



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Information Technology
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eAF DES Change Summary

Summary of DES changes applied to v.1.24.0.0



Purpose

The aim of this document is to summarise the changes applied to the Data Exchange Standard covering variation form for version 1.24.0.0 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 1.24.0.0, this document will reference the corresponding Change Request/defect reference number associated with the DES change.

Change Requests

1. SD-161811



1. eAF dictionary XSD changes:

Original eaf_Dictionary xsd schema definition:

```
<xs:complexType name="variationLine">
  <xs:sequence>
    <xs:element name="level">
      <xs:simpleType>
        <xs:restriction base="xs:integer">
          <xs:minInclusive value="1"/>
          <xs:maxInclusive value="3"/>
        </xs:restriction>
      </xs:simpleType>
    </xs:element>
    <xs:element name="fullCategory" type="xs:string"/>
    <xs:element name="subCategory" type="xs:string" minOccurs="0"/>
    <xs:element name="subtitle" type="xs:string"/>
    <xs:element name="hasSubLevel" type="xs:boolean"/>
    <xs:element name="procedureType">
      <xs:complexType>
        <xs:choice>
          <xs:element name="procedureTypeOne">
            <xs:complexType><xs:complexType name="variationLine">
<xs:sequence>
  <xs:element name="level">
    <xs:simpleType>
      <xs:restriction base="xs:integer">
        <xs:minInclusive value="1"/>
        <xs:maxInclusive value="3"/>
      </xs:restriction>
    </xs:simpleType>
  </xs:element>
  <xs:element name="fullCategory" type="xs:string"/>
  <xs:element name="subCategory" type="xs:string" minOccurs="0"/>
  <xs:element name="subtitle" type="xs:string"/>
  <xs:element name="hasSubLevel" type="xs:boolean"/>
  <xs:element name="procedureType">
    <xs:complexType>
      <xs:choice>
        <xs:element name="procedureTypeOne">
          <xs:complexType>
            <xs:sequence>
              <xs:element name="IA" type="rdm:yes-no"/>
              <xs:element name="IB" type="rdm:yes-no"/>
              <xs:element name="II" type="rdm:yes-no"/>
            </xs:sequence>
          </xs:complexType>
        </xs:element>
        <xs:element name="procedureTypeTwoA">
          <xs:complexType>
            <xs:sequence>
              <xs:element name="IAIN" type="rdm:yes-no"/>
              <xs:element name="IB9" type="rdm:yes-no"/>
            </xs:sequence>
          </xs:complexType>
        </xs:element>
        <xs:element name="procedureTypeTwoB">
          <xs:complexType>
            <xs:sequence>
              <xs:element name="IA" type="rdm:yes-no"/>
              <xs:element name="IB9" type="rdm:yes-no"/>
            </xs:sequence>
          </xs:complexType>
        </xs:element>
        <xs:element name="procedureTypeThree">
          <xs:complexType>
            <xs:sequence>
              <xs:element name="procedureTypeLabel" type="xs:string"/>
            </xs:sequence>
          </xs:complexType>
        </xs:element>
        <xs:element name="procedureTypeFour">
          <xs:complexType>
            <xs:sequence>
              <xs:element name="IA" type="rdm:yes-no"/>
            </xs:sequence>
          </xs:complexType>
        </xs:element>
        <xs:element name="procedureTypeFive">
          <xs:complexType>
            <xs:sequence>
              <xs:element name="IAIN" type="rdm:yes-no"/>
            </xs:sequence>
          </xs:complexType>
        </xs:element>
      </xs:choice>
    </xs:complexType>
  </xs:element>
</xs:sequence>
```

```

<xs:element name="implementationDate" minOccurs="0">
    <xs:complexType>
        <xs:sequence>
            <xs:element name="articleFive" type="rdm:yes-no" minOccurs="0"/>
            <xs:element name="date" type="xs:date" minOccurs="0"/>
            <xs:element name="comment" type="rdm:string50" minOccurs="0"/>
        </xs:sequence>
    </xs:complexType>
</xs:element>
<xs:element name="selected" type="rdm:yes-no" minOccurs="0"/>
</xs:sequence>
</xs:complexType>
<xs:complexType name="variationTable">
    <xs:sequence>
        <xs:element name="title" type="xs:string" minOccurs="0"/>
        <xs:element name="category" type="xs:string" minOccurs="0"/>
        <xs:element name="variationLine" type="rdm:variationLine" minOccurs="1" maxOccurs="unbounded"/>
        <xs:element name="hasNote" type="xs:boolean"/>
        <xs:element name="additionalNote" type="xs:string"/>
    </xs:sequence>
</xs:complexType>

```

New eaf_Dictionary xsd schema definition:

```

<xs:complexType name="condition">
    <xs:sequence>
        <xs:element name="isRelevant" type="rdm:yes-no" />
        <xs:element name="title" type="xs:string"/>
        <xs:element name="note" type="xs:string"/>"
```

</xs:sequence>

```

</xs:complexType>
<xs:complexType name="documentation">
    <xs:sequence>
        <xs:element name="isRelevant" type="rdm:yes-no"/>
        <xs:element name="title" type="xs:string"/>
        <xs:element name="note" type="xs:string"/>"
```

</xs:sequence>

```

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

2. Variations XSD changes:**Original variations xsd schema definition:**

```
<xs:element name="typesOfChanges">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="copyOfRelevantPages" type="rdm:yes-no" minOccurs="0"/>
      <xs:element name="variationCount" maxOccurs="unbounded">
        <xs:complexType>
          <xs:sequence>
            <xs:element name="section" type="xs:string"/>
            <xs:element name="count" type="xs:int"/>
          </xs:sequence>
        </xs:complexType>
      </xs:element>
      <xs:element name="variation" type="rdm:variationTable" maxOccurs="unbounded"/>
      <xs:element name="scope" type="xs:string"/>
    </xs:sequence>
  </xs:complexType>
</xs:element>
```

New variations xsd schema definition:

```
<xs:element name="typesOfChanges">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="copyOfRelevantPages" type="rdm:yes-no" minOccurs="0"/>
      <xs:element name="variationCount" maxOccurs="unbounded">
        <xs:complexType>
          <xs:sequence>
            <xs:element name="section" type="xs:string"/>
            <xs:element name="count" type="xs:int"/>
          </xs:sequence>
        </xs:complexType>
      </xs:element>
      <xs:element name="variation" type="rdm:variationItem" maxOccurs="unbounded"/>
      <xs:element name="scope" type="xs:string"/>
    </xs:sequence>
  </xs:complexType>
</xs:element>
```