eAF DES Change Summary

Summary of DES changes applied to v.1.26.0.0

An agency of the European Union

eAF DES Change Summary

Purpose
The aim of this document is to summarise the changes applied to the Data Exchange Standard covering variation and human forms for version 1.26.0.0 of the Electronic Application Forms.

It should be noted this document in no way replaces the current DES documents for each of the respective forms.

In all instances, and to facilitate understanding, an extract of the original schema definition is supplied, along with the updated version.

To enable cross reference to the release notes for 1.26.0.0, this document will reference the corresponding Change Request/defect reference number associated with the DES change.

Change Requests

1) SD-403904
2) SD-508617
3) SD-574469
4) SD-574425
5) SD-587679
6) SD-587688

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1. For 403904

maa_vet_schema changes:

(This is part of the xsd maa_vet_schema)

Original:

```xml
<!-- Begin Declaration -->
<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="rdm:string50"/>
    <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>
<!-- End Declaration -->
```

Changed to

```xml
<!-- Begin Declaration -->
<xs:element name="declaration">
<xs:complexType>
  <xs:sequence>
    <xs:element name="signature" type="rdm:contact-details-type"/>
    <xs:element name="dec-signature" type="xs:string"/>
    <xs:element name="function" type="rdm:string50"/>
    <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>
<!-- End Declaration -->
```

Original

```xml
<xs:element name="concerns">
<xs:complexType>
  <xs:sequence>
    <xs:element name="centralised-procedure" type="rdm:yes-no"/>
    <xs:element name="cp">
      <xs:complexType>
        <xs:sequence>
          <xs:element name="mandatory-scope" type="rdm:yes-no"/>
          <xs:element name="ms">
```

```xml
          <xs:complexType>
            <xs:sequence>
              <xs:element name="biotech_veterinary_medicinal_product" type="rdm:yes-no"/>
              <xs:element name="performance_enhancers" type="rdm:yes-no"/>
            </xs:sequence>
          </xs:complexType>
        </xs:element>
        <xs:element name="optional-scope" type="rdm:yes-no"/>
        <xs:element name="os">
          <xs:complexType>
            <xs:sequence>
              <xs:element name="new_active_substance" type="rdm:yes-no"/>
              <xs:element name="significant_innovation" type="rdm:yes-no"/>
              <xs:element name="immunological" type="rdm:yes-no"/>
              <xs:element name="acceptance_cvmp"/>
              <xs:element name="ema-product-number" type="xs:string"/>
            </xs:sequence>
          </xs:complexType>
        </xs:element>
        <xs:element name="generic-scope" type="rdm:yes-no"/>
        <xs:element name="gs">
          <xs:complexType>
            <xs:sequence>
              <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>
      </xs:sequence>
    </xs:complexType>
  </xs:element>
  <xs:element name="mutual-procedure" type="rdm:yes-no"/>
  <xs:element name="mutual-recognition-procedure" type="rdm:mutual-recognition-procedure" minOccurs="0"/>
  <xs:element name="decentralised-procedure" type="rdm:yes-no"/>
  <xs:element name="dp">
    <xs:complexType>
      <xs:sequence>
        <xs:element name="procedure_number" type="rdm:string30"/>
        <xs:element name="reference_member_state" type="xs:string"/>
        <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="waiver" type="xs:string"/>
        <xs:element name="proposed-common-renewal-date" type="xs:date"/>
      </xs:sequence>
    </xs:complexType>
  </xs:element>
  <xs:element name="national_procedure" type="rdm:yes-no"/>
```

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

Changed to
```
<xs:element name="concerns">
<xs:complexType>
  <xs:sequence>
    <xs:element name="centralised-procedure" type="rdm:yes-no"/>
    <xs:element name="cp">
      <xs:complexType>
        <xs:sequence>
          <xs:element name="mandatory-scope" type="rdm:yes-no"/>
          <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>
          <xs:element name="optional-scope" type="rdm:yes-no"/>
          <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>
      </xs:complexType>
    </xs:element>
    <xs:element name="mutual-procedure" type="rdm:yes-no"/>
    <xs:element name="mutual-recognition-procedure" type="rdm:mutual-recognition-
procedure" minOccurs="0"/>
```

```
<xs:element name="decentralised-procedure" type="rdm:yes-no"/>
<xs:element name="dp">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="procedure_number" type="rdm:string30"/>
      <xs:element name="reference_member_state" type="xs:string"/>
      <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>
<xs:element name="national_procedure" type="rdm:yes-no"/>
<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:sequence>
  </xs:complexType>
</xs:element>
  </xs:sequence>
</xs:complexType>
</xs:element>
```

Original
```
<xs:element name="change-market-authorization">
<xs:complexType>
  <xs:sequence>
    <xs:element name="yes" type="rdm:yes-no"/>
    <xs:element name="no" type="rdm:yes-no"/>
    <xs:element name="specify-yes" type="xs:string"/>
    <xs:element name="qualitative-change" type="rdm:yes-no"/>
    <xs:element name="qualitative-change-detail"/>
    <xs:element name="bioavailability" type="rdm:yes-no"/>
    <xs:element name="pharmacokinetics" type="rdm:yes-no"/>
    <xs:element name="strength-potency" type="rdm:yes-no"/>
    <xs:element name="pharma-form" type="rdm:yes-no"/>
    <xs:element name="route-of-admin" type="rdm:yes-no"/>
    <xs:element name="target-animal-species" type="rdm:yes-no"/>
    <xs:element name="product" type="rdm:product-type" maxOccurs="unbounded"/>
    <xs:element name="pharmaceutical-products" type="xs:string"/>
    <!-- <xs:element name="other-
changes" type="xs:string"/>  removed in version 7.3 word form -->
  </xs:sequence>
</xs:complexType>
</xs:element>
```

