no"/>
        <xs:element name="eudraGMP-certificate-reference" type="rdm:string100"/>
        <xs:element name="selectedeudraGMP-certificate-reference" minOccurs="0"/>
        <xs:element name="package-responsible-manufacturer" type="rdm:string250"/>
    </xs:sequence>
</xs:complexType>

```

To :

```

<xs:complexType name="manufacturer-batch-release">
    <xs:sequence>
        <xs:element name="contact-details" type="rdm:contact-details-type"/>
        <xs:element name="manufacturing-auth-number" type="rdm:string100"/>
        <xs:element name="attach-annex5-6" type="rdm:yes-no"/>
        <xs:element name="eudraGMP-auth-reference" type="rdm:string100"/>
        <xs:element name="selecteudraGMP-auth-reference" minOccurs="0"/>
        <xs:element name="attach-gmp-certificate" type="rdm:yes-no"/>
        <xs:element name="eudraGMP-certificate-reference" type="rdm:string100"/>
        <xs:element name="selectedeudraGMP-certificate-reference" minOccurs="0"/>
        <xs:element name="package-responsible-manufacturer" type="rdm:string250"/>
        <xs:element name="medicinal-product" maxOccurs="unbounded">
            <xs:complexType>
                <xs:sequence>
                    <xs:element name="medicinal-product-id" type="rdm:string250"/>
                </xs:sequence>
            </xs:complexType>
        </xs:element>
    </xs:sequence>
</xs:complexType>

```

From:

```

<xs:complexType name="manufacturer-batch-testing-site">
    <xs:sequence>
        <xs:element name="desc"/>
        <xs:element name="control-tests" minOccurs="1" maxOccurs="unbounded">
            <xs:complexType>
                <xs:sequence>
                    <xs:element name="control-test" type="rdm:control-term"/>
                </xs:sequence>
            </xs:complexType>
        </xs:element>
        <xs:element name="attach-auth-gmp" type="rdm:yes-no"/>
        <xs:element name="eudraGMP-auth-reference"/>
        <xs:element name="selecteudraGMP-auth-reference" type="rdm:yes-no"/>
        <xs:element name="contact-details" type="rdm:contact-details-type"/>
    </xs:sequence>
</xs:complexType>

```

To:

```
<xs:complexType name="manufacturer-batch-testing-site">
  <xs:sequence>
    <xs:element name="medicinal-product" maxOccurs="unbounded">
      <xs:complexType>
        <xs:sequence>
          <xs:element name="medicinal-product-id" type="rdm:string250"/>
        </xs:sequence>
      </xs:complexType>
    </xs:element>
    <xs:element name="desc"/>
    <xs:element name="control-tests" minOccurs="1" maxOccurs="unbounded">
      <xs:complexType>
        <xs:sequence>
          <xs:element name="control-test" type="rdm:control-term"/>
        </xs:sequence>
      </xs:complexType>
    </xs:element>
    <xs:element name="attach-auth-gmp" type="rdm:yes-no"/>
    <xs:element name="eudraGMP-auth-reference"/>
    <xs:element name="selecteudraGMP-auth-reference" type="rdm:yes-no"/>
    <xs:element name="contact-details" type="rdm:contact-details-type"/>
  </xs:sequence>
</xs:complexType>
```

From:

```
<xs:complexType name="manufacturer-pharmaceutical-product">
  <xs:sequence>
    <xs:element name="partial-product-desc" type="xs:string"/>
    <xs:element name="contact-details" type="rdm:contact-details-type"/>
    <xs:element name="desc" type="xs:string"/>
    .....
  </xs:sequence>
</xs:complexType>
```

To:

```
<xs:complexType name="manufacturer-pharmaceutical-product">
  <xs:sequence>
    <xs:element name="medicinal-product" maxOccurs="unbounded">
      <xs:complexType>
        <xs:sequence>
          <xs:element name="medicinal-product-id" type="rdm:string250"/>
        </xs:sequence>
      </xs:complexType>
    </xs:element>
    <xs:element name="partial-product-desc" type="xs:string"/>
    <xs:element name="contact-details" type="rdm:contact-details-type"/>
    <xs:element name="desc" type="xs:string"/>
    .....
  </xs:sequence>
</xs:complexType>
```

From:

```
<xs:element name="package-size" maxOccurs="unbounded">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="size" type="xs:string"/>
    </xs:sequence>
  </xs:complexType>
</xs:element>
```

To :

```
<xs:element name="package-size" maxOccurs="unbounded">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="size" type="xs:string"/>
      <xs:element name="unit" type="rdm:control-term"/>
    </xs:sequence>
  </xs:complexType>
</xs:element>
```

From:

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

To:

```
<xs:element name="materials" maxOccurs="unbounded">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="material" type="rdm:control-term"/>
    </xs:sequence>
  </xs:complexType>
</xs:element>
```

From:

```
<xs:complexType name="route-of-administrations">
  <xs:sequence>
```

```
  <xs:element name="route-of-administration" minOccurs="0" maxOccurs="unbounded">
    <xs:complexType>
      <xs:sequence>
        <xs:element name="name" type="rdm:control-term" minOccurs="1" maxOccurs="1"/>
        <xs:element name="code" type="rdm:control-term" minOccurs="1" maxOccurs="1"/>
        <xs:element name="target_species" maxOccurs="unbounded">
          <xs:complexType>
            <xs:sequence>
              <xs:element name="species" type="rdm:control-term"/>
            </xs:sequence>
          </xs:complexType>
        </xs:element>
      </xs:sequence>
    </xs:complexType>
  </xs:element>
</xs:sequence>
</xs:complexType>
```

To :

```
<xs:complexType name="route-of-administrations">
  <xs:sequence>
    <xs:element name="administrative-dose" type="rdm:control-term"/>
    <xs:element name="route-of-administration" minOccurs="0" maxOccurs="unbounded">
      <xs:complexType>
        <xs:sequence>
          <xs:element name="name" type="rdm:control-term" minOccurs="1" maxOccurs="1"/>
          <xs:element name="code" type="rdm:control-term" minOccurs="1" maxOccurs="1"/>
          <xs:element name="target_species" maxOccurs="unbounded">
            <xs:complexType>
              <xs:sequence>
                <xs:element name="species" type="rdm:control-term"/>
                <xs:element name="withdrawal-period-check" type="rdm:yes-no"/>
                <xs:element name="withdrawal-period" maxOccurs="unbounded">
                  <xs:complexType>
                    <xs:sequence>
                      <xs:element name="target-tissue" type="rdm:control-term"/>
                      <xs:element name="period" type="rdm:string30"/>
                    </xs:sequence>
                  </xs:complexType>
                </xs:element>
              </xs:sequence>
            </xs:complexType>
          </xs:element>
        </xs:sequence>
      </xs:complexType>
    </xs:element>
  </xs:sequence>
</xs:complexType>
```

```

        <xs:element name="units" type="xs:string"/>
        <xs:element name="note" type="xs:string"/>
      </xs:sequence>
    </xs:complexType>
  </xs:element>
</xs:sequence>
</xs:complexType>
</xs:element>
</xs:sequence>
</xs:complexType>
</xs:element>
</xs:sequence>
</xs:complexType>

```

From:

```

<xs:complexType name="substance-certificate-vet">
  <xs:sequence>
    <xs:element name="active-substances">
      .....
    </xs:element>
  </xs:sequence>
</xs:complexType>

```

To:

```

<xs:complexType name="substance-certificate-vet">
  <xs:sequence>
    <xs:element name="contact-details" type="rdm:contact-details-type"/>
    <xs:element name="active-substances">
      .....
    </xs:element>
  </xs:sequence>
</xs:complexType>

```

From:

```

<xs:element name="pharmaceutical-form-details" maxOccurs="unbounded">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="pharmaceutical-form-strengths" maxOccurs="unbounded">
        ....
      </xs:element>
      ....
    </xs:sequence>
  </xs:complexType>
</xs:element>

```

To:

```

<xs:element name="pharmaceutical-form-details" maxOccurs="unbounded">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="manufactured-item" type="xs:string"/>
      <xs:element name="pharmaceutical-form-strengths" maxOccurs="unbounded">
        ....
      </xs:element>
      ....
    </xs:sequence>
  </xs:complexType>
</xs:element>

```

From:

```
<xs:element name="excipient-overages" minOccurs="0" maxOccurs="unbounded">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="substance-code" type="rdm:control-term"/>
      <xs:element name="overage" type="rdm:string250"/>
    </xs:sequence>
  </xs:complexType>
</xs:element>
```

To:

```
<xs:element name="excipient-overages" minOccurs="0" maxOccurs="unbounded">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="substance-code" type="rdm:control-term"/>
      <xs:element name="overage" type="rdm:string250"/>
    </xs:sequence>
  </xs:complexType>
</xs:element>
```

```
<xs:element name="manufactured-form" maxOccurs="unbounded">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="manufactured-id" type="rdm:string250"/>
      <xs:element name="manufactured-dose" type="rdm:control-term"/>
      <xs:element name="presentation-unit" type="rdm:control-term"/>
    </xs:sequence>
  </xs:complexType>
</xs:element>
```

From:

```
<xs:complexType name="medicinal-product">
  <xs:sequence>
    <xs:element name="invented-name" type="rdm:string250"/>
    <xs:element name="pharmaceutical-products">
      <xs:complexType>
        <xs:sequence>
          <xs:element name="pharmaceutical-product" type="rdm:pharmaceutical-
product" maxOccurs="unbounded"/>
        </xs:sequence>
      </xs:complexType>
    </xs:element>
    <xs:element name="therapeutic-indications" maxOccurs="unbounded">
      <xs:complexType>
        <xs:sequence>
          <xs:element name="therapeutic-indication" type="xs:string"/>
        </xs:sequence>
      </xs:complexType>
    </xs:element>
    <xs:element name="atc" type="rdm:atc" maxOccurs="unbounded"/>
    <xs:element name="packages" type="rdm:packages" minOccurs="0"/>
    <xs:element name="route-of-administrations" type="rdm:route-of-administrations" minOccurs="0"/>
  </xs:sequence>
</xs:complexType>
```

To:

```
<xs:complexType name="medicinal-product">
  <xs:sequence>
    <xs:element name="medicinal-product-id" type="rdm:string250"/>
    <xs:element name="invented-name" type="rdm:string250"/>
    <xs:element name="pharmaceutical-products">
      <xs:complexType>
        <xs:sequence>
```

```

        <xs:element name="pharmaceutical-product" type="rdm:pharmaceutical-
product" maxOccurs="unbounded"/>
    </xs:sequence>
</xs:complexType>
</xs:element>
<xs:element name="therapeutic-indications" maxOccurs="unbounded">
    <xs:complexType>
        <xs:sequence>
            <xs:element name="therapeutic-indication" type="xs:string"/>
        </xs:sequence>
    </xs:complexType>
</xs:element>
<xs:element name="atc" type="rdm:atc" maxOccurs="unbounded"/>
<xs:element name="packages" type="rdm:packages" minOccurs="0"/>
<xs:element name="route-of-administrations" type="rdm:route-of-administrations" minOccurs="0"/>
</xs:sequence>
</xs:complexType>

```

From:

```

<xs:complexType name="manu-facility">
    <xs:sequence>
        <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="poBox" 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:string30"/>
        <xs:element name="locID" type="rdm:string30"/>
        <xs:element name="loc-modifiedDate" type="xs:date"/>
        <xs:element name="org-modifiedDate" type="xs:date"/>
        <xs:element name="language" type="rdm:string30"/>
        <xs:element name="phone" type="rdm:string50"/>
        <xs:element name="email" type="rdm:string100"/>
    </xs:sequence>
</xs:complexType>

```

To:

```

<xs:complexType name="manu-facility">
    <xs:sequence>
        <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="poBox" 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:string30"/>
        <xs:element name="locID" type="rdm:string30"/>
        <xs:element name="loc-modifiedDate" type="xs:date"/>
        <xs:element name="org-modifiedDate" type="xs:date"/>
        <xs:element name="language" type="rdm:string30"/>
    </xs:sequence>

```

```
<xs:element name="phone" type="rdm:string50"/>
<xs:element name="email" type="rdm:string100"/>
<xs:element name="function-description" type="xs:string"/>
<xs:element name="manu-steps" minOccurs="1" maxOccurs="unbounded">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="manu-step" type="rdm:control-term"/>
    </xs:sequence>
  </xs:complexType>
</xs:element>
</xs:sequence>
</xs:complexType>
```