

MAA-Human Form DES Changes

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

MAA HUMAN schema XSD

(maa_human.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="1.26.0.0">
```

To

```
<xs:schema xmlns:xs="http://www.w3.org/2001/XMLSchema" xmlns:thisfile="me"
xmlns:rdm="http://www.ema.eaf/dictionary/" xmlns:maa="http://www.ema.eaf/maa/"
targetNamespace="http://www.ema.eaf/maa/" elementFormDefault="qualified" version="1.28.0.0">
```

From

```
<xs:element name="declaration">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="medicinal-product" type="rdm:medicinal-product"/>
      <xs:element name="applicant" type="rdm:contact-details-type"/>
      <xs:element name="authorised" type="rdm:contact-details-type"/>
      <xs:element name="signature" type="rdm:contact-details-type"/>
      <xs:element name="dec-signature" type="xs:string"/>
      <xs:element name="function" type="xs:string"/>
      <xs:element name="place" type="rdm:string30"/>
      <xs:element name="date" type="xs:date"/>
      <xs:element name="annex5-4" type="rdm:yes-no"/>
      <xs:element name="annex5-1" type="rdm:yes-no"/>
    </xs:sequence>
  </xs:complexType>
</xs:element>
```

To

```
<xs:element name="declaration">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="product-invented-name" type="rdm:string250"/>
      <xs:element name="medicinal-product" type="rdm:medicinal-product" maxOccurs="unbounded"/>
      <xs:element name="active-substances-description" type="xs:string" minOccurs="0"/>
      <xs:element name="active-substances" minOccurs="0">
        <xs:complexType>
          <xs:sequence>
            <xs:element name="active-substances-details" minOccurs="1" maxOccurs="unbounded">
              <xs:complexType>
                <xs:sequence>
                  <xs:element name="active-substance-detail" type="xs:string"/>
                  <xs:element name="active-substance" type="rdm:ingredient" minOccurs="1"
maxOccurs="unbounded"/>
                </xs:sequence>
              </xs:complexType>
            </xs:element>
          </xs:sequence>
        </xs:complexType>
      </xs:element>
    </xs:sequence>
  </xs:complexType>
</xs:element>
  <xs:element name="applicant" type="rdm:contact-details-type"/>
  <xs:element name="authorised" type="rdm:contact-details-type"/>
  <xs:element name="signature" type="rdm:contact-details-type"/>
  <xs:element name="dec-signature" type="xs:string"/>
  <xs:element name="function" type="xs:string"/>
  <xs:element name="place" type="rdm:string30"/>
  <xs:element name="date" type="xs:date"/>
  <xs:element name="annex5-4" type="rdm:yes-no"/>
  <xs:element name="annex5-1" type="rdm:yes-no"/>
</xs:sequence>
```

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

From

```
<xs:element name="section1-6"> ... </xs:element>
```

To

```
<xs:element name="section1-6"> ... </xs:element>
<xs:element name="section1-7">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="prime-decision" type="rdm:yes-no"/>
      <xs:element name="prime-number" type="rdm:string500"/>
    </xs:sequence>
  </xs:complexType>
</xs:element>
```

From

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

To

```
<xs:element name="chapter-2">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="medicinal-product" type="rdm:medicinal-product" maxOccurs="unbounded"/>
      <xs:element name="annex5-19" type="rdm:yes-no"/>
    </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>
```

Dictionary XSD file

(eaf_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="1.26.0.0">
```

To

```
<xs:schema xmlns:xs="http://www.w3.org/2001/XMLSchema" xmlns:rdm="http://www.ema.eaf/dictionary/"
targetNamespace="http://www.ema.eaf/dictionary/" elementFormDefault="qualified"
attributeFormDefault="unqualified" version="1.28.0.0">
```

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>
```

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: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>

```

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" 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>

```

From

```

<xs:complexType name="manufacturer-active-substance"> ... </xs:complexType>

```

To

```

<xs:complexType name="manufacturer-active-substance"> ... </xs:complexType>
<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:sequence>
</xs:complexType>

```

```

    <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:element name="manu-functions" minOccurs="1" maxOccurs="unbounded">...</xs:element>
    <xs:element name="attach-annex-5-8" type="rdm:yes-no"/>
    <xs:element name="site-in-EEA" type="rdm:yes-no"/>
    <xs:element name="site-out-EEA" type="rdm:yes-no"/>
    <xs:element name="inside" maxOccurs="unbounded">...</xs:element>
    <xs:element name="outside" maxOccurs="unbounded">...</xs:element>
  </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:element name="manu-functions" minOccurs="1" maxOccurs="unbounded">...</xs:element>
    <xs:element name="attach-annex-5-8" type="rdm:yes-no"/>
    <xs:element name="site-in-EEA" type="rdm:yes-no"/>
    <xs:element name="site-out-EEA" type="rdm:yes-no"/>
    <xs:element name="inside" maxOccurs="unbounded">...</xs:element>
    <xs:element name="outside" maxOccurs="unbounded">...</xs:element>
  </xs:sequence>
</xs:complexType>
```

From