Changed to

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```xml
<xs:element name="change-market-authorization">
<xs:complexType>
  <xs:sequence>
    <xs:element name="yes" type="rdm:yes-no"/>
    <xs:element name="no" type="rdm:yes-no"/>
    <xs:element name="specify-yes" type="xs:string"/>
    <xs:element name="upd-product-identifier" type="xs:string"/>
    <xs:element name="upd-permanent-identifier" type="xs:string"/>
    <xs:element name="variation-procedure-number" type="xs:string"/>
    <xs:element name="qualitative-change" type="rdm:yes-no"/>
    <xs:element name="qualitative-change-detail"/>
    <xs:element name="bioavailability" type="rdm:yes-no"/>
    <xs:element name="pharmacokinetics" type="rdm:yes-no"/>
    <xs:element name="strength-potency" type="rdm:yes-no"/>
    <xs:element name="pharma-form" type="rdm:yes-no"/>
    <xs:element name="route-of-admin" type="rdm:yes-no"/>
    <xs:element name="target-animal-species" type="rdm:yes-no"/>
    <xs:element name="product" type="rdm:product-type" maxOccurs="unbounded"/>
    <xs:element name="pharmaceutical-products" type="xs:string"/>
    <!-- <xs:element name="other-
changes" type="xs:string"/>  removed in version 7.3 word form -->
  </xs:sequence>
</xs:complexType>
</xs:element>
```

Original
```xml
<xs:element name="article-12-3" type="rdm:yes-no"/>
```

Changed to
```xml
<xs:element name="article-8" type="rdm:yes-no"/>
```

Original
```xml
<xs:element name="article-13-1"/>
```

Changed to
```xml
<xs:element name="article-18"/>
```

Original
```xml
<xs:element name="section1-3-3">
<xs:complexType>
  <xs:sequence>
    <xs:element name="article13-3" type="rdm:yes-no"/>
    <xs:element name="first-rmp">
      <xs:complexType>
        <xs:sequence>
          <xs:element name="reference-medicinal-product" type="rdm:reference-medicinal-
product-type" maxOccurs="unbounded"/>
        </xs:sequence>
      </xs:complexType>
    </xs:element>
    <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="bioequilvalence" type="rdm:yes-no"/>
      </xs:sequence>
    </xs:complexType>
  </xs:element>
  <xs:element name="third-rmp">
    <xs:complexType>
      <xs:sequence>
        <xs:element name="reference-medicinal-product" type="rdm:reference-medicinal-
product-type" maxOccurs="unbounded"/>
      </xs:sequence>
    </xs:complexType>
  </xs:element>
  </xs:sequence>
</xs:complexType>
</xs:element>

Changed to
<xs:element name="section1-3-3">
<xs:complexType>
  <xs:sequence>
    <xs:element name="article19-1" type="rdm:yes-no"/>
    <xs:element name="cbArticle19_1_a_as" type="rdm:yes-no"/>
    <xs:element name="cbArticle19_1_a_ti" type="rdm:yes-no"/>
    <xs:element name="cbArticle19_1_a_strength" type="rdm:yes-no"/>
    <xs:element name="cbArticle19_1_a_roa" type="rdm:yes-no"/>
    <xs:element name="cbArticle19_1_a_pharma" type="rdm:yes-no"/>
    <xs:element name="cbArticle19_1_b" type="rdm:yes-no"/>
    <xs:element name="cbArticle19_1_c" type="rdm:yes-no"/>
    <xs:element name="first-rmp">
      <xs:complexType>
        <xs:sequence>
          <xs:element name="reference-medicinal-product" type="rdm:reference-medicinal-
product-type" maxOccurs="unbounded"/>
        </xs:sequence>
      </xs:complexType>
    </xs:element>
    <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="bioequilvalence" 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>
<xs:element name="third-rmp">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="reference-medicinal-product" type="rdm:reference-medicinal-
product-type" maxOccurs="unbounded"/>
    </xs:sequence>
  </xs:complexType>
</xs:element>
</xs:sequence>
</xs:complexType>
</xs:element>
```

Original
```
<xs:element name="section1-3-4">
<xs:complexType>
  <xs:sequence>
    <xs:element name="article-13-4" type="rdm:yes-no"/>
    <xs:element name="first-rmp">
      <xs:complexType>
        <xs:sequence>
          <xs:element name="reference-medicinal-product" type="rdm:reference-medicinal-
product-type" maxOccurs="unbounded"/>
          <xs:element name="date_of_authorisation" type="xs:date"/>
          <xs:element name="community" type="rdm:yes-no"/>
          <xs:element name="member_state" type="xs:string"/>
        </xs:sequence>
      </xs:complexType>
    </xs:element>
    <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="change-raw-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="manufacturing" type="rdm:yes-no"/>
          <xs:element name="other" type="rdm:yes-no"/>
        </xs:sequence>
      </xs:complexType>
    </xs:element>
    <xs:element name="third-rmp">
      <xs:complexType>
        <xs:sequence>
```

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

Changed to
```xml
<xs:element name="section1-3-4">
<xs:complexType>
  <xs:sequence>
    <xs:element name="article20" type="rdm:yes-no"/>
  </xs:sequence>
</xs:complexType>
</xs:element>
```

Original
```xml
<xs:element name="section1-3-5">
<xs:complexType>
  <xs:sequence>
    <xs:element name="article13-a" type="rdm:yes-no"/>
  </xs:sequence>
</xs:complexType>
</xs:element>
```

Changed to
```xml
<xs:element name="section1-3-5">
<xs:complexType>
  <xs:sequence>
    <xs:element name="article21" type="rdm:yes-no"/>
    <xs:element name="products">
      <xs:complexType>
        <xs:sequence>
          <xs:element name="product" type="rdm:product-type" maxOccurs="unbounded"/>
        </xs:sequence>
      </xs:complexType>
    </xs:element>
    <xs:element name="attach-letter" type="rdm:yes-no"/>
  </xs:sequence>
</xs:complexType>
</xs:element>
```

Original
```xml
<xs:element name="section1-3-6">
<xs:complexType>
  <xs:sequence>
    <xs:element name="article13-b" type="rdm:yes-no"/>
  </xs:sequence>
</xs:complexType>
```

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

Changed to
```
<xs:element name="section1-3-6">
<xs:complexType>
  <xs:sequence>
    <xs:element name="article22" type="rdm:yes-no"/>
  </xs:sequence>
</xs:complexType>
</xs:element>
```

Original
```
<xs:element name="section1-3-7">
<xs:complexType>
  <xs:sequence>
    <xs:element name="article13-c" type="rdm:yes-no"/>
    <xs:element name="products">
      <xs:complexType>
        <xs:sequence>
          <xs:element name="product" type="rdm:product-type" maxOccurs="unbounded"/>
        </xs:sequence>
      </xs:complexType>
    </xs:element>
    <xs:element name="attach-letter" type="rdm:yes-no"/>
  </xs:sequence>
</xs:complexType>
</xs:element>
```

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

Original
```
<xs:element name="section1-3-8">
<xs:complexType>
  <xs:sequence>
    <xs:element name="article13-d" type="rdm:yes-no"/>
  </xs:sequence>
</xs:complexType>
</xs:element>
```

Changed to
```
<xs:element name="section1-3-8">
```

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```xml
<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>
```

Original

```xml
<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>
```

Changed to

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

Original
```
<xs:element name="section1-5-1">
<xs:complexType>
  <xs:sequence>
    <xs:element name="article26-3" type="rdm:yes-no"/>
  </xs:sequence>
</xs:complexType>
</xs:element>
```

Changed to
```
<xs:element name="section1-5-1">
<xs:complexType>
  <xs:sequence>
    <xs:element name="article44-3" type="rdm:yes-no"/>
    <xs:element name="cvmp" type="xs:date"/>
    <xs:element name="cvmp-details" type="xs:string"/>
  </xs:sequence>
</xs:complexType>
</xs:element>
```

Original
```
<xs:element name="section1-5-2">
<xs:complexType>
  <xs:sequence>
    <xs:element name="article39-8" type="rdm:yes-no"/>
    <xs:element name="cvmp" type="xs:date"/>
    <xs:element name="cvmp-details" type="xs:string"/>
  </xs:sequence>
</xs:complexType>
</xs:element>
```

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Changed to

```
<xs:element name="section1-5-2">
<xs:complexType>
  <xs:sequence>
    <xs:element name="article40-1" type="rdm:yes-no"/>
  </xs:sequence>
</xs:complexType>
</xs:element>
```

Original

```
<xs:element name="section1-5-3">
<xs:complexType>
  <xs:sequence>
    <xs:element name="article13-5" type="rdm:yes-no"/>
  </xs:sequence>
</xs:complexType>
</xs:element>
```

Changed to

```
<xs:element name="section1-5-3">
<xs:complexType>
  <xs:sequence>
    <xs:element name="article40-2" type="rdm:yes-no"/>
  </xs:sequence>
</xs:complexType>
</xs:element>
```

Original

```
<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>
```

Changed to

```
<xs:element name="section1-5-4">
<xs:complexType>
  <xs:sequence>
    <xs:element name="article40-5" type="rdm:yes-no"/>
  </xs:sequence>
</xs:complexType>
</xs:element>
<xs:element name="section1-5-5">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="vaccine_antigen" type="rdm:yes-no"/>
    </xs:sequence>
  </xs:complexType>
</xs:element>
```

eAF DES Change Summary

```xml
<xs:element name="section1-5-6">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="vaccine_platform" type="rdm:yes-no"/>
    </xs:sequence>
  </xs:complexType>
</xs:element>
```

Original
```xml
<xs:element name="section2-1-3">
<xs:complexType>
  <xs:sequence>
    <xs:element name="atc" type="rdm:atc"/>
  </xs:sequence>
</xs:complexType>
</xs:element>
```

Changed to
```xml
<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>
```

Original
```xml
<xs:element name="section2-1-4">
<xs:complexType>
  <xs:sequence>
    <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>
```

Changed to
```xml
<xs:element name="section2-1-4">
```

eAF DES Change Summary

```xml
<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>
```

Original
```xml
<xs:element name="legal-status">
<xs:complexType>
  <xs:sequence>
    <xs:element name="proposed_administration">
      <xs:complexType>
        <xs:sequence>
          <xs:element name="surgeon" type="rdm:yes-no"/>
          <xs:element name="responcibility" type="rdm:yes-no"/>
          <xs:element name="other" type="rdm:yes-no"/>
        </xs:sequence>
      </xs:complexType>
    </xs:element>
    <xs:element name="proposed_dispensing">
      <xs:complexType>
        <xs:sequence>
          <xs:element name="subjectToMedicalPerscription" type="rdm:yes-no"/>
          <xs:element name="subjectToMedicalPerscription-details" minOccurs="0" maxOccurs="unbounded">
            <xs:complexType>
              <xs:sequence>
                <xs:element name="subject-package-size" type="xs:string"/>
                <xs:element name="subject-member-states" type="rdm:member-states"/>
              </xs:sequence>
            </xs:complexType>
          </xs:element>
          <xs:element name="notSubjectToMedicalPerscription" type="rdm:yes-no"/>
```

```xml
            <xs:element name="notSubjectToMedicalPerscription-
details" minOccurs="0" maxOccurs="unbounded">
                <xs:complexType>
                    <xs:sequence>
                        <xs:element name="non-subject-package-size" type="xs:string"/>
                        <xs:element name="non-subject-member-states" type="rdm:member-states"/>
                    </xs:sequence>
                </xs:complexType>
            </xs:element>
            <xs:element name="subjectToOther" type="rdm:yes-no"/>
            <xs:element name="specify" type="xs:string"/>
        </xs:sequence>
    </xs:complexType>
</xs:element>
<xs:element name="subject-medical-prescription">
    <xs:complexType>
        <xs:sequence>
            <xs:element name="renewed" type="rdm:yes-no"/>
            <xs:element name="renewed-member-states" type="rdm:member-states"/>
            <xs:element name="not-renewed" type="rdm:yes-no"/>
            <xs:element name="not-renewed-member-states" type="rdm:member-states"/>
            <xs:element name="special" type="rdm:yes-no"/>
            <xs:element name="special-member-states" type="rdm:member-states"/>
            <xs:element name="restricted" type="rdm:yes-no"/>
            <xs:element name="restricted-member-states" type="rdm:member-states"/>
        </xs:sequence>
    </xs:complexType>
</xs:element>
<xs:element name="not-subject-medical-prescription">
    <xs:complexType>
        <xs:sequence>
            <xs:element name="pharmaciesOnly" type="rdm:yes-no"/>
            <xs:element name="pharma-member-states" type="rdm:member-states"/>
            <xs:element name="pharmaciesAndNon" type="rdm:yes-no"/>
            <xs:element name="non-pharma-member-states" type="rdm:member-states"/>
            <xs:element name="surgeonsOnly" type="rdm:yes-no"/>
            <xs:element name="admin-member-states" type="rdm:member-states"/>
            <xs:element name="pharmaciesAndSurgeons" type="rdm:yes-no"/>
            <xs:element name="vet-care-member-states" type="rdm:member-states"/>
            <xs:element name="authDistributor" type="rdm:yes-no"/>
            <xs:element name="distributor-member-states" type="rdm:member-states"/>
            <xs:element name="generalSale" type="rdm:yes-no"/>
            <xs:element name="generalSale-member-states" type="rdm:member-states"/>
        </xs:sequence>
    </xs:complexType>
</xs:element>
<xs:element name="promotion">
    <xs:complexType>
        <xs:sequence>
            <xs:element name="professionalsOnly" type="rdm:yes-no"/>
            <xs:element name="professional-member-states" type="rdm:member-states"/>
            <xs:element name="professionalsAndPublic" type="rdm:yes-no"/>
            <xs:element name="public-member-states" type="rdm:member-states"/>
        </xs:sequence>
    </xs:complexType>
```

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

Changed to
```
<xs:element name="legal-status">
<xs:complexType>
  <xs:sequence>
    <xs:element name="no-prescription" type="rdm:yes-no"/>
    <xs:element name="no-prescription-retail-restricted-no" type="rdm:yes-no"/>
    <xs:element name="no-prescription-retail-restricted-yes" type="rdm:yes-no"/>
    <xs:element name="prescription" type="rdm:yes-no"/>
    <xs:element name="prescription-qualified-professionals" type="rdm:yes-no"/>
    <xs:element name="prescription-official-vet" type="rdm:yes-no"/>
    <xs:element name="prescription-veterinarians" type="rdm:yes-no"/>
    <xs:element name="prescription-veterinarians-use-possession" type="rdm:yes-no"/>
    <xs:element name="prescription-veterinarians-administration" type="rdm:yes-no"/>
    <xs:element name="prescription-special-supervision" type="rdm:yes-no"/>
    <xs:element name="prescription-psychotropic-administration" type="rdm:yes-no"/>
    <xs:element name="prescription-psychotropic-special-supervision" type="rdm:yes-no"/>
    <xs:element name="prescription-renewal" type="rdm:yes-no"/>
    <xs:element name="prescription-renewal-yes" type="rdm:yes-no"/>
    <xs:element name="prescription-renewal-no" type="rdm:yes-no"/>
    <xs:element name="prescription-narcotics-special-supervision" type="rdm:yes-no"/>
    <xs:element name="prescription-narcotics-administration" type="rdm:yes-no"/>
    <xs:element name="prescription-renewable-delivery" type="rdm:yes-no"/>
    <xs:element name="prescription-renewable-delivery-yes" type="rdm:yes-no"/>
    <xs:element name="prescription-renewable-delivery-no" type="rdm:yes-no"/>
    <xs:element name="prescription-except-some-packages" type="rdm:yes-no"/>
  </xs:sequence>
</xs:complexType>
</xs:element>
```