```
<xs:complexType name="packages">
  <xs:sequence>
    <xs:element name="package" minOccurs="0" maxOccurs="unbounded">
      <xs:complexType>
        <xs:sequence>
          <xs:element name="package-name" type="xs:string"/>
          <xs:element name="package-size" maxOccurs="unbounded">
            <xs:complexType>
              <xs:sequence>
                <xs:element name="size" type="xs:string"/>
              </xs:sequence>
            </xs:complexType>
          </xs:element>
          <xs:element name="package-description"/>
          <xs:element name="containers">
            <xs:complexType>
              <xs:sequence>
                <xs:element name="container" maxOccurs="unbounded">
                  <xs:complexType>
                    <xs:sequence>
                      <xs:element name="shelf-life" type="rdm:shelf-life" maxOccurs="unbounded"/>
                      <xs:element name="container-details" maxOccurs="unbounded">
                        <xs:complexType>
                          <xs:sequence>
                            <xs:element name="material" type="xs:string"/>
                            <xs:element name="container-type" type="rdm:control-term"/>
                            <xs:element name="closure-material" type="rdm:control-term"/>
                            <xs:element name="administrative-device" type="rdm:control-term"/>
                            <xs:element name="container-material" type="xs:string" minOccurs="0"/>
                            <xs:element name="closure" type="xs:string"/>
                            <xs:element name="content-of-container" type="xs:string" maxOccurs="unbounded"/>
                            <xs:element name="description"/>
                          </xs:sequence>
                        </xs:complexType>
                      </xs:element>
                    </xs:sequence>
                  </xs:complexType>
                </xs:element>
              </xs:sequence>
            </xs:complexType>
          </xs:element>
        </xs:sequence>
      </xs:complexType>
    </xs:element>
  </xs:sequence>
</xs:complexType>
```

```

        </xs:complexType>
      </xs:element>
    </xs:sequence>
  </xs:complexType>
</xs:element>
</xs:sequence>
</xs:complexType>
</xs:element>
<xs:element name="attachment" type="rdm:attachment"/>
<!-- This element has been modified two elements removed and another added -->
</xs:sequence>
</xs:complexType>
</xs:element>
</xs:sequence>
</xs:complexType>
To
<xs:complexType name="packages">
  <xs:sequence>
    <xs:element name="package" minOccurs="0" maxOccurs="unbounded">
      <xs:complexType>
        <xs:sequence>
          <xs:element name="package-name" type="xs:string"/>
          <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>
          <xs:element name="package-description"/>
          <xs:element name="containers">
            <xs:complexType>
              <xs:sequence>
                <xs:element name="container" maxOccurs="unbounded">
                  <xs:complexType>
                    <xs:sequence>
                      <xs:element name="shelf-life" type="rdm:shelf-life" maxOccurs="unbounded"/>
                      <xs:element name="container-details" maxOccurs="unbounded">
                        <xs:complexType>
                          <xs:sequence>
                            <xs:element name="materials" maxOccurs="unbounded">
                              <xs:complexType>
                                <xs:sequence>
                                  <xs:element name="material" type="rdm:control-term"/>
                                </xs:sequence>
                              </xs:complexType>
                            </xs:element>
                            <xs:element name="container-type" type="rdm:control-term"/>
                            <xs:element name="closure-material" type="rdm:control-term"/>
                            <xs:element name="administrative-device" type="rdm:control-term"/>
                            <xs:element name="container-material" type="xs:string" minOccurs="0"/>
                            <xs:element name="closure" type="xs:string"/>
                            <xs:element name="content-of-container" type="xs:string" maxOccurs="unbounded"/>
                            <xs:element name="description"/>
                          </xs:sequence>
                        </xs:complexType>
                      </xs:element>
                    </xs:sequence>
                  </xs:complexType>
                </xs:element>
              </xs:sequence>
            </xs:complexType>
          </xs:element>
        </xs:sequence>
      </xs:complexType>
    </xs:element>
    <xs:element name="attachment" type="rdm:attachment"/>
    <!-- This element has been modified two elements removed and another added -->
  </xs:sequence>
</xs:complexType>
</xs:element>
</xs:sequence>
</xs:complexType>

```

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:sequence>
            </xs:complexType>
          </xs:element>
        </xs:sequence>
      </xs:complexType>
    </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:element name="active-substances-description" type="xs:string" minOccurs="0"/>
      <xs:element name="active-substances" minOccurs="0">...</xs:element>
      <xs:element name="excipients" minOccurs="1" 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:element name="active-substances-description" type="xs:string" minOccurs="0"/>
      <xs:element name="active-substances" minOccurs="0">...</xs:element>
      <xs:element name="excipients" minOccurs="1" 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: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: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>

```