Original
```
<xs:element name="contact-pharmaco-vigilances">
<xs:complexType>
  <xs:sequence>
    <xs:element name="contact-pharmaco-vigilance" type="rdm:contact-details-type" maxOccurs="unbounded"/>
  </xs:sequence>
</xs:complexType>
</xs:element>
```

Changed to
```
<xs:element name="contact-pharmaco-vigilances">
<xs:complexType>
  <xs:sequence>
    <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"/>
```

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

Original
```xml
<!-- Begin Section 5 -->
<xs:element name="AnnexedDocuments">
<xs:complexType>
  <xs:sequence>
    <xs:element name="annex5-1" type="rdm:yes-no"/>
    <xs:element name="annex5-2" type="rdm:yes-no"/>
    <xs:element name="annex5-3" type="rdm:yes-no"/>
    <xs:element name="annex5-4" type="rdm:yes-no"/>
    <xs:element name="annex5-5" type="rdm:yes-no"/>
    <xs:element name="annex5-6" type="rdm:yes-no"/>
    <xs:element name="annex5-7" type="rdm:yes-no"/>
    <xs:element name="annex5-8" type="rdm:yes-no"/>
    <xs:element name="annex5-9" type="rdm:yes-no"/>
    <xs:element name="annex5-10" type="rdm:yes-no"/>
    <xs:element name="annex5-11" type="rdm:yes-no"/>
    <xs:element name="annex5-12" type="rdm:yes-no"/>
    <xs:element name="annex5-13" type="rdm:yes-no"/>
    <xs:element name="annex5-14" type="rdm:yes-no"/>
    <xs:element name="annex5-15" type="rdm:yes-no"/>
    <xs:element name="annex5-16" type="rdm:yes-no"/>
    <xs:element name="annex5-17" type="rdm:yes-no"/>
    <xs:element name="annex5-18" type="rdm:yes-no"/>
    <xs:element name="annex5-19" type="rdm:yes-no"/>
    <xs:element name="annex5-20" type="rdm:yes-no"/>
    <xs:element name="annex5-21" type="rdm:yes-no"/>
    <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"/>
  </xs:sequence>
</xs:complexType>
</xs:element>
<!-- End Section 5 -->
```

Changed to
```xml
<!-- Begin Section 5 -->
<xs:element name="AnnexedDocuments">
<xs:complexType>
  <xs:sequence>
    <xs:element name="annex5-1" type="rdm:yes-no"/>
    <xs:element name="annex5-2" type="rdm:yes-no"/>
    <xs:element name="annex5-3" type="rdm:yes-no"/>
    <xs:element name="annex5-4" type="rdm:yes-no"/>
    <xs:element name="annex5-5" type="rdm:yes-no"/>
    <xs:element name="annex5-6" type="rdm:yes-no"/>
    <xs:element name="annex5-7" type="rdm:yes-no"/>
```

```
    <xs:element name="annex5-8" type="rdm:yes-no"/>
    <xs:element name="annex5-9" type="rdm:yes-no"/>
    <xs:element name="annex5-10" type="rdm:yes-no"/>
    <xs:element name="annex5-11" type="rdm:yes-no"/>
    <xs:element name="annex5-12" type="rdm:yes-no"/>
    <xs:element name="annex5-13" type="rdm:yes-no"/>
    <xs:element name="annex5-14" type="rdm:yes-no"/>
    <xs:element name="annex5-15" type="rdm:yes-no"/>
    <xs:element name="annex5-16" type="rdm:yes-no"/>
    <xs:element name="annex5-17" type="rdm:yes-no"/>
    <xs:element name="annex5-18" type="rdm:yes-no"/>
    <xs:element name="annex5-19" type="rdm:yes-no"/>
    <xs:element name="annex5-20" type="rdm:yes-no"/>
    <xs:element name="annex5-21" type="rdm:yes-no"/>
    <xs:element name="annex5-22" type="rdm:yes-no"/>
    <xs:element name="annex5-23" type="rdm:yes-no"/>
  </xs:sequence>
</xs:complexType>
</xs:element>
<!-- End Section 5 -->
```

Eaf_dictionary changes:

(This is part of the xsd eaf dictionary)

Original
```
<xs:element name="flow_chart" type="rdm:yes-no"/>
<xs:element name="qualified-person-declaration" type="rdm:yes-no"/>
<xs:element name="inspected_gmp_compliance" type="rdm:yes-no"/>
<xs:element name="competent-authority" type="rdm:yes-no"/>
<xs:element name="gmp_cert" type="rdm:yes-no"/>
<xs:element name="gmpc" type="rdm:gmpc"/>
<xs:element name="gmp-compliance-other" type="rdm:yes-no"/>
<xs:element name="summary-information" type="rdm:yes-no"/>
<xs:element name="ph-eur-cert-suitability" type="rdm:yes-no"/>
<xs:element name="provide-copy" type="rdm:yes-no"/>
<xs:element name="qualification" type="xs:string" minOccurs="0"/>
<xs:element name="attach" type="rdm:yes-no" minOccurs="0"/>
<xs:element name="active-substance-master-file" type="rdm:yes-no"/>
<xs:element name="access-community-member-state" type="rdm:yes-no"/>
<xs:element name="written-confirmation" type="rdm:yes-no"/>
<xs:element name="ph-eur-cert">
```

Changed to
```
<xs:element name="flow_chart" type="rdm:yes-no"/>
<xs:element name="qualified-person-declaration" type="rdm:yes-no"/>
<xs:element name="inspected_gmp_compliance" type="rdm:yes-no"/>
<xs:element name="competent-authority" type="rdm:yes-no"/>
<xs:element name="gmp_cert" type="rdm:yes-no"/>
<xs:element name="gmpc" type="rdm:gmpc"/>
```

```xml
<xs:element name="gmp-compliance-other" type="rdm:yes-no"/>
<xs:element name="summary-information" type="rdm:yes-no"/>
<xs:element name="ph-eur-cert-suitability" type="rdm:yes-no"/>
<xs:element name="provide-copy" type="rdm:yes-no"/>
<xs:element name="qualification" type="xs:string" minOccurs="0"/>
<xs:element name="attach" type="rdm:yes-no" minOccurs="0"/>
<xs:element name="active-substance-master-file" type="rdm:yes-no"/>
<xs:element name="access-community-member-state" type="rdm:yes-no"/>
<xs:element name="ph-eur-cert">
```

Original

```xml
<xs:element name="vamf" minOccurs="1" maxOccurs="unbounded">
<xs:complexType>
  <xs:sequence>
    <xs:element name="is-vamf-issued"/>
    <xs:element name="substance-certificate" type="rdm:substance-certificate"/>
  </xs:sequence>
</xs:complexType>
</xs:element>
```

Changed to

```xml
<xs:element name="vamf" minOccurs="1" maxOccurs="unbounded">
<xs:complexType>
  <xs:sequence>
    <xs:element name="is-vamf-issued"/>
    <xs:element name="substance-certificate" type="rdm:substance-certificate-vet"/>
  </xs:sequence>
</xs:complexType>
</xs:element>
<xs:element name="ptmf" minOccurs="1" maxOccurs="unbounded">
<xs:complexType>
  <xs:sequence>
    <xs:element name="is-ptmf-issued"/>
    <xs:element name="substance-certificate" type="rdm:substance-certificate-vet"/>
    <xs:element name="provide-copy" type="rdm:yes-no" minOccurs="0"/>
  </xs:sequence>
</xs:complexType>
</xs:element>
```

Original

```xml
<xs:element name="waiver-amendment-psur" type="xs:string" />
```

Changed to

```xml
<xs:element name="waiver-amendment-psur" type="xs:string" minOccurs="0"/>
```

Original

```xml
<xs:element name="member-renewal" minOccurs="1" maxOccurs="unbounded">
<xs:complexType>
  <xs:sequence>
    <xs:element name="member-states" type="rdm:member-states"/>
    <xs:element name="proposed-agreed-renewal-date" type="xs:string" />
    <!-- xs:element name="agreed-common-renewal-date" type="xs:date"/ -->
```

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

Changed to
```
<xs:element name="member-renewal" minOccurs="1" maxOccurs="unbounded">
<xs:complexType>
  <xs:sequence>
    <xs:element name="member-states" type="rdm:member-states"/>
    <xs:element name="proposed-agreed-renewal-date" type="xs:string" minOccurs="0"/>
    <!-- xs:element name="agreed-common-renewal-date" type="xs:date"/ -->
  </xs:sequence>
</xs:complexType>
</xs:element>
```

Original
```
<xs:complexType name="reference-medicinal-product-type">
<xs:complexContent>
  <xs:extension base="rdm:product-type">
    <xs:sequence>
      <xs:element name="member-states" type="rdm:member-states"/>
      <xs:element name="community" type="rdm:yes-no"/>
      <xs:element name="mem-selected" type="rdm:yes-no"/>
      <xs:element name="member-state" type="rdm:string100"/>
      <xs:element name="date-authorization" type="xs:date"/>
      <xs:element name="member-state-source" type="rdm:string100" minOccurs="0"/>
      <xs:element name="bioavailability-ref-numbers" maxOccurs="unbounded">
        <xs:complexType>
          <xs:sequence>
            <xs:element name="bioavailability-ref-number" type="rdm:string100"/>
          </xs:sequence>
        </xs:complexType>
      </xs:element>
    </xs:sequence>
  </xs:extension>
</xs:complexContent>
</xs:complexType>
```

Changed to
```
<xs:complexType name="reference-medicinal-product-type">
<xs:complexContent>
  <xs:extension base="rdm:product-type">
    <xs:sequence>
      <xs:element name="member-states" type="rdm:member-states"/>
      <xs:element name="community" type="rdm:yes-no"/>
      <xs:element name="third-country" type="rdm:yes-no" minOccurs="0"/>
      <xs:element name="mem-selected" type="rdm:yes-no"/>
      <xs:element name="member-state" type="rdm:string100"/>
      <xs:element name="date-authorization" type="xs:date"/>
      <xs:element name="member-state-source" type="rdm:string100" minOccurs="0"/>
      <xs:element name="bioavailability-ref-numbers" maxOccurs="unbounded">
        <xs:complexType>
          <xs:sequence>
```

```xml
            <xs:element name="bioavailability-ref-number" type="rdm:string100"/>
        </xs:sequence>
      </xs:complexType>
    </xs:element>
  </xs:sequence>
  </xs:extension>
</xs:complexContent>
</xs:complexType>
```

Original
```xml
<xs:complexType name="substance-certificate-vet">
<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="ingredient-role" type="xs:string" minOccurs="0"/>
  <xs:element name="reference-number-certificate" type="rdm:string30"/>
  <xs:element name="National-ASMF-reference-number" type="rdm:string30"/>
  <xs:element name="Applicant-part-version-number" type="rdm:string30"/>
  <xs:element name="date-submission" type="xs:date" minOccurs="0"/>
  <xs:element name="date-last-update" type="xs:date" minOccurs="0"/>
  <xs:element name="country" type="xs:string"/>
  <xs:element name="certificate-holder">
    <xs:complexType>
      <xs:sequence>
        <xs:element name="name" type="rdm:string100"/>
        <xs:element name="manufacturer-name" type="rdm:string100"/>
      </xs:sequence>
    </xs:complexType>
  </xs:element>
</xs:sequence>
<xs:attribute name="type">
  <xs:annotation>
    <xs:documentation>text choice("CEP" | "ASMF" | "VAMF" | "PMF")</xs:documentation>
  </xs:annotation>
</xs:attribute>
</xs:complexType>
```

Changed to
```xml
<xs:complexType name="substance-certificate-vet">
<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>
```

```xml
<xs:element name="ingredient-role" type="xs:string" minOccurs="0"/>
<xs:element name="reference-number-certificate" type="rdm:string30"/>
<xs:element name="National-ASMF-reference-number" type="rdm:string30"/>
<xs:element name="Applicant-part-version-number" type="rdm:string30"/>
<xs:element name="date-submission" type="xs:date" minOccurs="0"/>
<xs:element name="date-last-update" type="xs:date" minOccurs="0"/>
<xs:element name="cep-confirmation" type="rdm:yes-no"/>
<xs:element name="country" type="xs:string"/>
<xs:element name="certificate-holder">
   <xs:complexType>
      <xs:sequence>
         <xs:element name="name" type="rdm:string100"/>
         <xs:element name="manufacturer-name" type="rdm:string100"/>
      </xs:sequence>
   </xs:complexType>
</xs:element>
</xs:sequence>
<xs:attribute name="type">
   <xs:annotation>
      <xs:documentation>text choice("CEP" | "ASMF" | "VAMF" | "PMF")</xs:documentation>
   </xs:annotation>
</xs:attribute>
</xs:complexType>
```

2. For 508617

variation changes:

(This is part of the xsd variations)

```
Original
<xs:element name="blueBox" maxOccurs="unbounded">
<xs:complexType>
  <xs:sequence>
    <xs:element name="memberState"/>
    <xs:element name="greenBox" maxOccurs="unbounded">
      <xs:complexType>
        <xs:sequence>
          <xs:element name="maNumbers" maxOccurs="unbounded">
            <xs:complexType>
              <xs:sequence>
                <xs:element name="maNumber" type="rdm:string30"/>
              </xs:sequence>
            </xs:complexType>
          </xs:element>
          <xs:element name="inventedName" type="rdm:string250"/>
          <xs:element name="maHolderName" type="rdm:string100"/>
          <xs:element name="pharmaceutical-form-name" type="rdm:control-term"/>
          <xs:element name="strength" type="xs:string"/>
          <xs:element name="units" type="rdm:control-term"/>
        </xs:sequence>
      </xs:complexType>
    </xs:element>
  </xs:sequence>
```

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

Changed to

```
<xs:element name="blueBox" maxOccurs="unbounded">
<xs:complexType>
  <xs:sequence>
    <xs:element name="memberState"/>
    <xs:element name="greenBox" maxOccurs="unbounded">
      <xs:complexType>
        <xs:sequence>
          <xs:element name="maNumbers" maxOccurs="unbounded">
            <xs:complexType>
              <xs:sequence>
                <xs:element name="maNumber" type="rdm:string30"/>
              </xs:sequence>
            </xs:complexType>
          </xs:element>
          <xs:element name="inventedName" type="rdm:string250"/>
          <xs:element name="maHolderName" type="rdm:string100"/>
          <xs:element name="pharmaceutical-form-name" type="rdm:control-term"/>
          <xs:element name="strength" type="xs:string"/>
          <xs:element name="units" type="rdm:control-term"/>
          <xs:element name="updPermanentId" type="rdm:string250"/>
          <xs:element name="updProductId" type="rdm:string250"/>
        </xs:sequence>
      </xs:complexType>
    </xs:element>
  </xs:sequence>
</xs:complexType>
</xs:element>
```

Original

```
<xs:element name="declarationOfApplicant">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="noOtherChanges" type="rdm:yes-no"/>
      <xs:element name="conditionsSet" type="rdm:yes-no"/>
      <xs:element name="requiredDocuments" type="rdm:yes-no"/>
      <xs:element name="nationalFees" type="rdm:yes-no"/>
      <xs:element name="submitted" type="rdm:yes-no"/>
      <xs:element name="sharing" type="rdm:yes-no"/>
      <xs:element name="implementedNext" type="rdm:yes-no" minOccurs="0"/>
      <xs:element name="implementedDate" type="rdm:yes-no" minOccurs="0"/>
      <xs:element name="impDate" type="xs:date" minOccurs="0"/>
      <xs:element name="impDateText" type="rdm:string50"/>
    </xs:sequence>
  </xs:complexType>
</xs:element>
```

Changed to

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

```xml
<xs:complexType>
  <xs:sequence>
    <xs:element name="noOtherChanges" type="rdm:yes-no"/>
    <xs:element name="conditionsSet" type="rdm:yes-no"/>
    <xs:element name="requiredDocuments" type="rdm:yes-no"/>
    <xs:element name="nationalFees" type="rdm:yes-no"/>
    <xs:element name="submitted" type="rdm:yes-no"/>
    <xs:element name="sharing" type="rdm:yes-no"/>
    <xs:element name="implementedNext" type="rdm:yes-no" minOccurs="0"/>
    <xs:element name="implementedDate" type="rdm:yes-no" minOccurs="0"/>
    <xs:element name="impDate" type="xs:date" minOccurs="0"/>
    <xs:element name="impDateText" type="rdm:string50"/>

    <!-- extra sections for vet -->
    <xs:element name="concern-other-Member-State" type="rdm:yes-no"/>
    <xs:element name="specify-yes" maxOccurs="unbounded">
      <xs:complexType>
        <xs:sequence>
          <xs:element name="country" type="rdm:control-term"/>
          <xs:element name="invented-name" type="xs:string"/>
          <xs:element name="submission-date" type="xs:date" minOccurs="0"/>
          <xs:element name="procedure-number" type="xs:string"/>
          <xs:element name="rbVariationStatus" type="rdm:radiobutton"/>
          <xs:element name="granting-date" type="xs:date" minOccurs="0"/>
          <xs:element name="refusal-date" type="xs:date" minOccurs="0"/>
          <xs:element name="withdrawal-date" type="xs:date" minOccurs="0"/>
        </xs:sequence>
      </xs:complexType>
    </xs:element>
    <!-- new section -->
    <!-- question1 -->
    <xs:element name="harmonisation-question1">
      <xs:complexType>
        <xs:sequence>
          <xs:element name="harmonised-ma" type="rdm:yes-no"/>
          <xs:element name="specify-yes" maxOccurs="unbounded">
            <xs:complexType>
              <xs:sequence>
                <xs:element name="procedure-number" type="xs:string"/>
                <xs:element name="specify-section" type="xs:string"/>
              </xs:sequence>
            </xs:complexType>
          </xs:element>
        </xs:sequence>
      </xs:complexType>
    </xs:element>

    <!-- question2 -->
    <xs:element name="harmonisation-question2">
      <xs:complexType>
        <xs:sequence>
          <xs:element name="harmonisation-achieved-worksharing" type="rdm:yes-no"/>
          <xs:element name="specify-yes" maxOccurs="unbounded">
            <xs:complexType>
              <xs:sequence>
```

```
                    <xs:element name="procedure-number" type="xs:string"/>
                    <xs:element name="specify-section" type="xs:string"/>
                </xs:sequence>
            </xs:complexType>
        </xs:element>
      </xs:sequence>
    </xs:complexType>
  </xs:element>
</xs:element>
```

Eaf_dictionary changes:

(This is part of the xsd eaf dictionary)

```
Original:
<xs:complexType name="variationItem">
<xs:sequence>
  <xs:element name="selected" type="rdm:yes-no" minOccurs="0"/>
  <xs:element name="title" type="xs:string" minOccurs="0"/>
  <xs:element name="identifier" type="xs:string" minOccurs="0"/>
  <xs:element name="shortName" type="xs:string" minOccurs="0"/>
  <xs:element name="typeIA" type="rdm:yes-no" minOccurs="0"/>
  <xs:element name="typeIAIN" type="rdm:yes-no" minOccurs="0"/>
  <xs:element name="typeIB" type="rdm:yes-no" minOccurs="0"/>
  <xs:element name="typeIBun" type="rdm:yes-no" minOccurs="0"/>
  <xs:element name="typeII" type="rdm:yes-no" minOccurs="0"/>
  <xs:element name="typeIIart29" type="rdm:yes-no" minOccurs="0"/>
  <xs:element name="article5" type="rdm:yes-no" minOccurs="0"/>
  <xs:element name="date" type="xs:date" minOccurs="0"/>
  <xs:element name="comment" type="rdm:string100" minOccurs="0"/>
  <xs:element name="conditions" minOccurs="0">
    <xs:complexType>
      <xs:sequence>
        <xs:element name="condition" type="rdm:condition" maxOccurs="unbounded"/>
      </xs:sequence>
    </xs:complexType>
  </xs:element>
  <xs:element name="documentations" minOccurs="0">
    <xs:complexType>
      <xs:sequence>
        <xs:element name="documentation" type="rdm:documentation" maxOccurs="unbounded"/>
      </xs:sequence>
    </xs:complexType>
  </xs:element>
  <xs:element name="typeIAapplicable" type="xs:boolean" />
  <xs:element name="typeIAINapplicable" type="xs:boolean" />
  <xs:element name="typeIBapplicable" type="xs:boolean" />
  <xs:element name="typeIBunapplicable" type="xs:boolean" />
  <xs:element name="typeIIapplicable" type="xs:boolean" />
  <xs:element name="typeIIart29applicable" type="xs:boolean" />
  <xs:element name="article5applicable" type="xs:boolean" />
  <xs:element name="conditionsapplicable" type="xs:boolean" />
  <xs:element name="documentationsapplicable" type="xs:boolean" />
</xs:sequence>
```

```
</xs:complexType>

Changed to:
<xs:complexType name="variationItem">
<xs:sequence>
  <xs:element name="selected" type="rdm:yes-no" minOccurs="0"/>
  <xs:element name="title" type="xs:string" minOccurs="0"/>
  <xs:element name="identifier" type="xs:string" minOccurs="0"/>
  <xs:element name="shortName" type="xs:string" minOccurs="0"/>
  <xs:element name="typeIA" type="rdm:yes-no" minOccurs="0"/>
  <xs:element name="typeIAIN" type="rdm:yes-no" minOccurs="0"/>
  <xs:element name="typeIB" type="rdm:yes-no" minOccurs="0"/>
  <xs:element name="typeIBun" type="rdm:yes-no" minOccurs="0"/>
  <xs:element name="typeII" type="rdm:yes-no" minOccurs="0"/>
  <xs:element name="typeIIart29" type="rdm:yes-no" minOccurs="0"/>
  <xs:element name="typeVet" type="xs:string"/>
  <xs:element name="article5" type="rdm:yes-no" minOccurs="0"/>
  <xs:element name="date" type="xs:date" minOccurs="0"/>
  <xs:element name="comment" type="rdm:string100" minOccurs="0"/>
  <xs:element name="conditions" minOccurs="0">
    <xs:complexType>
      <xs:sequence>
        <xs:element name="condition" type="rdm:condition" maxOccurs="unbounded"/>
      </xs:sequence>
    </xs:complexType>
  </xs:element>
  <xs:element name="documentations" minOccurs="0">
    <xs:complexType>
      <xs:sequence>
        <xs:element name="documentation" type="rdm:documentation" maxOccurs="unbounded"/>
      </xs:sequence>
    </xs:complexType>
  </xs:element>
  <xs:element name="typeIAapplicable" type="xs:boolean" />
  <xs:element name="typeIAINapplicable" type="xs:boolean" />
  <xs:element name="typeIBapplicable" type="xs:boolean" />
  <xs:element name="typeIBunapplicable" type="xs:boolean" />
  <xs:element name="typeIIapplicable" type="xs:boolean" />
  <xs:element name="typeIIart29applicable" type="xs:boolean" />
  <xs:element name="article5applicable" type="xs:boolean" />
  <xs:element name="conditionsapplicable" type="xs:boolean" />
  <xs:element name="documentationsapplicable" type="xs:boolean" />
</xs:sequence>
</xs:complexType>
```

3. For 574469

(This is part of the xsd maa_vet_schema)

Original:

```
<xs:element name="consideration_of_application">
    <xs:complexType>
        <xs:sequence>
            <xs:element name="section1-5-1">
```

```xml
                <xs:complexType>
                    <xs:sequence>
                        <xs:element name="article44-3" type="rdm:yes-no"/>
                        <xs:element name="cvmp" type="xs:date"/>
                        <xs:element name="cvmp-details" type="xs:string"/>
                    </xs:sequence>
                </xs:complexType>
            </xs:element>
            <xs:element name="section1-5-2">
                <xs:complexType>
                    <xs:sequence>
                        <xs:element name="article40-1" type="rdm:yes-no"/>
                    </xs:sequence>
                </xs:complexType>
            </xs:element>
            <xs:element name="section1-5-3">
                <xs:complexType>
                    <xs:sequence>
                        <xs:element name="article40-2" type="rdm:yes-no"/>
                    </xs:sequence>
                </xs:complexType>
            </xs:element>
            <xs:element name="section1-5-4">
                <xs:complexType>
                    <xs:sequence>
                        <xs:element name="article40-5" type="rdm:yes-no"/>
                    </xs:sequence>
                </xs:complexType>
            </xs:element>
            <xs:element name="section1-5-5">
                <xs:complexType>
                    <xs:sequence>
                        <xs:element name="vaccine_antigen" type="rdm:yes-no"/>
                    </xs:sequence>
                </xs:complexType>
            </xs:element>
            <xs:element name="section1-5-6">
                <xs:complexType>
                    <xs:sequence>
                        <xs:element name="vaccine_platform" type="rdm:yes-no"/>
                    </xs:sequence>
                </xs:complexType>
            </xs:element>
        </xs:sequence>
    </xs:complexType>
</xs:element>
```

Changed to:

```xml
<xs:element name="consideration_of_application">
    <xs:complexType>
        <xs:sequence>
            <xs:element name="section1-5-1">
                <xs:complexType>
                    <xs:sequence>
```

```xml
                    <xs:element name="article44-3" type="rdm:yes-no"/>
                    <xs:element name="cvmp" type="xs:date"/>
                    <xs:element name="cvmp-details" type="xs:string"/>
                </xs:sequence>
            </xs:complexType>
        </xs:element>
        <xs:element name="section1-5-2">
            <xs:complexType>
                <xs:sequence>
                    <xs:element name="article40-1" type="rdm:yes-no"/>
                </xs:sequence>
            </xs:complexType>
        </xs:element>
        <xs:element name="section1-5-3">
            <xs:complexType>
                <xs:sequence>
                    <xs:element name="article40-2" type="rdm:yes-no"/>
                </xs:sequence>
            </xs:complexType>
        </xs:element>
        <xs:element name="section1-5-4">
            <xs:complexType>
                <xs:sequence>
                    <xs:element name="article40-4" type="rdm:yes-no"/>
                </xs:sequence>
            </xs:complexType>
        </xs:element>
        <xs:element name="section1-5-5">
            <xs:complexType>
                <xs:sequence>
                    <xs:element name="article40-5" type="rdm:yes-no"/>
                </xs:sequence>
            </xs:complexType>
        </xs:element>
        <xs:element name="section1-5-6">
            <xs:complexType>
                <xs:sequence>
                    <xs:element name="vaccine_antigen" type="rdm:yes-no"/>
                </xs:sequence>
            </xs:complexType>
        </xs:element>
        <xs:element name="section1-5-7">
            <xs:complexType>
                <xs:sequence>
                    <xs:element name="vaccine_platform" type="rdm:yes-no"/>
                </xs:sequence>
            </xs:complexType>
        </xs:element>
    </xs:sequence>
</xs:complexType>
</xs:element>
```

4. **For SD-574425**

   (This is part of the xsd variations)

Original:

```xml
<xs:element name="extendedData" minOccurs="0">
    <xs:complexType>
        <xs:sequence>
            <xs:element name="not-applicable" type="rdm:yes-no"/>
            <xs:element name="article" type="rdm:radiobutton"/>
        </xs:sequence>
    </xs:complexType>
</xs:element>
```

Changed to:

```xml
<xs:element name="extendedData" minOccurs="0">
    <xs:complexType>
        <xs:sequence>
            <xs:element name="not-applicable" type="rdm:yes-no"/>

            <xs:element name="rb_vet">
                <xs:complexType>
                    <xs:sequence>
                        <xs:element name="article" type="rdm:radiobutton"/>
                    </xs:sequence>
                </xs:complexType>
            </xs:element>
            <xs:element name="rb_human">
                <xs:complexType>
                    <xs:sequence>
                        <xs:element name="article" type="rdm:radiobutton"/>
                    </xs:sequence>
                </xs:complexType>
            </xs:element>
        </xs:sequence>
    </xs:complexType>
</xs:element>
```

5. For SD-587679

maa_vet_schema changes:
(This is part of the xsd maa_vet_schema)

Original

```xml
<xs:element name="declaration">
    <xs:complexType>
        <xs:sequence>
            <xs:element name="signature" type="rdm:contact-details-type"/>
            <xs:element name="dec-signature" type="xs:string"/>
            <xs:element name="function" type="rdm:string50"/>
            <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>

Changed to
<xs:element name="declaration">
    <xs:complexType>
        <xs:sequence>
            <xs:element name="applicant" 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="rdm:string50"/>
            <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>
```

6. For SD-587688

Eaf dictionary changes:

(This is part of the xsd eaf_dictionary)

```
Original
<xs:complexType name="variationItem">
    <xs:sequence>
        <xs:element name="selected" type="rdm:yes-no" minOccurs="0"/>
        <xs:element name="title" type="xs:string" minOccurs="0"/>
        <xs:element name="identifier" type="xs:string" minOccurs="0"/>
        <xs:element name="shortName" type="xs:string" minOccurs="0"/>
        <xs:element name="typeIA" type="rdm:yes-no" minOccurs="0"/>
        <xs:element name="typeIAIN" type="rdm:yes-no" minOccurs="0"/>
        <xs:element name="typeIB" type="rdm:yes-no" minOccurs="0"/>
        <xs:element name="typeIBun" type="rdm:yes-no" minOccurs="0"/>
        <xs:element name="typeII" type="rdm:yes-no" minOccurs="0"/>
        <xs:element name="typeIIart29" type="rdm:yes-no" minOccurs="0"/>
        <xs:element name="typeVet" type="xs:string"/>

        <xs:element name="article5" type="rdm:yes-no" minOccurs="0"/>
        <xs:element name="date" type="xs:date" minOccurs="0"/>
        <xs:element name="comment" type="rdm:string100" minOccurs="0"/>
        <xs:element name="conditions" minOccurs="0">
            <xs:complexType>
                <xs:sequence>
                    <xs:element name="condition" type="rdm:condition"
maxOccurs="unbounded"/>
                </xs:sequence>
            </xs:complexType>
        </xs:element>
        <xs:element name="documentations" minOccurs="0">
            <xs:complexType>
                <xs:sequence>
```

```xml
                    <xs:element name="documentation" type="rdm:documentation"
maxOccurs="unbounded"/>
                </xs:sequence>
            </xs:complexType>
        </xs:element>
        <xs:element name="typeIAapplicable" type="xs:boolean" />
        <xs:element name="typeIAINapplicable" type="xs:boolean" />
        <xs:element name="typeIBapplicable" type="xs:boolean" />
        <xs:element name="typeIBunapplicable" type="xs:boolean" />
        <xs:element name="typeIIapplicable" type="xs:boolean" />
        <xs:element name="typeIIart29applicable" type="xs:boolean" />
        <xs:element name="article5applicable" type="xs:boolean" />
        <xs:element name="conditionsapplicable" type="xs:boolean" />
        <xs:element name="documentationsapplicable" type="xs:boolean" />
    </xs:sequence>
</xs:complexType>

Changed to

<xs:complexType name="variationItem">
    <xs:sequence>
        <xs:element name="selected" type="rdm:yes-no" minOccurs="0"/>
        <xs:element name="title" type="xs:string" minOccurs="0"/>
        <xs:element name="identifier" type="xs:string" minOccurs="0"/>
        <xs:element name="shortName" type="xs:string" minOccurs="0"/>
        <xs:element name="typeIA" type="rdm:yes-no" minOccurs="0"/>
        <xs:element name="typeIAIN" type="rdm:yes-no" minOccurs="0"/>
        <xs:element name="typeIB" type="rdm:yes-no" minOccurs="0"/>
        <xs:element name="typeIBun" type="rdm:yes-no" minOccurs="0"/>
        <xs:element name="typeII" type="rdm:yes-no" minOccurs="0"/>
        <xs:element name="typeIIart29" type="rdm:yes-no" minOccurs="0"/>
        <xs:element name="typeVet" type="xs:string"/>

        <xs:element name="alternative-timetable">
            <xs:complexType>
                <xs:sequence>
                    <xs:element name="alternative-timetable-rb" type="rdm:radiobutton"/>
                    <xs:element name="confirm-alternative-timetable-cb" type="rdm:yes-no"/>
                </xs:sequence>
            </xs:complexType>
        </xs:element>

        <xs:element name="article5" type="rdm:yes-no" minOccurs="0"/>
        <xs:element name="date" type="xs:date" minOccurs="0"/>
        <xs:element name="comment" type="rdm:string100" minOccurs="0"/>
        <xs:element name="conditions" minOccurs="0">
            <xs:complexType>
                <xs:sequence>
                    <xs:element name="condition" type="rdm:condition"
maxOccurs="unbounded"/>
                </xs:sequence>
            </xs:complexType>
        </xs:element>
        <xs:element name="documentations" minOccurs="0">
            <xs:complexType>
```

```
            <xs:sequence>
                <xs:element name="documentation" type="rdm:documentation"
maxOccurs="unbounded"/>
            </xs:sequence>
        </xs:complexType>
    </xs:element>
    <xs:element name="typeIAapplicable" type="xs:boolean" />
    <xs:element name="typeIAINapplicable" type="xs:boolean" />
    <xs:element name="typeIBapplicable" type="xs:boolean" />
    <xs:element name="typeIBunapplicable" type="xs:boolean" />
    <xs:element name="typeIIapplicable" type="xs:boolean" />
    <xs:element name="typeIIart29applicable" type="xs:boolean" />
    <xs:element name="article5applicable" type="xs:boolean" />
    <xs:element name="conditionsapplicable" type="xs:boolean" />
    <xs:element name="documentationsapplicable" type="xs:boolean" />
    </xs:sequence>
</xs:complexType>
```